BERMUDA

BERMUDA HEALTH COUNCIL AMENDMENT ACT 2021

2021 : 15

WHEREAS it is expedient to amend the Bermuda Health Council Act 2004 to facilitate the making of regulations to regulate prices at which drugs are sold to the public by providing for: the Bermuda Health Council (Drug Formulary) Regulations 2021; providing for revisions to be made to the Bermuda Drug Formulary, which is to be formulated under the Bermuda Health Council (Drug Formulary) Regulations 2021, subject to the negative resolution procedure; providing for penalties in the case of contravention of regulations; and providing for consequential amendments to the Pharmacy and Poisons Act 1979 and the Health Insurance (Health Service Providers and Insurers) (Claims) Regulations 2012;

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 may be cited as the Bermuda Health Council Amendment Act 2021.

Amends Bermuda Health Council Act 2004

2 (1) The Bermuda Health Council Act 2004 (the "Act") is amended in section 15 by inserting, after subsection (2), the following subsections—

"(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 for breach of the regulations.

(4) The Bermuda Drug Formulary provided for under the Bermuda Health Council (Drug Formulary) Regulations 2021, may be amended in regulations subject to the negative resolution procedure.".

(2) The Act is amended by inserting after section 15 the following new section—

"Council notices

15A (1) The Council may, by notice, publish information relating to its functions and required to be publicised as may be provided in the regulations made under section 15.

(2) The Council may publish a notice as provided for in subsection (1)—

(a) in the Gazette;

(b) on its website, at an address as may be specified in the regulations; or

(c) in such other manner as the Council may determine.

(3) Sections 6, 7 and 8 of the Statutory Instruments Act 1977 shall not apply to a notice published by the Council under this section. ".

Bermuda Health Council (Drug Formulary) Regulations 2021

3 The Bermuda Health Council (Drug Formulary) Regulations 2021, made pursuant to sections 5(h) and 15 of the Act and set out in Schedule 1, have effect.

Consequential amendments

4 Schedule 2 has effect with respect to amendments to the following—

(a) the Pharmacy and Poisons Act 1979;

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

Commencement

5 This Act shall come into operation on such day as the Minister may appoint by notice published in the Gazette.

SCHEDULE 1

(Section 3)

BERMUDA HEALTH COUNCIL (DRUG FORMULARY) REGULATIONS 2021

The Minister responsible for health, in exercise of the power conferred by sections 5(h) and 15 of the Bermuda Health Council Act 2004 and having consulted the Bermuda Health Council, makes the following Regulations:

Citation

1 These Regulations may be cited as the Bermuda Health Council (Drug Formulary) Regulations 2021.

Interpretation

2 In these Regulations, unless the context otherwise provides—

"the Act" means Bermuda Health Council Act 2004;

"Council" means the Bermuda Health Council established under section 3 of the Act;

"Council website" means the Bermuda Health Council uniform resource locator or internet address located at: www.bhec.bm;

"drug formulary" means the Bermuda Drug Formulary and has the meaning given in regulation 3;

"medical products" means the medications or other products used in medical treatments listed in the Bermuda Drug Formulary under regulation 3;

"national drug code" means a unique 10-digit number that is determined by the Council to identify all medications found in Bermuda and that is used as a reference number in all transactions involving purchase and importation, point of sale and insurance reimbursement of medications;

"Pharmacy and Therapeutics Committee" or "Committee" means the committee appointed under regulation 6;

"stakeholder" means a person or entity that participates in, or is associated with, the construction, maintenance or utilization of the Bermuda Drug Formulary, and includes—

(a) health providers;

(b) health care professionals;

(c) pharmacy owners and management;

(d) insurers; and

(e) such other person or category of persons as the Council may in writing determine to be a stakeholder.

Meaning of drug formulary

3 (1) For the purposes of these Regulations, the Bermuda Drug Formulary means a list of medications, other products used in medical treatments and relevant information, which are recommended by the Committee and approved by the Council, and includes—

(a) medications and medication-associated products;

(b) medical devices;

(c) relevant drug information;

(d) medical product costs; and

(e) such other detail or information as the Council may deem appropriate.

(2) The medications, products and information approved by the Council under subsection (1) shall be medically appropriate and cost-effective for patients in Bermuda.

