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HEALTHCARE SERVICES ACT 2020

HEALTHCARE SERVICES (ACUTE HOSPITAL 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 (Acute Hospital Service) Regulations 2023 and come into operation on 26 June 2023.

Definitions

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

"24-hour clinic service" means a healthcare service that is provided to a patient for the purpose of triaging to determine whether the patient needs to be admitted by the licensee to the approved permanent premises to receive care or treatment and (if it is determined that the patient need not be so admitted) stabilising his or her medical condition;

"acute hospital service" has the meaning given by paragraph 2 of the First Schedule to the Act;

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

"anaesthesia service" means a service that is provided to a patient undergoing a surgical or non-surgical procedure, where the administration of an anaesthetic is required;

"blood transfusion service" means —

(*a*) the collection of whole blood, or 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*);

"clinical laboratory service" has the meaning given by paragraph 2 of the First Schedule to the Act;

"clinical laboratory service licensee" means a person who holds a licence under the Act to provide a clinical laboratory service;

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

"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);

"compound", in relation to a therapeutic product, means to formulate, mix, assemble, package or label the therapeutic product, with the intention of dispensing or administering the therapeutic product to a patient in accordance with the written instructions of a qualified practitioner;

"dietetic service" means any of the following:

(*a*) assessing and determining a patient's nutritional needs;

(*b*) formulating and implementing a dietetic plan for a patient;

(*c*) assisting a patient in making dietary changes to promote and optimise the overall health of the patient;

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

"emergency ambulance" and "emergency ambulance service" have the meanings given by paragraph 2 of the First Schedule to the Act;

"emergency department service" means the practice of emergency medicine on a patient who —

(*a*) is suffering or believed to be suffering from an injury, or a condition of acute or sudden onset, that poses an immediate or urgent threat to the patient's life or jeopardises the health of the individual; and

(*b*) presents himself or herself for medical attention without any prior appointment, either by the patient's own means, by means of an emergency ambulance or a medical transport or any other means;

"emergency medicine" means the medical speciality concerned with the care of any illness or injury requiring immediate or urgent medical attention;

"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;

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

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

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

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

"intensive care service" means the specialised treatment given to a patient who is acutely unwell and requires critical medical care;

"licensee" means a person who holds a licence to provide an acute hospital service;

"medical condition", in relation to a patient, includes the patient's dental condition;

"medical transport" and "medical transport service" have the meanings given by paragraph 2 of the First Schedule to the Act;

"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;

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

"nursing personnel" means a registered nurse, an enrolled nurse or any other person who assists a registered nurse or an enrolled nurse in providing nursing care to patients;

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

"nutrition service" means the provision of food to any patient at any approved permanent premises;

"obstetric service" means the evaluation and treatment of a patient who requires antenatal care, intrapartum care or postnatal care;

"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 acute hospital service to the patient;

"peritoneal dialysis support" has the meaning given by paragraph 2 of the First Schedule to the Act;

"personnel", in relation to a licensee, means any individual employed or engaged by the licensee to assist the licensee in providing an acute hospital service;

"pharmaceutical service" means —

(*a*) the procurement, storage and control, dispensing, distribution, supply and administration of all medicinal products and health products stored at any approved permanent premises;

(*b*) the preparation of medicinal products or health products, other than the compounding of

therapeutic products, at any approved permanent premises; and

(*c*) the counselling and monitoring of patient drug therapy;

"pharmacist" means a person who is registered as a pharmacist under the Pharmacists Registration Act 2007 and holds a valid practising certificate under that Act;

"practice of dentistry" has the meaning given by section 2 of the Dental Registration Act 1999;

"qualified practitioner" means —

(*a*) a medical practitioner; or

(*b*) a registered dentist under the Dental Registration Act 1999 whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act;

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

"radiological service licensee" means a person who holds a licence under the Act to provide a radiological 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;

"rehabilitative service" means assisting or facilitating a patient in —

(*a*) regaining the patient's physical or cognitive ability that has been lost or impaired as a result of disease, injury or treatment; or

(*b*) returning to the patient's daily life and living in a normal or near-normal way,

and includes physical therapy, occupational therapy, speech and language therapy and cognitive therapy;

"relevant procedure" means —

(*a*) any surgical procedure; or

(*b*) any other procedure that requires the use of an anaesthetic;

