First published in the Government *Gazette*, Electronic Edition, on 22 June 2023 at 5 pm.

No. S 411

HEALTHCARE SERVICES ACT 2020

HEALTHCARE SERVICES (AMBULATORY SURGICAL CENTRE 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 (Ambulatory Surgical Centre Service) Regulations 2023 and come into operation on 26 June 2023.

Definitions

2. In these Regulations —

"acute hospital service licensee" means a person who is licensed to provide an acute hospital service;

"ambulatory surgical centre service" has the meaning given by paragraph 2 of the First Schedule to the Act;

"anaesthesiologist" means a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 in the branch of anaesthesiology;

"clinical privilege", in relation to a medical practitioner or dentist, means the type or types of relevant procedures that the medical practitioner or dentist is permitted to provide;

"clinical support personnel" means any individual (other than a medical practitioner or dentist) who is —

(*a*) a healthcare professional; or

(*b*) any other personnel of the licensee who is involved in providing care directly to any patient;

"collaborative prescribing practitioner" has the meaning given by regulation 2 of the Healthcare Services (Collaborative Prescribing Service) Regulations 2023 (G.N. No. S 398/2023);

"deep sedation" means a drug-induced depression of a patient's consciousness —

(*a*) during which the patient cannot be easily aroused but will respond purposefully following repeated or painful stimulation;

(*b*) where the patient's ability to independently maintain ventilatory function may be impaired;

(*c*) where the patient may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate; and

(*d*) where the patient's cardiovascular function is usually maintained;

"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 anaesthesia" has the meaning given by paragraph 2 of the First Schedule to the Act;

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

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

"licensee" means a person who holds a licence to provide an ambulatory surgical centre service;

"neuraxial anaesthesia" means the anaesthesia that is caused in a patient by the administration of an anaesthetic around the nerves of the central nervous system of the patient;

"nurse" means a registered nurse or an enrolled nurse;

"nursing service" means the provision of nursing care to a patient to assist the patient in attaining, maintaining or recovering his or her health;

"operating theatre" means a room with an aseptic environment that is equipped and designed to support the safe performance of any relevant procedure that requires general anaesthesia;

"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 ambulatory surgical centre 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 ambulatory surgical centre service;

"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;

"relevant healthcare provider" means —

(*a*) a person who is licensed to provide an ambulatory surgical centre service;

(*b*) a person who is licensed to provide an acute hospital service;

(*c*) a person who was licensed under the Private Hospitals and Medical Clinics Act 1980 to use any premises as a private hospital; or

(*d*) a person who was, under the Private Hospitals and Medical Clinics Act 1980 —

(i) licensed to use any premises as a medical clinic; and

(ii) approved to provide ambulatory surgery at those premises;

"relevant procedure" has the meaning given by paragraph 2 of the First Schedule to the Act;

"scope of practice", in relation to a licensee, means the type or types of relevant procedures provided by the licensee;

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

"surgical procedure" has the meaning given by paragraph 2 of the First Schedule to the Act;

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

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

(*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 Schedule are specified services for an ambulatory surgical centre service.

Prohibited service delivery modes

5. A licensee must not provide an ambulatory surgical centre service by any of the following service delivery modes:

(*a*) at any premises other than permanent premises;

(*b*) using a conveyance;

(*c*) by remote provision.

PART 3

GOVERNANCE OF SERVICE

Establishment of technical and clinical standards

6.—(1) A licensee must establish, implement and regularly review technical and clinical standards to govern the provision of the ambulatory surgical centre service.

(2) The licensee must ensure that —

(*a*) every personnel complies with the technical and clinical standards mentioned in paragraph (1);

(*b*) there is active management and review of the quality of clinical services and patient safety in the provision of the ambulatory surgical centre service; and

(*c*) the licensee's clinical support personnel are provided with adequate training and subject to regular competency assessments to enable them to perform their work effectively, safely and in compliance with the applicable laws, guidelines, policies, processes, procedures and protocols.

(3) A licensee must ensure that the following are documented:

(*a*) the technical and clinical standards mentioned in paragraph (1);

(*b*) every review conducted under paragraph (2)(*b*).

Licensee must appoint persons to oversee nursing services

7. A licensee must appoint one or more persons to oversee the nursing services provided in the course of the licensee's provision of the ambulatory surgical centre service, each of whom must be a registered nurse who has obtained post-registration qualification in operating theatre nursing.

