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No. S 388

HEALTHCARE SERVICES ACT 2020

HEALTHCARE SERVICES (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 (Blood Banking Service) (Amendment) Regulations 2023 and come into operation on 26 June 2023.

Amendment of regulation 2

2. In the Healthcare Services (Blood Banking Service) Regulations 2021 (G.N. No. S 1038/2021) (called in these Regulations the principal Regulations), in regulation 2(1) —

(*a*) replace the definition of "acute hospital" with —

> " "acute hospital service", "blood banking service", "simple in vitro diagnostic test" and "specified person" have the meanings given by paragraph 2 of the First Schedule to the Act;";

(*b*) after the definition of "blood component", insert —

> " "blood donation site" means any premises or conveyance that is occupied or used by a licensee for the collection of blood or blood components and the storage of blood or blood components incidental to their collection;";

(*c*) in the definition of "specified infectious disease", replace the semi-colon at the end with a full-stop; and

(*d*) delete the definition of "specified person".

New regulation 3A

3. In the principal Regulations, after regulation 3, insert —

"**Blood donation sites**

3A. Where a licensee is approved to provide a blood banking service using one or more approved conveyances or at any premises other than permanent premises, the licensee must not use those conveyances or those premises for any purpose other than as a blood donation site.".

Amendment of regulation 4

4. In the principal Regulations, in regulation 4 —

(*a*) in the regulation heading, replace "**premises or conveyances under licence**" with "**approved permanent premises**"; and

(*b*) replace paragraphs (1) and (2) with —

"(1) For the purposes of section 11A(2)(*e*) of the Act, an application for approval of any permanent premises for the provision of a blood banking service must specify every activity that the applicant intends to carry out at those premises.

(2) Where a licensee intends, at any time during the term of the licence granted to the licensee, to carry out at any approved permanent premises an activity not specified in the application for approval mentioned in paragraph (1), the licensee must notify the Director-General no later than 2 months before commencing that activity at the approved permanent premises.".

Amendment of regulation 5

5. In the principal Regulations, in regulation 5 —

(*a*) in the regulation heading, replace "**Skills**" with "**Qualifications, skills**";

(*b*) in paragraph (1)(*a*), after "following", insert "qualifications,"; and

(*c*) in paragraph (1)(*b*), replace sub-paragraph (i) with —

"(i) transfusion medicine —

(A) in relation to the provision of an acute hospital service by a person authorised by a licence to do; or

(B) in any private hospital licensed under the Private Hospitals and Medical Clinics Act 1980 before 26 June 2023, where the private hospital was licensed as a medical hospital, a surgical hospital or both; or".

Amendment of regulation 9

6. In the principal Regulations, in regulation 9(4), in the definition of "Clinical Nurse Leader", in paragraph (*b*), replace sub-paragraph (i) with —

"(i) transfusion medicine —

(A) in relation to the provision of an acute hospital service by a person authorised by a licence to do; or

(B) in any private hospital licensed under the Private Hospitals and Medical Clinics Act 1980 before 26 June 2023, where the private hospital was licensed as a medical hospital, a surgical hospital or both; or".

Amendment of regulation 11

7. In the principal Regulations, in regulation 11, delete paragraph (4).

New regulations 11A, 11B and 11C

8. In the principal Regulations, after regulation 11, insert —

"**Safety programme**

11A.—(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 donors 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.

Licensee must ensure personnel comply with safety programme

11B. A licensee must ensure that every personnel complies with the measures set out in the safety programme mentioned in regulation 11A.

Personal protective equipment must be provided

11C. A licensee must provide every personnel performing any work with personal protective equipment appropriate for the work performed.".

Amendment of regulation 16

9. In the principal Regulations, in regulation 16(1) —

(*a*) in sub-paragraph (*b*), delete "and" at the end;

(*b*) in sub-paragraph (*c*), replace the full-stop at the end with "; and"; and

(*c*) after sub-paragraph (*c*), insert —

"(*d*) ensure that a Clinical Governance Officer, or such other suitably qualified personnel designated by a Clinical Governance Officer —

(i) reviews the results of the external quality assurance programme mentioned in sub-paragraph (*c*); and

(ii) implements appropriate and effective actions to address any weakness or inadequacy in the provision of any test mentioned in sub-paragraph (*a*).".

Amendment of regulation 19

10. In the principal Regulations, in regulation 19(1) —

(*a*) in sub-paragraph (*b*), delete "and" at the end;

(*b*) in sub-paragraph (*c*), replace the full-stop at the end with "; and"; and

(*c*) after sub-paragraph (*c*), insert —

"(*d*) ensure that a Clinical Governance Officer, or such other suitably qualified personnel designated by a Clinical Governance Officer —

(i) reviews the results of the external quality assurance programme mentioned in sub-paragraph (*c*); and

(ii) implements appropriate and effective actions to address any weakness or inadequacy in the provision of any test mentioned in sub-paragraph (*a*).".

New regulation 19A

11. In the principal Regulations, after regulation 19, insert —

"**Simple in vitro diagnostic tests**

19A.—(1) This regulation applies to and in relation to the conduct of any simple in vitro diagnostic test that is incidental to the provision of a blood banking service by a licensee.

(2) The licensee must ensure that any simple in vitro diagnostic test on a specimen or an individual must be conducted —

(*a*) using testing material, where —

(i) the earlier of the following dates has not passed:

(A) the expiry date of the testing material;

(B) the shelf life of the testing material; and

(ii) the personnel who administers the test does not suspect or have any reason to suspect that the testing material is no longer fit for use; and

(*b*) in accordance with the instructions specified by the manufacturer of the testing material.

(3) The licensee must ensure that any testing material that may be used to conduct any simple in vitro diagnostic test is stored under the conditions, and handled in the manner, specified by the manufacturer of the testing material so as to lower the risk of contamination, unnecessary exposure of the testing material to the environment and early deterioration of the testing material.".

Amendment of regulation 20

12. In the principal Regulations, in regulation 20, after paragraph (2), insert —

"(3) The licensee must keep every record mentioned in paragraph (1) confidential and ensure that —

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

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

(4) In addition, where any information in a record mentioned in paragraph (1) 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.

(5) The licensee must —

(*a*) implement adequate safeguards and appropriate protocols and processes to protect all applicable records against accidental or unlawful loss, modification or destruction, or unauthorised access, disclosure, copying, use or modification;

(*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; and

(*c*) take reasonable care in the disposal or destruction of the applicable records so as to prevent unauthorised access to the records.

(6) In paragraph (5), "applicable record" means any record mentioned in paragraph (1) or (2).".

Amendment of regulation 21

13. In the principal Regulations, in regulation 21(2), replace "these Regulations" with "paragraph (1)".

Amendment of regulation 22

14. In the principal Regulations, in regulation 22(2) —

(*a*) in sub-paragraph (*b*), replace the full-stop at the end with a semi-colon; and

(*b*) after sub-paragraph (*b*), insert —

"(*c*) the distribution of blood or blood components.".

Amendment of regulation 24

15. In the principal Regulations, in regulation 24(1) —

(*a*) before "8(1)", insert "3A,";

(*b*) after "11(1) or (3)," insert "11A(1), 11B,"; and

(*c*) replace "20" with "20(1), (2), (3), (4) or (5)".

Made on 14 June 2023.

CHAN YENG KIT
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Ministry of Health,
Singapore.

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