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No. S 1

HEALTHCARE SERVICES ACT 2020

HEALTHCARE SERVICES ACT 2020 (AMENDMENT OF SCHEDULES) ORDER 2022

In exercise of the powers conferred by section 56 of the Healthcare Services Act 2020, the Minister for Health makes the following Order:

Citation and commencement

1. This Order is the Healthcare Services Act 2020 (Amendment of Schedules) Order 2022 and comes into operation on 3 January 2022 at 8 a.m.

Deletion and substitution of First and Second Schedules

2. The First and Second Schedules to the Healthcare Services Act 2020 are deleted and the following Schedules substituted therefor:

“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 long-term 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.

SECOND SCHEDULE

Section 56(3) and First Schedule

APPOINTED DAY FOR LICENSABLE HEALTHCARE SERVICES

<i>First column</i>	<i>Second column</i>
<i>Appointed day</i>	<i>Licensable healthcare service provided in healthcare establishment, medical clinic or private hospital licensed under Private Hospitals and Medical Clinics Act 1980</i>
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

Made on 3 January 2022.

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

[MH 78:44/1; AG/LEGIS/SL/122E/2020/16 Vol. 1]

(To be presented to Parliament under section 56(5) of the Healthcare Services Act 2020).