Consumer Pricing Tool to be initial Bermuda Drug Formulary

4 (1) The Consumer Pricing Tool for prescription drugs, which consists of a list of medications initially compiled by the Council in consultation with medical practitioners in Bermuda and which was published and implemented by the Council in February 2018, is, by virtue of these Regulations, deemed to be the Bermuda Drug Formulary made under these Regulations as from the date of the coming into operation of these Regulations.

(2) The Bermuda Drug Formulary shall be maintained and updated periodically as provided in these Regulations.

(3) The Council shall publish the approved Bermuda Drug Formulary and each updated version thereof on the Council website.

Council duties regarding drug formulary

5 (1) The Council shall, pursuant to section 5(h) of the Act and for the purposes of ensuring the availability in Bermuda of the medical products that are medically appropriate and cost-effective—

(a) facilitate consultation and develop and establish guidelines regarding the standard use of medications, therapies, and medication-associated products;

(b) cause the construction and maintenance of the Bermuda Drug Formulary;

(c) approve the constructed Bermuda Drug Formulary and each updated version thereof;

(d) assign prices for medical products included in the drug formulary based on local price data.

(2) Before approving any medical product for inclusion in the drug formulary, the Council shall ensure that its decision—

(a) is supported by evidence based on—

(i) clinical, legal, ethical, social, quality-of-life and safety grounds; and

(ii) the active and direct participation of relevant stakeholders;

(b) meets the standardization and quality requirements determined by the Council as appropriate;

(c) should, where possible, result in a cost reduction for patients in Bermuda.

(3) Where the Council determines not to implement a recommendation of the Committee for the drug formulary it shall—

(a) state the grounds for its decision and provide necessary evidence in support for the Committee to consider; and

(b) proceed with the decision only in the case where the Committee fails to satisfactorily counter the grounds advanced by the Council in support of that recommendation.

(4) The Council shall, for the purposes of the drug formulary—

(a) establish and enforce a national drug code as provided in regulation 11;

(b) participate in negotiations for the procurement of medications as provided in regulation 13.

Appointment of Pharmacy and Therapeutics Committee

6 (1) The Minister shall, in consultation with the Council, appoint the Pharmacy and Therapeutics Committee, which shall advise the Council on the medical products and information to be included in the Bermuda Drug Formulary and on the maintenance of the Bermuda Drug Formulary.

(2) The Committee shall consist of not more than nine persons, who are associated with the medical treatment process, appointed as follows—

(a) one member from the Board of Directors of the Council, who shall be chairperson of the Committee;

(b) one member from the secretariat of the Council;

(c) one member representing the pharmaceutical market in Bermuda, nominated by the Pharmacy Council;

(d) one member representing the health services market in Bermuda, nominated by a registered health statutory board;

(e) one international member representing the pharmaceutical market in the region;

(f) such other members representing relevant areas of health expertise as appointed on an ad-hoc basis by the Council.

(3) A member of the Committee shall be appointed for a period not exceeding two years on such terms and conditions as the Council may determine.

(4) The Committee shall, with the approval of the Council—

(a) meet as often as necessary or is expedient for the performance of its functions;

(b) where necessary, conduct its business and review materials in support of decision-making by the use of electronic means and other measures; and

(c) determine its own procedure.

Functions of Pharmacy and Therapeutics Committee

7 (1) The function of the Committee is to advise the Council on the formulation of the drug formulary by identifying those medical products that are most medically appropriate and cost-effective to best serve the health interests of people in Bermuda.

(2) Without derogating from the generality of paragraph (1), the Committee shall, for the purpose of recommending to the Council the medical products for inclusion in the drug formulary, perform the following functions—

(a) evaluate drug utilization in Bermuda by means of reviewing insurance claims data in relation to the applicable drug formulary;

(b) review and assess for inclusion in the drug formulary new drug applications, new drug classes, new clinical indications, new therapeutic advantages, new chemical entities, and new safety information;

(c) review and assess the therapeutic classes of the drug formulary at least every two years;

(d) determine, in collaboration with the Council, how medical products are to be requested for addition to or deletion from the drug formulary;

(e) determine, in collaboration with the Council, how medical products are to be reviewed for addition to or deletion from the drug formulary;

(f) maintain, in collaboration with the Council, the drug formulary approved for use to promote the safety, effectiveness, and affordability in accordance with the drug formulary principles under regulation 8;

(g) determine the process for managing drug product shortages.

