HEALTHCARE SERVICES ACT 2020

(No. 3 of 2020)

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An Act to provide for the regulation of healthcare services and other connected or incidental matters, to repeal the Private Hospitals and Medical Clinics Act (Chapter 248 of the 1999 Revised Edition), and to make consequential and related amendments to certain other Acts.

Be it enacted by the President with the advice and consent of the Parliament of Singapore, as follows:

PART 1

PRELIMINARY

Short title and commencement

1. This Act is the Healthcare Services Act 2020 and comes into operation on a date that the Minister appoints by notification in the *Gazette*.

General interpretation

- **2.**—(1) In this Act, unless the context otherwise requires
 - "applicant" means a person making an application;
 - "application", in relation to a licence, means an application under section 10;
 - "authorised officer", for any provision of this Act, means an individual who is appointed under section 7(2) as an authorised officer for that provision;
 - "Clinical Governance Officer", for a licensee, means an individual appointed under section 24(2) for that licensee;
 - "code of practice" means a code of practice issued or approved under section 38, and includes any code of practice as amended under that section;
 - "conveyance" means a vehicle, an aircraft or a vessel, that is registered under any written law, or a train in Singapore, and that is used to provide a healthcare service in Singapore;
 - "dentist" means an individual who is registered under the Dental Registration Act (Cap. 76) as a registered dentist and holds a valid practising certificate under that Act;
 - "Director" means the Director of Medical Services and includes any individual who is, for the time being, discharging the duties of the office of Director of Medical Services;
 - "grant" or "granted", in relation to a licence, includes
 - (a) grant or granted on renewal; and
 - (b) deemed granted under this Act;

- "key appointment holder", in relation to an applicant or a licensee, means
 - (a) if a company, limited liability partnership or other body corporate a member of the board of directors or committee or board of trustees or other governing body of the applicant or licensee;
 - (b) if a partnership a partner of the applicant or licensee; or
 - (c) in any other case any person, by whatever name called, who has general management or supervision of the business of the applicant or licensee;
- "licence" means a licence that is granted under this Act and that is in force;
- "licensed conveyance" means a conveyance specified in a licence authorising its use to provide a licensable healthcare service specified in the licence;
- "licensed premises" means the premises specified in a licence as premises at which a licensable healthcare service specified in the licence may be provided;
- "licensee" means the person to whom a licence is granted;
- "medical practitioner" means an individual who is registered under the Medical Registration Act (Cap. 174) as a medical practitioner and holds a valid practising certificate under that Act;
- "modification" and "modify", in relation to the conditions of a licence, include deleting, varying and substituting a condition, and adding a condition;
- "oral health therapist" means an individual who is registered under the Dental Registration Act as a registered oral health therapist and holds a valid practising certificate under that Act:
- "Principal Officer", for an applicant or a licensee, means an employee or officer of the applicant or licensee who —

- (a) is involved in the day-to-day management of the provision of the licensable healthcare services the licensee is authorised to provide;
- (b) has the capacity, on behalf of the licensee, to influence the compliance of the licensee's officers and employees with the requirements under this Act;
- (c) has access to and is authorised to provide any information relating to the licensee and the licensable healthcare services the licensee is authorised to provide that is required by or under this Act; and
- (d) is authorised to represent for the purposes of this Act the licensee in providing those licensable healthcare services;
- "public authority" means a body established or constituted by or under a public Act to perform or discharge a public function, but not a Town Council established under section 4 of the Town Councils Act (Cap. 329A);
- "public scheme" means a scheme that is established
 - (a) by or under any written law and administered by a public authority; or
 - (b) by the Government in any other manner,

for the purpose of providing financial relief, assistance or support to citizens or permanent residents of Singapore, or any part of them;

- "repealed Act" means the Private Hospitals and Medical Clinics Act (Cap. 248);
- "section 25 licensee" has the meaning given by section 25;
- "special licensable healthcare service" means a licensable healthcare service that is prescribed as a special licensable healthcare service;

- "specified committee" means a quality assurance committee, a service review committee or a clinical ethics committee, as the case may be;
- "step-in operator" means a person that is appointed under section 33 to take over the operations, or a part of the operations, of a licensee.
- (2) In this Act, a healthcare service is provided using a conveyance where the healthcare service is provided in or from the conveyance, moving or otherwise.
- (3) For the purpose of determining whether or not a person is a suitable person under the Act, the Director must have regard, and give such weight as the Director considers appropriate, to all the following matters:
 - (a) any evidence that the person is an undischarged bankrupt or has gone, or is likely to go, into compulsory or voluntary liquidation other than for the purpose of amalgamation or reconstruction;
 - (b) any prior conviction for committing (whether before, on or after the date of commencement of this section) any offence
 - (i) under this Act, the repealed Act or any applicable Act;
 - (ii) involving fraud or dishonesty, whether or not the conviction was in a Singapore court; or
 - (iii) specified in the Third Schedule to the Registration of Criminals Act (Cap. 268);
 - (c) any evidence of the cancellation, removal or suspension (whether before, on or after the date of commencement of this section) of the person's registration under any applicable Act for any reason;
 - (d) any evidence of the revocation or suspension (whether before, on or after the date of commencement of this section) of any licence granted to the person under this Act or the repealed Act.

- (4) To avoid doubt, the Director is not confined to consideration of the matters specified in subsection (3) and may take into account any other matters and evidence that may be relevant.
- (5) In subsection (3), "applicable Act" means any of the following Acts:
 - (a) the Allied Health Professions Act (Cap. 6B);
 - (b) the Dental Registration Act;
 - (c) the Medical Registration Act;
 - (d) the Nurses and Midwives Act (Cap. 209);
 - (e) the Optometrists and Opticians Act (Cap. 213A);
 - (f) the Pharmacists Registration Act (Cap. 230);
 - (g) the Traditional Chinese Medicine Practitioners Act (Cap. 333A).

Meanings of "healthcare service" and "licensable healthcare service"

3.—(1) In this Act —

"healthcare service" means any of the following services, whether or not provided for reward:

- (a) assessment, diagnosis, treatment, prevention or alleviation of an ailment, a condition, disability, disease, disorder or an injury affecting any part of the human body or mind;
- (b) nursing or rehabilitative care of an individual suffering from an ailment, a condition, disability, disease, disorder or an injury mentioned in paragraph (a);
- (c) conduct of any clinical procedure to change, or that is intended to change, the appearance or anatomy of an individual;
- (d) assessment of the health of an individual;

- (e) any other service of a medical or healthcare nature that is prescribed;
- "licensable healthcare service" means a healthcare service specified in the First Schedule.
- (2) In subsection (1), "clinical procedure"
 - (a) means any procedure that only a medical practitioner, a dentist or an oral health therapist is authorised under any written law to perform and which involves any of the following:
 - (i) puncture of the skin to inject, deliver, implant or anchor any substance or object into the human body, or to withdraw or remove blood, fluid or tissue from the human body;
 - (ii) penetration of any human body orifice to deliver into or remove any substance from the body;
 - (iii) external application of energy to any part of the human body that is capable of causing severe or irreversible injury to the body;
 - (iv) chemical or mechanical exfoliation of the skin that targets below the epidermis;
 - (v) manipulation or modification of the dental hard or soft tissues within the oral cavity that causes, or is capable of causing, changes to such tissues; but
 - (b) does not include any of the following:
 - (i) body piercing;
 - (ii) body tattooing;
 - (iii) application of intense pulsed light.

Purpose of Act

4. The purpose of this Act is to regulate the provision of healthcare services, including the premises and conveyances used for that purpose, so as to ensure the safety and welfare of, and the general continuity of healthcare provided to, people in Singapore.

Government healthcare service not affected

5. This Act does not apply to or in relation to any healthcare service provided by the Government.

Interface with other laws

- **6.** To avoid doubt, this Act does not affect the operation of any of the following:
 - (a) the Allied Health Professions Act;
 - (b) the Dental Registration Act;
 - (c) the Medical Registration Act;
 - (d) the Nurses and Midwives Act;
 - (e) the Optometrists and Opticians Act;
 - (f) the Pharmacists Registration Act;
 - (g) the Traditional Chinese Medicine Practitioners Act.

Administration of Act

- 7.—(1) The Director of Medical Services is, subject to the general or special directions of the Minister, responsible for the administration of this Act.
- (2) The Director may, in relation to any provision in this Act, appoint a public officer or an officer of any public authority to be an authorised officer for the purposes of that provision, either generally or in a particular case.
- (3) Subject to subsection (4), the Director may delegate the exercise of all or any of the powers conferred or duties imposed on the Director under this Act (except the power of appointment conferred by this section and the power of delegation conferred by this subsection) to an authorised officer; and any reference in the provision of this Act to the Director includes a reference to the authorised officer.
- (4) Any delegation under subsection (3) may be general or specific, and may be subject to any conditions or limitations that the Director may specify.

- (5) The Director may appoint, subject to any restrictions specified in the appointment, a suitably qualified individual who is neither a public officer nor an officer of a public authority to assist the Director in the administration of this Act.
- (6) The Director, every authorised officer and every individual appointed under subsection (5) are taken to be public servants for the purposes of the Penal Code (Cap. 224).

PART 2

LICENSING OF HEALTHCARE SERVICES

Provision of licensable healthcare service to be licensed

- **8.**—(1) A person must not provide a licensable healthcare service unless the person
 - (a) is authorised to do so by a licence under this Act; or
 - (b) is exempt from this section by or under this Act in relation to that licensable healthcare service.
- (2) A person that contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction
 - (a) to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 2 years or to both; but
 - (b) if the person has any previous qualifying conviction, to a fine not exceeding \$200,000 or to imprisonment for a term not exceeding 2 years or to both.
 - (3) In subsection (2), "qualifying conviction" means
 - (a) a conviction for an offence under subsection (2); or
 - (b) a conviction (before, on or after the date of commencement of this section) for an offence under section 5(2) of the repealed Act.

Unlicensed premises and unlicensed conveyances

9.—(1) A licensee that provides a licensable healthcare service at any premises that is not licensed premises, or uses any conveyance

that is not a licensed conveyance, shall be guilty of an offence and shall be liable on conviction —

- (a) in the case of a first offence, to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding 12 months or to both; but
- (b) if the person has a previous qualifying conviction, to a fine not exceeding \$100,000 or to imprisonment for a term not exceeding 12 months or to both.
- (2) In subsection (1), "qualifying conviction" means
 - (a) a conviction for an offence under subsection (1); or
 - (b) a conviction (before, on or after the date of commencement of this section) for an offence under section 5(2) or (4)(a) of the repealed Act.

Application for licence

- **10.**—(1) Every application for the grant of a licence must be made to the Director in accordance with this section.
 - (2) An application must
 - (a) be in the form and manner that the Director requires;
 - (b) be accompanied by a non-refundable application fee (if prescribed);
 - (c) include all the following particulars:
 - (i) the name and particulars of the applicant;
 - (ii) the licensable healthcare service that the applicant intends to provide or continue to provide under the authority of the licence applied for;
 - (iii) the business name by which the applicant intends to provide or continue to provide the licensable healthcare service;
 - (iv) if any premises are to be used or continue to be used to provide the licensable healthcare service, the address of those premises;

- (v) if any conveyance is to be used or continue to be used to provide the licensable healthcare service, the registration number and other particulars, and the name and particulars of the owner, of the conveyance;
- (vi) the name of the individual who is or is to be the Principal Officer;
- (vii) the name of the individual or individuals who is or are or is or are to be appointed the Clinical Governance Officer or Clinical Governance Officers;
- (viii) other prescribed particulars (if prescribed);
- (d) be accompanied by any other information or document that the Director requires to decide on the application; and
- (e) if required by the Director, be accompanied by a statutory declaration by the applicant verifying any information contained in or relating to the application.
- (3) In addition to the requirements under subsection (2), an application to renew a licence
 - (a) must ordinarily be made not later than the prescribed time before the date the licence expires (called in this subsection the renewal deadline); and
 - (b) if made later than the renewal deadline, must be accompanied by a late renewal application fee (if prescribed).
- (4) The Director may carry out any inquiries and investigations in relation to the application that are necessary for a proper consideration of the application, including inspections of the premises at which the licensable healthcare service is to be or continue to be provided, and the conveyance and the equipment used or to be used in connection with the licensable healthcare service.
- (5) The Director may refuse an application that is incomplete or otherwise not made in accordance with this section.

