

2009 Bill 34

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Second Session, 27th Legislature, 58 Elizabeth II

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THE LEGISLATIVE ASSEMBLY OF ALBERTA

# **BILL 34**

## **DRUG PROGRAM ACT**

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THE MINISTER OF HEALTH AND WELLNESS

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First Reading . . . . .

Second Reading . . . . .

Committee of the Whole . . . . .

Third Reading . . . . .

Royal Assent . . . . .

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## **BILL 34**

2009

### **DRUG PROGRAM ACT**

*(Assented to , 2009)*

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HER MAJESTY, by and with the advice and consent of the  
Legislative Assembly of Alberta, enacts as follows:

#### **Definitions**

**1** In this Act,

- (a) “approved drug” means a drug designated as an approved drug by the Minister under section 7;
- (b) “benefit” means a benefit that is payable under this Act;
- (c) “benefit period” means a period of time prescribed in the regulations in respect of the payment of a benefit;
- (d) “claim” means a claim for payment of a benefit;
- (e) “committee” means a committee established by the Minister under section 14;
- (f) “co-payment” means the amount determined in accordance with the regulations that may be required to be paid by a member toward the cost of a drug, a service or an approved drug;
- (g) “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 drug, a service or an approved drug prior to any benefit being paid;
- (h) “department” means the Government department administered by the Minister;

- (i) “dependant” means a person who meets the criteria for dependants set out in the regulations;
- (j) “drug” means
  - (i) a drug as defined in the *Pharmacy and Drug Act*,
  - (ii) a drug therapy,
  - (iii) a device,
  - (iv) a vaccine,
  - (v) a biologic, and
  - (vi) any material, substance or thing designated in the regulations as a drug;
- (k) “list” means the list of approved drugs established by the Minister under section 8;
- (l) “member” means a person who is enrolled as a member of a plan pursuant to this Act and the regulations;
- (m) “Minister” means the Minister determined under section 16 of the *Government Organization Act* as the Minister responsible for this Act;
- (n) “premium” means an amount of money payable to the Minister under this Act;
- (o) “provider” means a person designated in the regulations as a provider, or a person who belongs to a class of persons designated as providers;
- (p) “service” means
  - (i) a treatment, care, service or activity related or incidental to the provision, sale, distribution, purchase or pricing of drugs or approved drugs, and
  - (ii) any treatment, care, service or activity designated in the regulations as a service.

### **Establishment of drug program**

**2(1)** There is hereby established a drug program under the administration of the Minister for the purpose of providing funding for, or providing, drugs, services and approved drugs.

**(2)** The Minister may establish plans with respect to matters under subsection (1).

### **Membership**

**3(1)** Subject to the regulations, the Minister may enrol as a member of a plan any person who meets the eligibility and enrolment criteria set out in the regulations.

**(2)** The Minister may make regulations

- (a) respecting the eligibility and enrolment requirements that must be met for a person to become and remain a member of a plan, including but not limited to
  - (i) establishing different eligibility and enrolment requirements for different members and classes of members;
  - (ii) establishing exemptions from the eligibility and enrolment requirements for certain persons or classes of persons in the circumstances set out in the regulations;
  - (iii) deeming certain persons or persons within certain classes of persons to be members or to be eligible to be members of a plan;
- (b) respecting the exclusion of certain persons or persons within certain classes of persons from eligibility for membership in a plan;
- (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 purposes of assessing and verifying eligibility and enrolment;

- (e) respecting the circumstances under which the Minister may refuse, suspend, vary or discontinue a member'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 include different effective dates for different circumstances, members and classes of members.

(3) The Minister may provide a member with proof of enrolment, and may make regulations respecting the issuance to members of proofs of enrolment and any rules, terms, restrictions or conditions respecting the proof of enrolment.

(4) Subject to the regulations, a member must notify the Minister of a change in circumstances affecting the member's eligibility or the eligibility of any of the member's dependants.

