



BILL NO. 17

Government Bill

*3rd Session, 61st General Assembly
Nova Scotia
60 Elizabeth II, 2011*

An Act Respecting an Insured Prescription Drug Plan, including Fair Drug Pricing

CHAPTER 7
ACTS OF 2011

**AS ASSENTED TO BY THE ADMINISTRATOR OF THE PROVINCE
MAY 19, 2011**

The Honourable Maureen MacDonald
Minister of Health and Wellness

*Halifax, Nova Scotia
Printed by Authority of the Speaker of the House of Assembly*

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An Act Respecting an Insured Prescription Drug Plan, including Fair Drug Pricing

Be it enacted by the Governor and Assembly as follows:

1 This Act may be cited as the *Fair Drug Pricing Act*.

2 In this Act,

(a) “Administrator” means the body corporate that acts on behalf of the Minister and administers the Plan for the Minister;

(b) “beneficiary” means a person who is enrolled as a member of a program pursuant to this Act and the regulations;

(c) “benefit” means a drug, device or service designated by the Minister under this Act to which some level of coverage applies under a program;

(d) “benefit period” means a period of time prescribed in the regulations in respect of the payment of a benefit;

(e) “claim” means a claim for payment of a benefit;

(f) “committee” means a committee established by the Minister under this Act;

(g) “copayment” means the amount determined in accordance with the regulations that may be required to be paid by a beneficiary toward the cost of a benefit;

(h) “deductible” means an amount determined in accordance with the regulations that may be required to be paid by a member towards the cost of a benefit before any benefit is paid;

(i) “dependant” means a person who meets the criteria for dependants set out in the regulations;

(j) “device” has the same meaning as in the *Food and Drugs Act* (Canada);

(k) “drug” has the same meaning as in the *Food and Drugs Act* (Canada);

(l) “formulary” means

(i) the list of drugs designated as interchangeable by the Minister under Section 9,

(ii) the list of drugs, devices and services approved for sale by Health Canada but not designated by the Minister under Section 10,

(iii) the list of benefits established by the Minister under Section 11, and

(iv) the information with respect to criteria, standards, policies or guidelines for the Plan;

(m) “Minister” means the Minister of Health and Wellness;

(n) “Plan” means the Insured Prescription Drug Plan established by this Act;

- (o) “premium” means an amount of money payable to the Minister under this Act;
- (p) “prescriber” means a person authorized to prescribe a drug, device or service within the person’s regulated scope of practice;
- (q) “prescription” means a direction from a prescriber directing the dispensing of a drug, device or service or a mixture of drugs, devices or services for a specified person;
- (r) “program” means a program of benefits established by the Minister under the Plan;
- (s) “provider” means
 - (i) a pharmacy licensed under the *Pharmacy Act* that has confirmed agreement with the tariff between the Minister and the Pharmacy Association of Nova Scotia and has been designated as a provider, or in a class of providers, and
 - (ii) a supplier of drugs, devices or services that is not licensed as a pharmacy under the *Pharmacy Act* but is designated as a provider or in a class of providers;
- (t) “resident” has the same meaning as in the *Hospital Insurance Regulations*;
- (u) “service” means a treatment, care, service or activity related or incidental to the provision, sale, distribution, purchase or pricing of drugs or approved drugs;
- (v) “tariff” means payment to a provider for benefits established pursuant to subsection 14(2).

3 (1) There is hereby established an Insured Prescription Drug Plan under the administration of the Minister for the purpose of providing funding for, or providing, benefits.

(2) The Minister may establish programs under the Plan.

4 Coverage under the Plan is insurance of last resort as provided by the regulations.

5 A person is not eligible for coverage of benefits under this Act if the person is entitled to benefits

- (a) under the *Workers’ Compensation Act*;
- (b) from the Royal Canadian Mounted Police;
- (c) from the Department of National Defence;
- (d) from Veterans Affairs Canada;
- (e) under the non-insured health benefits for First Nations Inuit Health;
- (f) under any other Act of the Legislature or the Parliament of Canada; or
- (g) under any statute of any jurisdiction either within or outside of Canada.

6 (1) Subject to the regulations, the Minister may enrol as a beneficiary of a program any person who meets the eligibility and enrolment criteria set out in the regulations.

