DRAFT REGULATION FOR PUBLIC CONSULTATION

ONTARIO REGULATION

made under the

ONTARIO DRUG BENEFIT ACT

Amending O. Reg. 201/96

(GENERAL)

1. (1) Subsection 13 (2) of Ontario Regulation 201/96 is revoked and the following substituted:

(2) Subject to subsection (3), for the purposes of paragraph 3 of subsection 6 (1) of the Act, the mark up on the drug benefit price of a listed drug product is 8 per cent of the drug benefit price.

(3) For the purposes of paragraph 3 of subsection 6 (1) of the Act, the mark up on a listed drug product that when supplied has a total drug cost of $1,000 or more is 6 per cent of the drug benefit price.

(3.1) In subsection (3),

"total drug cost" means the amount that is calculated by multiplying the drug benefit price of the drug product supplied by the quantity of the drug product supplied.

(2) Subsection 13 (4) of the Regulation is amended by striking out "For the purpose" at the beginning and substituting "Subject to subsection (6), for the purpose".

(3) Subsection 13 (5) of the Regulation is amended by striking out "Despite subsection (4)" at the beginning of the portion before paragraph 1 and substituting "Despite subsection (4), but subject to subsection (6)".

(4) Section 13 of the Regulation is amended by adding the following subsection:

(6) For the purposes of subclause 6 (2) (c) (i) of the Act, the dispensing fee for a listed drug product supplied for an eligible person referred to in paragraph 5 of subsection 2 (1) of this Regulation shall be the amount determined in accordance with subsection (4) or (5), as the case may be, less $1.26.

2. (1) Paragraph 3 of subsection 17 (1) of the Regulation is revoked and the following substituted:

3. A mark up equal to,

i. 6 per cent of the drug benefit price, if the total drug cost of the product supplied is $1,000 or more, and

ii. 8 per cent of the drug benefit price, in any other case.

(2) Section 17 of the Regulation is amended by adding the following subsection:

(1.1) In paragraph 3 of subsection (1),

"total drug cost" means the amount that is calculated by multiplying the drug benefit price of the drug product supplied by the quantity of the drug product supplied.

3. (1) Clause 18 (8) (a) of the Regulation is revoked and the following substituted:

(a) the listed drug product is a product or belongs to a class of drug product that is specified by the executive officer and published on the Ministry website and the dispenser has determined that the quantity supplied should be less than the amount required under subsection (7) because, in the dispenser's professional opinion,

(i) the safety of the eligible person is a concern, or

(ii) there is a risk of abuse or diversion if the drug product is supplied to the eligible person;

(2) Section 18 of the Regulation is amended by adding the following subsection:

(8.1) Where the dispenser has made a determination under clause (8) (a),

(a) the dispenser shall make a written record of the reasons for his or her opinion;

(b) the dispenser shall notify the prescriber in writing about the determination and retain a copy of the notification; and

(c) the dispenser shall provide copies of the written record described in clause (a) and the written notification described in clause (b) to the executive officer on request.

(3) Subsections 18 (9), (10) and (11) of the Regulation are revoked and the following substituted:

(9) Where the dispenser has made a determination under clause (8) (c),

(a) the dispenser shall make a written record of the reasons for his or her opinion under subclause (8) (c) (i);

(b) the dispenser shall obtain in writing the agreement required under subclause (8) (c) (ii) of the eligible person or of the person presenting the prescription;

(c) the dispenser shall notify the prescriber in writing about the determination and retain a copy of the notification; and

(d) the dispenser shall provide copies of the written record, agreement and notification described in clauses (a), (b) and (c) to the executive officer on request.

(10) The executive officer shall not pay more than two dispensing fees for the supply of a listed drug product in a calendar month even if the prescription specifies intervals such that the listed drug product is to be dispensed in more than two intervals in the calendar month, unless,

(a) the listed drug product is dispensed in the circumstances described in clause (8) (a) or (b); or

(b) the listed drug product is a product or belongs to a class of drug product that is specified by the executive officer and published on the Ministry website.

(11) Pursuant to subsection 1.1 (9) of the Act, it is provided that the executive officer has the power,

(a) to specify a listed drug product or class of listed drug product for the purposes of clauses (8) (a) and (10) (b); and

(b) to designate a residential facility for the purposes of subclause (8) (b) (ii).

(4) Subsection 18 (11) of the Regulation, as re-made by subsection (3), is revoked and the following substituted:

(11) Pursuant to subsection 1.1 (9) of the Act, it is provided that the executive officer has the power,

(a) to specify a listed drug product or class of listed drug product for the purposes of clauses (8) (a) and (10) (b); and

(b) to designate a residential facility for the purposes of subclauses (8) (b) (ii) and (11.1) (a) (ii).