#### **Premiums, co-payments, deductibles, subsidies**

**4(1)** The Minister may make regulations

- (a) respecting premiums that may be required to be paid by members, including but not limited to regulations establishing different rates and levels of premiums for different members or classes of members and providing that premiums may be applied retroactively;
- (b) respecting times and methods of payment of premiums, including regulations respecting the collection and remittance of premiums, and to whom payments of premiums may be made on behalf of the Minister;
- (c) respecting co-payments that may be required to be paid by members, including but not limited to regulations establishing different rates and levels of co-payments for different members or classes of members and providing that co-payments may be applied retroactively;
- (d) establishing co-payments or deductibles that are applicable to drugs, services and approved drugs, including establishing different co-payments or deductibles for different drugs, services and approved drugs or different classes of drugs, services and approved drugs;

- (e) respecting deductibles that may be required to be paid by members, including but not limited to regulations establishing different rates and levels of deductibles for different members or classes of members and providing that deductions may be applied retroactively;
- (f) respecting subsidies that may be granted to members by the Minister, including but not limited to regulations establishing criteria for eligibility for subsidies, establishing different rates and levels of subsidies for different members or classes of members and providing that subsidies may be applied retroactively;
- (g) respecting the waiving of premiums, co-payments and deductibles, including but not limited to regulations establishing criteria for eligibility for waivers and providing that waivers may be applied retroactively;
- (h) respecting dependants, including regulations establishing the criteria that must be met for a person to be considered a dependant;
- (i) respecting benefit periods that may apply to the eligibility or enrolment of members or classes of members, to premiums, co-payments, deductibles, subsidies or waivers or to benefits payable under this Act;
- (j) respecting processes and criteria for the assessment and determination of whether a premium, co-payment, deductible, subsidy or waiver is applicable to a member or a class of members, including but not limited to criteria relating to a member's income or financial situation;
- (k) respecting the information a person may be required to provide to the Minister with respect to any matter under this section.

**(2)** Subject to the regulations, where a member is required to pay a premium, the member is liable and shall pay the premium to the Minister in advance of the payment of any benefits.

#### **Benefits and claims**

**5(1)** Subject to the regulations, the Minister may pay benefits to or on behalf of members and other persons.

(2) 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 regulations.

(3) Subject to the regulations, the Minister may

- (a) refuse, suspend, vary or discontinue payment of benefits to or on behalf of a member 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, and
- (e) take any steps permitted by this Act or the regulations to recover an inadvertent or improper payment of a benefit.

(4) The Minister may, in accordance with the regulations, require a member, provider or other person to provide information to the Minister for the purposes of this section.

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

#### **Independent consideration process**

6 The Minister may by regulation establish an independent consideration process respecting the provision of funding for drugs or approved drugs.

#### **Designation of approved drug**

7(1) Subject to the regulations, the Minister may designate a drug as an approved drug and add it to the list where the Minister considers it to be in the public interest to do so.

(2) The Minister's designation of a drug as an approved drug may include

- (a) assigning to the drug any attribute or distinction permitted by the regulations,
- (b) classifying the drug as belonging to one or more classes or groups of approved drugs,
- (c) determining whether the drug is interchangeable with other approved drugs,
- (d) determining whether any rules, terms, restrictions or conditions apply to the approved drug or the benefit payable in respect of the approved drug, and
- (e) taking any other steps permitted by the regulations.

**(3)** The Minister may, as a condition of designating a drug as an approved drug or continuing the designation of a drug as an approved drug, impose on any person any rules, terms, restrictions or conditions, including but not limited to

- (a) a requirement that the person enter into an agreement with the Minister in a form satisfactory to the Minister, and
- (b) rules, terms, restrictions or conditions respecting
  - (i) pricing of the drug,
  - (ii) the supply of the drug, and
  - (iii) information that must be provided to the Minister in respect of matters under this section.

**(4)** Subject to the regulations, the Minister may modify or cancel the designation of an approved drug if the Minister considers it to be in the public interest to do so.

**(5)** A drug becomes an approved drug on the effective date of its designation under subsection (1) and ceases to be an approved drug on the effective date specified by the Minister.

**(6)** A modification of the designation of an approved drug takes effect on the effective date specified by the Minister.

**(7)** The Minister may, on the Minister's own initiative, amend the designation or the modification or cancellation of the designation of an approved drug in order to correct any of the following:

- (a) a clerical or typographical error;
- (b) an accidental or inadvertent error, omission or similar mistake;
- (c) an error in computation;
- (d) any other error prescribed by regulation.