Grant or renewal of licence

- 11.—(1) After considering an application for the grant of a licence, the Director may
 - (a) on payment of a licence fee or renewal fee (if prescribed), grant the licence; or
 - (b) refuse to grant the licence.
- (2) A person may be granted more than one licence, whether for the provision of the same or a different licensable healthcare service.
- (3) In deciding whether a licence should be granted, the Director must have regard to, and give such weight as the Director considers appropriate to, all the following matters:
 - (a) whether the applicant is and, where necessary, the following persons are suitable persons to provide or be involved (as the case may be) in providing the licensable healthcare service to which the application relates:
 - (i) any key appointment holder of the applicant;
 - (ii) any person having a substantial interest in, or control of or direction over, the applicant's business;
 - (iii) any person having control of or direction over the applicant's operations at the premises or conveyance used, or to be used, to provide the licensable healthcare service;
 - (b) the suitability of every premises or conveyance (including the facilities and equipment in the premises or conveyance), and of every process or protocol, used or intended to be used for the provision of the licensable healthcare service;
 - (c) if the application relates to any special licensable healthcare service, whether the applicant is granted a licence to provide any licensable healthcare service prescribed as underlying to the special licensable healthcare service;

- (d) the likelihood of the applicant providing the licensable healthcare service to which the application relates in compliance with
 - (i) the requirements of this Act and any code of practice relating to that licensable healthcare service;
 - (ii) any other written law applicable to the applicant relating to the provision of the licensable healthcare service in a safe and proper manner; and
 - (iii) the rules of any public scheme established by or under any written law
 - (A) relating to the provision of the licensable healthcare service to which the application relates; and
 - (B) under which the applicant is accredited or of which the applicant is a participant;
- (e) the applicant's ability to provide the licensable healthcare service to all the applicant's patients or customers in a manner that is clinically and ethically appropriate;
- (f) whether the applicant
 - (i) holds, or has applied for, a licence for any other licensable healthcare service; or
 - (ii) has made arrangements with any other licensee for the provision of the licensable healthcare service to which the application relates;
- (g) whether there is any other relevant matter that makes it contrary to the public interest to grant or renew the licence.
- (4) To avoid doubt, the Director is not confined to consideration of the matters in subsection (3) and may
 - (a) take into account any other matters and evidence that may be relevant; and
 - (b) consult any person the Director thinks relevant, including any advisory committee the Director may appoint.

Form and validity of licence

- **12.**—(1) Every licence must
 - (a) state the licensable healthcare service that the licensee is authorised by the licence to provide;
 - (b) state every licensed premises at which the licensable healthcare service authorised by the licence is provided, or every licensed conveyance used to provide the licensable healthcare service authorised by the licence, as the case may be; and
 - (c) be in the form that the Director may determine.
- (2) Every licence granted or renewed under this Act continues in force for the period specified in the licence, unless it is earlier revoked or suspended under section 20, and may be renewed upon its expiry.

Licence conditions

- 13.—(1) In granting a licence to any person or renewing any licence, the Director may impose any conditions that the Director considers requisite or expedient having regard to the purposes of this Act.
 - (2) The Director may impose
 - (a) conditions generally applicable to all licences;
 - (b) conditions specially applicable to a particular licence; or
 - (c) conditions applicable to a particular class of licensable healthcare service.
- (3) In addition, every licence granted to a licensee to provide a special licensable healthcare service is subject to the condition that the licensee must at all times also be granted a licence for at least one of the licensable healthcare services prescribed as underlying to that special licensable healthcare service.
- (4) Without limiting subsection (1), the Director may grant a renewal of a licence with or without modifying the conditions of the licence, but section 14(2), (3) and (4) does not apply to or in relation

to granting a renewal of a licence with modifications to the conditions of the licence.

Modifying conditions of licence

- **14.**—(1) Subject to this section, it is lawful for the Director to modify the conditions of a licence (except the condition mentioned in section 13(3)) without compensating the licensee concerned.
- (2) Before modifying any condition of a licence, the Director must give notice to the licensee holding that licence
 - (a) stating that the Director proposes to make the modification in the manner specified in the notice; and
 - (b) specifying the time (being not less than 14 days after the date the notice is served on the licensee) within which the licensee may make written representations to the Director with respect to the proposed modification.
- (3) Upon receiving any written representation mentioned in subsection (2), the Director must consider that representation and may
 - (a) reject the representation;
 - (b) amend the proposed modification in any manner that the Director thinks fit having regard to the representation; or
 - (c) withdraw the proposed modification.
 - (4) Where
 - (a) the Director rejects any written representation under subsection (3)(a);
 - (b) the Director amends any proposed modification to the conditions of the licence under subsection (3)(b); or
 - (c) no written representation is received by the Director within the time specified in subsection (2)(b), or any written representation made under that paragraph is subsequently withdrawn, and the licensee has not given immediate effect to the modification,

the Director must issue a written direction to the licensee concerned requiring the licensee, within the time specified by the Director, to give effect to the modification as specified in the notice under subsection (2) or as amended by the Director, as the case may be.

Amendment of licence

- **15.**—(1) A licensee that intends to
 - (a) provide the licensable healthcare service to which the licence relates
 - (i) at any premises not specified in the licence; or
 - (ii) using any conveyance not specified in the licence;
 - (b) stop providing the licensable healthcare service to which the licence relates at any premises, or stop using any conveyance, specified in the licence; or
 - (c) amend any other particulars or information (except conditions) specified in the licence,

must apply to the Director to amend the licence.

- (2) Despite subsection (1)(a), a licensee may, instead of applying for an amendment of a licence, apply for a fresh licence under section 10.
- (3) An application to amend a licence under subsection (1) must be
 - (a) in the form and manner that the Director requires;
 - (b) made no later than the prescribed time before the licensee provides the licensable healthcare service at the new premises or uses the new conveyance, or before the amendment is to take effect, as the case may be; and
 - (c) accompanied by an application fee (if prescribed).
- (4) Different application fees may be prescribed in respect of different types of amendments to a licence.
- (5) In deciding whether an application under subsection (1) should be granted, the Director must have regard to, and give such weight as

the Director considers appropriate to, the matters mentioned in section 11(3).

- (6) The Director may, when granting approval for an application for an amendment of a licence, modify any of the conditions of the licence as the Director considers appropriate without compensating the licensee concerned, but section 14(2), (3) and (4) does not apply to or in relation to these modifications to the conditions of the licence.
- (7) Upon approval of an application for an amendment of a licence, the Director must issue to the licensee a duly amended licence which replaces the original licence.

Restriction on transfer of licence

- **16.**—(1) A licence, and any rights, benefits or privileges under the licence, are not transferable or assignable to any other person unless
 - (a) the licence contains a condition authorising the transfer or assignment; and
 - (b) the Director consents in writing to the transfer or assignment.
- (2) Any consent under subsection (1) may be given subject to compliance with any conditions that the Director thinks fit to impose, which may include conditions modifying, or requiring or otherwise providing for the making of modifications to, the conditions of the licence, but section 14(2), (3) and (4) does not apply to or in relation to these modifications to the conditions of the licence.
- (3) A transfer or an assignment, or a purported transfer or assignment, of a licence, or of any rights, benefits or privileges under the licence, is void and of no effect
 - (a) if the licence is not capable of transfer or assignment;
 - (b) if the transfer or assignment, or purported transfer or assignment, is in breach of a condition of the licence; or
 - (c) if there has, before the transfer or assignment or purported transfer or assignment, been a contravention of a condition

subject to compliance with which the consent required by subsection (1) is given.

Voluntary cessation of licensable healthcare service or surrender of licence

- 17.—(1) A licensee must not, without giving the Director prior notice
 - (a) wholly and permanently stop, except upon the lapsing of a licence
 - (i) providing any licensable healthcare service to which the licence relates; or
 - (ii) using any premises or conveyance specified in the licence for the provision of the licensable healthcare service; or
 - (b) for any reason surrender the licence.
- (2) A notice under subsection (1) must be given to the Director not later than the prescribed time before either of the following dates:
 - (a) the date on which the licensee is to wholly and permanently stop providing the licensable healthcare service to which the licence relates, or stop using the premises or conveyance specified in the licence, as the case may be;
 - (b) the date on which the licensee intends the surrender of the licence to take place.
- (3) No part of any licence fee, renewal fee or other fee may be refunded to the licensee upon the cessation of a licensable healthcare service or surrender of a licence under this section.

Lapse of licence

- **18.**—(1) Unless expired or earlier revoked under section 20, a licence lapses
 - (a) if the licensee is an individual on the date the licensee dies; or

- (b) if the licensee is a partnership or body corporate or an unincorporated association on the date the partnership, body corporate or association ceases to exist.
- (2) No part of any licence fee or other fee may be refunded to the licensee upon the lapse of a licence under this section.

Security deposit

- **19.**—(1) The Director may, upon granting a licence, require a licensee to give a performance bond, guarantee or other form of security on the terms and conditions and of the amount that the Director considers appropriate
 - (a) to ensure that the provisions of this Act and the conditions of the licence will be duly observed; and
 - (b) to meet any financial penalty arising out of any proceedings under section 20 against the licensee.
- (2) If a licensee fails to pay any financial penalty ordered under section 20, the Director may enforce the payment by forfeiting the whole or any part of any security deposit placed by the licensee under this section.

Regulatory action against licensees, etc.

- **20.**—(1) Subject to this section and section 21, the Director may, without compensation, take any regulatory action described in subsection (2) against a licensee if the Director is satisfied that
 - (a) the licence has been obtained by the licensee by fraud, or the licensee has, in connection with the application for the grant of the licence, made a statement or provided any information or document that is false, misleading or inaccurate in a material particular;
 - (b) the licensee is contravening or not complying with, or has contravened or failed to comply with
 - (i) any condition of the licence;
 - (ii) any duty of a licensee under section 23(2) or (3), 24 or 25;

- (iii) any other provision of this Act, the contravention of which is not an offence under this Act;
- (iv) any provision of a code of practice applicable to the licensee;
- (v) any direction issued to the licensee by the Director under this Act; or
- (vi) any requirement of the Director under section 19 or subsection (2)(b)(iii) to give a security deposit or a direction under this section to pay a financial penalty;
- (c) the licensee is no longer a suitable person to be granted a licence, having regard to the matters mentioned in section 2(3);
- (d) the licensee is, or is likely to be, declared a bankrupt or has gone, or is likely to go, into compulsory or voluntary liquidation other than for the purpose of amalgamation or reconstruction;
- (e) the licensee has made any assignment to, or composition with, the licensee's creditors or, if the licensee is a company, is unable to pay its debts;
- (f) the licensee, or any of the following individuals, is convicted of an offence under this Act committed during the term of the licence:
 - (i) where the licensee is a company, limited liability partnership or other body corporate — any member of the board of directors or committee or board of trustees or other governing body, or the chief executive, any manager, secretary or other similar officer or any person who purported to act in any such capacity;
 - (ii) where the licensee is a partnership any partner of the partnership;
- (g) any premises at which the licensee provides, or any conveyance the licensee uses to provide, the licensable

healthcare service to which the licence relates, or any part of those premises or that conveyance, or any equipment in those premises or that conveyance, is no longer safe or suitable for use in providing that licensable healthcare service;

- (h) the licensee is unable to continue providing the licensable healthcare service to which the licence relates
 - (i) in a safe manner; or
 - (ii) in a manner that is clinically and ethically appropriate; or
- (i) the public interest so requires.
- (2) The regulatory action that the Director may take against a licensee is as follows:
 - (a) with or without forfeiting any security deposit given by the licensee under this section or section 19, revoke a licence of that licensee;
 - (b) in lieu of paragraph (a), all or any of the following:
 - (i) censure the licensee in writing;
 - (ii) modify any condition of the licence;
 - (iii) require the licensee to give an additional security deposit in the form mentioned in section 19;
 - (iv) forfeit the whole or part of any security deposit given by the licensee under this section and section 19 but not exceeding the limit in sub-paragraph (viii);
 - (v) direct the licensee to do, or refrain from doing, any thing specified in the direction, and within the period specified in the direction (if specified), to rectify a contravention or non-compliance or prevent a recurrence of the contravention or non-compliance;
 - (vi) shorten (for not longer than prescribed) the term of the licence;

- (vii) suspend the licence for a period that the Director thinks fit;
- (viii) direct the licensee to pay, within a period specified, a financial penalty of the amount that the Director thinks fit, being
 - (A) not more than \$10,000 for each contravention or non-compliance mentioned in subsection (1)(b) that is the subject; or
 - (B) in any other case, not more than \$10,000.
- (3) The revocation of a licence under subsection (2)(a), the shortening of the term of a licence under subsection (2)(b)(vi), or the suspension of a licence under subsection (2)(b)(vii), may be in respect of
 - (a) the licensable healthcare service to which the licence relates;
 - (b) one or more premises at which the licensable healthcare service authorised by the licence is provided; or
 - (c) one or more conveyances used to provide the licensable healthcare service.
- (4) For the purposes of subsection (1)(e), a company is unable to pay its debts if it is a company which is deemed to be so unable under any written law relating to the insolvency of companies.
- (5) In any proceedings under this section in relation to the conviction of any person for an offence, the Director must accept the person's conviction as final.

Procedure for regulatory action against licensees, etc.