Composition of quality assurance committee

8.—(1) Every quality assurance committee appointed by a licensee must comprise not fewer than —

(*a*) where the licensee only provides dental procedures — 3 dentists;

(*b*) where the licensee does not provide dental procedures — 3 medical specialists; or

(*c*) where the licensee provides both dental and non-dental procedures — 3 dentists or medical specialists.

(2) The quality assurance committee mentioned in paragraph (1) must comprise at least 3 members who each has at least 3 years' experience providing surgical or dental surgical services on behalf of a relevant healthcare provider, among whom are members with the following qualifications, whichever is applicable:

(*a*) where the licensee only provides dental procedures —

(i) a dentist who is registered under section 14C(1) of the Dental Registration Act 1999 as a specialist in a branch of dentistry within the licensee's scope of practice and has surgical experience; and

(ii) a dentist —

(A) who is not registered under section 14C(1) of the Dental Registration Act 1999 as a specialist;

(B) who is registered under section 14C(1) of the Dental Registration Act 1999 as a specialist in a branch of dentistry within the licensee's scope of practice but in a different branch of dentistry from the dentist mentioned in sub-paragraph (i); or

(C) who is not, for the period the dentist is a member of the committee, employed, engaged or accredited by the licensee;

(*b*) where the licensee does not provide dental procedures —

(i) a medical specialist who is registered under section 22 of the Medical Registration Act 1997 as a specialist in a branch of medicine within the licensee's scope of practice; and

(ii) a medical specialist —

(A) who is registered under section 22 of the Medical Registration Act 1997 as a specialist in a branch of medicine within the licensee's scope of practice but in a different branch of medicine from the medical practitioner mentioned in sub-paragraph (i); or

(B) who is not, for the period the medical practitioner is a member of the committee, employed, engaged or accredited by the licensee;

(*c*) where the licensee provides both dental and non-dental procedures —

(i) a dentist who is registered under section 14C(1) of the Dental Registration Act 1999 as a specialist in a

branch of dentistry within the licensee's scope of practice and has surgical experience;

(ii) a medical specialist who is registered under section 22 of the Medical Registration Act 1997 as a specialist in a branch of medicine within the licensee's scope of practice; and

(iii) a dentist mentioned in sub-paragraph (*a*)(ii)(A), (B) or (C) or a medical practitioner mentioned in sub-paragraph (*b*)(ii)(A) or (B).

(3) In this regulation, "medical specialist" means a medical practitioner who is registered under section 22(1) of the Medical Registration Act 1999 as a specialist.

Additional functions and duties of quality assurance committee

9. Every quality assurance committee appointed by the licensee has the following functions and duties, in addition to the functions and duties under regulation 21(2) of the General Regulations:

(*a*) to grant clinical privileges to every medical practitioner and dentist before the licensee employs or engages the medical practitioner or dentist, in accordance with the framework established by the licensee under regulation 10;

(*b*) to recommend processes and procedures to the licensee to ensure that a dentist or medical practitioner only performs relevant procedures within the scope of the clinical privileges granted;

(*c*) to review any case where a medical practitioner or dentist is suspected to have performed a relevant procedure outside the scope of the clinical privileges granted;

(*d*) to review the pathological report for every procedure performed as part of the ambulatory surgical centre service, within 3 months after the date of the report;

(*e*) to review every case where blood transfusion was required during or after a procedure, within 4 months after the blood transfusion was performed;

(*f*) to document and keep records of every review mentioned in paragraph (*c*), (*d*) or (*e*).

Licensee must establish credentialing framework

10.—(1) A licensee must establish and implement a credentialing framework for the grant of clinical privileges to every medical practitioner and dentist employed or engaged by the licensee, taking into account the professional qualifications, experience, competency and skills of the medical practitioner or dentist, as the case may be.

(2) A licensee must —

(*a*) grant clinical privileges to a medical practitioner or dentist employed or engaged by the licensee in accordance with the framework mentioned in paragraph (1);

(*b*) regularly review the clinical privileges granted to the medical practitioner or dentist to ensure that he or she continues to have the necessary professional qualifications, experience, competency and skills to be so granted those clinical privileges; and

(*c*) ensure that the medical practitioner or dentist only provides care or treatment or performs procedures within the scope of the clinical privileges granted.

