



BERMUDA

BERMUDA HEALTH COUNCIL AMENDMENT (NO. 2) ACT 2024

2024 : 26

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WHEREAS it is expedient to amend the Bermuda Health Council Act 2004 with respect to the budget and funds of the Council; the prescribing of fees; matters relating to the licensing of health service providers; matters relating to the registration of high risk health technology; matters relating to civil penalties; and providing for indictable offences and penalties;

Be it enacted by The King's Most Excellent Majesty, by and with the advice and consent of the Senate and the House of Assembly of Bermuda, and by the authority of the same, as follows:

Citation

1 This Act, which amends the Bermuda Health Council Act 2004 ("the principal Act") may be cited as the Bermuda Health Council Amendment (No. 2) Act 2024.

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Amends section 2

2 Section 2 of the principal Act is amended by inserting the following definitions in their proper alphabetical order—

“financially-vested referral” means a referral made by a health service provider to itself or—

- (a) to another health service provider in which the referring health service provider has a financial interest;
- (b) to another health service provider in anticipation of a financial incentive or reward;

“high risk health technology” has the meaning given in section 16E;”.

Amends section 5

3 Section 5 of the principal Act is amended in subsection (1)—

(a) by inserting the following after paragraph (c)—

“(ca) to regulate the importation of high risk health technology into Bermuda; and to further regulate such technology through registration and monitoring;”;

(b) in paragraph (g) by inserting after “providers” the words “, and to establish, maintain and publish a register of licensed health service providers”.

Inserts sections 10A and 10B

4 The principal Act is amended by inserting the following after section 10—

“Budget

10A (1) The Council shall submit to the Minister and the Minister of Finance for their approval—

- (a) no later than three months prior to the commencement of each financial year, income and expenditure estimates in such detail as the Ministers may require relating to the activities of the Council for that financial year of operation of the Council; and
- (b) as soon as may be, any subsequent proposal to amend such estimates,

and the estimates, together with any amendments, upon being approved by the Ministers, shall be the Council’s budget for the financial year to which it relates.

(2) The Ministers may in any case, on the application of the Council, increase or decrease the period of three months specified in subsection (1)(a).

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Funds of the Council

10B The funds of the Council for the performance of its functions shall consist of—

- (a) grants from the Government out of moneys appropriated by the Legislature for the purposes of the Council;
- (b) any monies accruing to the Council from out of the mutual re-insurance fund; and
- (c) any other monies received by the Council, including fees and civil penalties.”.

Amends section 13

5 Section 13(2) of the Principal Act is repealed and replaced with the following—

“(2) Any person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of \$50,000.00 and on conviction on indictment to a fine of \$100,000.00.”.

Amends section 14

6 Section 14 of the principal Act is amended—

- (a) in the heading by deleting “Inspection” and substituting “Inspection of health service providers”;
- (b) by inserting the following after subsection (1)—

“(1A) The Council may, from time to time, engage the services of persons as inspectors who have subject-matter expertise.”;

- (c) in subsection (2) by inserting after the last occurrence of “provider”, the words “and any returns filed with the Council by that health service provider”;
- (d) by repealing and replacing subsection (3) with the following—

“(3) Any person who obstructs an inspector in carrying out his functions or fails to produce any records or returns reasonably required by an inspector commits an offence and is liable on summary conviction to a fine of \$20,000.00 or on conviction on indictment to a fine of \$30,000.00.”.

Amends section 15

7 Section 15 of the principal Act is amended—

- (a) in subsection (1)—
 - (i) by inserting the following paragraphs in their proper alphabetical order—

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- “(aa) prescribing fees, including application fees; prescribing different fees for different categories of health service providers; and prescribing the criteria by which fees may be reduced or waived;
- (ba) governing the establishment of standards of operation for health businesses;
- (bb) for establishing, maintaining and publishing the register of licensed health service providers;”;
- (ii) by repealing and replacing paragraph (c) with the following—
 - “(c) governing review of decisions of the Council including a decision to refuse an application, to impose restrictions on a licence, to impose a civil penalty, or to revoke a licence”;
- (iii) in paragraph (e) by inserting after “require” the words “, and prescribing the length of time records relating to such returns, statistics or other information must be retained by health service providers”;
- (iv) by inserting the following after paragraph (g)—
 - “(ga) imposing civil penalties for failing to comply with a condition attached to a licence or a requirement of the regulations, and the procedure by which civil penalties may be imposed;”;
- (b) by inserting the following after subsection (2)—
 - “(2A) When prescribing the amount of any fee under subsection (1)(aa), the Minister shall take into account the performance of that function by the Council to which the fee relates, and any matters incidental thereto.”.

Repeals section 16

8 Section 16 of the principal Act is repealed.

Inserts Part IIIA

9 The principal Act is amended by inserting the following after section 16—

**“PART IIIA
REGULATION AND REGISTRATION OF
HIGH RISK HEALTH TECHNOLOGY**

Importation of high risk health technology prohibited

16A (1) No person, group of persons or organization shall import high risk health technology into Bermuda except under and in accordance with a permit issued by the Council under regulations made under section 16D.

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(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of \$40,000.00 and on conviction on indictment to a fine of \$60,000.00.