- **21.**—(1) Before exercising any power under section 20, the Director must give notice to the licensee concerned
 - (a) stating that the Director intends to take regulatory action against the licensee under section 20;
 - (b) specifying the type of regulatory action in section 20(2) the Director proposes to take, and each instance of

- contravention or non-compliance that is the subject of the proposed action or the reason or reasons for the proposed regulatory action; and
- (c) specifying the time (being not less than 14 days after the date the notice is served on the licensee) within which written representations may be made to the Director with respect to the proposed regulatory action.
- (2) The Director may decide to take the appropriate regulatory action in section 20(2)
 - (a) after considering any written representation made to the Director pursuant to the notice mentioned in subsection (1); or
 - (b) after the time specified in the notice under subsection (1)(c), where no representation is so made or any written representation made is subsequently withdrawn.
- (3) However, subsection (2) does not apply where the licensee has died, is adjudged bankrupt, has been dissolved or wound up or has otherwise ceased to exist.
- (4) Where the Director decides under section 20(2) to take regulatory action against a licensee, the Director must serve on the licensee a notice of the decision.
- (5) A decision by the Director under section 20(2) takes effect only when the Director serves the notice in subsection (4) on the licensee concerned, or on a later date specified in the notice.
- (6) Any revocation, or shortening of the term, of any licence, or any direction issued under this section, does not affect
 - (a) the enforcement by any person of any right or claim against the licensee or former licensee, as the case may be; or
 - (b) the enforcement by the licensee or former licensee (as the case may be) of any right or claim against any person.
- (7) Where any financial penalty is imposed on a licensee under section 20(2)(b)(viii) for contravening or not complying with any matter in section 20(1)(b), any security deposit given by the licensee

under section 19 or 20(2)(b)(iii) to secure compliance by the licensee with the matter must not be forfeited by the Director for that contravention or non-compliance except to the extent necessary to pay the financial penalty.

- (8) A licensee that fails to pay any amount of a financial penalty imposed under section 20(2)(b)(viii) within the period specified for payment by the Director under that sub-paragraph is liable to pay interest at the same rate as for a judgment debt on the unpaid amount.
- (9) If the financial penalty imposed under section 20(2)(b)(viii) in relation to any regulatory action taken by the Director exceeds the total amount of the security deposit placed by the licensee under sections 19 and 20(2)(b)(iii), the amount of the excess is a debt due to the Government.
- (10) All financial penalties collected under section 20 must be paid into the Consolidated Fund.

Register of licensees

22. The Director must cause to be kept and maintained a register of licensees in the form and manner and containing the information that the Director thinks fit.

PART 3

SPECIAL DUTIES OF LICENSEES

Key appointment holders

- **23.**—(1) Every licensee must ensure that
 - (a) every key appointment holder of the licensee is in the opinion of the Director a suitable person to act in that capacity in relation to the licensee; and
 - (b) the composition of the key appointment holders satisfies the skills and competencies requirements prescribed or as specified in any code of practice if not prescribed.
- (2) Where the Director is satisfied that a key appointment holder of a licensee —

- (a) is not a suitable person to act in that capacity in relation to the licensee; or
- (b) does not possess any of the skills or competencies in subsection (1)(b), resulting in a contravention by the licensee of subsection (1)(b),

the Director may, without affecting the Director's power under section 20, issue a direction to the licensee to remove, within the period that the direction may specify, that key appointment holder from his or her appointment, and the licensee must comply with the direction, despite any other written law.

- (3) Every licensee must, within the prescribed period, notify the Director of
 - (a) the appointment of every key appointment holder of the licensee; and
 - (b) any change in any key appointment holder of the licensee.
- (4) A notification under subsection (3) must be made in the form and manner that the Director requires.

Appointment of Principal Officer and Clinical Governance Officer by licensee

- **24.**—(1) Every licensee must appoint a suitably qualified individual as the licensee's Principal Officer.
- (2) Every licensee that is authorised by a licence to provide a prescribed licensable healthcare service must appoint one or more suitably qualified individuals as the licensee's Clinical Governance Officer or Clinical Governance Officers to be responsible for the clinical and technical matters relating to the prescribed licensable healthcare service, and is or are to perform the functions in relation to the licensee, as may be prescribed.
- (3) For the purposes of subsections (1) and (2), an individual is a suitably qualified individual if the individual
 - (a) is a suitable person to act as the licensee's Principal Officer or Clinical Governance Officer, as the case may be; and

- (b) possesses the skills and competencies that are prescribed for the performance of the functions and duties of the licensee's Principal Officer or Clinical Governance Officer, as the case may be.
- (4) For the purposes of subsection (3), different skills and competencies may be prescribed in respect of different licensable healthcare services.
- (5) Every licensee must, within the prescribed period, notify the Director of the appointments in subsections (1) and (2) (if applicable), and any change in any of the appointments.
- (6) A notification of any change in an appointment under subsection (5) must be made in the form and manner that the Director requires.
 - (7) The licensee must ensure that
 - (a) the individual the licensee appoints as Principal Officer is suitably qualified to act as Principal Officer at all times during the term of the individual's appointment and the term of the licensee's licence; and
 - (b) every individual the licensee appoints as Clinical Governance Officer is suitably qualified to act as Clinical Governance Officer at all times during the term of the individual's appointment and the term of the licensee's licence.
- (8) Where an individual appointed as the licensee's Principal Officer or Clinical Governance Officer
 - (a) is not, or is no longer, suitable to act as Principal Officer or Clinical Governance Officer (as the case may be), the licensee must remove the individual from that individual's appointment as Principal Officer or Clinical Governance Officer (as the case may be), and appoint another individual as Principal Officer or Clinical Governance Officer, as the case may be; or
 - (b) for any other reason stops acting, or is unable to act, as Principal Officer or Clinical Governance Officer (as the

- case may be), the licensee must appoint another individual as Principal Officer or Clinical Governance Officer, as the case may be.
- (9) Where an individual appointed by a licensee as the licensee's Principal Officer or Clinical Governance Officer fails to perform any function of a Principal Officer or Clinical Governance Officer (as the case may be), the Director may, without affecting the Director's power under section 20, issue a direction to the licensee to remove and replace that individual as Principal Officer or Clinical Governance Officer (as the case may be), and the licensee must comply with that direction.
 - (10) Different periods may be prescribed for the licensee
 - (a) to remove an individual from that individual's appointment as Principal Officer or Clinical Governance Officer (as the case may be), and to appoint another individual as Principal Officer or Clinical Governance Officer, under subsection (8)(a); and
 - (b) to appoint an individual as Principal Officer or Clinical Governance Officer (as the case may be) under subsection (8)(b) where the individual previously appointed as Principal Officer or Clinical Governance Officer (as the case may be) stops acting, or is unable to act, in that capacity for any reason.

Appointment of specified committees

- **25.**—(1) This section applies only to a licensee of a prescribed category or description.
- (2) A section 25 licensee must appoint one or more specified committees as may be prescribed relating to
 - (a) the category or description of licensees to which the section 25 licensee belongs;
 - (b) any licensable healthcare service that is provided by the section 25 licensee; or

(c) any programme or activity undertaken or to be undertaken in relation to the provision of any licensable healthcare service by the section 25 licensee.

Ethics review of certain medical treatment

- **26.**—(1) This section applies only in relation to the provision of medical treatment of a prescribed category or description (called in this Act a prescribed medical treatment).
- (2) A licensee that intends to provide the prescribed medical treatment must, before the prescribed medical treatment is provided to the individual
 - (a) where the licensee is a section 25 licensee refer or cause to be referred the individual's case to at least one of the licensee's clinical ethics committees for an ethics review of the proposed prescribed medical treatment; or
 - (b) where the licensee is not a section 25 licensee refer or cause to be referred the individual's case to any clinical ethics committee appointed by a section 25 licensee for an ethics review of the proposed prescribed medical treatment.
- (3) A licensee may provide the prescribed medical treatment to the individual only if every clinical ethics committee that conducted an ethics review of the prescribed medical treatment is satisfied that the prescribed medical treatment is ethically appropriate.
 - (4) A person must not provide a prescribed medical treatment if—
 - (a) the individual's case has not been referred to a clinical ethics committee for an ethics review of the prescribed medical treatment under subsection (2); or
 - (b) any clinical ethics committee to which the individual's case is referred is not satisfied, following an ethics review under subsection (2), that the prescribed medical treatment is ethically appropriate.
- (5) A person (not being a licensee) that contravenes subsection (4) shall be guilty of an offence.

- (6) A licensee
 - (a) that fails to comply with subsection (2) or (3); or
 - (b) that allows a person to provide, or fails to take reasonable steps to prevent the person from providing, a prescribed medical treatment contrary to subsection (4),

shall be guilty of an offence.

(7) A person that is guilty of an offence under subsection (5) or (6) shall be liable on conviction to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

Record-keeping on healthcare service

- 27.—(1) A licensee must keep and maintain records, for the prescribed period and in the prescribed manner, where the records are relevant to the monitoring or evaluation of any aspect of any licensable healthcare service or the provision of any licensable healthcare service.
 - (2) A licensee must
 - (a) implement any prescribed safeguards to protect all records mentioned in subsection (1), and any computer system used to keep and maintain those records, against
 - (i) accidental or unlawful loss, modification or destruction; and
 - (ii) unauthorised access, disclosure, copying, use or modification;
 - (b) monitor and periodically evaluate the safeguards in paragraph (a) to ensure that
 - (i) the safeguards are effective; and
 - (ii) all individuals employed or authorised by the licensee who access or handle any record

- mentioned in subsection (1) comply with the safeguards; and
- (c) take all appropriate steps to ensure that each individual employed or authorised by the licensee who accesses or handles any record mentioned in subsection (1) is aware of
 - (i) the safeguards mentioned in paragraph (a); and
 - (ii) the individual's role and responsibility in maintaining the confidentiality, integrity and availability of the records.
- (3) A licensee must take reasonable care in the disposal or destruction of any record mentioned in subsection (1) so as to prevent unauthorised access to, or unauthorised disclosure or reproduction of, the record or any information in that record.
- (4) A licensee must not, in purported compliance with a requirement under subsection (1), make a record of any matter or thing in such a way that the matter or thing is not recorded accurately or completely or the record is not up to date.
- (5) A licensee that contravenes any requirement under this section shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both.

Approval of employment of individuals by certain licensees

- **28.**—(1) A licensee that provides a licensable healthcare service that is prescribed for the purposes of this section (called in this section a section 28 licensee)
 - (a) except with the Director's prior written approval, must not employ any individual who has been convicted of any prescribed offence (called in this section a restricted individual);
 - (b) must obtain the prescribed information, in the prescribed form and manner, from every individual
 - (i) that the section 28 licensee employs; or

- (ii) who seeks employment with the section 28 licensee;
- (c) must maintain records of the information mentioned in paragraph (b) in accordance with this section; and
- (d) must provide to the Director any information that the Director may require in respect of
 - (i) any individual that the section 28 licensee employs or has employed; or
 - (ii) any individual who seeks or has sought employment with the section 28 licensee.
- (2) In deciding whether an approval under subsection (1)(a) should be granted, the Director must have regard, and give such weight as the Director considers appropriate, to all the following matters:
 - (a) the nature of the duties and responsibilities that the restricted individual will be deployed or required to perform or undertake by the section 28 licensee;
 - (b) the nature and circumstances of the offence or offences of which the restricted individual was convicted;
 - (c) the likelihood that the restricted individual will re-offend or commit offences of the same or similar nature as the offence or offences mentioned in paragraph (b).
- (3) To avoid doubt, the Director is not confined to consideration of the matters in subsection (2) and may take into account any other matters and evidence that may be relevant.
- (4) For the purposes of subsection (1)(c), a section 28 licensee must maintain the records of the information mentioned in subsection (1)(b)
 - (a) throughout the duration of the individual's employment with the section 28 licensee; and
 - (b) for a period of 2 years following the cessation or termination for any reason of the individual's employment with the section 28 licensee.
- (5) A section 28 licensee that fails to comply with subsection (1)(a) shall be guilty of an offence and shall be liable on conviction to a fine

not exceeding \$50,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

Use of term or name

- **29.**—(1) Subject to subsection (2), a licensee
 - (a) must not use any term or name, or any abbreviation or derivative of that term or name, in any language, that incorrectly describes a licensable healthcare service that the licensee is authorised to provide under the licensee's licence; and
 - (b) must not use the term "Singapore" or "National", or any abbreviation or derivative of those terms, in the licensee's name or logo except with the Director's approval.
- (2) A licensee must not use any term or name, or any abbreviation or derivative of that term or name, in any language, that misleads or causes confusion, or is likely to mislead or cause confusion, as to the licensable healthcare service provided by the licensee.
- (3) A person that is not a licensee commits an offence if the person uses any prescribed term or name, or any abbreviation or derivative of that prescribed term or name, in any language, to convey the impression that the person provides any service, or engages in any activity, that is the same or similar to a service or an activity which may be provided only by a person authorised to provide a licensable healthcare service under a licence granted under this Act.
- (4) A person that is guilty of an offence under subsection (3) shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