(3) A licensee must regularly review the credentialing criteria, processes and procedures under the framework mentioned in paragraph (1) to ensure that they are up to date.

PART 4

REQUIREMENTS RELATING TO PERSONNEL

No employment or engagement of unauthorised persons to practise medicine or dentistry

11. A licensee must not employ or engage any person —

(*a*) to practise medicine or do any act as a medical practitioner unless the person is a medical practitioner; or

(*b*) to practise dentistry unless the person is a dentist.

Qualifications, skills and competencies for Clinical Governance Officer

12. For the purposes of section 24(3)(*b*) of the Act, an individual is suitably qualified to be appointed a Clinical Governance Officer for an ambulatory surgical centre service or a specified service for an ambulatory surgical centre service if the individual —

(*a*) where the licensee only provides dental procedures —

(i) is registered under section 14(1) or (2) of the Dental Registration Act 1999 as a fully registered dentist;

(ii) holds a valid practising certificate under the Dental Registration Act 1999; and

(iii) has either of the following:

(A) registration under section 14C(1) of the Dental Registration Act 1999 as a specialist;

(B) at least 5 years of full-time work experience within a period of 10 years providing dental surgical services on behalf of a relevant healthcare provider; or

(*b*) in any other case —

(i) is registered under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner;

(ii) holds a valid practising certificate under the Medical Registration Act 1997; and

(iii) has either of the following:

(A) registration under section 22 of the Medical Registration Act 1997 as a specialist;

(B) at least 5 years of full-time work experience within a period of 10 years providing surgical services on behalf of a relevant healthcare provider.

Surgical assistants for procedures

13.—(1) A licensee must ensure that the number, qualifications and experience of persons assisting in a surgical procedure is adequate and appropriate to the type and nature of the surgical procedure.

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

(*a*) where the surgical procedure is a dental procedure — there is at least one registered nurse or dental surgery assistant with relevant operating theatre experience of not less than 6 months assisting the dentist in the surgical procedure; and

(*b*) where the surgical procedure is not a dental procedure — there is at least one registered nurse with relevant operating theatre experience of not less than 6 months assisting the medical practitioner in the surgical procedure.

Staffing requirements for post-operative patient care

14. A licensee must ensure that —

(*a*) there is an adequate number of nurses at each of the licensee's approved permanent premises to monitor every patient at those premises who has undergone a relevant procedure; and

(*b*) there is an adequate number of medical practitioners at each of the licensee's approved permanent premises to assess every patient at those premises and provide medical care or intervention if necessary.

Standards for healthcare professionals

15.—(1) A licensee must establish, implement and regularly review processes and standards for every area of work undertaken by personnel who are healthcare professionals and clinical support personnel.

(2) Without limiting paragraph (1), the licensee must—

(*a*) establish, implement and regularly review processes and standards for healthcare professionals and clinical support

personnel undertaking any activity in the licensee's provision of the ambulatory surgical centre service in the following areas:

(i) preparation, dispensing and administration of medication;

(ii) collection, packing and labelling of specimens;

(iii) precautions to be taken to avoid contamination and degradation of specimens;

(iv) proper and safe use of medical and surgical equipment, instruments, appliances, materials and facilities;

(v) prevention, management, control and containment of the spread of any infection at those approved permanent premises; and

(*b*) ensure that each healthcare professional and clinical support personnel has demonstrated, and documented to have demonstrated, that he or she is able to implement the processes or standards relevant to the area of work undertaken by the healthcare professional or clinical support personnel.

PART 5

REQUIREMENTS FOR PREMISES AND EQUIPMENT

Premises must be set up appropriately

16. A licensee must ensure that —

(*a*) each approved permanent premises is sufficiently spacious and appropriately equipped to enable the ambulatory surgical centre service (including any essential life-saving measure) to be provided to a patient in a proper, effective and safe manner;

(*b*) there is sufficient lighting and ventilation at every approved permanent premises;

(*c*) 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; and

(*d*) toilet facilities are available in each approved permanent premises, or assistance with toileting needs is provided to patients where needed.

Pre-operative waiting area

17. A licensee must ensure that each approved permanent premises includes an area that is designated for the use of patients undergoing preparation before an operation.

Operating theatre

18. A licensee must ensure that every operating theatre at each approved permanent premises is appropriately designed, built, furnished and equipped to enable the provision of the ambulatory surgical centre service in a proper, effective and safe manner.