**(8)** A designation, modification or cancellation that is amended under subsection (7) remains effective as of the date of the original designation, modification or cancellation unless a different date is specified by the Minister in making the amendment.

#### **List of approved drugs**

**8(1)** The Minister may establish and maintain a list of approved drugs for which benefits may be paid.

**(2)** The list must set out the drugs designated as approved drugs for the purposes of this Act, and may set out

- (a) the classes, groups, attributes or other distinctions relating to the approved drugs,
- (b) the benefit payable for an approved drug or for a class or group of approved drugs,
- (c) criteria, standards, policies and guidelines respecting the designation of drugs as approved drugs,
- (d) the approved drugs that are designated as interchangeable with other approved drugs,
- (e) whether any rules, terms, restrictions or conditions apply to an approved drug or a class or group of approved drugs,
- (f) information or notices required in relation to the drug program, and
- (g) any other information the Minister considers necessary or advisable.

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

### **Publication of list**

- 9(1)** The Minister may publish the list in accordance with the regulations and in any other form the Minister considers advisable.
- (2)** In the event of a conflict between published versions of the list, the version published in accordance with the regulations prevails.

### **Interest and order for payment**

- 10(1)** The Minister may assess interest and impose a penalty on the unpaid portion of a premium or other amount owing to the Minister under this Act.
- (2)** The Minister may by regulation establish the rate of interest for the purpose of subsection (1).
- (3)** An amount or any part of an amount payable under this Act by a person to the Minister that has not been paid may be certified by the Minister on the expiration of 30 days after the mailing of a notice to the person who is in arrears of payment at the person's last known address.
- (4)** A certificate under subsection (3) shall on production to the clerk of the Court of Queen's Bench be registered in the Court as a judgment of the Court and when registered has the same force and effect and may be proceeded on as if the certificate were a judgment obtained in the Court for a debt in the amount specified in the certificate.
- (5)** No costs or fees may be charged by a clerk of the Court for registration of a certificate under this section and no costs or fees may be charged by a Registrar of Titles under the *Land Titles Act* for the filing of a writ of enforcement.
- (6)** In addition to any other remedies provided in this Act, when any money is payable by the Minister to a person while that person is indebted to the Crown, the Minister may withhold from the money payable the amount by which the person is indebted, or any part of the debt, and apply the amount withheld in reduction or extinguishment of the debt.

### **Requests for proposals**

- 11** The Minister may issue, conduct, evaluate or conclude requests for proposals, requests for information, requests for

quotations or any similar activity in respect of drugs, services, approved drugs or any other matter under this Act.

#### **Agreements**

**12** Notwithstanding section 41 of the *Alberta Health Care Insurance Act*, the Minister may negotiate and conclude agreements with any person, government or unincorporated group of persons respecting

- (a) the provision, sale, distribution, purchase or pricing of drugs, services or approved drugs,
- (b) services related to the administration and operation of the drug program, and
- (c) any other matter under this Act.

#### **Delegation**

**13** The Minister may delegate any power, duty or function of the Minister, except the power to make a regulation as defined in the *Regulations Act*, to any person the Minister considers appropriate.

#### **Committees**

**14(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 established under this section,

- (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 established pursuant to this section may exercise the powers and shall perform the duties and functions that the Minister approves or confers or imposes on it.

(4) The Minister may require any person appointed to a committee established pursuant to this section, before beginning the person's duties, to take an oath that the person will not, except as authorized by the Minister, divulge any information received by the person in the course of the person's duties as a member of the committee.

(5) Subject to the regulations, a committee established pursuant to this section may make rules governing the calling of its meetings, the procedure to be used at its meetings, the conduct of business at its meetings, reporting and any other matters as required.

#### **Advisor**

**15(1)** The Minister may engage an advisor

- (a) to assist or advise the Minister or a committee, or
- (b) to inquire into a matter and report to the Minister or a committee,

with respect to any matter under this Act.

(2) The Minister may authorize and provide for the payment of remuneration and expenses incurred by the advisor in the course of the advisor's duties.

