

ONTARIO REGULATION
made under the
ONTARIO DRUG BENEFIT ACT
Amending O. Reg. 201/96
(General)

Note: Ontario Regulation 201/96 has previously been amended. Those amendments are listed in the Table of Regulations – Legislative History Overview which can be found at www.e-Laws.gov.on.ca.

1. (1) Paragraph 4 of section 11 of the Regulation is amended by striking out “paragraphs 1, 2 and 3, if required” in the portion before subparagraph i and substituting “paragraphs 1, 2 and 3, if applicable, and if required”.

(2) Section 11 of the Regulation is amended by adding the following subsections:

(2) Paragraphs 1, 2 and 3 of subsection (1) do not apply where there is evidence satisfactory to the executive officer that the product would be the only drug product of its type that has been proposed to be designated as interchangeable with an original drug product.

(3) Where the circumstances described in subsection (2) exist, the executive officer may, in the executive officer’s sole discretion, negotiate an agreement in respect of the product with the manufacturer for any drug benefit price, but in no case may the interchangeable product be priced higher than the original product.

(4) For greater certainty, where the executive officer and the manufacturer cannot agree as to a drug benefit price under subsection (3), the executive officer shall not list the drug product.

2. (1) Paragraph 5 of subsection 12.1 (1) of the Regulation is amended by striking out “paragraph 6” and substituting “paragraphs 6 and 6.1”.

(2) Subsection 12.1 (1) of the Regulation is amended by adding the following paragraph:

- 6.1 Paragraph 5 does not apply with respect to a product that has been designated as interchangeable with an original product where there is evidence satisfactory to the executive officer that,
- i. the product is the only drug product of its type that is designated as interchangeable with an original drug product, and has been so designated for at least two years, and
 - ii. removing the product's listing would result in significant patient safety or access concerns, or significant increased costs to the Government of Ontario.

(3) Section 12.1 of the Regulation is amended by adding the following subsection:

(3) Where the circumstances described in paragraph 6 or 6.1 of subsection (1) exist, the executive officer may, in the executive officer's sole discretion, negotiate an agreement with the manufacturer for any drug benefit price, but in no case may the interchangeable product be priced higher than the original product.

3. (1) Section 14 of the Regulation is amended by adding the following subsection:

(3) The operator of a pharmacy may submit a claim for payment in accordance with subsection 6 (3) of the Act where the executive officer is satisfied that,

- (a) the operator of a pharmacy has been unable to purchase inventory at the drug benefit price of the drug product published in the Formulary on October 23, 2006 plus the allowable mark up under subsection 13 (2) of this Regulation; or
- (b) the operator of a pharmacy is unable to acquire an interchangeable drug product and must dispense the original product or an interchangeable product with a higher drug benefit price.

(2) Clause 14 (3) (a) of the Regulation, as made by subsection (1), is revoked.

4. (1) Paragraph 1 under the heading "Use of Professional Allowances" and subheading "Professional allowances may never be used for:" in Schedule 3 to the Regulation is revoked and the following substituted:

1. Advertising or promotional materials, such as store flyers, except in association with clinic days, education days, disease management and prevention initiatives and clinical pharmacy services mentioned in paragraphs 3, 4, 6 and 8 of the definition of "professional allowance" in subsection 1 (8) of the regulation.

(2) Paragraph 6 under the heading “Use of Professional Allowances” and subheading “Professional allowances may never be used for:” in Schedule 3 to the Regulation is revoked.

(3) Paragraph 13 under the heading “Use of Professional Allowances” and subheading “Professional allowances may never be used for:” in Schedule 3 to the Regulation is amended by adding “except as directly related to a private counselling area mentioned in paragraph 7 of the definition of “professional allowance” in subsection 1 (8) of the regulation” at the end.

5. (1) Subject to subsections (2) and (3), this Regulation comes into force on the day it is filed.

(2) Section 2, subsection 3 (1) and section 4 shall be deemed to have come into force on October 1, 2006.

(3) Subsection 3 (2) comes into force on March 1, 2007.