"renal dialysis service" means the provision of haemodialysis or peritoneal dialysis support by a licensee only to patients who are admitted by the licensee to the licensee's approved permanent premises, and includes the provision of any healthcare service that is incidental to the provision of haemodialysis or peritoneal dialysis support, other than a clinical laboratory service or radiological service;

"resuscitation service" means the treatment of, or implementation of an emergency procedure on, a person for the purpose of resuscitating the person;

"surgical procedure" means —

(*a*) an invasive operative procedure during which skin or mucous membranes and connective tissue are incised; or

(*b*) a procedure that is carried out using an instrument that is introduced through a natural body orifice;

"surgical service" means the conduct of a surgical procedure on a patient;

"therapeutic product" means a health product categorised as a therapeutic product in the First Schedule to the Health Products Act 2007.

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 service

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 acute hospital service.

Prohibited service delivery modes

5. A licensee must not provide an acute hospital 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

REQUIREMENTS RELATING TO PERSONNEL

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

6. 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.

Licensee must establish credentialing framework

7.—(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 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

APPROVED PERMANENT PREMISES, EQUIPMENT, ETC.

Approved permanent premises, equipment, etc.

8.—(1) A licensee must ensure that —

(*a*) every approved permanent premises is open to patients and operating at all times;

(*b*) every approved permanent premises is designed and built in a manner that provides a proper, safe and conducive environment for the treatment of every patient, including a patient who suffers from a physical disability;

(*c*) every approved permanent premises is adequately and properly equipped to address the mobility requirements of every patient, including a patient who suffers from a physical disability; and

(*d*) a security system is established and implemented at every approved permanent premises to ensure the safety of the personnel, patients and visitors at every approved permanent premises.

(2) A licensee must —

(*a*) ensure that there is a process to facilitate prompt access to adequate supplies of equipment, materials and other supplies which are necessary for the provision of any acute hospital service in a proper, effective and safe manner; and

(*b*) where there is any instruction manual for any equipment or material mentioned in sub-paragraph (*a*) — ensure that the instruction manual is made available for reference by any personnel who uses or intends to use the equipment or material.

Backup utilities

9.—(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 acute hospital service in a proper, effective and safe manner.

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

(*a*) the emergency water supply, power and lighting are sufficient to ensure that any 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.

Recovery area

10.—(1) A licensee must ensure that there are adequate and proper facilities in every approved permanent premises 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 approved permanent premises includes an area that is designated for the use of patients recovering after an operation;

(*c*) there is sufficient 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.

Notification of addition or removal of beds

11. A licensee who intends to add or remove a bed at any approved permanent premises used for the provision of an acute hospital service must, no later than 2 months before the bed is added or removed, notify the Director-General of the intended addition or removal.

PART 5

REQUIREMENTS RELATING TO PATIENT CARE

Division 1 — General

General requirements relating to patient care

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

(2) A licensee must ensure the safety, comfort and privacy of every patient receiving care or treatment at any approved permanent premises.

Staffing requirements

13.—(1) A licensee must ensure that there is an adequate number of personnel present at every approved permanent premises so as to enable the licensee to provide an acute hospital service to every patient at those premises in a proper, effective and safe manner.

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

(*a*) 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; and

(*b*) every patient is assigned an attending medical practitioner who has overall responsibility for the patient's general medical condition.

Informed care

14.—(1) A licensee must inform a patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient of the following matters, as soon as practicable:

(*a*) any change in the patient's medical condition or the occurrence of any incident, that requires the patient to receive a new or different type of care, treatment or procedure;

(*b*) any change in the patient's care plan that will result in the patient receiving a new or different type of care, treatment or procedure.

(2) Subject to paragraph (3), where a patient requires a new or different type of care, treatment or procedure, the licensee must (as soon as practicable but before the care or treatment is provided to, or the procedure is conducted on, the patient) obtain the consent from the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient for the provision of the care or treatment or the conduct of the procedure.

(3) Paragraph (2) does not apply 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.

Transport of patients

15. A licensee must not permit any person to offer, or provide, an emergency ambulance service or a medical transport service to any of the licensee's patients at any approved permanent premises if the person does not hold a licence under the Act to provide an emergency ambulance service or a medical transport service, as the case may be.