(11.1) Despite subsection (10), where the listed drug product is a product or belongs to a class of drug product that has been specified by the executive officer and published on the Ministry's website, the executive officer shall not pay more than five dispensing fees in a year for the supply of the listed drug product, even if the intervals specified in the prescription provide for the listed drug product to be dispensed more than five times in the year, unless the listed drug product is supplied,

(a) to an eligible person who is a resident of,

(i) a long-term care home under the *Long-Term Care Homes Act, 2007*, or

(ii) any other residential facility funded by the Government of Ontario that is designated by the executive officer and published on the Ministry website;

(b) to an eligible person who is entitled to receive drug benefits under the *Ontario Works Act, 1997*; or

(c) in accordance with clause 18 (8) (c) and subsection 18 (9) of this Regulation.

(11.2) For the purposes of subsection (11.1),

"year" is a period of 365 days, with the first year commencing on the day the first claim for payment for the relevant listed drug product is submitted by the dispenser to the executive officer following the coming into force of subsection (11.1), and all subsequent years commencing on the day the first claim for payment for the relevant listed drug product is submitted by the dispenser to the executive officer following the end of the previous year.

(11.3) Pursuant to subsection 1.1 (9) of the Act, it is provided that the executive officer has the power to specify a listed drug product or class of listed drug product for the purposes of subsection (11.1).

4. Section 19 of the Regulation is revoked and the following substituted:

19. (1) For the purposes of subsections 4 (6) and 6 (5) of the Act, the executive officer shall not pay the amount determined under subsection 4 (5) of the Act in respect of a prescription that contains a direction that there be no substitutions unless the following conditions are met:

1. In the case of a written prescription, the direction is made by the prescriber writing "no sub" or "no substitutions" on the prescription.

2. The eligible person for whom the listed drug product is supplied has previously been administered and experienced an adverse reaction to,

    i. another drug product that is interchangeable with the drug product supplied, in the case where only one product has been designated as interchangeable with the drug product supplied and is generally available for sale in Ontario, or

    ii. two drug products that are interchangeable with the drug product supplied, in the case where two or more products have been designated as interchangeable with the drug product supplied and are generally available for sale in Ontario.

3. The adverse reaction described in paragraph 2 is documented for each applicable interchangeable product as follows:

    i. In the case of a written prescription, the prescription is accompanied by an adverse drug reaction reporting form completed and signed by the prescriber

in which the interchangeable product that caused the adverse reaction is identified.

ii. In the case of a verbal prescription, the prescriber satisfies the operator of the pharmacy or the dispensing physician that an adverse drug reaction reporting form in which the interchangeable product that caused the adverse reaction is identified has been completed and signed by the prescriber and will be delivered to the operator of the pharmacy or the dispensing physician forthwith.

(2) In paragraph 3 of subsection (1),

"adverse drug reaction reporting form" means the Health Canada adverse drug reaction reporting form available from Health Canada or from the Ministry.

5. Section 20.1 of the Regulation is revoked and the following substituted:

20.1 (1) For the purposes of subsection 6 (1) of the Act and subsection 17 (1) of this Regulation, the maximum co-payment that the operator of a pharmacy or a physician may charge a person other than the executive officer in respect of supplying a listed drug product for an eligible person is $2 or the operator's usual and customary dispensing fee, whichever is less, unless a different co-payment is provided for under section 20.2.

(2) The maximum co-payments described in subsection (1) and paragraph 3 of subsection 20.2 (5) may only be charged by an operator of a pharmacy or a physician if the executive officer is required to pay the operator of the pharmacy or the physician a dispensing fee under the Act and this Regulation.

6. (1) Paragraph 1 of subsection 20.2 (5) of the Regulation is amended by striking out the portion before subparagraph i and substituting the following:

1. Until the eligible person's allowable drug costs for the fiscal period reach the deductible amount, the maximum co-payment that may be charged shall be the amount equal to the full amount otherwise payable by the executive officer under section 6 of the Act, or section 17 of this Regulation, as the case may be, in respect of the supply of the drug product less,

. . . . .

(2) Subparagraph 1 i of subsection 20.2 (5) of the Regulation is amended by striking out "$4.17" at the end and substituting "$6.00".

Commencement

7. (1) Subject to subsection (2), this Regulation comes into force on the day it is filed.

(2) Sections 1, 2 and 4 and subsection 3 (4) come into force on October 1, 2015.