Registration of high risk health technology

16B (1) No person, group of persons or organization shall operate high risk health technology unless the technology is registered by the Council under regulations made under section 16D.

(2) A person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of \$40,000.00 and on conviction on indictment to a fine of \$60,000.00.

Inspection of high risk health technology

16C (1) The Minister may designate public officers as inspectors.

(2) The Council may, from time to time, engage the services of persons as inspectors who have the required subject-matter expertise.

(3) An inspector may at all reasonable times, enter and inspect any premises where registered high risk health technology is being operated or where the inspector has reason to believe that high risk health technology is being operated, and require the production of any records relating to the technology or any returns filed with the Council in relation to the technology.

(4) Any person who obstructs an inspector in carrying out his functions or fails to produce any records or returns reasonably required by an inspector commits an offence and is liable on summary conviction to a fine of \$20,000.00 or on conviction on indictment to a fine of \$30,000.00.

Regulations: high risk health technology

16D (1) The Minister, after consultation with the Council, may make regulations—

- (a) governing applications for the importation of high risk health technology;
- (b) governing applications for the registration and re-registration of high risk health technology;
- (c) prescribing fees, including application fees; prescribing different fees for different categories of high risk health technology; and prescribing criteria by which fees may be reduced or waived;
- (d) governing review of decisions of the Council including a decision to refuse an application, to impose conditions on importation or restrictions on registration, to impose a civil penalty, or to suspend or cancel the registration of high risk health technology;

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- (e) governing the establishment of standards of operation for high risk health technology in consultation with any statutory or professional body, and where there is no statutory or professional body, in accordance with international best practice;
 - (f) requiring registered owners of high risk health technology to supply such returns, statistics or other information as the Council may require, and prescribing the length of time records relating to such returns, statistics or other information must be retained by the owners;
 - (g) governing the disposal of high risk health technology and their by-products;
 - (h) governing inspections of high risk health technology, their maintenance and use;
 - (i) creating offences for any contravention of the regulations;
 - (j) governing the procedure for imposing civil penalties;
 - (k) necessary or convenient to be prescribed for carrying out or giving effect to this Part.
- (2) When prescribing the amount of any fee under subsection (1)(c), the Minister shall take into account the performance of that function by the Council to which the fee relates, and any matters incidental thereto.
- (3) Regulations made under this section may provide—
- (a) that any part or extract of the regulations shall be displayed in any prescribed manner or place; and
 - (b) for offences subject to a fine not exceeding \$50,000.00 for breach of the regulations.
- (4) Regulations made under subsection (1) are subject to the affirmative resolution procedure.

Meaning of high risk health technology

16E In this Part—

“high risk health technology” means any instrument, apparatus or machine requiring calibration, maintenance, repair, user training and decommissioning, used for the purpose of diagnosis and treatment of disease or rehabilitation which satisfied any of the following criteria—

- (a) for therapy to administer energy to a patient, or exchange energy to or from a patient, for example an x-ray machine;
- (b) to supply energy that will be absorbed by a patient’s body, for example a linear accelerator;

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- (c) to administer or remove medicine, body fluids or other substances in a way that is potentially hazardous to the patient, having regard to the substances, the part of the body concerned and the characteristics of the device, for example a dialysis machine;
- (d) to be used to image in vivo distribution of radiopharmaceuticals in patients, for example a positron emission tomography (PET) scanner;
- (e) a medical device or equipment to emit ionizing radiation and to be used for diagnostic or therapeutic interventional radiology including but not limited to a CT scanner and a magnetic resonance imaging machine,

but does not include an implantable, disposable or single use medical device.”.

Inserts section 16F

10 The principal Act is amended by inserting the following after the heading entitled “PART IV MISCELLANEOUS”—

“Civil Penalties

16F (1) A health service provider is liable to a civil penalty, as the Council considers appropriate, for failing to comply with a condition of its licence or a requirement imposed in regulations made under section 15.

(2) The registered owner of high risk health technology is liable to a civil penalty, as the Council considers appropriate, for failing to comply with a condition of registration or a requirement imposed in regulations made under section 16D.

(3) In this section, “appropriate” means a civil penalty that is effective, proportionate, and dissuasive, but does not exceed—

- (a) \$10,000.00 for the purposes of subsection (1);
- (b) \$15,000.00 for the purposes of subsection (2).

(4) The Council shall not impose a civil penalty where it is satisfied that the health service provider or registered owner of high risk health technology took all reasonable steps and exercised all due diligence to ensure that the condition or requirement would be complied with.

(5) The Council shall publish on its website a statement of principles in which it proposes to exercise its powers to impose a civil penalty; and the Council shall in the same manner publish material changes to the principles.

(6) A civil penalty may be recovered by the Council as a civil debt.”.

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Amends section 18

11 Section 18(2) of the principal Act is amended by deleting all the words in the continuation and substituting “commits an offence and is liable on summary conviction to a fine of \$10,000.00 or on conviction on indictment to a fine of \$25,000.00.

Commencement

12 This Act comes into operation on such day as the Minister responsible for health appoints by notice published in the Gazette.

[Assent Date: 11 October 2024]

[Operative Date: 16 October 2024]