Use of licensed premises or licensed conveyance for other purposes

- **30.**—(1) Subject to subsection (3), a licensee must not use, or allow any other person to use, the whole or any part of any licensed premises or licensed conveyance for any purpose other than
 - (a) the provision of a licensable healthcare service which the licensee is authorised to provide under the licence;
 - (b) the provision of any service, or carrying out of any activity, that is incidental to the provision of the licensable healthcare service in paragraph (a); or
 - (c) the provision of any healthcare service which is not licensable and is prescribed, subject to any conditions prescribed.
- (2) The Director may, subject to any conditions that the Director may impose, permit a licensee to use, or allow any other person to use, any part (but not the whole) of any licensed premises or licensed conveyance for any purpose that is not mentioned in subsection (1).
- (3) Except where provided in subsections (1)(b) and (c) and (2), a person that is not a licensee must not use the whole or any part of any licensed premises or licensed conveyance for any purpose.
- (4) A licensee that contravenes subsection (1), or fails to comply with any condition under subsection (2), shall be guilty of an offence.
- (5) Any person (not being a licensee) that contravenes subsection (3), or fails to comply with any condition under subsection (1)(c) or (2), shall be guilty of an offence.
- (6) A person that is guilty of an offence under subsection (4) or (5) shall be liable on conviction to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

Advertisement of licensable healthcare services

- **31.**—(1) A person must not advertise, or cause to be advertised, a licensable healthcare service unless the person
 - (a) is a licensee authorised to provide that licensable healthcare service; or
 - (b) is acting on the authority of the licensee mentioned in paragraph (a) in advertising the licensable healthcare service or causing the licensable healthcare service to be advertised.
- (2) For every advertisement of a licensable healthcare service by or caused by a licensee or a person mentioned in subsection (1)(b), the licensee and that person (if applicable) must ensure that the advertisement complies and is published in accordance with all prescribed requirements relating to the medium the advertisement appears in, and the content and form of the advertisement.
- (3) A person that fails to comply with subsection (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

PART 4

STEP-IN ARRANGEMENTS FOR DESIGNATED LICENSEES

Application of this Part

32. This Part applies only in relation to a licensee of a prescribed category or description (called in this Part a designated licensee).

Step-in order

- **33.**—(1) The Minister may make an order under this section (called a step-in order) if
 - (a) one or more licences of a designated licensee are suspended, revoked or surrendered;

- (b) a designated licensee
 - (i) is, or is likely to be, declared a bankrupt;
 - (ii) has gone, or is likely to go, into compulsory or voluntary liquidation other than for the purpose of amalgamation or reconstruction; or
 - (iii) is, or is likely to be, placed under judicial management of a judicial manager under any written law relating to the insolvency of companies;
- (c) a designated licensee is contravening or not complying with any provision of this Act;
- (d) a designated licensee is carrying on its operations in a manner that is detrimental, or is likely to be detrimental, to the interests of the designated licensee's patients or customers; or
- (e) the Minister considers it in the public interest to do so, and on receipt of the written opinion of the Director that it is necessary to take over some or all of the operations of the designated licensee to ensure that the designated licensee's patients or customers receive the appropriate healthcare services or an adequate provision of healthcare services.
- (2) Before a step-in order is made under subsection (1), but subject to subsection (3), the Minister must give the designated licensee concerned a reasonable opportunity to make written representations in respect of the proposed step-in order.
- (3) Where the Minister is of the opinion that it is necessary to make a step-in order on an expedited basis (called in this Part an expedited step-in order) in order to protect the safety and health of the designated licensee's patients or customers, the Minister may make an expedited step-in order, which takes effect on the date the order is served on the designated licensee.

- (4) A step-in order or an expedited step-in order
 - (a) may order the designated licensee
 - (i) to revoke the appointment of the designated licensee's Principal Officer or Clinical Governance Officer, and appoint another individual as the designated licensee's Principal Officer or Clinical Governance Officer (as the case may be) for the period specified in that order;
 - (ii) to revoke the appointment of all or any of the designated licensee's key appointment holders, and appoint another individual or other individuals as the designated licensee's key appointment holder or holders for the period specified in that order;
 - (iii) to transfer the designated licensee's patients or customers to the care or treatment of another licensee for the period specified in that order;
 - (iv) to appoint another licensee to provide a licensable healthcare service provided by the designated licensee for the period specified in that order; and
 - (v) to appoint a person to advise the designated licensee in the proper conduct of the designated licensee's business and operations;
 - (b) may authorise the Director
 - (i) to directly take over, or appoint a step-in operator to take over, the operations of the designated licensee or a specified part of those operations; and
 - (ii) to do any thing mentioned in paragraph (a);
 - (c) may specify that
 - (i) the step-in operator has the functions and powers in relation to the operations of the designated licensee that are specified in the order;

- (ii) the designated licensee is to stop providing healthcare services to specified patients or customers on and from a specified date;
- (iii) the step-in operator must have access to, and take control or management of, the premises or other assets and other property (including intellectual property), licences and employees used or required by the designated licensee for the purpose of carrying on the operations specified in the order; and
- (iv) the Director must have access to, and be able to make copies of or take extracts from, any document or record in the possession or under the control of the designated licensee that is relevant to the order;
- (d) where an order mentioned in paragraph (a)(iii) or (iv) is made, may specify, in addition to any matter that may be specified under paragraph (c), that
 - (i) the designated licensee must notify the Director of the identity of the other licensee mentioned in paragraph (a)(iii) or (iv); and
 - (ii) the other licensee must have access to, and be able to make copies of or take extracts from, any document or record in the possession or under the control of the designated licensee for the purpose of the order; and
- (e) may contain ancillary directions that may
 - (i) contain directions about how the costs of, and revenue generated from, providing the healthcare services are to be dealt with:
 - (ii) fix the remuneration and expenses to be paid by the designated licensee concerned to any person appointed under paragraph (a)(v) to advise the designated licensee in the proper conduct of the designated licensee's business and operations;

- (iii) specify the period for which the step-in order or expedited step-in order applies; and
- (iv) specify any other conditions that may apply.
- (5) Any decision of the Minister under subsection (1) or (3) is final.
- (6) A step-in order or an expedited step-in order operates to the exclusion of rights that are inconsistent with the step-in order or expedited step-in order, as the case may be.
- (7) Subject to subsections (8) and (9), the designated licensee mentioned in the step-in order or expedited step-in order, as the case may be
 - (a) must facilitate the handover of the operations to the step-in operator as specified in the step-in order or expedited step-in order, as the case may be;
 - (b) must not obstruct the step-in operator's access to the property of the designated licensee or the exercise by the step-in operator of the step-in operator's responsibilities under this section; and
 - (c) must comply with reasonable directions given by the step-in operator in the exercise of the step-in operator's responsibilities under this section.
- (8) Where a step-in order or an expedited step-in order mentioned in subsection (4)(a)(iii) is made, the designated licensee must facilitate the transfer of the designated licensee's patients or customers to the other licensee mentioned in subsection (4)(a)(iii).
- (9) Where a step-in order or an expedited step-in order mentioned in subsection (4)(a)(iv) is made, the designated licensee
 - (a) must facilitate the provision of the licensable healthcare service by the other licensee mentioned in subsection (4)(a)(iv); and
 - (b) must not obstruct that other licensee's access to and use of the property of the designated licensee for the purpose of the provision of the licensable healthcare service.

(10) A designated licensee that fails to comply with subsection (7), (8) or (9) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

Duration of step-in order or expedited step-in order

- **34.**—(1) The Minister may revoke a step-in order or an expedited step-in order at any time.
- (2) The appointment of a step-in operator in relation to the operations of a designated licensee or a specified part of those operations may be revoked by the Minister at any time
 - (a) if the Minister is satisfied that
 - (i) the reasons for the appointment have ceased to exist; or
 - (ii) it is no longer necessary for the protection of the designated licensee's patients or customers; or
 - (b) on any other ground,

and upon the revocation, the step-in operator ceases to be in control of those operations or that specified part of those operations.

Rules and saving for step-in arrangements

- **35.**—(1) The Minister may make rules to give effect to this Part, including making provision for applying, omitting or modifying provisions of any written law relating to the insolvency of companies (if applicable) where a step-in order or an expedited step-in order is made.
 - (2) Nothing effected or to be effected by, or done under, this Part
 - (a) is to be regarded as placing any person in breach of contract or confidence or as otherwise making any person guilty of a civil wrong;

- (b) is to be regarded as placing any person in breach of, or as constituting a default under, any Act or other law or obligation or any provision in any agreement, arrangement or understanding including, but not limited to, any provision or obligation prohibiting, restricting or regulating the assignment, transfer, sale or disposal of any property or the disclosure of any information;
- (c) is to be regarded as fulfilling any condition that allows a person to exercise a power, right or remedy in respect of, or to terminate, any agreement or obligation;
- (d) is to be regarded as giving rise to any remedy for a party to any contract or instrument, or as causing or permitting the termination of any contract or instrument, because of a change in the beneficial or legal ownership of any designated property;
- (e) is to be regarded as causing any contract or instrument to be void or otherwise unenforceable, or as frustrating any contract; or
- (f) releases any surety or other obligor wholly or in part from any obligation.

PART 5

ENFORCEMENT AND MONITORING COMPLIANCE

Power to obtain information

- **36.**—(1) The Director or an authorised officer may by notice require any licensee to provide, within a reasonable period or at the time or frequency, and in the form and manner, specified in the notice, all documents and information which
 - (a) relate to any matter which the Director considers necessary to carry out the Director's functions or duties under this Act; and

- (b) are
 - (i) within the knowledge of that licensee; or
 - (ii) in the licensee's custody or under the licensee's control.
- (2) The power to require a licensee to provide any document or information under subsection (1) includes the power
 - (a) to require that licensee, or any individual who is or was an officer or employee of the licensee, to provide an explanation of the document or information;
 - (b) if the document or information is not provided, to require that licensee or individual to state, to the best of the licensee's or individual's knowledge and belief, where it is and how it may be obtained; and
 - (c) if the information is recorded otherwise than in legible form, to require the information to be made available to the Director in legible form.
- (3) A person that, without reasonable excuse, fails to do anything required of the person by notice under subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

(4) A person —

- (a) that intentionally alters, suppresses or destroys any document or information which the person is, has been or may be required by a notice under subsection (1) to provide; or
- (b) that, in providing any document or information required under subsection (1), makes any statement which the person knows to be false or misleading in a material particular or recklessly makes such a statement,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$10,000 or to imprisonment for a term not exceeding 12 months or to both.

- (5) For the purposes of subsection (3), it is a reasonable excuse for a person to refuse or fail to provide any document or information which the person is required by a notice under subsection (1) to provide if doing so might tend to incriminate that person.
- (6) The Director is entitled without payment to keep any document or information provided to the Director under subsection (1).

Publication of information

- 37.—(1) The Director may publish, or cause to be published, in a form and manner determined by the Director, any information which the Director or an authorised officer has acquired or generated in the course of the Director or authorised officer exercising the functions, performing the duties or generally administering or enforcing this Act as the Director considers necessary or expedient to publish in the public interest.
- (2) Without limiting subsection (1), the Director may publish information relating to
 - (a) the lapsing, shortening, suspension or revocation of a licence or an exemption granted to any person;
 - (b) the making of a step-in order or an expedited step-in order against a designated licensee;
 - (c) the making of a direction under this Act against any person;
 - (d) the censure of any person;
 - (e) the removal of and replacement of any key appointment holder, Principal Officer or Clinical Governance Officer of a licensee;
 - (f) the acceptance by any person of an offer to compound any offence under this Act; and
 - (g) the conviction of any person for any offence under this Act.
- (3) This section does not override any restriction on the disclosure of any information under this Act.

Codes of practice

- **38.**—(1) The Director may
 - (a) issue one or more codes of practice applicable to all licensees or the licensees providing specified licensable healthcare services;
 - (b) approve as a code of practice applicable to all licensees or the licensees providing specified licensable healthcare services any document prepared by a person other than the Director if the Director considers the document suitable for this purpose; or
 - (c) amend or revoke any code of practice issued under paragraph (a) or approved under paragraph (b),

with respect to all or any of the matters in subsection (2).

- (2) The matters for the purposes of subsection (1) are
 - (a) the conduct of licensees;
 - (b) the measures necessary for licensees to deal with any plague, epidemic, outbreak, fire, flood, earthquake or disaster (natural or otherwise) or any other public emergency;
 - (c) the clinical and ethical aspects of licensable healthcare services;
 - (d) the appropriateness of care in relation to the provision of licensable healthcare services;
 - (e) the management and operations of licensees, the provision of licensable healthcare services, the quality of licensable healthcare services and the management and care of patients and customers;
 - (f) the maintenance or operation of any facilities and equipment used in relation to the provision of licensable healthcare services; and
 - (g) the health, security and safety of persons who are engaged in any work relating to the provision of licensable healthcare services.

