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PRIVATE HOSPITALS AND MEDICAL CLINICS ACT (CHAPTER 248)

PRIVATE HOSPITALS AND MEDICAL CLINICS (AMENDMENT NO. 3) REGULATIONS 2021

In exercise of the powers conferred by section 22 of the Private Hospitals and Medical Clinics Act, the Minister for Health makes the following Regulations:

Citation and commencement

1. These Regulations are the Private Hospitals and Medical Clinics (Amendment No. 3) Regulations 2021 and come into operation on 3 January 2022.

Amendment of regulation 8

2. Regulation 8 of the Private Hospitals and Medical Clinics Regulations (Rg 1) (called in these Regulations the principal Regulations) is amended by deleting the words “, medical clinic or clinical laboratory” and substituting the words “or medical clinic”.

Amendment of regulation 9

3. Regulation 9 of the principal Regulations is amended by deleting paragraph (4).

Amendment of regulation 10

4. Regulation 10(1) of the principal Regulations is amended by deleting sub-paragraph (e).

Amendment of regulation 12

5. Regulation 12 of the principal Regulations is amended —
(a) by deleting paragraph (2); and

- (b) by deleting the words “paragraphs (1) and (2)” in paragraph (3) and substituting the words “paragraph (1)”.

Amendment of regulation 24

6. Regulation 24 of the principal Regulations is amended —

- (a) by deleting the words “shall have a laboratory service which shall be under the supervision of a qualified person and the laboratory shall comply with regulations 50 to 55” in paragraph (1) and substituting the words “must provide a clinical laboratory service that is licensed under the Healthcare Services Act 2020”; and
- (b) by deleting paragraph (2).

Amendment of regulation 29

7. Regulation 29 of the principal Regulations is amended by deleting paragraphs (1) and (2) and substituting the following paragraph:

“(1) Every private hospital (other than a psychiatric hospital, convalescent hospital, maternity home or nursing home) must —

- (a) provide a radiological service that is licensed under the Healthcare Services Act 2020; and
- (b) be equipped with at least one static X-ray machine and one mobile X-ray machine.”.

Amendment of regulation 29A

8. Regulation 29A of the principal Regulations is amended —

- (a) by deleting sub-paragraph (b) of paragraph (1) and substituting the following sub-paragraph:

“(b) by a person licensed to provide a radiological service under the Healthcare Services Act 2020.”; and

- (b) by deleting the words “other private hospital, medical clinic or clinical laboratory, as the case may be” in

paragraph (2) and substituting the words “person mentioned in paragraph (1)(b)”.

Amendment of regulation 42

9. Regulation 42(3) of the principal Regulations is amended by deleting the words “50 to 55” in sub-paragraph (b) and substituting the words “47 to 51”.

Amendment of regulation 44

10. Regulation 44 of the principal Regulations is amended by deleting paragraph (a) and substituting the following paragraph:

“(a) by a person licensed to provide a clinical laboratory service under the Healthcare Services Act 2020;”.

Deletion of Part IV and new regulations 47 to 51

11. Part IV of the principal Regulations is deleted and the following regulations substituted therefor:

“Clinical laboratory and radiology service facilities

47.—(1) The licensee of a medical clinic that provides a clinical laboratory service or a radiology service to patients of the medical clinic must ensure that all facilities in the medical clinic used for the provision of the clinical laboratory service or radiology service are adequate for —

- (a) the proper and efficient performance of every category of test or radiological examination that the medical clinic provides; and
- (b) the functions of the clinical laboratory service or radiology service to be performed with accuracy, timeliness and safety.

(2) The licensee of a medical clinic that provides a clinical laboratory service or a radiology service to patients of the medical clinic must ensure that all the equipment used for the clinical laboratory service or radiology service is regularly checked for accuracy and calibration.

Quality control for clinical laboratory tests and radiology examinations

48.—(1) The licensee of a medical clinic that provides a clinical laboratory service or a radiology service to patients of the medical clinic must ensure that there is an effective and documented quality control programme for the clinical laboratory service or radiology service.

(2) The licensee of a medical clinic mentioned in paragraph (1) must —

- (a) ensure that quality control measures (including external quality assessments) are taken for every type of test and radiological examination performed at the medical clinic;
- (b) keep proper records and details of the quality control measures taken at the medical clinic under sub-paragraph (a); and
- (c) submit to the Director as and when required by the Director any of the records kept under sub-paragraph (b).