#### **Providers**

**16(1)** The Minister may by regulation designate persons as providers, or classes of persons as classes the persons within which are providers, for the purposes of this Act and the regulations.

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

- (a) requiring a provider to comply with any criteria, standards, policies and other guidelines specified by the Minister;
- (b) respecting the information that providers or classes of providers must provide to members and the public;
- (c) respecting exempting specified providers or classes of providers from some or all of the requirements of this Act or the regulations;

- (d) requiring a provider to comply with any other provision of this Act or the regulations.

#### **Additional Ministerial powers**

**17** In addition to the Minister's other powers under this Act, for the purposes of the administration of this Act and to protect, promote or maintain health, to prevent illness, to diagnose or treat illness or to rehabilitate or care for any person or class of persons, the Minister may provide funding or provide for or arrange for the provision of drugs, services or approved drugs to any person or class of persons.

#### **Records**

**18** The Minister may make regulations requiring a person to create or maintain records in relation to any matter under this Act.

#### **Forms**

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

#### **Inspection**

**20(1)** In this section, "record" means any book, record, report, document, prescription, invoice, purchase order or other information or thing in written, photographic, magnetic, electronic or other form.

**(2)** The Minister may designate one or more persons as inspectors for the purposes of this Act.

**(3)** Subject to subsection (4), an inspector may enter and inspect any place for the purpose of determining whether this Act and the regulations are being complied with.

**(4)** An inspector shall not enter a private dwelling place without the consent of the owner or occupant except under the authority of an order made under subsection (10).

**(5)** In carrying out an inspection an inspector may

- (a) at any reasonable hour, enter in or on the place that is the subject of the inspection;

- (b) demand the production for examination of any record and make copies of it or remove it temporarily for the purpose of making copies;
- (c) require any person in the place to answer any relevant question and direct the person to answer the question under oath.

**(6)** When acting under the authority of this section, an inspector shall carry identification in a form approved by the Minister and shall present it on request to the occupant of the place being inspected.

**(7)** If an inspector removes any record during an inspection, the inspector

- (a) shall give a receipt for the record to the person from whom it was taken, and
- (b) shall return the thing within a reasonable time after it has served the purposes for which it was taken.

**(8)** On request, an inspector shall provide a copy of any records removed during an inspection to the person from whom they were taken.

**(9)** A person who is the subject of an inspection, or an owner or occupant of a place that is the subject of an inspection, shall co-operate with the inspector.

**(10)** If a person

- (a) refuses to allow an inspector to conduct an inspection, or
- (b) hinders or interferes with an inspector who is conducting an inspection,

the inspector may apply to the Court of Queen's Bench for an order directing the person to do or refrain from doing anything as the Court considers necessary in order to enable the inspector to conduct the inspection, and the Court may make any order it considers appropriate in the circumstances.

**(11)** An application under subsection (10) may be made ex parte if the Court considers it appropriate in the circumstances.

(12) On completing an inspection an inspector may, and at any time required by the Minister an inspector shall, provide a report to the Minister setting out the findings of the inspection.

#### **Enforcement orders**

**21(1)** Where, in the opinion of the Minister, a person has contravened or failed to comply with a provision of this Act or the regulations, the Minister may issue an enforcement order in accordance with the regulations.

(2) An enforcement order shall specify

(a) the measures that must be taken, and

(b) the person or persons who must take those measures,

in order to effect compliance with this Act and the regulations.

(3) An enforcement order shall contain the reasons for making it and must be served on the person or persons to whom it is directed.

(4) If a person to whom an enforcement order is directed fails to comply with the enforcement order, the Minister may apply to the Court of Queen's Bench for an order of the Court directing that person to comply with the enforcement order.

(5) If a person to whom an enforcement order is directed fails to comply with the enforcement order, the Minister may take whatever action the Minister considers necessary to carry out the terms of the enforcement order.

(6) Costs incurred by the Minister under this section are amounts owing to the Minister under this Act and are recoverable in accordance with section 10.

(7) Where an enforcement order is issued to more than one person, all persons named in the order are jointly responsible for carrying out the terms of the order and are jointly and severally liable for payment of the costs of doing so, including any costs incurred by the Minister.