Recovery area

19.—(1) A licensee must ensure that there are adequate and proper facilities to accommodate patients after undergoing any relevant procedure involving the administration of anaesthetics.

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

(*a*) there is a bed available for each patient who undergoes a relevant procedure, for the patient to rest and recover after the relevant procedure;

(*b*) the premises include an area that is designated for the use of patients recovering after an operation;

(*c*) there is adequate resuscitative equipment in the area mentioned in sub-paragraph (*b*); and

(*d*) there is adequate space for the movement of personnel for the monitoring of patients and treatment of complications.

Observation area

20. A licensee must ensure that each approved permanent premises includes an area that is designated for the use of patients who have been moved out of the recovery area mentioned in regulation 19, where the patients are observed and monitored by the licensee's personnel and in which there is —

(*a*) adequate furniture for patients to sit or lie down;

(*b*) monitoring equipment; and

(*c*) a resuscitation trolley.

Holding area

21. A licensee must ensure that —

(*a*) each approved permanent premises includes an area that is designated to hold bodies in the event that there is a death on the premises; and

(*b*) the temperature in the area mentioned in paragraph (*a*) is maintained at 18ºC or below.

Environment cleaning

22. A licensee must ensure that every approved permanent premises 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.

Equipment sterilisation to prevent infection

23. A licensee must prevent the occurrence of, or manage, control or contain the spread of, any infection that is, or is suspected to be, connected with the provision of an ambulatory surgical centre service by ensuring the following:

(*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;

(*c*) each 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 6

REQUIREMENTS RELATING TO PROVISION OF SERVICE

Anaesthesia service

24.—(1) A licensee must ensure that the administration to a patient of any anaesthetic that causes deep sedation, general anaesthesia or neuraxial anaesthesia is performed in the provision of an ambulatory surgical centre service only by an anaesthesiologist.

(2) A licensee must —

(*a*) either —

(i) ensure that sufficient supplies of anaesthetic, anaesthetic delivery equipment and patient

monitoring devices are kept and maintained at every approved permanent premises; or

(ii) establish, implement and regularly review processes to ensure that the licensee may obtain the supplies mentioned in sub-paragraph (i) at any time;

(*b*) before administering any type of anaesthetic to cause any anaesthesia in a patient, properly inform the patient of the risks and benefits of, and (if any) the alternatives to, the anaesthesia;

(*c*) having satisfied the condition mentioned in sub-paragraph (*b*) in respect of a patient, keep and maintain proper and accurate records of this fact;

(*d*) where any anaesthetic is administered to a patient for the purpose of conducting a relevant procedure on the patient — ensure that the patient is regularly monitored throughout the procedure by the person who administered the anaesthetic, using the appropriate patient monitoring device; and

(*e*) establish, implement and regularly review processes and procedures to ensure the continued monitoring and care of the patient mentioned in sub-paragraph (*d*) after completion of the procedure mentioned in that sub-paragraph.

Relevant procedure must be suitable for patient

25.—(1) A licensee must ensure that —

(*a*) a relevant procedure is not offered to or performed on any patient at any approved permanent premises unless the approved permanent premises has the appropriate equipment and facilities to ensure that the relevant procedure may be carried out safely and effectively;

(*b*) a relevant procedure is not offered to or performed on any patient for whom that relevant procedure would be inappropriate; and

(*c*) every medical practitioner or dentist who offers a relevant procedure to a patient documents the reasons for doing so and includes such documentation as part of the patient's clinical management and care plan.

(2) A licensee must ensure that before a relevant procedure is performed on a patient —

(*a*) the medical practitioner or dentist (as the case may be) assesses that the patient is a suitable candidate for the relevant procedure; and

(*b*) where a relevant procedure may only be performed on an individual who is under deep sedation, general anaesthesia or neuraxial anaesthesia, an anaesthesiologist assesses that the patient is a suitable candidate for the administration of anaesthetics that cause the deep sedation, general anaesthesia or neuraxial anaesthesia, as the case may be.

(3) The licensee must ensure that the assessment mentioned in paragraph (2) includes —

(*a*) the taking of a comprehensive medical and surgical history of the patient;

(*b*) physical examination of the patient; and

(*c*) the conduct of relevant tests and investigations.