Division 2 — Provision of mandatory services

Requirement to provide certain aspects of acute hospital service

16. In the course of providing an acute hospital service at any approved permanent premises, a licensee must ensure that each of the following aspects of the service is available to every patient who requires it:

(*a*) anaesthesia service;

(*b*) blood transfusion service;

(*c*) dietetic service;

(*d*) intensive care service;

(*e*) nursing service;

(*f*) nutrition service;

(*g*) pharmaceutical service;

(*h*) resuscitation service;

(*i*) surgical service;

(*j*) 24-hour clinic service.

Anaesthesia service

17.—(1) A licensee must ensure that the administration of any anaesthetic to cause deep sedation, general anaesthesia or neuraxial anaesthesia in a patient is only performed by an anaesthesiologist or another medical practitioner or dentist under the supervision of 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*) establish, implement and regularly review processes and procedures to determine whether a particular anaesthetic is suitable to be administered on a patient;

(*c*) 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;

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

(*e*) where any anaesthetic is administered to a patient for the purpose of conducting a surgical or any other bodily invasive 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

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

completion of the procedure mentioned in that sub-paragraph.

(3) In this regulation —

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

"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;

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

"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.

Blood transfusion service

18. A licensee must ensure that an adequate supply of blood and blood products, and appropriate facilities for the proper storage and administration of blood and blood products to a patient, are readily available at every approved permanent premises.

Dietetic service and nutrition service

19. A licensee must —

(*a*) assess the medical condition of every patient and determine whether a dietetic plan needs to be formulated for the patient;

(*b*) where it is determined that a dietetic plan needs to be formulated for a patient, ensure that —

(i) the dietetic plan is formulated, taking into account the patient's medical condition, and meets the patient's nutritional requirements; and

(ii) food for the patient that is prepared or otherwise provided by the licensee is prepared or provided in accordance with the dietetic plan;

(*c*) ensure that a dietitian assesses the nutritional value of any food provided by the licensee to every patient; and

(*d*) ensure that food provided by the licensee to every patient is prepared and served in a safe and hygienic manner.

Intensive care service

20.—(1) A licensee must designate an area at every approved permanent premises for the provision of any intensive care service, and ensure that that area is appropriately equipped to ensure the provision of any intensive care service in a proper, effective and safe manner.

(2) In addition to paragraph (1), a licensee who provides an obstetric service must —

(*a*) be capable of providing any intensive care service to a neonate in a proper, effective and safe manner;

(*b*) designate an area at the approved permanent premises (that is separate and apart from the area mentioned in paragraph (1)) for the provision of any intensive care service to a neonate; and

(*c*) ensure that the area mentioned in sub-paragraph (*b*) is appropriately equipped to ensure the provision of any intensive care service to a neonate in a proper, effective and safe manner.

Nursing service

21.—(1) A licensee must ensure that there is an adequate number of nursing personnel —

(*a*) present at every approved permanent premises; and

(*b*) who have the appropriate qualifications, experience and competency to provide timely and appropriate nursing care to the licensee's patients.

(2) A licensee must ensure that the provision of any nursing service at every approved permanent premises is —

(*a*) in accordance with the policies and procedures mentioned in paragraph (3) and the approved standards of nursing practice; and

(*b*) under the supervision of a registered nurse.

(3) A licensee must establish, implement and regularly review written policies and procedures to provide guidance for the provision of any nursing service, including —

(*a*) the assignment of a suitable nurse who possesses the appropriate qualifications, experience, competency and skills, to take charge of the nursing care of a patient, taking into account the patient's medical needs and condition;

(*b*) the prompt recognition of any untoward change in a patient's condition to facilitate any appropriate intervention by a medical practitioner or another personnel with the necessary qualifications, experience, competency and skills; and

(*c*) the determination of the care, treatment or procedure that needs to be provided to a patient according to the change in the patient's medical needs and condition.

(4) A licensee must ensure that —

(*a*) within a reasonable period of time after a patient is admitted by the licensee to any approved permanent premises, a registered nurse assesses the nursing needs of the patient;

(*b*) a nursing care plan is proposed for the patient;

(*c*) the nursing care plan includes measures to continuously evaluate the patient for the purpose of determining, at any time, the patient's state of health and the quality of nursing service provided to the patient;

(*d*) a nurse is charged with the implementation of the nursing care plan for the patient;

(*e*) every nursing service is carried out in accordance with the nursing care plan; and

(*f*) the implementation of the nursing care plan and the patient's response to any nursing service are documented, in accordance with the approved standards of nursing practice.

