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c 28 Prescription Drug Cost Regulation Act, 1986

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CHAPTER 28

**An Act to provide for the
Protection of the Public in respect of the
Cost of Certain Prescription Drugs**

Assented to July 10th, 1986

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

1. In this Act,

Definitions

“designated” means designated by the regulations;

“dispenser” means a person who dispenses a drug pursuant to a prescription;

“drug” means a drug as defined in clause 113 (1) (d) of the *Health Disciplines Act*;

R.S.O. 1980,
c. 196

“inspector” means a person appointed under section 12 of this Act;

“interchangeable product” means a drug or combination of drugs identified by a specific product name or manufacturer and designated as interchangeable with one or more other such products;

“operator of a pharmacy” means the holder of a certificate of accreditation for the operation of a pharmacy under section 135 of the *Health Disciplines Act*;

“prescription” means a direction from a person authorized to prescribe drugs within the scope of his or her practice of a health discipline directing the dispensing of a drug or mixture of drugs for a specified person;

“Registrar” means the Registrar of the Ontario College of Pharmacists;

“regulations” means the regulations made under this Act.

Application
of this Act

R.S.O. 1980,
c. 410

2. This Act does not apply to the dispensing of a drug in or by a hospital approved as a public hospital under the *Public Hospitals Act* if the drug is dispensed for a patient or an out-patient of the hospital.

Over the
counter
drugs
excepted

3. Subsections 4 (2) and (3) and sections 5, 6, 7, 9 and 10 do not apply in respect of an interchangeable product that does not require a prescription for sale.

Substitution
where named
product

4.—(1) If a prescription directs the dispensing of a specific interchangeable product, the dispenser may dispense in its place another product that is designated as interchangeable with it.

Request for
interchange-
able
product

(2) If a prescription directs the dispensing of a specific interchangeable product, the dispenser, on the request of the person for whom the product was prescribed or the person presenting the prescription, shall dispense in its place another product that is designated as interchangeable with it.

Inform
customer

(3) If a prescription directs the dispensing of a specific interchangeable product, the dispenser shall not supply that product without informing the person for whom the product was prescribed or the person presenting the prescription, in the manner prescribed by the regulations, of the right to request an interchangeable product.

Exceptions

(4) Subsection (3) does not apply if,

- (a) the amount to be charged for supplying the product specified in the prescription is not more than the least amount that would have been charged for supplying a product that is interchangeable with it and available in the dispenser's inventory;
- (b) a claim for payment will be submitted to the Minister of Health under section 5 of the *Ontario Drug Benefit Act, 1986* in respect of the supplying of the product; or
- (c) the product is being supplied pursuant to a repeat of the prescription.

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Selection
of inter-
changeable
product

(5) If a prescription directs the dispensing of a product that is not designated as an interchangeable product and there is an interchangeable product that contains a drug or drugs in the same amounts of the same active ingredients in the same dosage form as the product prescribed, the dispenser may dispense the interchangeable product.

(6) Subsections (1), (2), (3) and (5) do not apply to a prescription that includes, Exception

- (a) in the case of a written prescription, the handwritten words “no sub” or “no substitution”; or
- (b) in any other case, a direction recorded by the dispenser that there be no substitution.

5. If a prescription directs the dispensing of a drug for which there are interchangeable products without identifying a specific product name or manufacturer, the dispenser shall dispense an interchangeable product of that drug. Dispensing generic drug

6.—(1) Every operator of a pharmacy shall set a single specific amount as a usual and customary dispensing fee in respect of dispensing interchangeable products and shall file a statement with the Registrar setting out that fee. Maximum dispensing fee

(2) An operator of a pharmacy may change the usual and customary dispensing fee by filing a statement with the Registrar setting out the new fee. Change of fee

(3) The usual and customary dispensing fee becomes effective on the day the statement is received by the Registrar. Effective date of fee

(4) Every operator of a pharmacy shall post in the pharmacy, in the manner prescribed by the regulations, a notice containing the usual and customary dispensing fee filed with the Registrar and any other information prescribed by the regulations respecting the charge for interchangeable products. Notify customers

7.—(1) In this section, “best available price”, in respect of a particular manufacturer’s drug product in a particular dosage form and strength for which a prescription is dispensed, means the lowest price, calculated per gram, milliliter, capsule, tablet or other appropriate unit, for which that product in that dosage form and strength can be purchased in Canada for wholesale or retail sale in Ontario, Best available price

- (a) as determined by the Minister from such sampling as the Minister considers appropriate; or
- (b) as estimated by the Minister, if the Minister considers the information reasonably available to the Minister is insufficient for the purpose of ascertaining the best available price,

which price shall be prescribed by the regulations, and in calculating that price, the Lieutenant Governor in Council shall

deduct the value of any price reduction granted by the manufacturer or wholesaler or their representatives in the form of rebates, discounts, refunds, free goods or any other benefits of a like nature.

Determining
base price

(2) The base price for supplying a drug product pursuant to a prescription shall be,

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- (a) where the drug product is not an interchangeable product and the product is a listed drug product as defined in the *Ontario Drug Benefit Act, 1986*, the best available price of that product;
- (b) where the person issuing the prescription has specified that there shall be no substitutions, the best available price of the product prescribed;
- (c) where the person presenting the prescription has requested the dispensing of a particular interchangeable product, the best available price of that product; and
- (d) in all other cases, the best available price that is the lowest among the products in the person's inventory that are interchangeable with the product supplied.