(2) The Governor in Council may make regulations

(a) respecting the eligibility and enrolment requirements that must be met for a person to become and remain a beneficiary of a program, including but not limited to

(i) establishing different eligibility and enrolment requirements for different beneficiaries and classes of beneficiaries,

(ii) establishing exemptions from the eligibility and enrolment requirements for certain persons or classes of persons in the circumstances set out in the regulations, and

(iii) deeming certain persons or persons within certain classes of persons to be beneficiaries or to be eligible to be beneficiaries of a program;

(b) respecting the exclusion of certain persons or certain classes of persons from eligibility as beneficiaries of a program;

(c) respecting criteria for determining eligibility, including but not limited to criteria respecting residency, assessment of income, fixed ineligibility periods and temporary absences;

(d) respecting the information that persons may be required to provide to the Minister for the purpose of assessing and verifying eligibility and enrolment;

(e) respecting the circumstances under which the Minister may refuse, suspend, vary or discontinue a beneficiary's enrolment;

(f) respecting the establishment of effective dates for eligibility and enrolment, and for refusal, suspension, variance and discontinuance of eligibility and enrolment, which may be different for different circumstances, beneficiaries and classes of beneficiaries.

(3) The Minister may provide a beneficiary with proof of enrolment.

(4) The Governor in Council may make regulations respecting the issuance to beneficiaries of proofs of enrolment and any rules, terms, restrictions or conditions respecting the proof of enrolment.

(5) Subject to the regulations, a beneficiary shall notify the Minister of a change in circumstances affecting the beneficiary's eligibility or the eligibility of any of the beneficiary's dependants.

(6) Participation by a beneficiary in a program is deemed to be consent by the beneficiary for the release of information required

(a) to determine the person's eligibility for a program; and

(b) for audits under the program, including the release of copies of prescriptions.

7 (1) The Governor in Council may make regulations

(a) respecting premiums that may be required to be paid by beneficiaries, including but not limited to establishing different rates and levels of premiums for dif-

ferent beneficiaries or classes of beneficiaries and providing that premiums may be applied retroactively;

(b) respecting times and methods of payment of premiums, including the collection and remittance of premiums, and to whom payments of premiums may be made on behalf of the Minister;

(c) respecting copayments that may be required to be paid by beneficiaries, including but not limited to establishing different rates and levels of copayments for different beneficiaries or classes of beneficiaries and providing that copayments may be applied retroactively;

(d) respecting deductibles that may be required to be paid by beneficiaries, including but not limited to establishing different rates and levels of deductibles for different beneficiaries or classes of beneficiaries and providing that deductibles may be applied retroactively;

(e) establishing copayments or deductibles that are applicable to benefits, including establishing different copayments or deductibles for different benefits or different classes of benefits;

(f) respecting the waiving of premiums, copayments and deductibles, including but not limited to establishing criteria for eligibility for waivers and providing that waivers may be applied retroactively;

(g) respecting dependants and family units, including establishing the criteria that must be met for a person to be considered a dependant or part of a family unit;

(h) respecting benefit periods that may apply to the eligibility or enrolment of beneficiaries or classes of beneficiaries, to premiums, copayments, deductibles or waivers or to benefits payable under this Act;

(i) respecting processes and criteria for the assessment and determination of whether a premium, copayment, deductible or waiver is applicable to a beneficiary or a class of beneficiaries, including but not limited to criteria relating to a beneficiary's income or financial situation;

(j) respecting the information a person may be required to provide to the Minister with respect to any matter under this Section;

(k) respecting penalties for unpaid premiums, deductibles and copayments.

(2) Subject to the regulations, where a beneficiary is required to pay a premium, the beneficiary is liable for and shall pay the premium to the Minister.

8 (1) Subject to the regulations, the Minister may pay benefits to or on behalf of beneficiaries and other persons.

(2) To be eligible for payment,

(a) a claim must contain all the information required by the Minister and be in a form required by the Minister;

(b) claims for benefits must be submitted within six months of the day on which the benefit giving rise to the claim was provided; and

(c) the date of a claim must not be more than one year from the original date of the prescription on which the claim for the benefit is based.

