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## No. S 389

### HEALTHCARE SERVICES ACT 2020

#### HEALTHCARE SERVICES (CORD BLOOD BANKING SERVICE) (AMENDMENT) REGULATIONS 2023

In exercise of the powers conferred by section 57 of the Healthcare Services Act 2020, the Minister for Health makes the following Regulations:

#### **Citation and commencement**

1. These Regulations are the Healthcare Services (Cord Blood Banking Service) (Amendment) Regulations 2023 and come into operation on 26 June 2023.

#### **Amendment of regulation 2**

2. In the Healthcare Services (Cord Blood Banking Service) Regulations 2021 (G.N. No. S 1037/2021) (called in these Regulations the principal Regulations), in regulation 2 —

(a) replace the definition of “acute hospital” with —

““acute hospital service” and “cord blood banking service” have the meanings given by paragraph 2 of the First Schedule to the Act;

“acute hospital service licensee” means a person who is licensed under the Act to provide an acute hospital service;” and

(b) replace the definition of “transplanting clinician” with —

““transplanting clinician”, in relation to an acute hospital service licensee, means a medical practitioner —

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- (a) who is employed or engaged by the acute hospital service licensee to transplant cord blood to a recipient; or
  - (b) who is permitted by the acute hospital service licensee to transplant cord blood to a recipient at any approved permanent premises of that licensee.”.

#### **Amendment of regulation 4**

3. In the principal Regulations, in regulation 4 —

- (a) in the regulation heading, replace “**Skills**” with “**Qualifications, skills**”; and
- (b) after “following”, insert “qualifications,”.

#### **Amendment of regulation 5**

4. In the principal Regulations, in regulation 5 —

- (a) in paragraph (1), delete “applicable”;
- (b) in paragraph (2), delete sub-paragraph (j);
- (c) in paragraph (3)(b), delete “and” at the end;
- (d) in paragraph (3)(c), replace the full-stop at the end with “; and”; and
- (e) in paragraph (3), after sub-paragraph (c), insert —
  - “(d) implement appropriate and effective actions to address any weakness or inadequacy in the provision of the cord blood banking service.”.

#### **Amendment of regulation 8**

5. In the principal Regulations, in regulation 8(1) and (2)(a), replace “licensed premises” with “approved permanent premises”.

#### **New regulations 8A, 8B and 8C**

6. In the principal Regulations, after regulation 8, insert —

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**“Safety programme**

**8A.**—(1) For every approved permanent premises, a licensee must develop and implement a safety programme setting out appropriate and effective safety measures to prevent the occurrence of any adverse incident and reduce any hazard at the approved permanent premises.

(2) Without limiting paragraph (1), a safety programme must contain appropriate and effective measures for —

- (a) electrical safety and safety of water supply and outlets;
- (b) the handling and disposal of sharp apparatus and objects that can readily puncture or cut human skin when encountered;
- (c) the safety of all infant donors or mothers of infant donors (as the case may be) and personnel during the conduct of any test;
- (d) waste management;
- (e) spills management;
- (f) ensuring that there is adequate space, ventilation and lighting for every personnel to perform work safely;
- (g) ensuring that all safety or emergency equipment is kept in good working order and there is an adequate stock of materials required for the handling of any medical emergency or adverse incident; and
- (h) ensuring the cleanliness of the approved permanent premises.

(3) The licensee must keep up-to-date documentation of the policies and processes of the safety programme mentioned in paragraph (1) and make the documentation available to every personnel.

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**Licensee must ensure personnel comply with safety programme**

**8B.** A licensee must ensure that every personnel complies with the measures set out in the safety programme mentioned in regulation 8A.

**Personal protective equipment must be provided**

**8C.** A licensee must provide every personnel performing any work with personal protective equipment appropriate for the work performed.”.

**Amendment of regulation 10**

7. In the principal Regulations, in regulation 10 —

(a) in paragraph (3), replace sub-paragraphs (b) and (c) with —

“(b) the medical history of the father of the potential infant donor and every member of the father’s immediate family;” and

(b) replace paragraph (7) with —

“(7) In this regulation, “immediate family”, in relation to an individual, means —

(a) the individual’s biological son or daughter;

(b) the individual’s biological father or mother;

(c) the individual’s biological brother or sister;  
and

(d) the individual’s biological grandfather or grandmother, whether paternal or maternal.”.

**Amendment of regulation 11**

8. In the principal Regulations, in regulation 11(a) —

(a) in sub-paragraph (i), delete “or blood banking service”;  
and

(b) in sub-paragraph (ii), delete “or blood bank”.

### **Replacement of regulation 18**

9. In the principal Regulations, replace regulation 18 with —

#### **“Import of processed cord blood**

**18.** A licensee must not import processed cord blood from a person outside Singapore unless that person is accredited by an accreditation body acceptable to the Director-General.”.

### **Replacement of regulation 20**

10. In the principal Regulations, replace regulation 20 with —

#### **“Information about infant donor and mother of infant donor**

**20.—(1)** A licensee must —

(a) collect all information that ensures the linkage of all cord blood units collected from an infant donor and the mother of that infant donor; and

(b) keep and maintain accurate records of all information mentioned in sub-paragraph (a).

(2) The licensee must keep every record mentioned in paragraph (1)(b) (called an applicable record) confidential and ensure that —

(a) the confidentiality, integrity and security of every applicable record are maintained at all times; and

(b) every personnel handling any applicable record is aware of his or her role and responsibility in maintaining the confidentiality, integrity and security of the applicable record.

(3) In addition, where any information in an applicable record is in the form of an extract or aggregated compilation, the licensee must ensure that the confidentiality, integrity and security of the information in the extract or aggregated compilation are maintained at all times.

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- (4) The licensee must —
- (a) implement adequate safeguards and appropriate protocols and processes to protect the applicable records against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification; and
  - (b) periodically monitor and evaluate the safeguards, protocols and processes mentioned in sub-paragraph (a) to ensure that they are effective and being complied with by the staff involved in handling the applicable records.”.

### **Amendment of regulation 21**

11. In the principal Regulations, in regulation 21(2)(e), replace “the licensed premises” with “every approved permanent premises of the licensee”.

### **Amendment of regulation 26**

12. In the principal Regulations, in regulation 26(1) —
- (a) after “8(1),”, insert “8A(1), 8B,”;
  - (b) replace “16(1), (3) or (4)” with “16(1), (3), (4) or (5)”;
  - (c) replace “20” with “20(1), (2), (3) or (4)”.

### **Miscellaneous amendments**

13.—(1) In the principal Regulations, in the following provisions, replace “Director” with “Director-General”:

Regulation 4(c)(v)

Regulation 11(a)(ii)

Regulation 24(2)(c).

(2) In the principal Regulations, in the following provisions, replace “acute hospital” wherever it appears with “acute hospital service licensee”:

Regulation 9(4)(a)(iv)

Regulation 16(4)

Regulation 22(1), (2) and (3).

Made on 14 June 2023.

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

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