(5) A licensee must ensure that there are close supervision, adequate training and regular competency assessments of every nursing personnel so as to enable the personnel to provide nursing care in a proper, effective and safe manner.

(6) In this regulation —

"approved standards of nursing practice" means the standards established by the Singapore Nursing Board for the practice of nursing in Singapore;

"Singapore Nursing Board" means the Singapore Nursing Board established under section 3 of the Nurses and Midwives Act 1999.

Pharmaceutical service

22.—(1) A licensee must ensure that the provision of a pharmaceutical service at any approved permanent premises is in

accordance with the policies and procedures mentioned in paragraph (2) and under the supervision of a pharmacist.

(2) A licensee must establish, implement and regularly review policies and procedures to provide guidance for the provision of pharmaceutical services, including —

(*a*) the storage, preparation, dispensing and administration of any medicinal product or health product;

(*b*) the proper and accurate keeping and maintenance of records relating to the storage, preparation, dispensing and administration of any medicinal product or health product;

(*c*) the prevention of any mix up, contamination, or early degradation of any medicinal product or health product that is stored or used at the approved permanent premises;

(*d*) the measures to prevent any medicinal product or health product that has been recalled from its manufacturer, from being dispensed or distributed; and

(*e*) informing every patient who has been dispensed or administered or has consumed the medicinal product or health product mentioned in sub-paragraph (*d*) of the recall.

(3) A licensee must ensure that —

(*a*) there is an adequate supply of medicinal products and health products at every approved permanent premises where a pharmaceutical service is provided; and

(*b*) the medicinal products and health products are properly stored at the approved permanent premises.

Resuscitation service

23.—(1) A licensee must, at all times, be capable of providing any resuscitation service to any person at any approved permanent premises.

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

(*a*) establish, implement and regularly review emergency procedures which would ensure —

(i) the rapid and accurate assessment of any person who is in need of any resuscitation service (called in this regulation the patient); and

(ii) the timely delivery of any resuscitation service to the patient to stabilise or resuscitate the patient;

(*b*) for every approved permanent premises, ensure that adequate and appropriate facilities, equipment and drugs for the implementation of any emergency procedure are readily available in all areas where patients receive accommodation, care or treatment;

(*c*) ensure 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 resuscitation service; and

(*d*) ensure that every personnel who provides any resuscitation service to a patient is adequately trained —

(i) to provide the resuscitation service in a proper, effective and safe manner; and

(ii) in the use of the equipment that is needed to deliver the resuscitation service.

Surgical service

24.—(1) A licensee must —

(*a*) ensure that every surgical operation, invasive procedure or endoscopic procedure that needs to be carried out in an aseptic environment is carried out in an operating theatre at the licensee's approved permanent premises;

(*b*) ensure that every operating theatre is appropriately designed, built, furnished and equipped to enable the provision of any surgical service in a proper, effective and safe manner;

(*c*) before conducting any surgical procedure on a patient, ensure that the medical practitioner or dentist who is to conduct the surgical procedure properly informs the patient of the risks and benefits of, and (if any) the alternatives to, the surgical procedure;

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

(*e*) minimise the risk of infection of the surgical site of the patient on which any surgical procedure is conducted; and

(*f*) ensure that only the appropriate surgical procedure is conducted on a patient and the surgical procedure is conducted in a proper, effective and safe manner.

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

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

(*b*) 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.

24-hour clinic service

25.—(1) A licensee must ensure that —

(*a*) every patient is triaged and assessed in a timely manner by a healthcare professional with the appropriate qualifications, experience, competency and skills; and

(*b*) the appropriate care or treatment is provided to, or the appropriate procedure is conducted on, the patient in accordance with the results of the triage.

(2) A licensee must establish, implement and regularly review policies and procedures for assessing whether a patient needs to be admitted or discharged.

Division 3 — Provision of specified services

Prohibition against use of terms "A&E", etc.

26. A licensee must not use the term "general hospital", "A&E", "Accident and Emergency Department" or "Emergency Department", or any abbreviation or derivative of that term, in any language, to convey the impression that the licensee provides any emergency department service, unless the licensee is approved to provide an emergency department service as a specified service for the acute hospital service.

