

# ONTARIO REGULATION

made under the

## DRUG INTERCHANGEABILITY AND DISPENSING FEE ACT

Amending Reg. 935 of R.R.O. 1990

(General)

Note: Regulation 935 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](http://www.e-Laws.gov.on.ca).

**1. Section 1 of Regulation 935 of the Revised Regulations of Ontario, 1990 is amended by adding the following subsection:**

(3) For the purposes of subsection 7 (2) of the Act, “the lowest amount” means the lowest amount determined without reference to the drug benefit price of the drug published in the Formulary.

**2. (1) Paragraph 4 of subsection 7 (2) of the Regulation is amended by striking out “paragraphs 1, 2 and 3, where the product” in the portion before subparagraph i and substituting “paragraphs 1, 2 and 3, if applicable, where the product”.**

**(2) Section 7 of the Regulation is amended by adding the following subsections:**

(3) Paragraphs 1, 2 and 3 of subsection (2) 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.

(4) Where the circumstances described in subsection (3) 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.

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

**3. (1) Paragraph 4 of subsection 8 (1) of the Regulation is amended by striking out “paragraph 5” and substituting “paragraphs 5 and 5.1”.**

**(2) Subsection 8 (1) of the Regulation is amended by adding the following paragraph:**

- 5.1 Paragraph 4 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 designation would result in significant patient safety or access concerns, or significant increased costs to the Government of Ontario.

**(3) Section 8 of the Regulation is amended by adding the following subsection:**

(3) Where the circumstances described in paragraph 5 or 5.1 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.

**4. (1) Paragraph 1 under the heading "Fundamental Principles" in Schedule 1 to the Regulation is revoked and the following substituted:**

1. Payments from manufacturers to operators of pharmacies, or companies that own, operate or franchise pharmacies, including their directors, officers, employees or agents, in the form of a professional allowance must be used only for any or all of the activities set out in paragraphs 1 to 8 of the definition of "professional allowance" in subsection 2 (1) of the regulation.

**(2) Paragraph 1 under the heading "Use of Professional Allowances" and subheading "Professional allowances may never be used for:" in Schedule 1 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 2 (1) of the regulation.

**(3) Paragraph 6 under the under the heading "Use of Professional Allowances" and subheading "Professional allowances may never be used for:" in Schedule 1 to the Regulation is revoked.**

**(4) Paragraph 13 under the under the heading "Use of Professional Allowances" and subheading "Professional allowances may never be used for:" in Schedule 1 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 2 (1) of the regulation” at the end.**

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

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