#### **Injunction re commission of offence**

**22** Where, on the application of the Minister, it appears to the Court of Queen's Bench that a person has done, is doing or is about

to do any act or thing constituting or directed toward the commission of an offence under this Act or the failure to comply with an enforcement order of the Minister under this Act, the Court may issue an injunction ordering any person named in the application

- (a) to refrain from doing that act or thing, or
- (b) to do any act or thing that it appears to the Court may prevent the commission of an offence under this Act.

### **Offences**

**23** A person who

- (a) knowingly provides false or misleading information or records pursuant to a requirement of this Act or the regulations to provide information or records,
- (b) provides false or misleading information or records pursuant to a requirement of this Act or the regulations to provide information or records,
- (c) knowingly fails to provide information, answers or records as required by this Act or the regulations,
- (d) fails to provide information, answers or records as required by this Act or the regulations,
- (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

- (g) for a first offence, to a fine not exceeding \$50 000, and
- (h) for a 2nd or subsequent offence, to a fine not exceeding \$100 000.

### **Continuing offences**

**24** A person who is guilty of an offence under this Act or the regulations is liable on conviction for each day or part of a day on which the offence occurs or continues.

**Limitation period**

**25** A prosecution for an offence under this Act may not be commenced more than 2 years after the later of

- (a) the date on which the alleged offence was committed, or
- (b) 6 months after the date on which evidence of the offence first came to the attention of the Minister.

**Additional fine where monetary benefit acquired by offender**

**26** Where a person is convicted of an offence under this Act and the court is satisfied that as a result of the commission of the offence a monetary benefit accrued to the offender, the court may order the offender to pay, in addition to any fine imposed under section 23, a fine in an amount equal to the court's estimation of the amount of the monetary benefit.

**Liability of directors and officers**

**27(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 purposes 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.

**Court orders relating to penalty**

**28** When a person is convicted of an offence under this Act or the regulations, in addition to any other penalty that may be imposed under this Act, the court may, having regard to the nature of the offence and the circumstances surrounding its commission, make and vary in accordance with the regulations an order addressing additional matters prescribed by regulation.

### **Decision of Minister final**

**29** 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 shall 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.

### **Protection from liability**

**30(1)** No liability attaches to, and no action or proceeding may be brought against, the Crown, the Minister, an inspector, 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 shall 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) shall not be admitted in evidence in any proceedings.

### **Crown immunity**

**31(1)** In this section,

- (a) "Crown" means the Crown in right of Alberta and includes a Minister of the Crown and agents and employees of the Crown;
- (b) "undertaking" means the undertaking entitled "Undertaking by Alberta Health", dated May 18, 1998 and provided to Apotex Inc.

**(2)** On the coming into force of this section, the undertaking

- (a) has no legal effect,

- (b) is unenforceable by Apotex Inc., and all obligations, liabilities, rights and interests of Apotex Inc. arising out of the undertaking and the circumstances giving rise to the undertaking are hereby declared to have ceased to exist, and
- (c) is unenforceable by any third party claiming through Apotex Inc., and all obligations, liabilities, rights and interests in respect of any third party are hereby declared to have ceased to exist,

and all future causes of action in law or equity against the Crown in respect of the undertaking are extinguished without costs.

### **Regulations**

**32(1)** The Minister may make regulations respecting the establishment and administration of plans, including but not limited to regulations respecting the effective date of a plan, the purposes of a plan, and the rules, terms, restrictions, conditions and exemptions that apply to a plan.

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

- (a) establishing the drugs, services and approved drugs for which benefits may be paid;
- (b) determining the amounts of benefits payable, including but not limited to whether a benefit should cover the cost of a drug, service or approved drug in whole or in part;
- (c) respecting the modification and discontinuance of benefits;
- (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) establishing different benefits or levels of benefits in respect of different drugs, services and approved drugs or different classes of drugs, services and approved drugs;
- (h) imposing rules, terms, restrictions and conditions on the payment of benefits, including but not limited to imposing different rules, terms, restrictions and conditions for payment of benefits for different drugs, services and approved drugs or different classes of drugs, services and approved drugs;
- (i) respecting the circumstances in which the Minister may refuse, suspend, vary or discontinue payment of benefits.

