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c 27 Ontario Drug Benefit Act, 1986

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CHAPTER 27

**An Act to Authorize and Regulate the
Payment by the Minister to Specified Persons
on Behalf of Specified Classes of Persons for the
Dispensing of Specified 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;

“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 14;

“listed drug product” means a drug or combination of drugs identified by a specific product name or manufacturer and designated as a listed drug product;

“listed substance” means a substance, other than a drug, designated as a listed substance;

“Minister” means the Minister of Health;

“operator of a pharmacy” means,

(a) the holder of a certificate of accreditation for the operation of a pharmacy under section 135 of the *Health Disciplines Act*, or

(b) the operator of a pharmacy operated in or by a hospital that is a public hospital under the *Public Hospitals Act*;

R.S.O. 1980,
c. 410

“physician” means a person licensed to engage in the practice of medicine under Part III 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;

“regulations” means the regulations made under this Act.

Eligible persons

2.—(1) A person who is a member of a designated class of persons is an eligible person.

Persons deemed eligible persons
R.S.O. 1980,
c. 151

(2) This Act applies to persons entitled to receive drug benefits under the *Family Benefits Act* and the regulations under it as if those persons were eligible persons.

Application of this Act
R.S.O. 1980,
c. 197

3. This Act applies in respect of the supplying of listed drug products for eligible persons unless that supplying is an insured service as defined in the *Health Insurance Act*.

Billing prohibited

4.—(1) No operator of a pharmacy shall charge, or accept payment from, a person other than the Minister in respect of supplying a listed drug product for an eligible person pursuant to a prescription, unless the charge or payment is authorized by the regulations.

Idem

(2) No physician shall charge, or accept payment from, a person other than the Minister in respect of supplying a listed drug product for an eligible person, unless the charge or payment is authorized by the regulations.

Exception

(3) Subsections (1) and (2) do not apply to an operator of a pharmacy or a physician who supplies a listed drug product for an eligible person without knowing or having reasonable grounds to believe that the person is an eligible person.

Payment of claim of operator

5.—(1) An operator of a pharmacy who submits to the Minister a claim for payment in respect of supplying a listed drug product for an eligible person pursuant to a prescription is entitled to be paid by the Minister the amount provided for under section 6.

Agreement re price

(2) The Minister may pay an operator of a pharmacy an amount different from the amount provided for under section 6 in respect of a claim under subsection (1) if the Minister has a written agreement to that effect with the operator.

Payment of claim of physician

(3) A physician who submits to the Minister a claim for payment in respect of supplying a listed drug product for an eligible person is entitled to be paid by the Minister the amount provided for by the regulations.

(4) The person submitting a claim under subsection (1) or (3) shall include in it the information prescribed by the regulations. Information in claim

(5) Eligible persons shall be deemed to have authorized persons submitting claims under subsection (1) or (3) to include in the claims the information mentioned in subsection (4). Deemed authorization

6.—(1) The amount the Minister shall pay under subsection 5 (1) in respect of a listed drug product is the sum of the dispensing fee referred to in subsection (2) and the amount provided for by the regulations. Amount Minister to pay

(2) The dispensing fee the Minister shall pay to operators of pharmacies under subsection (1) for dispensing listed drug products for eligible persons shall be, Dispensing fee

(a) where the pharmacy is operated in a hospital approved as a public hospital under the *Public Hospitals Act*, the amount prescribed by the regulations; R.S.O. 1980. c. 410

(b) where the listed drug product does not require a prescription for sale and is designated as one to which this clause applies, no dispensing fee; and

(c) in all other cases, the lesser of,

(i) the amount determined under section 7, or

(ii) the amount the operator charges under subsection 6 (1) of the *Prescription Drug Cost Regulation Act, 1986* (usual and customary dispensing fee). 1986, c. 28

(3) Despite subsection (1), where the Minister is satisfied that an operator of a pharmacy was not reasonably able to purchase any listed drug product of a drug at a price less than or equal to the amount provided for by the regulations for the purpose of subsection (1), the amount that the Minister shall pay under subsection 5 (1) is the sum of the dispensing fee referred to in subsection (2) and the cost to the operator of purchasing the least expensive listed drug product of the drug that is in the operator's inventory. Exception