Attending medical practitioner or dentist for each patient

26. A licensee must ensure that each patient is assigned a medical practitioner or dentist (as the case may be) who —

(*a*) is the licensee's personnel;

(*b*) has overall responsibility for the patient's general medical condition at all times that the patient is at any of the licensee's approved permanent premises; and

(*c*) has an arrangement with an acute hospital licensee that enables the medical practitioner or dentist (as the case may be) to admit a patient into the care of the acute hospital service licensee.

Safe provision of relevant procedures

27.—(1) A licensee must ensure that —

(*a*) only an appropriate relevant procedure is performed on a patient, and the relevant procedure is performed in a proper, effective and safe manner;

(*b*) the patient or the patient's caregiver is informed of all relevant perioperative care instructions before the relevant procedure starts; and

(*c*) appropriate post-operative care instructions are given to the patient or the patient's caregiver, including the patient's care needs and the signs and symptoms of possible adverse reactions that the patient may experience after the relevant procedure.

(2) Without limiting paragraph (1)(*a*), the licensee must establish and implement the following:

(*a*) in relation to surgical procedures — perioperative measures to minimise the risk of surgical site infections;

(*b*) protocols and processes to ensure that the correct surgical procedure is performed on the correct patient at the correct surgical site and (where applicable) the correct implant, prosthesis or invasive device is inserted into the patient.

Nursing services

28. A licensee must deploy an adequate number of nurses to monitor the patients in any approved permanent premises at all times to ensure that there is prompt recognition of, and delivery of appropriate medical intervention or treatment to, a patient whose condition worsens.

Post-operative care

29.—(1) A licensee must ensure that each patient who has undergone a relevant procedure is monitored and given appropriate post-operative care for recovery and management of adverse effects from the procedure or from the administration of anaesthetics.

(2) Without limiting paragraph (1), the licensee must, in relation to each patient, ensure that during the post-operative observation period —

(*a*) one or more of the licensee's personnel observe and monitor the patient at intervals and for the length of time appropriate to the relevant procedure performed and the anaesthetics administered;

(*b*) timely and appropriate post-operative treatment is given to the patient where necessary;

(*c*) one or more of the licensee's personnel assists the patient with toileting needs where necessary; and

(*d*) adequate nutrition and hydration are given to or available to the patient.

Discharge of patients

30.—(1) A licensee must ensure that a patient who has undergone a relevant procedure is discharged only after he or she has been assessed by a medical practitioner or dentist who is the licensee's personnel to be fit for discharge.

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

(*a*) there is a protocol for the discharge of patients;

(*b*) the attending medical practitioner or dentist (who is the licensee's personnel) for a patient assesses whether the patient is fit for discharge;

(*c*) where the attending medical practitioner or dentist for a patient is not available to assess whether the patient is fit for discharge, another medical practitioner or dentist (who is the licensee's personnel) assesses the patient for this purpose instead;

(*d*) a patient is not asked to leave the approved permanent premises before the patient is assessed to be fit for discharge;

(*e*) a patient who is assessed to be fit for discharge leaves the premises within 6 hours after the time the patient is so assessed; and

(*f*) a patient who is assessed to be fit for discharge but who has not left the premises continues to be monitored by the licensee's personnel.

Patients must not be accommodated for more than 12 hours

31. A licensee must ensure that the period from the time the patient is registered for admission at any approved permanent premises for the relevant procedure to —

(*a*) the time the patient is assessed to be fit for discharge; or

(*b*) the time the patient is transferred to the care of an acute hospital service licensee,

as the case may be, does not exceed 12 hours.

Post-discharge follow-up

32. A licensee must ensure that —

(*a*) where necessary, appropriate instructions for follow-up care are provided to a patient who has been assessed fit for discharge; and

(*b*) the licensee's personnel gives the patient or the patient's caregiver information on the appropriate person to contact if the patient has an emergency medical need arising from the relevant procedure or the administration of anaesthetics.

Conduct of ultrasound imaging

33.—(1) A licensee must not conduct an ultrasound imaging on a patient, unless a medical practitioner, dentist 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 ambulatory surgical centre service;

(*b*) at the licensee's approved permanent premises; and

(*c*) by the licensee's personnel who is —

(i) a medical practitioner who is trained in the conduct of ultrasound imaging;

(ii) a dentist who is trained in the conduct of ultrasound imaging;

(iii) a radiographer who is a duly qualified allied health professional; or

(iv) a sonographer.