Application of regulations 28, 29 and 30

27. Regulations 28, 29 and 30 apply to a licensee who is approved to provide an emergency department service.

Personnel requirements for licensees approved to provide emergency department service

28.—(1) Unless paragraph (2) applies, a licensee must ensure that —

(*a*) at all times, at least one medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of emergency medicine, is present at every approved permanent premises at which the emergency department service is or is to be provided; and

(*b*) the provision of any emergency department service to any patient is under the supervision of the medical practitioner mentioned in sub-paragraph (*a*).

(2) Where a licensee only provides an emergency department service to children, the licensee must ensure that —

(*a*) at all times, at least one medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in paediatric medicine and has received such training in emergency medicine as may be specified by the Director-General, is present at every

approved permanent premises at which the emergency department service is or is to be provided; and

(*b*) the provision of any emergency department service to any child is under the supervision of the medical practitioner mentioned in sub-paragraph (*a*).

(3) To avoid doubt, where a licensee provides the emergency department service to both adults and children, the licensee must comply with paragraphs (1) and (2).

(4) In addition to paragraph (1), (2) or (3) (as the case may be), a licensee must —

(*a*) ensure the prompt deployment of personnel with the necessary qualifications, experience, competency and skills at every approved permanent premises to ensure the provision of the emergency department service to any patient in a proper, effective and safe manner;

(*b*) ensure that the provision of any nursing service in support of the provision of an emergency department service to a patient is supervised by a registered nurse who is the licensee's personnel and —

(i) has obtained such qualification in emergency nursing, as may be specified by the Director-General; and

(ii) has at least 2 years of full-time work experience in providing nursing care as a registered nurse, in support of the provision of any emergency department service (whether by the licensee or another licensee).

Requirements relating to equipment, etc., for licensees approved to provide emergency department service

29.—(1) A licensee must —

(*a*) for every approved permanent premises where an emergency department service is or is to be provided, designate separate areas at the approved permanent

premises as the ambulance unloading bay and the resuscitation area;

(*b*) ensure that the ambulance unloading bay is located near to, and is easily accessible from, the resuscitation area;

(*c*) designate an area within the emergency department as the area at which patients with different patient acuity are treated and observed; and

(*d*) ensure that there is a bed available for each patient at the resuscitation area.

(2) In this regulation —

"ambulance unloading bay" means the area at which an ambulance transporting a patient to the approved permanent premises may stop or park for the unloading of the patient;

"emergency department" means the area at the approved permanent premises that is designated as the area at which emergency department services are provided to patients;

"patient acuity", in relation to a patient, means the severity of the patient's illness or medical condition;

"resuscitation area" means an area within the emergency department at which any resuscitation service may be provided to a patient.

Provision of emergency department service

30.—(1) A licensee must —

(*a*) physically segregate and manage any patient who has a highly infectious disease or is contaminated with a hazardous material; and

(*b*) provide prompt resuscitation service and management of a patient who has a time-sensitive condition.

(2) In this regulation, "time-sensitive condition" means a medical condition that can lead to severe complications or result in long-term disability or death if it is not treated promptly, and includes an acute

myocardial infarction, burn, inhalation injury, poisoning, stroke or trauma.

Division 4 — Provision of other aspects of acute hospital service

Rehabilitative service

31. Where a licensee provides any rehabilitative service to a patient, the licensee must —

(*a*) establish, implement and regularly review processes and procedures to assess every patient as to whether the patient requires and (if so) is suitable to receive any rehabilitative service; and

(*b*) where a patient has been assessed to require and is suitable to receive any rehabilitative service, ensure that —

(i) a rehabilitative plan, that has been approved or endorsed by a duly qualified allied health professional for that service, is proposed and communicated to the patient; and

(ii) the rehabilitative service is provided by a personnel who is trained in rehabilitation, and in accordance with the rehabilitative plan.

Application of regulations 33 to 36

32. Regulations 33 to 36 apply to a licensee who provides a renal dialysis service at any approved permanent premises.

Patients must be monitored when undergoing haemodialysis

33.—(1) A licensee must ensure that every patient undergoing haemodialysis at any approved permanent premises is monitored by a nursing personnel or a medical practitioner so that the patient can receive the appropriate and timely medical care in the event the patient's condition deteriorates.