(3) The Committee, in collaboration with the Council, shall, with respect to the drug formulary stakeholders, develop—

(a) appropriate educational programmes to enhance knowledge of drug therapy and practices;

(b) a standard communication process for the purpose of disseminating information on—

(i) changes to the drug formulary; and

(ii) the process for submitting an application for inclusion or removal of a drug and the criteria for selection.

(4) The Council shall publish on the Council website the Committee's deliberations, decisions and supporting documentation.

Drug formulary principles

8 (1) The Committee shall, for the purpose of making recommendations to the Council relating to maintaining and updating of the Bermuda Drug Formulary, consider decisions, with respect to the medical products and information listed on the drug formulary, that are supported by scientific evidence and appropriate standards of practice as provided in paragraph (2).

(2) The Committee shall consider decisions as referred to in paragraph (1) by—

(a) conducting an aggregated analysis of insurance claims data for population health trends and in alignment with therapeutic needs of patients and the identification of relevant conditions;

(b) assessing peer-reviewed medical literature, including randomized clinical trials (in particular, drug comparison studies), pharmacoeconomic studies, and outcomes research data;

(c) employing published practise guidelines adopted from an established and validated international source or developed by a generally acceptable and verifiable (evidence-based) process;

(d) comparing the efficacy, safety, quality, as well as the type and frequency of side effects and potential drug interactions among alternative drug products with the current drug formulary;

(e) assessing the likely impact of a drug product on patient compliance when compared to alternative products;

(f) basing decisions on a thorough evaluation of the benefits, risks and potential outcomes for patients;

(g) considering and assessing such other matters as the Council shall deem appropriate.

(3) The risks referred to in paragraph (2)(f) are those that encompass adverse drug events relating to adverse drug reactions and medication errors, such as those caused by confusing product names or labels.

(4) In addition to the matters in paragraphs (1) and (2), the Committee may, where appropriate, evaluate recommendations made for the drug formulary by taking into account such economic considerations as the Council may determine as necessary.

(5) The Committee shall make recommendations for the inclusion of drugs in the drug formulary based on the health needs of the people of Bermuda.

Formulary exception process

9 (1) The Committee shall, in relation to medications that are not listed on the drug formulary or in the case of medications that may require prior authorization, propose for

the Council's approval the formulary exception process that is to apply with respect to such medications.

(2) The Council shall approve a formulary exception process that is timely, uncomplicated and efficient.

Data submission requirements to facilitate drug formulary

10 (1) The Council shall, for the purposes of maintaining the drug formulary, require submission of data from insurers, health professional institutions, importers, the Department of Customs and the Department of Financial Assistance, as provided in this regulation.

(2) Each insurer licensed by the Council shall submit to the Council on a monthly date determined by the Council—

(a) transaction level data;

(b) national drug codes;

(c) pharmaceutical sales data; and

(d) such other data, as may be deemed necessary and reasonable by the Council.

(3) Data on dealings in pharmaceuticals shall be submitted to the Council on a monthly date determined by the Council by—

(a) health professional institutions, with respect to pharmaceutical purchasing and sales, including compounding and components purchased for the creation of medical products;

(b) the Department of Customs and importers, with respect to medical products imported for sale in Bermuda;

(c) the Department of Financial Assistance, with respect to medical product reimbursements made.

(4) The Council shall determine the detail and format of the data to be submitted under paragraphs (2) and (3).

(5) In this regulation "health professional institutions" include pharmacies, medical practices, hospitals, overseas providers with direct patient sales and any other speciality services dealing with medical products listed in the Bermuda Drug Formulary.

Establishment of national drug code

11 (1) In order to monitor the level of compliance with, and safety of, the drug formulary, the Council shall establish a national drug code for Bermuda that shall—

(a) consist of relevant drug codes relating to the medical products found in the Bermuda Drug Formulary; and

(b) form part of the Bermuda Drug Formulary.

(2) The Council shall update and maintain the national drug code and publish it on the Council website.

National drug code requirements

12 (1) A stakeholder or other entity referred to in paragraph (2) shall cause the relevant drug code from the national drug code established by the Council under regulation 11 to be clearly stated on products and documentation as provided in paragraph (2).