(3) All claims for benefits are subject to assessment and approval by the Minister, and the amount of benefits to be paid, the rules, terms, restrictions and conditions under which benefits may be paid and the person to whom benefits are to be paid must be determined in accordance with the conditions and maximum tariffs pursuant to subsection 14(2).

(4) Subject to the regulations, the Minister may

(a) restrict, refuse, suspend, vary or discontinue payment of benefits to or on behalf of a beneficiary or other person;

(b) co-ordinate payment of benefits with other insurers and other reimbursement programs;

(c) reassess or adjust claims;

(d) require a person to reimburse the Minister, in whole or in part, for any benefit paid;

(e) take any steps permitted by this Act or the regulations to recover an inadvertent or improper payment of a benefit; and

(f) establish processes for audits and investigations of beneficiary claims.

(5) The Minister may, in accordance with the regulations, require a beneficiary, provider or other person to provide information to the Minister as the Minister deems necessary for the purpose of this Section.

(6) Nothing in this Act or the regulations is to be construed so as to prevent a beneficiary or other person entitled to a benefit from assuming the responsibility for payment for a drug, device or service for which a benefit is payable if the member or other person so desires.

9 (1) Subject to the regulations, the Minister may designate a drug to be interchangeable with one or more drugs or benefits.

(2) The Minister may amend the designation or modify or cancel the designation of interchangeability of a drug or benefit.

10 (1) Subject to the regulations, the Minister may designate a drug, device or service as a benefit.

(2) The Minister's designation of a benefit may include

(a) assigning to the drug, device or service any attribute or distinction permitted by the regulations;

(b) classifying the drug, device or service as belonging to one or more classes or groups of benefits;

(c) determining whether the drug is interchangeable with other drugs;

(d) determining whether any rules, terms, restrictions or conditions apply to the benefit payable; and

(e) taking any other steps permitted by the regulations.

(3) The Minister may, as a condition of designating a benefit or continuing the designation of a benefit,

(a) require that a person enter into an agreement with the Minister in a form satisfactory to the Minister; and

(b) impose on any person any rules, terms, restrictions or conditions as prescribed in the regulations.

(4) Subject to the regulations, the Minister may amend, modify or cancel the designation of a benefit.

(5) A drug, device or service becomes a benefit on the effective date of its designation under subsection (1) and ceases to be a benefit on the effective date specified by the Minister.

(6) A modification of the designation of a benefit takes effect on the effective date specified by the Minister.

11 (1) The Minister may establish and maintain a list of benefits.

(2) The list must set out the benefits for the purposes of this Act, and may set out

(a) the classes, groups, attributes or other distinctions relating to the benefits;

(b) the amount payable for a benefit;

(c) criteria, standards, policies and guidelines respecting the benefits;

(d) the benefits that are designated as interchangeable with other benefits and drugs;

(e) whether any rules, terms, restrictions or conditions apply to a benefit or a class or group of benefits;

(f) information or notices required in relation to the Plan; and

(g) any other information the Minister considers necessary or advisable.

(3) The list is not a guide for the prescribing of drugs, devices or services or the provision of treatment or care.

12 (1) The Minister may publish the benefit list in a formulary or in any other form the Minister considers advisable.

(2) In the event of a conflict between published versions of the benefit list, the version posted electronically prevails.

13 The Minister may issue, conduct, evaluate or conclude requests for proposals, requests for expressions of interest, requests for information, requests for quotations, tenders or any similar activity in respect of

- (a) drugs, devices or services;
- (b) classes, group attributes or other attributes of drugs, devices or services; and
- (c) any other matter under this Act.

14 (1) The Minister may enter into agreements with any person or government respecting

- (a) the provision, sale, distribution, purchase or pricing of drugs, devices or services;
- (b) rebates related to the provision, sale, distribution, purchase or pricing of drugs, devices or services;
- (c) services related to the administration and operation of the Plan; and
- (d) any other matter under this Act.

(2) Subject to the approval of the Governor in Council, the Minister may enter into agreements respecting conditions and maximum tariffs payable to providers for providing benefits to beneficiaries.

15 The Minister may delegate any power, duty or function of the Minister under this Act or the regulations to any person the Minister considers appropriate.

16 (1) The Minister may establish any committees the Minister considers necessary or desirable in connection with any matters under this Act.