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

(*a*) implement protocols for the recognition of any deterioration in a patient's condition, provision of medical care and escalation for further medical care;

(*b*) ensure that every medical practitioner, registered nurse and enrolled nurse employed or engaged by the licensee for the provision of the renal dialysis service is familiar with the signs and symptoms of patient deterioration and is able to identify these signs and symptoms;

(*c*) ensure that any deterioration in a patient's condition is brought to the attention of the appropriate personnel in a timely manner; and

(*d*) ensure that all dialysis machines are equipped with the appropriate equipment or device —

(i) to enable the licensee's personnel to visually monitor the clinical and dialysis parameters of a patient undergoing haemodialysis; and

(ii) that will give an audiovisual alarm if there is any machine fault detected, or if the patient's clinical or dialysis parameters fall outside of the acceptable range during haemodialysis.

Standards for equipment for renal dialysis service

34.—(1) A licensee must ensure that every piece of equipment used by or on a patient in the licensee's provision of the renal dialysis service is safe and effective for clinical use.

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

(*a*) every part of any equipment (other than any part designed for single use only) is appropriately disinfected or sterilised in accordance with the specifications by the manufacturer of the equipment before and after it is used for dialysis;

(*b*) each equipment is installed, and used or operated properly, in accordance with the instructions of the manufacturer of the equipment; and

(*c*) in relation to a licensee who provides haemodialysis —

(i) where reusable dialysers are used — the dialysers are cleaned and prepared for reuse in the manner required or recommended in the manufacturer's operator manual for the dialyser;

(ii) any dialyser must only be used for one patient;

(iii) each dialysis machine is drained, rinsed and disinfected after each dialysis, at the end of each day and at any other interval required or recommended in the manufacturer's operator manual for the dialysis machine; and

(iv) where there is a blood leak, the affected dialysis machine is rinsed and disinfected in the manner required or recommended in the manufacturer's operator manual for the dialysis machine.

Quality of water and dialysis fluid

35.—(1) A licensee who provides haemodialysis must ensure that any water or dialysis fluid used for haemodialysis meets the applicable chemical and microbiological standards, and is safe and appropriate for use.

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

(*a*) the water used for haemodialysis is treated by reverse osmosis;

(*b*) there are protocols and procedures on the collection and testing of the water and dialysis fluid;

(*c*) the water and dialysis fluid are regularly tested for chemical and microbiological contaminants;

(*d*) appropriate methods are used for the collection and testing of the water and dialysis fluid;

(*e*) the water treatment equipment and haemodialysis water distribution systems are appropriately designed, built, and maintained to prevent treated water from being contaminated or exposed to the risk of being contaminated;

(*f*) water treatment systems are isolated from the potable water supply;

(*g*) the water treatment equipment and haemodialysis water distribution system include pressure gauges, flow meters, sample ports, and other ancillary equipment necessary to allow monitoring of the performance and the system as a whole;

(*h*) there are protocols and procedures for the regular disinfection of all water treatment equipment and haemodialysis water distribution systems; and

(*i*) records of each disinfection are kept.

Prevention of transmission of blood borne viruses and pathogenic bacteria

36.—(1) A licensee who provides haemodialysis must ensure that there is no transmission of blood borne viruses and pathogenic bacteria between haemodialysis patients, and between any haemodialysis patient and any of the licensee's personnel.

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

(*a*) before a patient starts receiving haemodialysis, the patient must be tested to determine the level of each of the patient's liver markers and for each specified infectious disease, unless the patient is assessed by a medical practitioner to be in a critical condition and requires haemodialysis without delay;

(*b*) any patient who at any time has a liver marker which level is above the normal range or tests positive for any specified infectious disease is referred to an appropriate medical practitioner;

(*c*) every specified patient receives haemodialysis in a different room or a physically segregated area from a patient who is not a specified patient;

(*d*) for any period during which a licensee provides haemodialysis to a specified patient, any machine or equipment that has been used for a specified patient is not used for a patient who is not a specified patient;

(*e*) where a dialyser has been used by a patient who has a specified infectious disease — the dialyser is not reused; and

(*f*) where a dialysis machine has been used by a patient who has a specified infectious disease — the dialysis machine undergoes complete chemical disinfection after each such use, and the chemical disinfection is performed in accordance with the manufacturer's recommendations.