- (3) A code of practice may, in particular, specify the duties and obligations of any licensee in relation to the licensee's business operation insofar as it relates to the provision of licensable healthcare services in Singapore.
- (4) If any provision in any code of practice is inconsistent with any provision of this Act, that provision, to the extent of the inconsistency
 - (a) is to have effect subject to this Act; or
 - (b) having regard to this Act, is not to have effect.
- (5) Where any code of practice is issued, approved, amended or revoked by the Director under subsection (1), the Director must
 - (a) publish a notice of the issue, approval, amendment or revocation (as the case may be) of the code of practice to every licensee to whom the code of practice applies;
 - (b) specify in the notice in paragraph (a) the date of issue, approval, amendment or revocation, as the case may be; and
 - (c) ensure that, so long as the code of practice remains in force, copies of that code of practice are made available (including on a website designated by the Director for this purpose), free of charge, to the licensees to whom the code of practice applies.
- (6) Until the notice in subsection (5) is published in accordance with that subsection
 - (a) no code of practice, and no amendment to any code of practice issued or approved under this section, has any force or effect as an approved code of practice; and
 - (b) no revocation of any code of practice issued or approved under this section has any force or effect.
- (7) A code of practice issued or approved under this section does not have legislative effect.
- (8) Subject to subsection (9), every licensee must comply with the relevant codes of practice applicable to the licensee.

- (9) The Director may, either generally or for any period that the Director may specify, waive the application of any code of practice, or any part of the code of practice, issued or approved under this section to any licensee.
- (10) Any contravention or failure by a person to comply with a code of practice that applies to the person
 - (a) does not of itself render the person liable to criminal proceedings; but
 - (b) in any proceedings (criminal or otherwise under this Act), may be relied on by any party to those proceedings as tending to establish or negate any liability which is in question in those proceedings.

Directions concerning health, safety or welfare of individuals, etc.

- **39.**—(1) The Director may give a direction to a licensee if the Director has reasonable grounds to believe that
 - (a) there are circumstances that may endanger, or are likely to endanger, the health, safety or welfare of
 - (i) individuals affected by the provision of a licensable healthcare service by the licensee; or
 - (ii) the general public in connection with the provision of a licensable healthcare service by the licensee; or
 - (b) the licensable healthcare service is being, or is likely to be, provided in a manner contrary to the rules of professional conduct and ethics applicable to any individual engaged in providing that service.
 - (2) A direction given under subsection (1)
 - (a) may require the licensee to do, or refrain from doing, any thing or things of any description that the direction may specify; and
 - (b) may be varied or revoked at any time by the Director.

(3) To avoid doubt —

- (a) a direction under subsection (1)(a) may require the licensee to stop the provision of a licensable healthcare service until the Director is satisfied that the circumstances in subsection (1)(a) no longer exist; and
- (b) a direction under subsection (1)(b) may require the licensee to stop the provision of a licensable healthcare service until the Director is satisfied that the licensee has ceased to, and will not, provide that service in the manner mentioned in subsection (1)(b).
- (4) Before giving a direction under subsection (1) to a licensee, the Director must, unless the Director in respect of that direction considers that it is not practicable or desirable, give notice to the licensee
 - (a) stating that the Director intends to give a direction to the licensee under this section and the nature of the direction; and
 - (b) specifying the time (being not less than 14 days after the date the notice is served on the licensee) within which written representations may be made to the Director with respect to the proposed direction.
 - (5) The Director may give or not give the direction
 - (a) after considering any written representation made to the Director pursuant to the notice in subsection (4); or
 - (b) after the time specified in the notice under subsection (4)(b), where no representation is so made or any written representation made is subsequently withdrawn.
- (6) The Director must serve on the licensee concerned a notice of the Director's decision under subsection (5).
- (7) A direction given under subsection (1) takes effect from the date on which the notice under subsection (6) is given, or on such other date as the notice may specify.

- (8) Every licensee must comply with every direction given under this section to the licensee as soon as it takes effect.
- (9) A licensee that fails to comply with any direction given to that licensee under subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$50,000 or to imprisonment for a term not exceeding 12 months or to both and, in the case of a continuing offence, to a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

Directions relating to quality assurance committees, etc.

- **40.**—(1) The Director may give a direction to a section 25 licensee to do anything required in this section, within the time and in the manner that the direction may specify.
- (2) A direction given under subsection (1) may relate to a quality assurance committee appointed by a section 25 licensee, and require the section 25 licensee to do any of the following:
 - (a) to require the quality assurance committee to conduct a further evaluation of any prescribed adverse event identified by that committee;
 - (b) to take any steps and implement any measures that the direction may specify, and report to the Director on the steps taken or measures implemented so as to
 - (i) prevent the occurrence or recurrence of any prescribed adverse event; or
 - (ii) implement any recommendation of the quality assurance committee to improve the quality of the licensable healthcare service provided by the section 25 licensee.
- (3) A direction given under subsection (1) may relate to a service review committee appointed by a section 25 licensee, and require the licensee
 - (a) to require the service review committee to conduct a further evaluation of any trend or pattern of events identified by that committee in connection with the

- section 25 licensee's provision of a licensable healthcare service, or undertaking of a programme in relation to the provision of a licensable healthcare service, that does not comply with any prescribed service requirements or code of practice applicable to that licensable healthcare service or programme, as the case may be; or
- (b) to take any steps and implement any measures that the direction may specify, and to report to the Director on the steps taken or measures implemented so as to
 - (i) prevent the occurrence or recurrence of any event that does not comply with any prescribed service requirements or code of practice applicable to any licensable healthcare service or programme (as the case may be) that the service review committee is appointed for; or
 - (ii) ensure that the section 25 licensee complies with the prescribed service requirements or code of practice mentioned in sub-paragraph (i).
- (4) A direction given under subsection (1) may relate to a clinical ethics committee appointed by a section 25 licensee, and require the licensee to require that committee to conduct a further ethics review of
 - (a) any proposed prescribed medical treatment mentioned in section 26 for an individual; or
 - (b) any other clinical case for which an ethics review is requested by the Director, the section 25 licensee or the medical practitioner in charge of that clinical case.
- (5) A direction mentioned in subsection (2)(b)(ii) or (3)(b)(ii) may require the section 25 licensee
 - (a) to change any of the section 25 licensee's procedures or practices in the provision of the licensable healthcare service; or
 - (b) to remove an individual from that individual's appointment as the section 25 licensee's Principal Officer or Clinical

Governance Officer (as the case may be), and appoint another individual as Principal Officer or Clinical Governance Officer, as the case may be.

- (6) Where the Director has reasonable grounds to believe that a quality assurance committee, service review committee or clinical ethics committee appointed by a section 25 licensee is not performing any function or discharging any duty under this Act in a proper or satisfactory manner, the Director may direct the section 25 licensee
 - (a) to remove or replace any member of that committee;
 - (b) to appoint one or more additional members to that committee; or
 - (c) to dissolve that committee and appoint another such committee in its place.

Powers of entry, inspection and search, etc.

- **41.**—(1) The Director or an authorised officer may, at any time and without notice and without warrant, enter, inspect and search any premises or conveyance, and the facilities in the premises or conveyance, that are being used, or that the Director or authorised officer has reasonable cause to believe are being used, to provide any healthcare service or to store any information relating to the provision of any healthcare service, for the purpose of
 - (a) investigating an offence under this Act or a contravention of or non-compliance with a provision under this Act;
 - (b) investigating whether any condition or restriction imposed on a licence or an approval is being complied with; or
 - (c) assessing whether the practices and procedures of a licensee are in compliance with this Act or an applicable code of practice.
- (2) For the purposes of subsection (1), the Director or authorised officer may
 - (a) inspect and make copies of or take extracts from, or require the occupier or any person having the management or

- control of the premises or conveyance to provide copies of or extracts from, any book, document, record or electronic material;
- (b) inspect and make copies of or take extracts from, or require the occupier or any person having the management or control of the premises or conveyance to provide copies of or extracts from, any medical record of any individual —
 - (i) who has been or is being treated or examined at the premises or conveyance; or
 - (ii) to whom a licensee has provided or is providing a licensable healthcare service,

even though the prior consent of that individual has not been obtained;

- (c) inspect, test, examine, remove and detain any apparatus, appliance, equipment or instrument used or found in the premises or conveyance;
- (d) inspect any test or procedure relating to any provision of a healthcare service that has been or is being conducted in the premises or conveyance, and inspect, test, examine, remove and detain any article used for or in connection with the test or procedure;
- (e) inspect, test, examine, remove and detain any blood sample, blood product, human tissue or fluid, any product of the human body, dialysate, chemical, pharmaceutical or any other substance found in the premises or conveyance; and
- (f) inspect, test, examine, remove and detain any container, article or other thing that the Director or authorised officer reasonably believes to contain or to have contained blood, blood product, human tissue or fluid, any product of the human body, dialysate, chemical, pharmaceutical or any other substance.
- (3) The Director or an authorised officer may seize from any premises or conveyance —

- (a) any blood sample, blood product, human tissue or fluid, any product of the human body, dialysate, chemical, pharmaceutical or any other substance;
- (b) any container, article or other thing that the Director or authorised officer reasonably believes to contain or to have contained blood, blood product, human tissue or fluid, any product of the human body, dialysate, chemical, pharmaceutical or any other substance; or
- (c) any book, document, record, electronic material, apparatus, appliance, equipment or instrument,

which the Director or authorised officer reasonably believes to be the subject matter of an offence under this Act or a contravention of or non-compliance with a provision under this Act, or to be connected with the commission of such an offence, contravention or non-compliance.

- (4) Where any article or document has been seized under subsection (3)
 - (a) the Director or authorised officer who seized the article or document must give written notice of the seizure to the person from whom it was seized, if the name and address of that person are known;
 - (b) the article or document may be kept or stored at the premises or conveyance where it was seized or may, at the direction of the Director or authorised officer, be removed to any other place
 - (i) to be kept or stored; or
 - (ii) for testing or examination; and
 - (c) in any case under paragraph (b)(i), the Director or authorised officer may
 - (i) mark, seal or label the article or document in any manner that the Director or authorised officer thinks fit for the purpose of indicating that it is under detention; and

- (ii) lock or seal the whole or part of the premises or conveyance in which the article or document is being detained.
- (5) Any person that, without the permission of the Director or authorised officer
 - (a) interferes, tampers with, removes or otherwise disposes of any article or document seized under subsection (3);
 - (b) alters, counterfeits, defaces, destroys, erases or removes any mark, seal or label placed by the Director or authorised officer under subsection (4)(c)(i); or
 - (c) opens, breaks or otherwise tampers with the lock or seal placed by the Director or authorised officer on the whole or part of any premises or conveyance under subsection (4)(c)(ii),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both.

- (6) Any individual who is present at any premises or conveyance mentioned in subsection (1) must render all necessary assistance and cooperation to the Director or an authorised officer as are necessary for an entry, inspection, investigation or otherwise for the exercise of his or her powers under this Act in relation to those premises or that conveyance.
 - (7) The Director or an authorised officer may
 - (a) require any person
 - (i) to provide any information within the person's knowledge; or
 - (ii) to produce any book, document, record, electronic material, article or thing within the person's possession for inspection by the Director or authorised officer and make copies of the book, document or other record, or to provide the Director or authorised officer with copies of the book, document or other record;

- (b) orally examine any person supposed to be acquainted with the facts and circumstances of any contravention or suspected contravention of a provision under this Act, and must —
 - (i) reduce to writing any statement made by the person so examined who is bound to state truly the facts and circumstances with which the person is acquainted;
 - (ii) read the statement over to the person so examined;
 - (iii) if the person does not understand English, interpret, or cause to be interpreted, the statement in a language that the person understands; and
 - (iv) require the person so examined to sign the statement, after correction, if any; and
- (c) require, by written order, the attendance before the Director or authorised officer of any person, being within the limits of Singapore, who, from information given or otherwise, appears to be acquainted with the facts and circumstances of any matter under this Act, and that person must attend as so required.

Offence of obstructing, etc., Director or authorised officer in exercise of powers, etc.

- **42.**—(1) Any person that
 - (a) refuses to give access to, or obstructs, hinders, impedes or delays, the Director or an authorised officer in the exercise of any power under this Act;
 - (b) without reasonable excuse, neglects or refuses to provide any information or produce any book, document, record, electronic material, article or thing which that person is required by or under this Act to provide or produce to the Director or an authorised officer; or
 - (c) neglects or refuses to attend before the Director or an authorised officer as required by or under this Act,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both.

(2) For the purposes of subsection (1)(b), it is a reasonable excuse for a person to refuse or fail to provide any information, produce any book, document or record or answer any question if doing so might tend to incriminate that person.

