

A BILL

entitled

BERMUDA HEALTH COUNCIL AMENDMENT ACT 2016

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	Consequential Amendments

WHEREAS it is expedient to amend the Bermuda Health Council Act 2004 and to make consequential amendments;

Be it enacted by The Queen'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 Act 2016.

Amends section 2

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

“financial interest” includes—

- (a) any contribution to the ultimate beneficial ownership or shareholding of a health service provider, whether by a loan or otherwise;

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- (b) any share-holding of five per cent or greater in the capital of a health service provider;
- (c) any entitlement to receive any dividend or income derived from a health service provider;

“financially vested referrals” means a referral made to a health service provider or health facility which offers to the referring health service provider a financial incentive or other reward for making such referrals;

“high risk health technology” means any medical device or medical equipment used for the purposes of diagnosis and treatment of disease or rehabilitation which satisfies any of the following criteria—

- (a) penetrates the skin, tissue and bone;
- (b) makes contact with the skin, tissue and bone of significant duration;
- (c) affects the vital organs including the heart, brain, and lungs;
- (d) creates systemic effects throughout the body rather than localized effects to a targeted site,

and includes a CT scanner, MRI machine, X-ray machine, radiation emitting equipment, diagnostic imaging machines, laser or surgical equipment, medical imaging equipment, nuclear medical instruments or devices, dialysis machines, and equipment that uses sound waves;

“interest” means a financial interest or significant influence;

“self-referral” means a referral made to a health service provider in which the referring health service provider, or a member of the provider’s family, has an interest;

“significant influence” means—

- (a) an entitlement to—
  - (i) participate in the management or operation of a health service provider;
  - (ii) elect or appoint any person to manage or operate a health service provider; or
- (b) the ability to indirectly influence the management or operation of a health service provider;”.

Amends section 5

3 Section 5 of the principal Act is amended—

- (a) in paragraph (c) by inserting after “fees,” the words “guidelines,”;
- (b) by inserting the following after paragraph (d)—

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“(da) to monitor the use of high risk health technology, and to regulate the importation of such technology into Bermuda;”.

Amends section 14

4 Section 14 of the principal Act is amended—

- (a) in the heading by deleting “Inspection” and substituting “Inspection: health service providers”;
- (b) in subsection (1) by inserting after “may” the words “appoint persons or”;
- (c) in subsection (3) by deleting “\$5,000.00” and substituting “\$20,000.00”.

Amends section 15

5 Section 15 of the principal Act is amended—

- (a) in the title by deleting “Regulations” and substituting “Regulations: health service providers”;
- (b) by inserting the following in their proper alphabetical order—
  - “(da) governing interests, self-referrals, and financially vested referrals;
  - (ba) prescribing the fees for application and renewal of licences;
  - (fa) prescribing the length of time for which records relating to returns must be retained;”;
- (c) in paragraph (g) by inserting after “regulations” the words “, and imposing penalties including civil penalties”.

Repeals section 16

6 Section 16 of the principal Act is repealed.

Inserts Part IIIA

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

“PART IIIA

REGULATION AND IMPORTATION OF  
HIGH RISK HEALTH TECHNOLOGY

Importation of high risk health technology prohibited

16A (1) The importation of high risk health technology into Bermuda is prohibited except under a certificate of entry issued by the Council.

(2) Any person who contravenes subsection (1) commits an offence and is liable on summary conviction to a fine of \$20,000.00 or to imprisonment for twelve months or to both such fine and imprisonment.

(3) For the avoidance of doubt, this section does not apply to high risk health technology in transit through Bermuda in any ship or aircraft, provided such technology remains in the ship or aircraft.

Principle for determining application to import high risk health technology  
16B When determining an application to import high risk health technology, the paramount consideration of the Council shall be health system planning and capacity, and ensuring patient safety.

Inspection: high risk health technology

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

(2) An inspector may at all reasonable times enter and inspect any premises where high risk health technology is operated by a health service provider and may require the production of records relating to fees and services provided by that health service provider.