(3) In this regulation —

"specified infectious disease" means any of the following infections:

(*a*) Hepatitis B infection;

(*b*) Hepatitis C infection;

(*c*) human immunodeficiency virus infection;

"specified patient" means a patient —

(*a*) with a Hepatitis B infection and is HbsAg positive or HBV DNA positive; or

(*b*) who has not been tested for Hepatitis B infection.

Conduct of ultrasound imaging

37.—(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 acute hospital service;

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

(*c*) by a personnel of the licensee, who has the appropriate qualifications, skills and competencies to conduct the ultrasound imaging.

Testing of specimen

38. 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 acute hospital service.

Conduct of simple in vitro diagnostic test

39.—(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.

Division 5 — Provision of clinical laboratory service and radiological service

Clinical laboratory service

40.—(1) A licensee must ensure that every approved permanent premises is equipped with facilities and equipment for the provision of a clinical laboratory service, in accordance with paragraph (2), to every patient who requires such service.

(2) A clinical laboratory service mentioned in paragraph (1) must be provided at the approved permanent premises —

(*a*) by the licensee under a clinical laboratory service licence; or

(*b*) by a clinical laboratory service licensee who is permitted to provide the service at the approved permanent premises.

(3) Despite paragraphs (1) and (2), a licensee may make arrangements for a test to be conducted for the patient at any premises other than the approved permanent premises, if —

(*a*) the test is not a specified test; and

(*b*) the conduct of the test is by —

(i) a clinical laboratory service licensee; or

(ii) a person who operates a clinical laboratory outside Singapore that is accredited by an accreditation body approved by the Director-General.

(4) To avoid doubt, the clinical laboratory service licensee mentioned in paragraph (2)(*b*) or (3)(*b*)(i) (as the case may be) remains responsible to comply with the licence conditions imposed on, and the duties of, the clinical laboratory service licensee under the Act, these Regulations and any other regulations made under the Act.

(5) In this regulation, "specified test" means a test specified in the Second Schedule.

Radiological service

41.—(1) A licensee must ensure that every approved permanent premises is equipped with at least one static x-ray machine and at

least one mobile x-ray machine for the provision of a radiological service, in accordance with paragraph (2), to any patient who requires such service.

(2) A radiological service mentioned in paragraph (1) must be provided at the approved permanent premises —

(*a*) by the licensee under a radiological service licence; or

(*b*) by a radiological service licensee who is permitted to provide the service at the approved permanent premises.

(3) Despite paragraphs (1) and (2), a licensee may make arrangements for a radiological examination to be conducted for the patient at any premises other than the approved permanent premises, if —

(*a*) the radiological examination is not a specified examination; and

(*b*) the conduct of the radiological examination is by a radiological service licensee.

(4) To avoid doubt, the radiological service licensee mentioned in paragraph (2)(*b*) or (3)(*b*) (as the case may be) remains responsible to comply with the licence conditions imposed on, and the duties of, the radiological service licensee under the Act, these Regulations and any other regulations made under the Act.

(5) In this regulation, "specified examination", in relation to a licensee, means —

(*a*) where the licensee is approved to provide an emergency department service — a plain radiography examination, an ultrasound imaging, a computed tomography or a magnetic resonance imaging; or

(*b*) in any other case — a plain radiography examination.

PART 6

INFECTION CONTROL, INCIDENT MANAGEMENT AND EMERGENCY PREPAREDNESS

Infection control obligation

42.—(1) Without limiting regulation 41 of the General Regulations, a licensee must —

(*a*) establish an infection prevention and control programme (called in this regulation the IPC programme) that satisfies the conditions mentioned in paragraph (2);

(*b*) appoint an infection prevention and control committee to assist the licensee in establishing, implementing and regularly reviewing the IPC programme;

(*c*) ensure that the infection prevention and control committee comprises the appropriate number of personnel with the appropriate qualifications, skills and competencies for the purpose of carrying out the licensee's functions mentioned in sub-paragraph (*b*);

(*d*) keep proper and accurate records of —

(i) the implementation of the IPC programme; and

(ii) every infection prevention and control activity carried out at the approved permanent premises;

(*e*) ensure that only equipment, material or articles that are reprocessed through high-level disinfection or sterilisation in accordance with the specifications by the manufacturer of the equipment, material or articles (as the case may be) and are not subsequently contaminated, are used in any endoscopic, operative or any other invasive procedure on a patient;

(*f*) ensure that 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

(*g*) ensure that 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.