Testing of specimens

34. A licensee must not test any specimen for a patient unless —

(*a*) a medical practitioner, dentist 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 ambulatory surgical centre service.

Conduct of simple in vitro diagnostic test

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

Instructions for self-collection of specimens

36. 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) the licensee must provide the patient with —

(*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.

Essential life-saving measures must be available

37.—(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; and

(*b*) at all times, be capable of providing any essential life-saving measures to any patient who is at risk of death.

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

(*a*) there is a comprehensive and detailed response plan to resuscitate, treat and transfer unstable patients;

(*b*) the licensee's personnel promptly assesses a patient who shows any sign of being unwell at any time after a relevant procedure and delivers the necessary treatment to stabilise the patient;

(*c*) any patient who remains unwell despite the delivery of treatment to stabilise the patient is transferred to the care of an acute hospital service licensee who is equipped to deliver the appropriate treatment to the patient;

(*d*) all necessary arrangements with one or more acute hospital service licensees are in place to ensure a transfer mentioned in sub-paragraph (*c*) takes place without delay at any time;

(*e*) any patient who requires conveyance by an emergency ambulance is conveyed by an emergency ambulance operated by an emergency ambulance service licensee;

(*f*) 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; and

(*g*) 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.

Emergency blood supply

38.—(1) A licensee must make the necessary arrangements to ensure that the licensee has access to a supply of blood that is readily available for use at each approved permanent premises in the event of an emergency.

(2) Paragraph (1) does not apply in relation to a licensee who only performs ophthalmology procedures that have a low risk of surgical blood loss on patients who are assessed not to require perioperative blood transfusion.

PART 7

MISCELLANEOUS

Backup utilities

39.—(1) A licensee must ensure that there is access to emergency water supply, power and lighting in every approved permanent premises to ensure the provision of an ambulatory surgical centre service in a proper, effective and safe manner.

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

(*a*) the emergency water supply, power and lighting are sufficient to ensure that any relevant procedure that has commenced may be safely completed; and

(*b*) where any life support equipment is used, the life support equipment is connected to an emergency power supply at all times during its use.

Price transparency

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

Disclosure of approved institution status

41.—(1) A licensee who is an approved institution must display or otherwise make available at every approved permanent premises, 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:

(*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.

Display of charges

42. A licensee must ensure that the fees charged by the licensee for the following components of an ambulatory surgical centre service provided by the licensee are displayed or made available at each approved permanent premises:

(*a*) the conduct of each relevant procedure;

(*b*) the use of surgical facilities;

(*c*) any other aspect of the ambulatory surgical centre service (including post-operative care charges, medication and other consumables).

Financial counselling

43.—(1) A licensee must, before providing any care or treatment to, or conducting a procedure on, a patient, provide information on the fees charged by the licensee for the care, treatment or procedure, to the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient.

(2) For the purposes of paragraph (1), the information on the fees for the care, treatment or procedure must include —

(*a*) the estimated range of the fees for the care, treatment or procedure;

(*b*) the fee benchmark for the same or similar care, treatment or procedure 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 care, treatment or procedure, if any.

(3) A licensee need not comply with paragraph (1) if the patient is assessed by a medical practitioner to be in a critical condition and needs to receive the care, treatment or procedure without delay.

(4) The licensee must, after providing the information mentioned in paragraph (2) 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 such acknowledgment as part of the patient's patient health record.

(5) In this regulation, "medisave account" means a medisave account maintained under section 13 of the Central Provident Fund Act 1953.

Offences

44.—(1) A person who contravenes regulation 11, 16(*a*), 18, 19, 23(1), 24(1) or (2), 25(1) or (2), 27, 29, 30, 37, 38 or 39 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.

THE SCHEDULE

Regulation 4

SPECIFIED SERVICES

1. The following are specified services for an ambulatory surgical centre service:

(*a*) Collaborative prescribing service

(*b*) Liposuction

(*c*) Proton beam therapy

(*d*) Radiation oncology and radiation therapy

2. In this Schedule —

"collaborative prescribing service" has the meaning given by regulation 2 of the Healthcare Services (Collaborative Prescribing Service) Regulations 2023 (G.N. No. S 398/2023);

"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

(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.

Made on 20 June 2023.

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

[MH 78:44/1; AG/LEGIS/SL/122E/2020/24 Vol. 1]