(4) Despite subsection (1), where a prescription includes a direction that there be no substitutions and the Minister is satisfied that the operator of the pharmacy was not reasonably able to purchase the listed drug product prescribed at a price less than or equal to the amount provided for by the regu- Idem

- 1986, c. 28
- lations for the purpose of subsection (1), the amount that the Minister shall pay under subsection 5 (1) is the sum of the dispensing fee referred to in subsection (2) and the price designated under subsection 7 (1) of the *Prescription Drug Cost Regulation Act, 1986* as the best available price for that product.
- Idem (5) For the purpose of subsection (3), the cost to the operator of a pharmacy of purchasing a listed drug product shall be calculated in the manner provided for by the regulations.
- Definition 7.—(1) In this section, “Association” means the Ontario Pharmacists Association.
- Determination of dispensing fee (2) The Minister and the Association may by agreement, with or without referring the matter to a fee negotiating committee, determine the dispensing fee the Minister shall pay to operators of pharmacies under subsection 6 (2).
- Idem (3) An agreement made under subsection (2) may establish classes of operators of pharmacies and provide for an amount payable in respect of each class.
- Fee negotiating committee (4) There may be established from time to time as provided under subsection (6) a fee negotiating committee to be composed of,
- (a) three voting members appointed by the Minister;
 - (b) three voting members appointed by the Association; and
 - (c) a chairman, who shall not have a vote, to be appointed jointly by the Minister and the Association.
- Remuneration of chairman (5) The remuneration and expenses of the chairman shall be paid for by the Ministry of Health.
- Mandatory negotiation (6) The Minister or the Association may, by notice in writing to the other, require that negotiation of the dispensing fee be conducted by a fee negotiating committee.
- Appointment of committee (7) Not later than seven days after the notice has been received, the Minister and the Association shall each appoint three persons to serve as members of the fee negotiating committee and shall jointly appoint a chairman of the committee.
- Negotiation (8) The committee shall begin its negotiations as soon as reasonably possible on a date to be named by the chairman.

- (9) If, after both sides on the committee have negotiated in good faith, the Minister or the Association believes that the committee's negotiations have reached an impasse, that person, by written notice to the chairman and the other person, may request that the chairman recommend a dispensing fee to the committee. Negotiations at impasse
- (10) The chairman may obtain and use any relevant information that the chairman believes may be useful in formulating the recommendation. Chairman's recommendation
- (11) The chairman shall recommend a dispensing fee to the committee within thirty days after being requested to do so and shall provide the committee with the information upon which the recommendation was based. Idem
- (12) The committee shall resume its negotiations within seven days after receiving the chairman's recommendation. Negotiations resume
- (13) At any time after the committee resumes its negotiations under subsection (12), the Minister or the Association may make public the recommendation and the information upon which it was based, after first giving the other person twenty-four hours written notice of the intention to do so. Recommendations made public
- (14) If, after both sides on the committee have resumed negotiations in good faith, the Minister or the Association believes that the committee's negotiations have again reached an impasse, that person, by written notice to the chairman and the other person, may terminate the negotiations. Terminate negotiations
- (15) If, at any time in the negotiating process, a majority of the committee, including at least two persons appointed by the Minister and at least two persons appointed by the Association, agree on the appropriate dispensing fee, the chairman on behalf of the committee shall submit that dispensing fee to the Minister and to the Association as the committee's proposed dispensing fee. Committee agreement
- (16) The Minister and the Association shall in writing notify each other of their acceptance or rejection of the committee's proposed dispensing fee within fourteen days after receiving it. Notice of acceptance
- (17) If the Minister or the Association rejects the committee's proposed dispensing fee, the committee shall resume its negotiations within seven days thereafter and this section applies as if the committee had not proposed a dispensing fee. Rejection of proposed dispensing fee

Dispensing
fee

(18) The dispensing fee for the purpose of subsection 6 (2) shall be,

- (a) if the Minister and the Association both accept the committee's proposed dispensing fee, the dispensing fee proposed;
- (b) if the Minister and the Association otherwise agree to a dispensing fee, the dispensing fee agreed upon; or
- (c) in all other cases, the dispensing fee provided for by the regulations.