(2) The relevant drug code shall be stated as follows—

(a) each insurer shall include the relevant code on all claims, reimbursements and mandated transaction level data reports;

(b) the entities in Bermuda mentioned in paragraph (3) shall include the relevant code on—

(i) pharmaceutical imports documentation;

(ii) accounting records for pharmaceutical sales;

(iii) labels on the pharmaceutical products;

(iv) point of sale records, including receipts and invoices;

(v) claim forms to be submitted to insurance companies for reimbursement;

(c) the Department of Customs shall maintain a record of all pharmaceutical imports with each pharmaceutical product identified by the relevant drug code for tracking and confirmation purposes, which drug code shall also be submitted to the Council;

(d) an international vendor shall include the relevant Bermuda based national drug code for any sale of pharmaceuticals to Bermuda on identifying documentation (including shipping, inventory, receipts, or invoices) as well as on each item being imported.

(3) The entities to which paragraph (2)(b) is applicable are—

(a) pharmacies;

(b) health professionals (including hospitals) that purchase or sell, or purchase and sell, pharmaceutical products; and

(c) local importers or distributors of pharmaceutical products.

(4) The Council may, by notice, prescribe such other matters relating to the national drug code as it determines necessary.

Council participation in drug purchase negotiations

13 (1) The Council shall, for the purpose of deriving cost-effective medical products, participate as one of the negotiators on behalf of Bermuda for the procurement of medical products—

(a) in bulk from international suppliers; and

(b) at a reduced rate from suppliers in Bermuda.

(2) For the purposes of the negotiations referred to in paragraph (1), the Council may cooperate with the Government, any pharmacy or entity involved in the purchasing of medical products for Bermuda.

(3) The Council shall, for the purpose of listing in the drug formulary the lowest price for medical products, determine the price of each medical product in relation to the price at which the medical product was supplied.

Council notices

14 The Council may, by notice, publish—

(a) amendments to the definition of "Council website" under regulation 2;

(b) the Bermuda Drug Formulary as may, from time to time, be approved under regulation 4;

(c) the appointment of members of the Pharmacy and Therapeutics Committee provided for under regulation 6;

(d) the formulary exception process as may, from time to time, be approved under regulation 9;

(e) the national drug code as may, from time to time, be approved under regulation 11;

(f) such requirements, under regulation 12 relating to the national drug code, as the Council may determine necessary.

Offences

15 Any person who fails to comply with—

(a) requirements to appropriately dispense medications and other products used in medical treatments in accordance with the Bermuda Drug Formulary;

(b) the prices stipulated in the Bermuda Drug Formulary for the sale of medications and other products used in medical treatments;

(c) requirements to submit information and data to the Council as provided in regulation 10;

(d) requirements to use the national drug code as provided in regulation 12,

commits an offence and is liable on summary conviction to a fine of $50,000.

SCHEDULE 2

(Section 4)

CONSEQUENTIAL AMENDMENTS

Amendments to the Pharmacy and Poisons Act 1979

Inserts section 46A

1 The Pharmacy and Poisons Act 1979 (the "Act") is amended by inserting after section 46 the following new section—

"Prescription drug pricing

46A (1) Where any person supplies a prescription drug to another person, he shall inform the person purchasing the drug of—

(a) the cost of the drug—

(i) covered by insurance, in the case where the person purchasing the drug is insured; and

(ii) payable by the person purchasing the drug; and

(b) the amount of the dispensing fee charged by the person supplying the drug.

(2) A person who contravenes subsection (1) commits an offence against this Act.".

Amends section 55

2 The Act is amended in section 55—

(a) in subsection (2) by inserting after the word "46," the word "46A,";

(b) in subsection (3)(a) by deleting "$5,000" and substituting "20,000";

(c) in subsection (3)(b) by deleting "$15,000" and substituting "50,000".

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

Inserts regulation 4A

3 The Health Insurance (Health Service Providers and Insurers) (Claims) Regulations 2012 (the "Regulations") are amended by inserting after regulation 4 a new regulation 4A as follows—

"Drug codes

4A A health service provider shall when submitting a claim under paragraph 4, state the information required relating to the medications and pharmaceuticals that have been prescribed in accordance with the drug codes applicable to such

medications and pharmaceuticals as set out in the national drug code established by the Bermuda Health Council.".

Amends Schedules 1 and 2

4 The Regulations are amended—

(a) in Schedule 1, by inserting after paragraph 15 the following paragraph—

"16. Drug codes applicable to the drugs and pharmaceuticals prescribed";

(b) in Schedule 2, by inserting after paragraph 9 the following paragraph—

"10. Drug codes applicable to the drugs and pharmaceuticals prescribed".

[Assent Date: 31 March 2021]

[Operative Date: 10 September 2021]