Maximum
charge for
supplying
drug
products

(3) No person shall charge more for supplying a drug product pursuant to a prescription than the sum of,

- (a) the base price determined under subsection (2);
- (b) the percentage of that price, not less than 10 per cent and not greater than 20 per cent, that is prescribed by the regulations; and
- (c) that person's usual and customary dispensing fee unless a greater amount is provided for in the regulations.

No
liability
for
dispensing
interchange-
able
products

8. If an interchangeable product is dispensed in accordance with this Act, no action or other proceeding lies or shall be instituted against the person who issued the prescription, the dispenser or any person who is responsible in law for the acts of either of them on the grounds that an interchangeable product other than the one prescribed was dispensed.

Dispense
entire
quantity

9.—(1) Every person who dispenses a drug pursuant to a prescription shall dispense the entire quantity of the drug prescribed at one time unless before the drug is dispensed the

person presenting the prescription in writing authorizes the dispensing of the drug in smaller quantities.

(2) Despite subsection (1), the regulations may authorize dispensing a drug in less than the entire quantity prescribed under specified conditions. Exception

(3) The regulations may designate specific drugs that are to be exempt from the application of subsection (1). Idem

10. Every person who dispenses a drug pursuant to a prescription shall provide with the drug, in the manner prescribed by the regulations, particulars of the amount charged. Inform customer of cost of drugs

11. The Ontario College of Pharmacists is responsible for the enforcement of this Act in respect of operators of pharmacies and dispensers in pharmacies. Enforcement

12.—(1) The Ontario College of Pharmacists may appoint inspectors for the purpose of enforcing this Act. Inspectors

(2) An inspector may examine any records, in whatever form, in the possession or under the control of an operator of a pharmacy if the inspector believes on reasonable grounds that the records will assist the inspector in determining whether this Act and the regulations have been complied with. Examine books

(3) An inspector may, upon giving a receipt for it, take away a record for the purpose of making a copy, but the copy shall be made and the record shall be returned as promptly as reasonably possible. Copies

(4) An inspector may at any reasonable time on producing proper identification enter any business premises where the inspector believes a record referred to in subsection (2) may be located for the purpose of an inspection. Entry

13.—(1) Any person who, Offence

(a) contravenes subsection 4 (2) (dispense product requested);

(b) contravenes subsection 4 (3) (inform customer of interchangeable product);

(c) contravenes section 5 (dispense interchangeable when generic prescribed);

- (d) contravenes section 6 (usual and customary dispensing fee set and posted);
- (e) contravenes section 7 (maximum allowable charge);
- (f) contravenes section 9 (dispense entire quantity);
- (g) contravenes section 10 (inform person of cost); or
- (h) obstructs any person carrying out an inspection under section 12,

and any director or officer of a corporation who authorizes or permits such a contravention by a corporation is guilty of an offence under this Act and liable to a penalty of not more than \$10,000.

Idem

(2) The maximum penalty that may be imposed upon a corporation is \$50,000 and not as provided in subsection (1).

Regulations

14.—(1) The Lieutenant Governor in Council may make regulations,

- (a) prescribing conditions to be met by products or by manufacturers of products in order to be designated as interchangeable with other products;
- (b) designating a product as interchangeable with one or more other products where the Lieutenant Governor in Council considers it advisable in the public interest to do so, but a product shall not be designated as interchangeable with another product if,
 - (i) it does not contain a drug or drugs in the same amounts of the same active ingredients in the same dosage form as the other product, or
 - (ii) the product or its manufacturer has not met the conditions described in clause (a);
- (c) providing for the maximum amounts chargeable for drug products (section 7);
- (d) prescribing circumstances in which persons may charge more than their usual and customary dispensing fees.

(2) Subject to the approval of the Lieutenant Governor in Council and with prior review by the Minister, the Council of the Ontario College of Pharmacists may make regulations. ^{Idem}

- (a) prescribing the manner in which persons shall be informed of the right to request an interchangeable product (subsection 4 (3));
- (b) prescribing the information to be included in a notice (subsection 6 (4)) and the manner of posting a notice;
- (c) authorizing dispensing a drug in less than the entire quantity prescribed and specifying the conditions under which that authority is to apply (subsection 9 (2));
- (d) designating specific drugs that are to be exempt from the application of subsection 9 (1);
- (e) prescribing the information concerning cost to be provided on sale and how it is to be provided (section 10);
- (f) requiring operators of pharmacies to retain specified records respecting their purchase of drugs for the purposes of this Act and prescribing the period of time those records shall be retained.

(3) Where the Minister requests in writing that the Council of the Ontario College of Pharmacists make, amend or revoke a regulation under subsection (2) and the Council has failed to do so within sixty days after the request, the Lieutenant Governor in Council may make the regulation, amendment or revocation specified in the request. ^{Idem}

(4) A regulation made under subsection (1) or (2) may be general or particular in its application. ^{Idem}

15.—(1) Clauses 113 (1) (e) and (i) of the *Health Disciplines Act*, being chapter 196 of the Revised Statutes of Ontario, 1980, are repealed.

(2) Section 155 of the said Act is repealed.

(3) Clause 158 (2) (b) of the said Act is repealed.

Commence-
ment

16. This Act comes into force on a day to be named by proclamation of the Lieutenant Governor.

Short title

17. The short title of this Act is the *Prescription Drug Cost Regulation Act, 1986*.