(2) The Minister may, with respect to any committee,

- (a) appoint or provide for the manner of the appointment of its members;
- (b) prescribe the term of office of any member;
- (c) designate a chair, vice-chair and secretary; and
- (d) authorize, fix or provide for the payment of remuneration and expenses to its members.

(3) A committee may exercise the powers and shall perform the duties and functions that the Minister approves or confers or imposes on it.

17 (1) The Minister may designate persons as providers, or classes of persons as classes of providers, for the purpose of this Act and the regulations.

(2) The Governor in Council may make regulations respecting the activities of providers in relation to any matters under this Act, including but not limited to regulations

- (a) respecting the designation of providers or classes of providers;

(b) requiring a provider or a class of provider to comply with any criteria, standards, policies and other guidelines specified by the Minister;

(c) respecting the information that providers or classes of providers must provide to the Plan and beneficiaries;

(d) respecting exempting specified providers or classes of providers from some or all of the requirements of this Act or the regulations;

(e) imposing rules, terms, restrictions or conditions respecting rebates and professional allowances paid to providers in relation to benefits;

(f) respecting processes for audits, investigations and appeals of provider claims;

(g) respecting the constitution and powers of an appeal panel;

(h) respecting the circumstances under which interest may be charged under subsection 23(5) and the rate at which that interest may be charged;

(i) respecting the auditing techniques necessary to conduct audits.

(3) Except as authorized by the Plan, providers may not charge beneficiaries amounts in excess of the maximum tariffs established pursuant to subsection 14(2).

18 (1) The Minister may directly or indirectly collect personal information, subject to such conditions as may be prescribed in the regulations, for purposes related to the administration of this Act or for such other purposes as may be prescribed in the regulations.

(2) The Minister may use personal information, subject to such conditions as may be prescribed in the regulations, for purposes related to the administration of this Act or for such other purposes as may be prescribed in the regulations.

(3) The Minister shall disclose personal information if all conditions prescribed in the regulations have been met and the disclosure is necessary for purposes related to the administration of this Act or for such other purposes as may be prescribed in the regulations, but shall not disclose the information if, in the Minister's opinion, the disclosure is not necessary for those purposes.

(4) Subject to such conditions as may be prescribed in the regulations, the Minister may enter into agreements to collect, use or disclose personal information for purposes related to the administration of this Act or for such other purposes as may be prescribed in the regulations.

(5) An agreement under subsection (4) must provide that personal information collected or disclosed under the agreement will be used only

(a) to verify the accuracy of information held or exchanged by a party to the agreement;

(b) to administer or enforce a law administered by a party to the agreement;
and

(c) for a purpose prescribed by regulation under subsection (4).

(6) An agreement under subsection (4) must provide that personal information collected, used or disclosed under the agreement is confidential and establish mechanisms for maintaining the confidentiality of the information.

(7) Before disclosing personal information obtained under this Act or under an agreement, the person who obtained it shall delete from it all names and identifying numbers, symbols or other particulars assigned to individuals unless

(a) disclosure of the names or other identifying information is necessary for the purposes described in subsection (3) or (4); or

(b) disclosure of the names or other identifying information is otherwise authorized under the *Freedom of Information and Protection of Privacy Act*.

19 The Minister may prescribe forms to be used for the purpose of this Act.

20 (1) A provider shall maintain patient or prescription records for all claims for benefits as required by this Act and the regulations.

(2) Every provider who makes a claim for benefits shall provide to the Administrator, upon the Administrator's request the particulars of the claim and documentation to support the claim as required by this Act and the regulations.

(3) The Minister may require that a provider, prescriber, or beneficiary supply further information to the Minister or the Administrator if the information is required to substantiate a claim.

21 (1) The Minister may appoint auditors who are responsible for performing the duties and functions under this Section.

(2) In order to determine compliance with the Plan, an audit may be performed under this Section to determine compliance with this Act, the regulations, policies and the terms and conditions of participation in the Plan.

(3) Audits performed under this Act must be performed according to generally accepted auditing standards and may be performed using techniques prescribed by the regulations that are considered necessary to complete audits according to the required standard.

(4) An auditor performing an audit may examine and copy those prescriptions, documents, papers and records that the auditor considers necessary to complete the audit in the manner required by this Act and the regulations.