(2) For the purposes of paragraph (1)(*a*), the IPC programme must be in writing and include the following matters:

(*a*) standard operating procedures relating to the infection prevention and control of any infection at the licensee's approved permanent premises;

(*b*) policies and guidelines relating to the prevention, identification, control and management and elimination of any infection that is acquired in or brought into the licensee's approved permanent premises, including the practice of good hand hygiene and in the use of personal protective equipment;

(*c*) policies and the appropriate processes for the training and competency assessment of the licensee's personnel to ensure that the personnel are familiar with and are able to comply with the matters mentioned in sub-paragraphs (*a*) and (*b*);

(*d*) surveillance plans to monitor every incident at the licensee's approved permanent premises that involves an epidemiologically important organism or an infection that is acquired at the approved permanent premises;

(*e*) plans to carry out regular audits on the personnel, patients and environment of the licensee's approved permanent premises to ensure that the IPC programme is being implemented effectively.

Emergency management system

43.—(1) A licensee must establish, implement and regularly review an effective command and control system to manage both of the following:

(*a*) an emergency at the approved permanent premises;

(*b*) a medical emergency in Singapore.

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

(*a*) establish and equip an operationally-ready emergency response team to manage an emergency mentioned in that paragraph;

(*b*) establish, implement and regularly review processes and procedures to control and manage an emergency, including any radiation emergency or incident;

(*c*) with respect to a radiation emergency or incident, establish, implement and regularly review processes and procedures to prevent, identify, control and manage any radiation emergency or incident, including strategies to isolate every area or patient who is affected by radiation, setting up isolation facilities for every affected patient, and the use of equipment to prevent, control and manage the spread of radiation;

(*d*) review the processes and procedures mentioned in sub-paragraph (*b*) annually;

(*e*) train every personnel who is in the emergency response team in the processes and procedures mentioned in sub-paragraph (*b*); and

(*f*) participate in any exercise specified by the Director-General that is for the purpose of evaluating the emergency preparedness and response capabilities of the healthcare system in Singapore.

(3) In this regulation, "command and control system" means a system comprising personnel, procedures, equipment and facilities (including information management facilities) which are necessary for the purpose of conducting any emergency management operation.

PART 7

MISCELLANEOUS

Keeping of other records

44. 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 acute hospital 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 acute hospital service.

Price transparency

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

Display of charges, etc.

46.—(1) A licensee must ensure that the fees charged by the licensee for an acute hospital service are displayed or otherwise made available at every approved permanent premises.

(2) The charges mentioned in paragraph (1) for an acute hospital service must include —

(*a*) the consultation fee that is applicable to the patient; and

(*b*) the ward charges.

Disclosure of approved institution status

47.—(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 medical institution under any public scheme providing financial assistance that is established by the Government.

Financial counselling

48.—(1) A licensee must, before providing any care or treatment to, or conducting a procedure on, a patient, provide the 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 payable for the care, treatment or procedure must include —

(*a*) the estimated price 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 the 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

49.—(1) A person who contravenes regulation 6, 8(1) or (2), 9(1) or (2), 10(1) or (2), 12(1) or (2), 16, 17(1) or (2), 18, 20(1) or (2), 23(1) or (2), 24(1) or (2), 33(1) or (2), 34(1) or (2), 35(1) or (2), 36(1) or (2), 40(1), 41(1) or 42(1) 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

SPECIFIED SERVICES

1. The following are specified services for an acute hospital service:

(*a*) collaborative prescribing service;

(*b*) emergency department service;

(*c*) proton beam therapy;

(*d*) radiation oncology and radiation therapy.

2. In this Schedule —

"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 is —

(*a*) 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.

SECOND SCHEDULE

Regulation 40(5)

SPECIFIED TEST

1. Arterial blood gas test

2. Blood glucose test

3. Full blood count

4. Partial thromboplastin time test

5. Peripheral blood film test

6. Prothrombin time test

7. Renal panel test

8. A test to ascertain the level of any of the following cardiac markers in the blood of an individual:

(*a*) Troponin

(*b*) Creatine kinase

(*c*) Creatine kinase MB

Made on 21 June 2023.

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

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