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

Regulations: high risk health technology

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

- (a) governing the applications for the issue of certificates of entry;
- (b) governing applications for the registration and renewal of registration of high risk health technology;
- (c) prescribing the fees for applications for certificates of entry, registration and renewal of registration of high risk health technology;
- (d) establishing an appeals procedure where applications in respect of certificates of entry, registration, or self referrals and financially vested referrals are refused, and in respect of conditions and restrictions attached to registration, or where registration is cancelled;
- (e) prescribing professional and other qualifications required by health service providers or health professionals who operate high risk health technology;
- (f) requiring health service providers who own or operate high risk health technology to supply such returns, statistics or other information as the Council may require;

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- (g) prescribing the length of time within which records relating to returns must be retained;
- (h) with respect to the disposal of high risk health technology;
- (i) governing inspections, their management and conduct;
- (j) creating offences for any contravention of the regulations, and imposing penalties including civil penalties;
- (k) necessary or convenient to be prescribed for carrying out or giving effect to this Part.

(2) Regulations made under subsection (1) are subject to the affirmative resolution procedure.”.

### Consequential amendments

8 The Schedule (Consequential Amendments) has effect.

### Commencement

9 This Act, and section 13 of the principal Act, come into operation on such day as the Minister may appoint by notice published in the Gazette.

SCHEDULE

(section 8)

CONSEQUENTIAL AMENDMENTS

Amends the Health Insurance (Health Service Providers and Insurers) (Claims) Regulations 2012

1 The Health Insurance (Health Service Providers and Insurers) (Claims) Regulations 2012 is amended by revoking paragraph 12(2)(a).

Amends the Health Insurance (Standard Health Benefit) Regulations 1971

2 (1) Regulation A1 of the Health Insurance (Standard Health Benefit) Regulations 1971 is amended by inserting the following definitions in their proper alphabetical order—

“health professional” has the meaning given in section 2 of the Bermuda Health Council Act 2004;

“health service provider” has the meaning given in section 2 of the Bermuda Health Council Act 2004.”;

(2) Regulation 3 of the Health Insurance (Standard Health Benefit) Regulations 1971 is amended—

(a) in subparagraph (v)(b) by deleting “at such other facility,” and substituting “by a health service provider which is licensed under section 15 of the Bermuda Health Council Act 2004,”;

(b) by revoking and replacing subparagraph (xiv) with the following—

“(xiv) diagnostic imaging services provided by—

(aa) a diagnostic facility which is registered under section 163 of the Public Health Act 1949;

(bb) a health service provider which is licensed under section 15 of the Bermuda Health Council Act 2004, and in respect of which the reimbursement rates have been approved by the Council;”;

(c) by revoking and replacing subparagraph (xv) with the following—

“(xv) health care services provided in the home of a patient who resides at home by—

(aa) a health service provider, which is licensed by the Council under section 15 of the Bermuda Health Council Act 2004, at such rates chargeable in respect of such services as may be approved by the Council;

(bb) a health professional, at such rates chargeable in respect of such services as may be approved by the Council;”.

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Amends the Public Health Act 1949

3 (1) Section 161(1) of the Public Health Act 1949 is amended by inserting the following definitions in their proper alphabetical order—

“high risk health technology” has the meaning given in section 2 of the Bermuda Health Council Act 2004;

“high risk health technology facility” means a facility in which high risk health technology is operated;”.

(2) Section 162 of the Public Health Act 1949 is amended by inserting the following after subsection (1B)—

“(1C) No person shall operate a high risk health technology facility unless that facility is registered under this Part.”.