Agreement

(19) The Minister and the Association may enter into a written agreement respecting any aspect of the negotiation of the dispensing fee, and in the event of a conflict between a provision of the agreement and a provision of this section, the agreement prevails.

Unlisted
drugs,
special case

8.—(1) If a physician informs the Minister that the proper treatment of a patient who is an eligible person requires the administration of a drug for which there is not a listed drug product, the Minister may make this Act apply in respect of the supplying of that drug as if it were a listed drug product by so notifying the physician.

Notice to
operator

(2) An operator of a pharmacy is not liable for contravening this Act or the regulations in respect of supplying a drug referred to in subsection (1) unless the operator has received notice from the physician or from the Minister that this Act applies to that supplying.

Agreement
re listed
substance

9.—(1) The Minister may make an agreement with a supplier of a listed substance, providing for payment of a specified amount for supplying the listed substance to an eligible person under the direction of a physician.

Supplier
not to
charge

(2) Except as the agreement authorizes, the supplier shall not charge, or accept payment from, any person other than the Minister for supplying the listed substance to an eligible person under the direction of a physician.

Exception

(3) Subsection (2) does not apply to a supplier of a listed substance who supplies the listed substance to an eligible person without knowing or having reasonable grounds to believe that the person is an eligible person.

Refusal to
dispense
prohibited

10. No operator of a pharmacy shall refuse to supply a listed drug product for an eligible person in order to avoid the

operation of a provision of this Act but an operator may refuse to supply a listed drug product for an eligible person if the proper exercise of professional judgment so requires.

11.—(1) An operator of a pharmacy may notify the Minister that the operator elects not to accept payment from the Minister under section 5. Opting out

(2) Beginning ninety days after the day the Minister receives the notice under subsection (1), the operator is not entitled to payment from the Minister under section 5 and is not required to supply listed drug products for eligible persons under section 10. Idem

12. The Minister may consult with persons or organizations representing eligible persons, manufacturers of listed drug products, operators of pharmacies, physicians and suppliers of listed substances with respect to the amounts payable by the Minister and other matters of mutual concern arising out of this Act and the regulations. Minister to consult

13.—(1) No person who administers this Act or the regulations shall disclose any information about an eligible person or about the supplying of listed drug products to an eligible person. Confidentiality

(2) Subsection (1) does not apply to the disclosure of information, Exception

(a) to the person's counsel;

(b) with the consent of the eligible person;

(c) in connection with the administration of this Act, the *Prescription Drug Cost Regulation Act, 1986*, the *Health Disciplines Act*, the *Health Insurance Act*, the *Ministry of Health Act*, any other Act administered by the Minister of Health, the *Coroners Act*, the *Provincial Offences Act* or the *Criminal Code* (Canada), or any regulations made thereunder; or 1986, c. 28
R.S.O. 1980,
cc. 196, 197,
280, 93, 400

R.S.C. 1970,
c. C-34

(d) if the communication does not disclose the identity of a drug that was prescribed or supplied for an identified eligible person.

14.—(1) The Minister may appoint inspectors for the purposes of this section. Inspectors

Examine
books

(2) An inspector may examine any records, in whatever form, in the possession or under the control of an operator of a pharmacy or a physician, if the inspector believes on reasonable grounds that the records will assist the inspector in determining the accuracy and completeness of a claim for payment of the operator or physician or of information they are required to submit under this Act or the regulations, or in determining whether they have complied with this Act and the regulations.

Idem

(3) An inspector may examine records, in whatever form, in the possession or under the control of a wholesaler or manufacturer, if the inspector believes on reasonable grounds that the records will assist the inspector in determining the accuracy and completeness of a claim for payment of an operator of a pharmacy or physician or in determining whether the wholesaler or manufacturer have complied with this Act and the regulations.

Copies

(4) In carrying out an inspection under subsection (2), the 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.

Idem

(5) In carrying out an inspection under subsection (3), the inspector may, upon giving a receipt therefor, take away a sales record or a marketing record or both for the purpose of making a copy, but the copy shall be made and the record shall be returned as promptly as reasonably possible.

Entry

(6) An inspector may at any reasonable time, on producing proper identification, enter business premises where the inspector believes a record referred to in subsection (2) or (3) may be located for the purpose of an inspection.