(3) The Director may —

- (a) issue guidelines specifying the standards for the performance of tests or radiological examinations; and
- (b) implement evaluation programmes, including surprise checks, on the accuracy of test or radiological examination results.

(4) The licensee of a medical clinic must obtain the prior approval of the Director in writing before any of the following tests is first performed in the medical clinic:

- (a) human immunodeficiency virus test;
- (b) acid-fast bacilli smear testing;
- (c) malaria parasite testing;
- (d) legionella test;

(e) blood group (ABO) test;

(f) Rhesus type test.

(5) An application for the Director's approval to perform a test under paragraph (4) —

(a) must be made in the form or manner that the Director requires; and

(b) must be submitted to the Director not less than 90 days before the date on which the medical clinic is to commence performing the test.

Records of specimens and radiological images

49. The licensee of a medical clinic that provides a clinical laboratory service or a radiology service to patients of the medical clinic must keep records of specimens and radiological images, which must include —

(a) the name of the patient from whom the specimen or radiological image was taken, the patient's age, identification number and address;

(b) the name of the person who referred the patient for the test or radiological examination;

(c) the date and type of test or radiological examination performed;

(d) the result of each test or radiological examination; and

(e) the name of the person who performed the test or radiological examination.

Report on tests and radiological examinations

50.—(1) Every report of any test or radiological examination performed by a medical clinic that provides a clinical laboratory service or a radiology service to patients of the medical clinic must be retained by the medical clinic.

(2) The report must state the name and address of the medical clinic and must be signed by the licensee of the medical clinic or the licensee's authorised representative, who must be a person

suitably qualified to report on the test or radiological examination.

(3) Where a test or a radiological examination to which the report relates has been outsourced under regulation 51, the report must —

- (a) state clearly the name and address of the person who performed the test or radiological examination; and
- (b) be accompanied by the original copy of the report of the person who performed the test or radiological examination.

Outsourcing of performance of test and radiological examination

51.—(1) Subject to paragraph (2), all tests and radiological examinations to be performed by a medical clinic that provides a clinical laboratory service or a radiology service to patients of the medical clinic must be performed at the licensed premises of the medical clinic.

(2) The licensee of a medical clinic mentioned in paragraph (1) must not outsource the performance of any test or radiological examination or any part of a test or a radiological examination except to —

- (a) a person licensed to provide a clinical laboratory service or a radiological service under the Healthcare Services Act 2020, as the case may be; or
- (b) any foreign clinical laboratory that has been accredited by an accreditation body approved by the Director.”.

Amendment of regulation 57

12. Regulation 57 of the principal Regulations is amended by deleting the words “, clinical laboratories”.

Amendment of regulation 59

13. Regulation 59 of the principal Regulations is amended —

(a) by deleting the words “ “clinical laboratory”, “medical laboratory”,”; and

(b) by deleting the words “, clinical laboratory”.

Miscellaneous amendment

14. The principal Regulations are amended by deleting the words “, clinical laboratory” wherever they appear in the following provisions:

Regulation 4(1) and (2)

Regulation 5(5)(a) and (7A)

Regulation 7

Regulation 9(1) and (2) and regulation heading

Regulation 10(1) and (3)

Regulation 12(3)

Regulation 56B

Regulation 58.

Amendment of Second Schedule

15. The Second Schedule to the principal Regulations is amended by deleting item 4 and substituting the following item:

“4. Nuclear medicine therapy and in vivo nuclear medicine assay services.”.

Amendment of Fourth Schedule

16. Item 1 of the Fourth Schedule to the principal Regulations is amended by deleting paragraphs (f) and (g).

Deletion of Fifth Schedule

17. The Fifth Schedule to the principal Regulations is deleted.

*[G.N. Nos. S 223/2003; S 237/2003; S 411/2003;
S 308/2008; S 831/2010; S 189/2011; S 450/2013;
S 493/2014; S 213/2015; S 450/2015; S 169/2016;
S 110/2017; S 430/2017; S 103/2018; S 414/2018;
S 73/2021; S 285/2021]*

Made on 29 December 2021.

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