(3) Section 163 of the Public Health Act 1949 is amended—

(a) in subsection (1) by deleting the word “and” at the end of paragraph (c), and by inserting the following after paragraph (c)—

“(ca) a register of high risk health technology facilities; and”;

(b) in subsection (2)—

(i) in paragraph (a) by inserting after “hospitals,” the words “high risk health technology facilities,”;

(ii) in paragraph (a)(i) by inserting after “hospital” the words “, high risk health technology facility”;

(iii) in paragraph (a)(iii)(A) by inserting after “hospital” the words “, a high risk health technology facility”;

(iv) in paragraph (f) by inserting after “hospitals,” the words “high risk health technology facilities,”;

(v) in paragraph (g)—

(A) by inserting after the word “hospital” at its first occurrence the words “, a high risk health technology facility”;

(B) by inserting after the word “hospital” at its second occurrence the words “, high risk health technology facility”;

(c) in subsection (3)—

(i) by inserting after “hospital,” at its first occurrence the words “a high risk health technology facility,”;

(ii) by inserting after “hospital” at its second occurrence the words “, high risk health technology facility”.

(4) Section 164 of the Public Health Act 1949 is amended—

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- (a) by inserting after “hospital” wherever it occurs the words “, high risk health technology facility”;
- (b) in the proviso by inserting after “home,” the words “a hospital, a high risk health technology facility”.

Amends the Radiation Act 1972

4 (1) Section 1 of the Radiation Act 1972 is amended by inserting the following definition in its proper alphabetical order—

“health service provider” has the meaning given in section 2 of the Bermuda Health Council Act 2004;”.

(2) Section 3 of the Radiation Act 1972 is amended by inserting the following after subsection (2)—

“(2A) Notwithstanding subsection (2), every application for a licence under this Act in respect of an irradiating apparatus which is intended to be imported for use in Bermuda by a health service provider, shall be accompanied by a certificate of entry issued under the Bermuda Health Council Act 2004.”.



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### EXPLANATORY MEMORANDUM

This Bill seeks to amend the Bermuda Health Council Act 2004 (the “principal Act”) as follows—

Clause 1 is self explanatory.

Clause 2 amends section 2 of the principal Act by inserting a definition for “high risk health technology”.

Clause 3 amends section 5 of the principal Act by providing for the Bermuda Health Council (“the Council”) to issue guidelines, and to monitor high risk health technology and regulate its importation into Bermuda.

Clause 4 amends section 14 of the principal Act by amending the section heading to refer to health service providers. It also provides for the Minister to appoint persons as inspectors (in addition to designating public officers as inspectors as is presently provided).

Clause 5 amends section 15 of the principal Act by amending the section heading to refer to health service providers. It also provides for Regulations to be made prescribing fees in respect of applications for licences; the time for which health service providers must retain records which relate to returns provided by them to the Council; and for regulations to impose penalties including civil penalties.

Clause 6 repeals section 16 of the principal Act as fees will be prescribed by regulations made under section 15 of the principal Act.

Clause 7 amends the principal Act by inserting a new Part IIIA which prohibits the importation of high risk health technology without a certificate of entry issued by the Council. Among other things, Part IIIA also provides for a principle to guide the Council’s decision when considering an application to import high risk health technology; the power to enter premises and inspect records relating to the use of high risk health technology; and for the Minister to make regulations respecting such technology.

Clause 8 provides a schedule of consequential amendments as follows—

Paragraph 1 of the Schedule revokes paragraph 12(2)(a) of the Health Insurance (Health Service Providers and Insurers) (Claims) Regulations 2012, as the matter referred to in that paragraph is now dealt with under regulations made under section 15 of the principal Act.

Paragraph 2 of the Schedule amends the Health Insurance (Standard Health Benefit) Regulations 1971 by inserting definitions for “health professional” and “health service provider”. Subparagraph (2)(a), (b) and (c) makes amendments to the wording of the various provisions mentioned therein by clarifying that health service providers are licensed under the principal Act, and that the rates are approved by the Council under the Health Insurance Act 1970.

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Paragraph 3 of the Schedule amends the Public Health Act 1949 by providing for the Minister responsible for health to register, inspect and regulate high risk health technology facilities.

Paragraph 4 of the Schedule inserts a new section 3(2A) under the Radiation Act 1972 which provides for the Minister responsible for health to require an application for a licence under that Act to be accompanied by a certificate of entry issued by the Council, where the applicant is a health service provider who intends to import an irradiating apparatus into Bermuda.

Clause 9 provides for commencement of the Act.