**(3)** The Minister 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 the information that must be provided by a member or other person for the purpose of assessing, approving, reassessing and adjusting claims and payment of benefits;
- (e) respecting the times within which and the manner in which claims must be made;
- (f) respecting reimbursement and recovery of inadvertent or improper payments of benefits.

**(4)** The Minister may make regulations

- (a) respecting the designation of any material, substance or thing as a drug;
- (b) respecting the designation of any treatment, care, service or activity as a service;

- (c) respecting the designation, or modification or cancellation of a designation, of a drug as an approved drug, including but not limited to regulations respecting the criteria or other factors that may or must be considered in making a designation, or in modifying or cancelling a designation, of a drug as an approved drug, which may include different criteria in respect of different drugs or different classes of drugs;
  - (d) respecting the attributes or other distinctions that may be assigned to approved drugs and the classification of drugs as belonging to one or more classes or groups of approved drugs;
  - (e) respecting the process for designating a drug as an approved drug and the information that must be provided to the Minister for that purpose;
  - (f) respecting the criteria that must or may be considered for the purpose of designating an approved drug as interchangeable with other approved drugs;
  - (g) respecting the amendment of a designation, or of the modification or cancellation of a designation, of an approved drug;
  - (h) respecting the rules, terms, restrictions and conditions that may apply to an approved drug or a class or group of approved drugs;
  - (i) respecting the establishment of an independent consideration process, including but not limited to establishing criteria for review and other matters;
  - (j) respecting the contents of notices and the method of providing notices under this Act or the regulations;
  - (k) respecting the publication of the list and additional information that may be set out in the list.
- (5) The Minister may make regulations
- (a) respecting files, records, documents, papers or information that may be admitted into evidence notwithstanding section 30(2);

- (b) respecting the issuance of enforcement orders and the conditions and requirements they may or must contain;
- (c) respecting the functions of committees established under section 14;
- (d) establishing conflict of interest rules for committee members;
- (e) prescribing additional matters that may be addressed by a court in making or varying an order under section 28;
- (f) defining terms used but not defined in this Act.

#### **Adoption by reference**

**33(1)** A regulation made by the Minister under this Act may adopt or incorporate in whole or in part or with modifications documents that set out standards, practices, policies, codes of practice, guidelines, objectives, methods or other rules of any government, organization or person, including, without limitation, any standards, practices, policies, codes of practice, guidelines, objectives or methods developed by the Minister, as they read at a particular time or as amended or replaced from time to time, relating to any matter in respect of which a regulation may be made under this Act.

**(2)** Where a standard, practice, policy, code of practice, guideline, objective, method or other rule is adopted or incorporated by regulation under this Act, the Minister shall ensure that a copy of the standard, practice, code of practice, guideline, objective, method or other rule is made available to the public.

#### **Transitional regulations**

**34(1)** The Lieutenant Governor in Council may make regulations

- (a) respecting the transition to this Act of any of the powers, duties or other matters relating to, and any obligations, liabilities, rights and interests arising from, drug and service programs and policies that were in existence immediately before the coming into force of this Act, and
- (b) providing for any matter that the Minister considers is not provided for or is insufficiently provided for in this Act.

**(2)** A regulation made under subsection (1) is repealed on the earliest of the following:

- (a) the coming into force of an amendment to this Act or another Act that provides for the matter dealt with in the regulation;
- (b) the coming into force of a regulation that repeals the regulation made under subsection (1);
- (c) the expiration of 2 years from the day that the regulation made under subsection (1) comes into force.

**(3)** The repeal of a regulation under subsection (2)(b) or (c) does not affect anything done, incurred or acquired under the authority of that regulation before the repeal of that regulation.

**(4)** A regulation shall not be made under subsection (1) after the expiration of 3 years from the day on which this section comes into force, but any regulation made under subsection (1) that is in force on the expiration of that 3-year period remains in force until it is repealed under subsection (2).

**(5)** A regulation shall not be made under subsection (1) that alters the provisions of subsection (2) or that extends the 3-year period provided for in subsection (4).

**Coming into force**

**35** This Act, except sections 31 and 34, comes into force on Proclamation.