False or misleading statements, information or documents

- **43.** A person that, in relation to any matter under this Act
 - (a) makes any statement, or provides any information or document, that is false or misleading in a material particular; and
 - (b) knows or ought reasonably to know that, or is reckless as to whether, the statement, information or document is false or misleading in a material particular,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding \$20,000 or to imprisonment for a term not exceeding 12 months or to both.

Disposal of articles, documents, substances, etc.

- **44.**—(1) Any article, substance or document produced, detained or seized under this Act must
 - (a) where the article, substance or document is produced in any criminal trial, be dealt with in accordance with section 364(1) of the Criminal Procedure Code (Cap. 68); or
 - (b) in any other case, be returned to the owner or reported to a Magistrate's Court.
- (2) Where the report of any article, substance or document is made to a Magistrate's Court under subsection (1)(b), the Magistrate's Court may order the article, substance or document
 - (a) to be forfeited; or

- (b) to be disposed of in any manner that the Magistrate's Court thinks fit.
- (3) This section does not affect any right to retain or dispose of property which may exist in law apart from this section.

Offences by corporations

- **45.**—(1) Where, in a proceeding for an offence under this Act, it is necessary to prove the state of mind of a corporation in relation to a particular conduct, evidence that
 - (a) an officer, employee or agent of the corporation engaged in that conduct within the scope of his or her actual or apparent authority; and
- (b) the officer, employee or agent had that state of mind, is evidence that the corporation had that state of mind.
- (2) Where a corporation commits an offence under this Act, a person
 - (a) who is
 - (i) an officer of the corporation; or
 - (ii) an individual involved in the management of the corporation and in a position to influence the conduct of the corporation in relation to the commission of the offence; and
 - (*b*) who
 - (i) consented or connived, or conspired with others, to effect the commission of the offence;
 - (ii) is in any other way, whether by act or omission, knowingly concerned in, or is party to, the commission of the offence by the corporation; or
 - (iii) knew or ought reasonably to have known that the offence by the corporation (or an offence of the same type) would be or is being committed, and failed to take all reasonable steps to prevent or stop the commission of that offence,

shall be guilty of that same offence as is the corporation, and shall be liable on conviction to be punished accordingly.

- (3) A person mentioned in subsection (2) may rely on a defence that would be available to the corporation if it were charged with the offence with which the person is charged and, in doing so, the person bears the same burden of proof that the corporation would bear.
 - (4) To avoid doubt, this section does not affect the application of
 - (a) Chapters V and VA of the Penal Code; or
 - (b) the Evidence Act (Cap. 97) or any other law or practice regarding the admissibility of evidence.
- (5) To avoid doubt, subsection (2) also does not affect the liability of the corporation for an offence under this Act, and applies whether or not the corporation is convicted of the offence.
 - (6) In this section
 - "corporation" includes a limited liability partnership within the meaning of section 2(1) of the Limited Liability Partnerships Act (Cap. 163A);
 - "officer", in relation to a corporation, means any director, partner, chief executive, manager, secretary or other similar officer of the corporation, and includes
 - (a) any person purporting to act in any such capacity; and
 - (b) for a corporation whose affairs are managed by its members, any of those members as if the member were a director of the corporation;

"state of mind" of a person includes —

- (a) the knowledge, intention, opinion, belief or purpose of the person; and
- (b) the person's reasons for the intention, opinion, belief or purpose.

Offences by unincorporated associations or partnerships

- **46.**—(1) Where, in a proceeding for an offence under this Act, it is necessary to prove the state of mind of an unincorporated association or a partnership in relation to a particular conduct, evidence that
 - (a) an employee or agent of the unincorporated association or partnership engaged in that conduct within the scope of his or her actual or apparent authority; and
- (b) the employee or agent had that state of mind, is evidence that the unincorporated association or partnership had that state of mind.
- (2) Where an unincorporated association or a partnership commits an offence under this Act, a person
 - (a) who is
 - (i) an officer of the unincorporated association or a member of its governing body;
 - (ii) a partner in the partnership; or
 - (iii) an individual involved in the management of the unincorporated association or partnership and in a position to influence the conduct of the unincorporated association or partnership (as the case may be) in relation to the commission of the offence; and
 - (*b*) who
 - (i) consented or connived, or conspired with others, to effect the commission of the offence;
 - (ii) is in any other way, whether by act or omission, knowingly concerned in, or is party to, the commission of the offence by the unincorporated association or partnership; or
 - (iii) knew or ought reasonably to have known that the offence by the unincorporated association or partnership (or an offence of the same type) would be or is being committed, and failed to take all

reasonable steps to prevent or stop the commission of that offence,

shall be guilty of the same offence as is the unincorporated association or partnership (as the case may be), and shall be liable on conviction to be punished accordingly.

- (3) A person mentioned in subsection (2) may rely on a defence that would be available to the unincorporated association or partnership if it were charged with the offence with which the person is charged and, in doing so, the person bears the same burden of proof that the unincorporated association or partnership would bear.
 - (4) To avoid doubt, this section does not affect the application of
 - (a) Chapters V and VA of the Penal Code; or
 - (b) the Evidence Act or any other law or practice regarding the admissibility of evidence.
- (5) To avoid doubt, subsection (2) also does not affect the liability of an unincorporated association or a partnership for an offence under this Act, and applies whether or not the unincorporated association or partnership is convicted of the offence.
 - (6) In this section
 - "officer", in relation to an unincorporated association (other than a partnership), means the president, the secretary, or any member of the committee of the unincorporated association, and includes
 - (a) any person holding a position analogous to that of president, secretary or member of a committee of the unincorporated association; and
 - (b) any person purporting to act in any such capacity;

"partner" includes a person purporting to act as a partner;

"state of mind" of a person includes —

(a) the knowledge, intention, opinion, belief or purpose of the person; and

(b) the person's reasons for the intention, opinion, belief or purpose.

Composition of offences

- **47.**—(1) The Director may compound any offence under this Act that is prescribed as a compoundable offence by collecting from a person reasonably suspected of having committed the offence a sum not exceeding the lower of the following:
 - (a) one half of the amount of the maximum fine that is prescribed for the offence;
 - (b) \$10,000.
- (2) On payment of the sum of money, no further proceedings are to be taken against that person in respect of the offence.
- (3) All sums collected under this section must be paid into the Consolidated Fund.

PART 6

APPEALS

Appeals to Minister

- **48.**—(1) The former holder of a licence revoked under section 20(2)(a) (called the appellant) may appeal to the Minister against the Director's decision under that section to revoke the licence.
- (2) An applicant for a licence (called the appellant) may appeal to the Minister against any refusal by the Director under section 11(1)(b) to grant the applicant the licence.
- (3) A licensee that is aggrieved by any of the following decisions of the Director (called the appellant) may appeal to the Minister against the decision:
 - (a) any refusal of the Director under section 11(1)(b) to grant on renewal the licensee's licence;
 - (b) any regulatory action taken against the licensee under section 20(2)(b);

- (c) any direction of the Director under section 23(2) to remove an individual from his or her appointment as a key appointment holder of the appellant;
- (d) any direction of the Director under section 24(9) to remove an individual from his or her appointment as the appellant's Principal Officer or Clinical Governance Officer and replace that individual.
- (4) A section 25 licensee (called the appellant) may appeal to the Minister against a direction made by the Director under section 40.
 - (5) An appeal under this section
 - (a) must be in writing;
 - (b) must specify the grounds on which it is made; and
 - (c) must be made within the prescribed period after the appellant is notified of the Director's decision or direction (as the case may be) that is appealed against.
- (6) The Minister may reject an appeal of an appellant that fails to comply with subsection (5).
 - (7) After consideration of an appeal, the Minister may
 - (a) reject the appeal and confirm the Director's decision or direction, as the case may be; or
 - (b) allow the appeal and substitute or vary the Director's decision or direction, as the case may be.
 - (8) The Minister's decision on an appeal is final.
- (9) Every appellant must be notified of the Minister's decision under subsection (7).
- (10) An appeal against the Director's decision or direction, as the case may be
 - (a) does not affect the operation of the decision or direction (as the case may be) appealed against or prevent the taking of action to implement the decision or direction, as the case may be; and

(b) unless otherwise directed by the Minister, the decision or direction (as the case may be) appealed against must be complied with until the determination of the appeal.

Appeal Advisory Board

- **49.**—(1) The Minister may, before deciding an appeal under section 48, refer the appeal (called in this section the referred appeal) to an Appeal Advisory Board established under this section.
- (2) The Appeal Advisory Board must submit to the Minister a written report on the referred appeal, and may include in that report any recommendations that the Board thinks fit.
- (3) The Minister must, before deciding on the referred appeal, consider the report submitted under subsection (2), but is not bound by the recommendations in the report.
- (4) The Minister may from time to time appoint one or more Appeal Advisory Boards, each comprising
 - (a) 2 members who are members of any professional body that the Minister thinks fit; and
 - (b) a lay person.
 - (5) The members of an Appeal Advisory Board
 - (a) are to be appointed by the Minister for any period that the Minister may determine and may be re-appointed;
 - (b) may be removed from his or her office by the Minister; and
 - (c) may resign from his or her office, by written notice to the Minister.
- (6) At any meeting of an Appeal Advisory Board, all members must be present to constitute a quorum.
- (7) Subject to this Act, the Appeal Advisory Board may determine its own procedures.

Minister may designate others to hear appeals

- **50.**—(1) The Minister may designate any of the following persons to hear and determine, in the Minister's place, any appeal or a specific appeal under section 48:
 - (a) the Second Minister (if any) for his or her Ministry;
 - (b) any Minister of State, including a Senior Minister of State, for his or her Ministry;
 - (c) any Parliamentary Secretary, including a Senior Parliamentary Secretary, to his or her Ministry.
- (2) A reference to the Minister in sections 48 and 49(1), (2) and (3) includes a reference to a person designated under subsection (1).

PART 7

MISCELLANEOUS

Confidentiality of information, etc.

- **51.**—(1) Except in criminal proceedings for an offence under this Act, the Director and an authorised officer are not compellable in any proceedings to give evidence in respect of, or to produce, any document, information, electronic material or data storage device which has been obtained from any licensee or any other person in the course of carrying out any investigation or performing any duty or function under this Act.
- (2) The Director and an authorised officer must not disclose any medical information contained in the medical record of any individual, or information relating to the condition, treatment or diagnosis of any individual, that has come to the knowledge of the Director or authorised officer in the course of carrying out any investigation or performing any duty or function under this Act, unless the disclosure is made
 - (a) under or for the purpose of administering and enforcing
 - (i) this Act;
 - (ii) the CareShield Life and Long-Term Care Act 2019 (Act 26 of 2019);

- (iii) the Health Products Act (Cap. 122D);
- (iv) the Human Biomedical Research Act 2015 (Act 29 of 2015);
- (v) the Human Organ Transplant Act (Cap. 131A);
- (vi) the Infectious Diseases Act (Cap. 137);
- (vii) the Medical and Elderly Care Endowment Schemes Act (Cap. 173A);
- (viii) the Medicines Act (Cap. 176);
 - (ix) the MediShield Life Scheme Act 2015 (Act 4 of 2015);
 - (x) the National Registry of Diseases Act (Cap. 201B);
 - (xi) the Termination of Pregnancy Act (Cap. 324); or
- (xii) the Voluntary Sterilization Act (Cap. 347);
- (b) for the purpose of making a complaint or providing information
 - (i) under Part V of the Allied Health Professions Act;
 - (ii) under Part V of the Dental Registration Act;
 - (iii) under Part 7 of the Medical Registration Act;
 - (iv) in respect of the matters in section 37(1) of the Nurses and Midwives Act;
 - (v) in respect of the matters in section 20(3) of the Optometrists and Opticians Act;
 - (vi) under Part VI of the Pharmacists Registration Act; or
 - (vii) under Part IVA of the Traditional Chinese Medicine Practitioners Act; or
- (c) for any other purpose with the consent of the person to whom the information relates or the representative of that person.

- (3) Subject to subsection (4), an individual who is or was a member of a quality assurance committee appointed by a section 25 licensee is not competent or compellable
 - (a) to produce before any court, tribunal, board or person any document in that individual's possession or under that individual's control that was created by, at the request of or solely for the purpose of, the quality assurance committee; or
 - (b) to disclose to any court, tribunal, board or person any information that has come to that individual's knowledge as a member of the quality assurance committee.
- (4) Subsection (3) does not apply to a requirement made by any court, tribunal, board or person for the production of any document or the disclosure of any information in proceedings in respect of any act or omission by a quality assurance committee or by an individual as a member of a quality assurance committee, unless the Director directs otherwise.
- (5) A finding or recommendation by a quality assurance committee as to the need for change or improvement in relation to any licensable healthcare service provided, or any practice or procedure carried out, by the section 25 licensee that appointed the quality assurance committee is not admissible in any proceedings as evidence that the licensable healthcare service, practice or procedure (as the case may be) is or was inappropriate or inadequate.
 - (6) In this section
 - "medical information" means information about an individual that relates to the assessment, diagnosis, treatment, prevention or alleviation of an ailment, a condition, disability, disease or disorder or an injury affecting any part of the human body or mind;

"representative" —

(a) in relation to a deceased person, means his or her executor, administrator or next-of-kin;

- (b) in relation to an infant, means one of his or her parents or his or her guardian; and
- (c) in relation to a person (P) who lacks capacity within the meaning of the Mental Capacity Act (Cap. 177A), means
 - (i) a donee of a lasting power of attorney which is granted by *P* under the Mental Capacity Act, and under which *P* confers on the donee authority to consent on *P*'s behalf to the disclosure; or
 - (ii) a deputy who is appointed or deemed to be appointed for *P* by the court under the Mental Capacity Act, and who is conferred power to consent on *P*'s behalf to the disclosure.