Offence

15.—(1) A person who,

- (a) contravenes section 4 (charges a person other than the Minister);
- (b) contravenes subsection 9 (2) (supplier charges contrary to agreement);
- (c) contravenes section 10 (refuses to dispense);
- (d) refuses to submit information or knowingly furnishes false or incomplete information required to be submitted under this Act or the regulations; or

- (e) obstructs a person carrying out an inspection under section 14.

and any director or officer of a corporation who authorizes or permits such a contravention by the corporation, is guilty of an offence and on conviction is liable to a penalty of not more than \$5,000 for a first offence and \$10,000 for a second and subsequent offence.

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

16.—(1) A manufacturer of a drug product that is designated or being considered for designation as a listed drug product shall, Conditions for listing

- (a) supply that drug product for the same price to all purchasers in Ontario, other than public hospitals purchasing solely for use in the treatment of patients and out-patients in the hospital, where the purchasers purchase the same quantity of individual units of the drug product in the same dosage form and strength; and
- (b) give to the Minister, on request, the information prescribed by the regulations concerning the production and sale of the drug product.

(2) Where a manufacturer of a drug product contravenes this section or obstructs a person carrying out an inspection under section 14, the Lieutenant Governor in Council may refuse to designate the drug product as a listed drug product, or, where it is already so designated, may remove that designation. Idem

17.—(1) This Act applies with necessary modifications in respect of designated pharmaceutical products and, for the purpose, a designated pharmaceutical product shall be deemed to be a listed drug product. Pharmaceutical products

(2) Section 16 and subsections 18 (2) to (5) do not apply for the purpose of subsection (1). Application of s. 16 and subss. 18 (2-5)

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

- (a) designating eligible classes of persons for the purposes of section 2;

- (b) prescribing conditions to be met by products or by manufacturers of products in order for the products to be eligible for designation as listed drug products;
- (c) designating a product as a listed drug product where the Lieutenant Governor in Council considers it advisable in the public interest to do so, but a product shall not be so designated if it or its manufacturer has not met the conditions described in clause (b);
- (d) designating substances other than drugs that are listed substances;
- (e) authorizing the charges that are permitted under section 4;
- (f) prescribing the information to be included in a claim under subsection 5 (4);
- (g) respecting the amounts payable by the Minister under section 5;
- (h) requiring operators of pharmacies and manufacturers and wholesalers of listed drug products to file reports to the Minister concerning the cost to operators of pharmacies and wholesalers of purchasing any drugs and prescribing the information to be included in such reports and the frequency with which such reports are to be made;
- (i) requiring operators of pharmacies and physicians 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;
- (j) prescribing the manner of calculating the cost to an operator of a pharmacy of purchasing a listed drug product for the purpose of subsection 6 (3);
- (k) designating listed drug products that do not require a prescription for sale for the purpose of clause 6 (2) (b);
- (l) designating pharmaceutical products for the purpose of section 17;

- (m) respecting any matter considered necessary or advisable to carry out the intent and purposes of this Act.

(2) In determining the amounts payable by the Minister under subsections 5 (1) and (2), the Lieutenant Governor in Council shall prescribe from time to time the best available price of the drug, Idem

- (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,

and prescribe a percentage of the best available price, not less than 10 per cent nor greater than 20 per cent, to be added to it.

(3) In determining the best available price for a drug, no account shall be taken of a purchase of the drug for use solely in the treatment of hospital patients and out-patients. Idem

(4) In this section, "best available price" for a drug in a particular dosage form and strength, means the lowest amount, calculated per gram, milliliter, tablet, capsule or other appropriate unit, for which a listed drug product of that drug in that dosage form and strength can be purchased in Canada for wholesale or retail sale in Ontario and in calculating that amount, 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. Best available price

(5) Subsection (2) does not apply in respect of listed drug products designated by the regulations for the purpose of clause 6 (2) (b). Exception

(6) A regulation made under this section may be general or particular in its application. Regulations

(7) A regulation is, if it so provides, effective with reference to a period before it is filed. Retroactive

Commence-
ment

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

Short title

20. The short title of this Act is the *Ontario Drug Benefit Act, 1986*.