(5) An examination of records referred to in subsection (4) includes electronic records, and an auditor may make a copy of those records, including electronic records, in a manner that the auditor considers necessary, including photocopying, scanning and electronic copying of data.

(6) Where reasonably necessary to determine compliance under this Act, an auditor or other person appointed or designated by the Minister under this Act may, at reasonable times,

without a warrant, enter a provider's business premises to inspect the documents referred to in subsection (4).

(7) A provider shall provide the information required by an auditor under this Act in order to determine compliance with this Act and that information may be provided by mail, facsimile or electronic transmission.

(8) An examination of records required under this Section may include an examination of information, documentation or other records held by a provider regarding a beneficiary's insurer and any records of payment to that insurer or other method of obtaining coverage for the drugs or related products.

22 (1) The Minister may set deadlines for providing information to auditors acting under Section 21.

(2) The time period set by the Minister under subsection (1) may be varied with the agreement of the parties.

23 (1) The Administrator may audit, assess and investigate a provider's claim for benefits as prescribed in the regulations and shall determine the amounts payable for such claims in accordance with this Act and the regulations.

(2) Where, following an audit performed under this Act, it is determined that a payment has been made to a provider or a prescriber in excess of the amount that was required to be paid under the Plan, the excess amount is a debt due to Her Majesty in right of the Province.

(3) Amounts that are determined to have been paid in excess must be recovered in the manner prescribed by the regulations.

(4) Notwithstanding subsection (2), the Administrator may recover the amounts paid in excess in a different manner where there is an agreement with the provider to do so.

(5) The Administrator may charge interest on amounts paid in excess in the circumstances and at a rate prescribed by the regulations.

24 Where it has been determined under Section 23 that excess payments have been made to a provider, the Administrator shall, in writing, notify the provider

- (a) of the amount of the money paid in excess and the manner of calculating the amount;
- (b) that the excess amount is a debt due to Her Majesty in right of the Province;
- (c) that the amount may be recovered; and
- (d) of the provider's right to an appeal under Section 25.

25 (1) Where the Administrator has completed an audit under Section 23 and has made a determination, a provider may refer the matter to an appeal panel pursuant to the regulations and the appeal panel shall make a decision in accordance with the regulations.

(2) A provider may further appeal the appeal panel's decision to the Minister.

26 Any decision made by the Minister in the exercise of the Minister's discretion under this Act or the regulations is final and conclusive and may not be set aside by any court unless the decision was made or the discretion was exercised in bad faith or for an improper purpose.

27 A person who

(a) on behalf of himself or herself or on behalf of another person, obtains or receives benefits to which that person or the other person is not entitled to obtain or receive under this Act or the regulations;

(b) provides false or misleading information or records pursuant to a requirement of this Act or the regulations to provide information or records;

(c) fails to provide information, answers or records as required by this Act or the regulations;

(d) aids or abets another person in applying for, obtaining or receiving any benefits under this Act that the person is not eligible for under this Act;

(e) contravenes an enforcement order; or

(f) contravenes or fails to comply with any provision of this Act or the regulations, is guilty of an offence and liable on summary conviction to

(g) for a first offence, a fine not exceeding twenty-five thousand dollars; and

(h) for a second or subsequent offence, a fine not exceeding fifty thousand dollars.

28 A prosecution for an offence under this Act may not be commenced more than two years after the later of

(a) the date on which the alleged offence was committed; and

(b) six months after the date on which evidence of the offence first came to the attention of the Minister.

29 (1) Where a corporation commits an offence under this Act or the regulations, any officer, director or agent of the corporation who directed, authorized, assented to, acquiesced in or participated in the commission of the offence is guilty of the offence and is liable to the punishment provided for the offence, whether or not the corporation has been prosecuted for or convicted of the offence.

(2) For the purpose of this Act, an act or thing done or omitted to be done by a director, officer, official, employee or agent of a corporation in the course of that person's employment or in the exercise of that person's powers or the performance of that person's duties is deemed also to be an act or thing done or omitted to be done by the corporation.

