Healthcare Services (Blood Banking Service) Regulations 2021

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No. S 1038

HEALTHCARE SERVICES ACT 2020
(ACT 3 OF 2020)

HEALTHCARE SERVICES (BLOOD BANKING SERVICE) REGULATIONS 2021

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 (Blood Banking Service) Regulations 2021 and come into operation on 3 January 2022.

Definitions

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

"acute hospital" includes a private hospital licensed under the Private Hospitals and Medical Clinics Act 1980 which is licensed as a medical hospital, a surgical hospital or both;

"blood" means whole human blood;

"blood component" includes plasma, red blood cells, white blood cells, platelets and cryoprecipitate;

"Clinical Governance Officer" means a Clinical Governance Officer appointed by a licensee under section 24(2) of the Act;

"donor" means an individual who donates blood or any blood component;

"licensee" means a person who holds a licence to provide a blood banking service;

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

"specified infectious disease" means an infectious disease specified in the First Schedule;

"specified person" means either of the following persons to whom a licensee distributes blood or blood components:

(*a*) a person authorised by a licence to provide a blood banking service or clinical laboratory service;

(*b*) a person licensed to use any premises or conveyance as a healthcare establishment, medical clinic or private hospital under the Private Hospitals and Medical Clinics Act 1980.

(2) In these Regulations, blood or a blood component is treated as suitable for clinical use if —

(*a*) the blood or blood component, as the case may be —

(i) has undergone all of the tests specified in Part 1 of the Second Schedule; and

(ii) in relation to an infectious disease specified in the first column of Part 2 of the Second Schedule, has undergone all of the tests specified opposite that infectious disease in the second column of Part 2 of that Schedule and is determined to not be infected with that infectious disease; and

(*b*) every test mentioned in sub-paragraph (*a*) is carried out using appropriate test kits that have been validated for the purpose of donor testing.

Application of Regulations

3. Unless otherwise expressly provided in these Regulations —

(*a*) the provisions of these Regulations apply in addition to the provisions of the Healthcare Services (General) Regulations (G.N. No. S 1035/2021) (called in these Regulations the General Regulations); and

(*b*) the provisions of these Regulations prevail to the extent that any provision of these Regulations is inconsistent with the provisions of the General Regulations.

Activities at premises or conveyances under licence

4.—(1) For the purposes of section 10(2)(*c*)(viii) of the Act, an applicant for the grant or renewal of a licence to provide a blood banking service must specify in the licence application, in relation to each licensed premises or licensed conveyance, every activity that the applicant intends to carry out at those premises or using that conveyance.

(2) Where a licensee intends, at any time during the term of the licence granted to the licensee, to carry out at any licensed premises or using any licensed conveyance any activity not specified in the licence, the licensee must notify the Director no later than one month before commencing that activity at the licensed premises or using the licensed conveyance, as the case may be.

(3) In this regulation, "activity", in relation to an applicant or a licensee, means any of the following:

(*a*) the collection of blood or blood components from donors;

(*b*) the testing of blood or blood components;

(*c*) the processing of blood or blood components;

(*d*) the distribution of blood or blood components;

(*e*) the storage of blood or blood components incidental to any activity mentioned in sub-paragraphs (*a*) to (*d*).

Skills and competencies of Clinical Governance Officer

5.—(1) For the purposes of section 24(3)(*b*) of the Act, a licensee must appoint as a Clinical Governance Officer of a blood banking service a fully registered medical practitioner with —

(*a*) either of the following skills and competencies:

(i) registration under section 22 of the Medical Registration Act 1997 as a specialist in the branch of haematology;

(ii) both of the following:

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

(B) training in transfusion medicine; and

(*b*) at least 5 years of work experience in Singapore in —

(i) transfusion medicine in any acute hospital; or

(ii) any other area relevant to the provision of a blood banking service with any licensee.

(2) In paragraph (1), "fully registered medical practitioner" has the meaning given by section 2 of the Medical Registration Act 1997.

Disqualifications for Clinical Governance Officer

6. A licensee must not appoint as a Clinical Governance Officer any individual who has been subject to a decision or an order made under Part 7 of the Medical Registration Act 1997 by a Disciplinary Tribunal appointed under that Act in the 3 years preceding the individual's appointment.

Duties and responsibilities of Clinical Governance Officer

7.—(1) A Clinical Governance Officer of a blood banking service must oversee —

(*a*) the conduct and provision, in relation to the provision of the blood banking service by the licensee, of all assessments of donors and blood and blood