Service of documents

- **52.**—(1) A document that is permitted or required by this Act to be served on a person may be served as described in this section.
- (2) A document permitted or required by this Act to be served on an individual may be served
 - (a) by giving it to the individual personally;
 - (b) by sending it by prepaid registered post to the address specified by the individual for the service of documents or, if no address is so specified, the individual's residential address or business address;
 - (c) by leaving it at the individual's residential address with an adult apparently resident there, or at the individual's business address with an adult apparently employed there;
 - (d) by affixing a copy of the document in a conspicuous place at the individual's residential address or business address;
 - (e) by sending it by fax to the fax number last known to the person giving or serving the document as the fax number for the service of documents on the individual; or

- (f) by sending it by email to the individual's last email address.
- (3) A document permitted or required by this Act to be served on a partnership (other than a limited liability partnership) may be served
 - (a) by giving it to any partner or other similar officer of the partnership;
 - (b) by leaving it at, or by sending it by prepaid registered post to, the partnership's business address;
 - (c) by sending it by fax to the fax number used at the partnership's business address; or
 - (d) by sending it by email to the partnership's last email address.
- (4) A document permitted or required by this Act to be served on a body corporate (including a limited liability partnership) may be served
 - (a) by giving it to the body corporate's secretary or other similar officer, or the limited liability partnership's manager;
 - (b) by leaving it at, or by sending it by prepaid registered post to, the body corporate's registered office or principal office in Singapore;
 - (c) by sending it by fax to the fax number used at the body corporate's registered office or principal office in Singapore; or
 - (d) by sending it by email to the body corporate's last email address.
 - (5) Service of a document under this section takes effect
 - (a) if the document is sent by fax and a notification of successful transmission is received, on the day of transmission;

- (b) if the document is sent by email, at the time that the email becomes capable of being retrieved by the person to whom the document is sent; and
- (c) if the document is sent by prepaid registered post, 2 days after the day the document was posted (even if it is returned undelivered).
- (6) However, service of any document under this Act on a person by email may be effected only with the person's prior consent (express or implied) to service in that way.
- (7) This section does not apply to documents to be served in proceedings in court.
 - (8) In this section —

"business address" means —

- (a) in the case of an individual, the individual's usual or last known place of business, or place of employment, in Singapore; or
- (b) in the case of a partnership (other than a limited liability partnership), the partnership's principal or last known place of business in Singapore;

"document" includes a notice or an order permitted or required by this Act to be served;

"last email address" means —

- (a) the last email address given by the addressee concerned to the person giving or serving the document as the email address for the service of documents under this Act; or
- (b) the last email address of the addressee concerned known to the person giving or serving the document;

"residential address" means an individual's usual or last known place of residence in Singapore.

General exemption

53. The Minister may, by order in the *Gazette*, exempt any person, premises or conveyance or any class of persons, premises or conveyances, from all or any of the provisions of this Act, either generally or in a particular case and subject to any conditions that the Minister may impose.

Jurisdiction of courts

54. Despite the Criminal Procedure Code, a District Court has jurisdiction to try any offence under this Act and has power to impose the full penalty or punishment for any such offence.

Protection from personal liability

- **55.** No liability shall lie personally against
 - (a) the Director;
 - (b) any authorised officer;
 - (c) any individual appointed under section 7(5) to assist the Director in the administration of this Act;
 - (d) any member of any quality assurance committee appointed by a section 25 licensee or any person acting under the direction of such a member; or
 - (e) any member of an Appeal Advisory Board appointed by the Minister under section 49,

who, acting in good faith and with reasonable care, does or omits to do anything in the execution or purported execution of this Act.

Amendment of Schedules

- **56.**—(1) The Minister may, by order in the *Gazette*, amend the First or Second Schedule.
- (2) In making an order under subsection (1), the Minister may include provisions of a saving or transitional nature consequent on the enactment of the order as the Minister may consider necessary or expedient.

- (3) In particular, the Minister may, in making an order under subsection (1) in relation to the Second Schedule, provide for different appointed days for different licensable healthcare services provided in private hospitals, medical clinics, clinical laboratories or healthcare establishments within the meaning given by section 2 of the repealed Act.
- (4) For the purposes of this Act, "appointed day", for a licensable healthcare service provided in a private hospital, medical clinic, clinical laboratory or healthcare establishment within the meaning given by section 2 of the repealed Act, means a date that licensable healthcare service is specified in the First Schedule.
- (5) Every order made under subsection (1) must be presented to Parliament as soon as possible after publication in the *Gazette*.

Regulations

- **57.**—(1) The Minister may make regulations for carrying out or giving effect to this Act.
- (2) In particular, the Minister may make regulations for any of the following:
 - (a) the duties and responsibilities of licensees;
 - (b) the form and manner in which an application for or in relation to any licence under this Act may be made, and the information and documents required to be provided in connection with such an application;
 - (c) the fees to be paid in respect of applications for and the grant (including the late renewal) of any licence or approval, and otherwise in connection with the administration of this Act, and the waiver, reduction or refund of fees charged;
 - (d) the records of patients, customers and staff that licensees must keep and maintain and the provision of returns and other information with respect to the provision of licensable healthcare services;
 - (e) the requirements as to the number and qualifications of nursing and other staff to be employed by licensees;

- (f) the apparatus, appliances, equipment and instruments to be provided and maintained by licensees;
- (g) the requirements as to the emergency ambulances and medical transports used by licensees for the provision of licensable healthcare services, and the apparatus, appliances, equipment and instruments the emergency ambulances and medical transports are equipped with;
- (h) the minimum standards of accommodation, sanitisation and other amenities to be provided by licensees;
- (i) the standards of cleanliness and hygiene to be observed, and infection control measures to be undertaken, by licensees;
- (*j*) the safety and welfare of patients and customers of licensees, and the quality of care and continuity of care to be provided by licensees for their patients and customers;
- (k) the management, control, superintendence and care of the facilities and services provided by licensees;
- (*l*) the skills, competencies, functions and duties of the key appointment holders of licensees;
- (m) the minimum qualifications, functions, duties and responsibilities of the Principal Officer and Clinical Governance Officers of licensees;
- (n) the specified committees that section 25 licensees are required to appoint, including
 - (i) the functions and duties of any specified committee;
 - (ii) the licensable healthcare services, or the programmes or activities relating to the provision of any licensable healthcare service, for which any specified committee is appointed; and
 - (iii) the composition and procedures of and responsibilities that apply to any specified committee, including —

- (A) the disclosure and treatment of conflicts of interest or potential conflicts of interest of a member of that committee;
- (B) the appointment of any person to oversee or supervise the activities of that committee in the performance of that committee's functions and duties; and
- (C) the keeping and maintenance of records, for the period and in the manner prescribed, relating to any activity, finding or recommendation of that committee, and the implementation of any such recommendation by the section 25 licensee that appointed that committee;
- (o) the duties of section 25 licensees in relation to any recommendations of any specified committee appointed by those licensees, including the taking of any corrective actions to implement those recommendations and the keeping and maintenance of records relating to those corrective actions;
- (p) the records in relation to any matter that is relevant to monitoring or evaluating any aspect of any licensable healthcare service or the provision of any licensable healthcare service, including the safeguards that licensees must implement to protect those records, and any computer system used to keep and maintain those records, against
 - (i) accidental or unlawful loss, modification or destruction; and
 - (ii) unauthorised access, disclosure, copying, use or modification;
- (q) the service standards and other requirements or conditions that apply to the provision of licensable healthcare services;
- (r) the measures licensees must take to promote or facilitate price transparency for patients and customers, including

- requirements for bill itemisation, financial counselling and display of fees chargeable;
- (s) the requirements for advertisements of licensable healthcare services relating to the media those advertisements appear in, and the content and form of those advertisements;
- (t) the manner in which appeals may be made to the Minister under this Act and the procedure for those appeals;
- (u) all matters and things required or permitted to be prescribed under or for the purposes of this Act.
- (3) The regulations made under this section may
 - (a) prescribe different requirements for different licensable healthcare services;
 - (b) prescribe different fees for different licensable healthcare services;
 - (c) prescribe for different section 25 licensees to appoint different specified committees;
 - (d) prescribe the offences under this Act that may be compounded; and
 - (e) provide that any contravention of any provision of the regulations shall be an offence punishable with a fine not exceeding \$20,000 or with imprisonment for a term not exceeding 12 months or with both and, in the case of a continuing offence, with a further fine not exceeding \$1,000 for every day or part of a day during which the offence continues after conviction.

Repeal of Private Hospitals and Medical Clinics Act

58. The Private Hospitals and Medical Clinics Act (Cap. 248) is repealed.

Consequential and related amendments to other Acts

59.—(1) Section 2(1) of the CareShield Life and Long-Term Care Act 2019 (Act 26 of 2019) is amended by inserting, immediately after

the words "Private Hospitals and Medical Clinics Act (Cap. 248)" in paragraph (a) of the definition of "healthcare institution", the words "or a provider of licensable healthcare services licensed under the Healthcare Services Act 2020".

- (2) The Criminal Procedure Code (Cap. 68, 2012 Ed.) is amended
 - (a) by inserting, immediately after the words "Private Hospitals and Medical Clinics Act (Cap. 248)" in sections 247(7)(a), 249(4)(a), 252(4)(a) and 255(4)(a), the words "or in respect of which a licence is granted under the Healthcare Services Act 2020"; and
 - (b) by inserting, immediately after the words "the Private Hospitals and Medical Clinics Act" in sections 249(15)(a), 252(12)(a) and 255(11)(a), the words "or in respect of which a licence is granted under the Healthcare Services Act 2020".
- (3) Section 2 of the Human Biomedical Research Act 2015 (Act 29 of 2015) is amended by deleting the word "or" at the end of paragraph (a) of the definition of "healthcare institution", and by inserting immediately thereafter the following paragraph:
 - "(aa) the holder of a licence granted under the Healthcare Services Act 2020 which specifies any premises or conveyance; or".
- (4) Section 2 of the Human Organ Transplant Act (Cap. 131A, 2012 Ed.) is amended by deleting the definition of "licensee" and substituting the following definition:
 - ""licensee", in relation to a hospital, means a person
 - (a) to whom a licence has been issued under the Private Hospitals and Medical Clinics Act (Cap. 248) in respect of the hospital; or
 - (b) who is authorised to provide an acute hospital service under a licence granted under the Healthcare Services Act 2020;".

- (5) Section 10(1) of the Infectious Diseases Act (Cap. 137, 2003 Ed.) is amended by inserting, immediately after the words "healthcare establishment" in paragraph (b), the words "or holder of a licence granted under the Healthcare Services Act 2020".
- (6) Section 25(1) of the Medical and Elderly Care Endowment Schemes Act (Cap. 173A, 2001 Ed.) is amended by inserting, immediately after paragraph (c), the following paragraphs:
 - "(ca) where the organisation is the holder of a licence granted under the Healthcare Services Act 2020, the licence is revoked or suspended or otherwise ceases to be in force;
 - (cb) where the premises at which approved services are provided are licensed premises within the meaning given by section 2(1) of the Healthcare Services Act 2020, the organisation's licence under that Act in relation to those premises is revoked or suspended or otherwise ceases to be in force;".
- (7) Section 2 of the National Registry of Diseases Act (Cap. 201B, 2008 Ed.) is amended
 - (a) by deleting the word "or" at the end of paragraph (a) of the definition of "healthcare institution", and by inserting immediately thereafter the following paragraph:
 - "(aa) any premises or conveyance specified in a licence granted under the Healthcare Services Act 2020; or"; and
 - (b) by deleting the word "person" in the definition of "manager" and substituting the word "individual".
 - (8) [Deleted by Act 31 of 2022 wef 01/11/2022]
- (9) Section 2 of the Voluntary Sterilization Act (Cap. 347, 2013 Ed.) is amended
 - (a) by inserting, immediately after paragraph (a) of the definition of "health institution", the following paragraph:
 - "(aa) any premises specified in a licence granted under the Healthcare Services Act 2020

- authorising the holder of the licence to provide an acute hospital service;";
- (b) by deleting the word "or" at the end of paragraph (b) of the definition of "health institution", and by inserting immediately thereafter the following paragraph:
 - "(ba) any premises specified in a licence granted under the Healthcare Services Act 2020 authorising the holder of the licence to provide an ambulatory surgical centre service; or"; and
- (c) by deleting the definition of "specialist medical clinic" and substituting the following definition:
 - ""specialist medical clinic" means either of the following where a registered medical practitioner who is registered under section 22 of the Medical Registration Act as a specialist in any prescribed branch of medicine works:
 - (a) a medical clinic that is licensed under the Private Hospitals and Medical Clinics Act;
 - (b) any premises specified in a licence granted under the Healthcare Services Act 2020 authorising the holder of the licence to provide a medical clinic service;".