30 (1) No liability attaches to, and no action or proceeding may be brought against, Her Majesty in right of the Province, the Minister, an auditor, a member of a committee, an advisor or any person acting under the authority of the Minister for anything done or omitted to be

done by any of them in good faith while exercising their powers and performing their duties under this Act.

(2) Notwithstanding any other enactment, and except as otherwise provided by the regulations,

(a) a member of a committee or an advisor acting under the authority of this Act may not be compelled as a witness, or required to testify, give evidence or produce any file, record, document, paper or information, respecting any matter under this Act; and

(b) any file, record, document, paper or information in the custody of any of the persons referred to in clause (a) may not be admitted in evidence in any proceedings.

31 (1) The Governor in Council may make regulations respecting the establishment and administration of programs, including but not limited to the effective date of a program, the purposes of a program and the rules, terms, restrictions, conditions and exemptions that apply to a program.

(2) The Governor in Council may make regulations respecting the benefits payable under this Act, including but not limited to regulations

(a) establishing information that must be provided to the Minister in respect of matters under this subsection;

(b) imposing rules, terms, restrictions or conditions respecting the pricing and supply of a benefit and conditions of designating or continuing the designation of a benefit;

(c) determining whether the cost of a drug, device or service is covered in whole or in part;

(d) respecting the criteria and other factors that may or must be considered in establishing, modifying or discontinuing a benefit;

(e) respecting conditions that may be imposed on a person with respect to establishing and continuing a benefit;

(f) establishing different benefits or levels of benefits for different persons or classes of persons;

(g) respecting the circumstances in which the Minister may refuse, suspend, vary or discontinue payment of benefits.

(3) The Governor in Council may make regulations respecting the assessment, approval, reassessment and adjustment of claims and the payment of benefits, including but not limited to regulations

(a) establishing to whom and the manner in which benefits may be paid;

(b) establishing rules, terms, restrictions and conditions under which claims may be assessed, reassessed, adjusted and approved for payment of benefits;

(c) establishing rules, terms, restrictions and conditions for the co-ordination of assessment of claims and payment of benefits with insurers and other reimbursement programs;

(d) respecting reimbursement and recovery of inadvertent or improper payments of benefits;

(e) respecting the manner of recovering benefits under Section 23;

(f) respecting reciprocal arrangements with other provinces of Canada for the provision of benefits conferred under the Plan.

(4) The Governor in Council may make regulations

(a) respecting the process for designating a drug, device or service as a benefit and the information that must be provided to the Minister for that purpose;

(b) respecting the criteria that must or may be considered for the purpose of designating a drug as interchangeable with other drugs;

(c) prescribing conditions to be met by a drug or a manufacturer of a drug in order to be designated or continue to be designated as interchangeable with other drugs;

(d) respecting the contents of notices and the method of providing notices under this Act or the regulations;

(e) requiring a person to create or maintain records in relation to any matter under this Act or the regulations;

(f) respecting the provision of information to the Minister by a beneficiary, provider, or other person;

(g) respecting conditions under which the Minister may collect, use or disclose personal information and under for what purposes such information may be collected, used or disclosed;

(h) prescribing conditions under which the Minister may enter into agreements for the collection, use or disclosure of personal information under this Act;

(i) establishing conflict of interest rules for committee members;

(j) incorporating and adopting by reference, in whole or in part, a written standard, practice, rule, regulation, guideline, code or document as it reads on a prescribed day or as it is amended from time to time;

(k) defining any word or expression used but not defined in this Act;

(l) further defining any word or expression defined in this Act;

(m) respecting any matter that the Governor in Council considers necessary or advisable to carry out effectively the intent and purpose of this Act.

32 The exercise by the Governor in Council of the authority contained in subsections 6(2) and (4), 7(1) and 17(2) and Section 31 is regulations within the meaning of the *Regulations Act*.

33 Clause 2(h) of Chapter 197 of the Revised Statutes of Nova Scotia, 1989, the *Health Services and Insurance Act*, is repealed and the following clause substituted:

(h) “Insured Prescription Drug Plan” means the Insured Prescription Drug Plan under the *Fair Drug Pricing Act*.

34 Section 4, clause 5(c), subsection 17(3) and Sections 25 and 26 of Chapter 197 are repealed.

35 This Act comes into force on such day as the Governor in Council orders and declares on proclamation.