Saving and transitional provisions

- **60.**—(1) Subject to the adaptations provided in the Third Schedule, this Act applies to and in relation to
 - (a) the provision of any licensable healthcare service in any premises or conveyance as a private hospital, medical clinic, clinical laboratory or healthcare establishment authorised by a licence under the repealed Act that —

- (i) is issued before the appointed day for that licensable healthcare service; and
- (ii) is in force immediately before that appointed day; and
- (b) every application under the repealed Act for the grant of a licence under the repealed Act to use any premises or conveyance as a private hospital, medical clinic, clinical laboratory or healthcare establishment which is pending on the day immediately before the appointed day for private hospitals, medical clinics, clinical laboratories or healthcare establishments, as the case may be.
- (2) For a period of 2 years after the date of commencement of this section, the Minister may, by regulations, prescribe any additional provisions of a saving or transitional nature consequent on the enactment of this section that the Minister may consider necessary or expedient.
- (3) Nothing in this section or the Third Schedule affects section 16 of the Interpretation Act (Cap. 1).

FIRST SCHEDULE

Sections 3(1) and 56(4)

LICENSABLE HEALTHCARE SERVICES

- 1. For the purposes of the definition of "licensable healthcare service" in section 3, "licensable healthcare service" means any of the following:
 - (a) Blood banking service;
 - (b) Clinical laboratory service;
 - (c) Cord blood banking service;
 - (d) Emergency ambulance service;
 - (e) Medical transport service;
 - (f) Nuclear medicine assay service;
 - (g) Nuclear medicine imaging service;
 - (h) Radiological service.

2. In this Schedule and the Second Schedule —

"blood" means whole human blood;

- "blood banking service" means a service relating to blood or blood components for therapeutic transfusion that comprises all or any of the following activities:
 - (a) the collection of blood or blood components;
 - (b) the testing, processing and distribution of blood or blood components;
 - (c) the storage of blood or blood components incidental to any activity mentioned in paragraph (a) or (b),

but does not include any of the following:

- (d) the temporary storage of any blood or blood component by a specified person, where the storage is incidental to the provision of the blood or blood component to the patients of the specified person;
- (e) the temporary storage by a specified person (A) of any blood or blood component received from another specified person (B), where
 - (i) the blood or blood component is intended to be provided by A to B's patients; and
 - (ii) the storage is incidental to A's provision of the blood or blood component to B's patients;
- (f) the distribution of any blood or blood component to a specified person (C) on a named patient basis, where C does not further distribute the blood or blood component to another specified person (D) for use by any patient of D other than on a named patient basis;
- (g) the distribution of any blood or blood component that is approaching its expiry date in the possession of a specified person to another specified person, for the sole purpose of preventing the wastage of the blood or blood component, as the case may be;
- (h) the distribution of any blood or blood component in the possession of a specified person to another specified person in response to a national emergency or any other emergency (such

as a fire or an explosion) that causes loss of life or injury to individuals;

- (i) a cord blood banking service;
- "blood component" includes plasma, red blood cells, white blood cells, platelets and cryoprecipitate;
- "clinical laboratory service" means the examination or testing of any matter derived from the body of any individual for the purpose of
 - (a) assessing the health, condition or genetic predisposition of that individual or any other individual;
 - (b) predicting or providing a prognosis of the health or medical condition of that individual or any other individual;
 - (c) diagnosing a disease, disability or condition or an injury of the body or mind of that individual or any other individual;
 - (d) determining the intervention to be taken, or the effect of any intervention taken, of a disease, disability or condition or an injury of the body or mind of an individual;
 - (e) ascertaining the result of a medical or surgical treatment given to that individual or any other individual; or
 - (f) assessing the health, condition or suitability of any human biological material that is used, or is intended to be used, in relation to any healthcare service,

but does not include any of the following:

- (g) a nuclear medicine assay service;
- (h) the testing of any matter derived from the body of any individual that only involves the use of a simple in vitro diagnostic test
 - (i) by a person licensed under the Private Hospitals and Medical Clinics Act 1980 to use any premises or conveyance as a healthcare institution within the meaning of that Act and that is incidental to the provision of the services authorised under that Act to be provided in the healthcare institution by that person; or
 - (ii) by a licensee and that is incidental to the provision of the licensable healthcare service that the licensee is licensed to provide;

"cord blood" means the whole blood (including haematopoietic progenitor cells) remaining in the placental and umbilical cord blood vessels after an umbilical cord has been clamped;

"cord blood banking service" —

- (a) means
 - (i) the handling, processing and storage of cord blood; and
 - (ii) the distribution of cord blood for use with any individual (including the individual from whom the cord blood was obtained); and
- (b) includes the screening of donors of cord blood;

"emergency ambulance" means a vehicle which —

- (a) is used or intended to be used to convey by land any patient (including an emergency patient); and
- (b) is equipped for the provision of clinical care to, and the clinical monitoring of, the patient while the patient is being conveyed;

"emergency ambulance service" means —

- (a) the conveyance by land using an emergency ambulance of any patient (including an emergency patient); and
- (b) the provision of clinical care to, and the clinical monitoring of, the patient while the patient is being conveyed in the emergency ambulance;
- "emergency patient" means an individual who is suffering or believed to be suffering from an injury, or a condition of acute or sudden onset, that poses an immediate threat to the individual's life or jeopardises the longterm health of the individual;
- "medical transport" means a vehicle (other than an emergency ambulance) which
 - (a) is used or intended to be used to convey by land any patient (except a patient who is an emergency patient before being conveyed); and
 - (b) is equipped for the clinical care and monitoring of the patient, if necessary, while the patient is being conveyed;

"medical transport service" means —

- (a) the conveyance by land using a medical transport of any patient (except a patient who is an emergency patient before being conveyed); and
- (b) the clinical care and monitoring of the patient, if necessary, while the patient is being conveyed in the medical transport;
- "nuclear medicine assay service" means the use of radioactive substances (including radionuclides), applied to a specimen obtained from a patient, for the purpose of medical diagnosis or monitoring the effects of medical therapy through the use of an assay;
- "nuclear medicine imaging service" means the use of radioactive substances (including radionuclides), administered to a patient, for the purpose of medical diagnosis or monitoring the effects of medical therapy through the use of an imaging apparatus;
- "radiological service" means the use of ionising or non-ionising radiation for any of the following purposes:
 - (a) examination of the body, or any matter derived from the body, of an individual;
 - (b) assessment of the health or condition of an individual;
 - (c) observation and diagnosis of a disease, disability or condition or an injury of the body or mind of an individual;
 - (d) determining, predicting or providing a prognosis of the health or condition of an individual;
 - (e) minimally invasive image-guided biopsy of breast, thyroid, any superficial lump or bump or any superficial lymph node,

but does not include any of the following:

- (f) the provision of any dental cone beam computed tomography on the dental alveolar region, periapical x-ray or orthopantomogram for dental purposes —
 - (i) by a person licensed under the Private Hospitals and Medical Clinics Act 1980 to use any premises or conveyance as a healthcare institution or by a licensee; and
 - (ii) that is incidental to the provision of dental services by that person or licensee;

- (g) the provision of ultrasound imaging services
 - (i) by a person licensed under the Private Hospitals and Medical Clinics Act 1980 to use any premises as a medical clinic; and
 - (ii) that is incidental to the provision of services authorised under the Private Hospitals and Medical Clinics Act 1980 to be provided in the medical clinic by that person;
- (h) a nuclear medicine imaging service;
- "simple in vitro diagnostic test" means an in vitro diagnostic test that is designed to return a test result without the need to interpret raw test data and requires
 - (a) no specimen processing;
 - (b) no more than 3 steps of analytical test procedures;
 - (c) the use of self-contained reagent cartridges or strips or no precise measurement required for reagent preparation;
 - (d) no specifications for a controlled testing environment for returning an accurate test result; and
 - (e) only portable analysers with automated calibration, quality control and self-diagnosing malfunction features when used;
- "specified person", in relation to a licensee authorised to provide a blood banking service, means either of the following persons to whom that licensee distributes blood or blood components:
 - (a) a person authorised by a licence under this Act to provide a blood banking service or clinical laboratory service;
 - (b) a person licensed under the Private Hospitals and Medical Clinics Act 1980 to use any premises or conveyance as a healthcare establishment, medical clinic or private hospital.

 [S 1/2022 wef 03/01/2022]

SECOND SCHEDULE

Section 56(3) and First Schedule

APPOINTED DAY FOR LICENSABLE HEALTHCARE SERVICES

First column	Second column
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SECOND SCHEDULE — continued

Appointed day	Licensable healthcare service provided in healthcare establishment, medical clinic or private hospital licensed under Private Hospitals and Medical Clinics Act 1980
3 January 2022	(a) Blood banking service
	(b) Clinical laboratory service
	(c) Cord blood banking service
	(d) Nuclear medicine assay service
	(e) Nuclear medicine imaging service
	(f) Radiological service

[S 1/2022 wef 03/01/2022]

THIRD SCHEDULE

Section 60(1) and (3)

SAVING AND TRANSITIONAL PROVISIONS

- 1.—(1) Subject to sub-paragraph (2), where immediately before the appointed day for a licensable healthcare service
 - (a) the licensable healthcare service is provided in a private hospital, medical clinic, clinical laboratory or healthcare establishment within the meaning given by section 2 of the repealed Act;
 - (b) there is in force a licence under the repealed Act to use those premises or the conveyance as a private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be; and
 - (c) there is in force an approval (if required) under the repealed Act to provide the licensable healthcare service at the private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be,

the licence and approval continue in force, so far as not inconsistent with the provisions of this Act, as if they are a licence granted under this Act to provide that licensable healthcare service for the period the licence and approval had been granted under the repealed Act.

(2) The licence treated as continuing in force under sub-paragraph (1) continues in force until the earliest of the following:

THIRD SCHEDULE — continued

- (a) the date the licence would have expired under the repealed Act if this Act had not been enacted;
- (b) the date the licence ceases or is surrendered under section 17 of this Act;
- (c) the date the licence is revoked under section 20 of this Act.
- (3) From an appointed day for a licensable healthcare service, the repealed Act ceases to apply to and in relation to that service provided in the private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be.
- 2. Where, immediately before the date of commencement of section 58 of this Act
 - (a) a healthcare service that is not a licensable healthcare service is provided in a private hospital, medical clinic, clinical laboratory or healthcare establishment within the meaning given by section 2 of the repealed Act;
 - (b) there is in force a licence under the repealed Act to use those premises or the conveyance as a private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be; and
 - (c) there is in force an approval (if required) under the repealed Act to provide the healthcare service that is not a licensable healthcare service at the private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be,

the licence and approval continue in force despite section 58 of this Act, and the repealed Act as in force immediately before that date continues in force insofar as it relates to that healthcare service provided in that private hospital, medical clinic, clinical laboratory or healthcare establishment (as the case may be) subject to that licence until paragraph 1 applies.

- 3.—(1) Where immediately before the appointed day for a licensable healthcare service
 - (a) an application is made to the Director under the repealed Act
 - (i) for or to renew a licence to use any premises or conveyance as a private hospital, medical clinic, clinical laboratory or healthcare establishment for the provision of that licensable healthcare service; or
 - (ii) for an approval (if required) to provide the licensable healthcare service at a private hospital, medical clinic, clinical laboratory or healthcare establishment, as the case may be; and

THIRD SCHEDULE — continued

- (b) the application is pending immediately before the appointed day, the application is deemed to be an application made under section 10 of this Act.
- (2) Anything that has been started by the Director in connection with an application mentioned in sub-paragraph (1) may be carried on and completed by the Director under the corresponding provisions in Part 2 of this Act.

4. Where —

- (a) an appeal has been made to the Minister under section 10(1) of the repealed Act before the date of commencement of section 58 of this Act; and
- (b) the appeal has not been dealt with or disposed of immediately before that date,

the appeal may be dealt with or disposed of under the repealed Act as if this Act had not been enacted.

5. Subject to paragraph 1(3), the repealed Act continues to apply insofar as it relates to the provision of a healthcare service which is not a licensable healthcare service and provided in a private hospital, medical clinic, clinical laboratory or healthcare establishment, until that service becomes a licensable healthcare service.