Notice of Proposed Regulations to Amend Ontario Regulation 935 under the Drug Interchangeability and Dispensing Fee Act and Ontario Regulation 201/96 under the Ontario Drug Benefit Act

Introduction

The Minister of Health and Long-Term Care [Minister] on behalf of the Government of Ontario invites public comments on proposed regulations to amend Ontario Regulation 935 [Reg. 935] under the *Drug Interchangeability and Dispensing Fee* [DIDFA] and Ontario Regulation 201/96 [O. Reg. 201/96] under the *Ontario Drug Benefit Act* [ODBA].

The DIDFA and the ODBA require that the Minister publish a notice on the ministry's web site concerning certain proposed regulations under the ODBA and DIDFA. This notice pertains to two proposed regulations: one which proposes to amend Reg. 935 and the other which proposes to amend O. Reg. 201/96.

The content of the final regulations are at the discretion of the Lieutenant Governor in Council, who may make the regulations with any changes that the Lieutenant Governor in Council considers appropriate.

Content of Proposed Regulations

The proposed regulations would amend O. Reg. 201/96 and Reg. 935 in the following way.

Summary of proposed regulation amending Reg. 935 under the DIDFA

Section 1 would

- clarify that the term "lowest amount" in s. 7(2) of the DIDFA means the lowest amount determined without reference to the drug benefit price of the drug published in the Formulary.

Section 2 would

- amend s.7 of Reg. 935 to permit the executive officer, in the executive officer's sole discretion, to negotiate an agreement in respect of a product with a manufacturer for a drug benefit price that is different from the flat 50% price rule as set out in paragraphs 1, 2 and 3 of s. 7(2) of Reg. 935, 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. In no case may the drug benefit price for the interchangeable product be higher than the price of the original product. For

greater certainty, if the executive officer and the manufacturer cannot agree as to a drug benefit price, the executive officer may not list the drug product.

Section 3 would

- amend s.8 of Reg. 935 to provide that the condition (that an interchangeable product's drug benefit price, where that product is a listed drug product under the ODBA, may not be more than the price that could be proposed to the executive officer under s. 7(2) of Reg. 935 in order for the product to continue to be designated as interchangeable) does not apply where there is evidence satisfactory to the executive officer that:
  1. the product is the only drug product of its type that is designated as interchangeable with an original product, and has been so designated for at least two years; and
  2. removing the product's designation would result in significant patient safety or access concerns, or significant increased costs to the Government of Ontario

- amend s.8 of Reg. 935 to permit the executive officer, in the executive officer's sole discretion, to negotiate an agreement with a manufacturer regarding the designated interchangeable product, where an exception to the flat 50% price rule exists, for a drug benefit price that is different from the flat 50% price rule. In no case may the drug benefit price for that product be higher than the drug benefit price of the original product.

Section 4 would

- make a technical amendment to paragraph 1 under the heading "Fundamental Principles" in Schedule 1 of Reg. 935 [the Code of Conduct] to refer to activities set out in paragraphs 1 to 8 of the definition of "professional allowance" in s. 2(1) of Reg. 935.

- clarify in the Code of Conduct that professional allowances may also be used for:
  1. advertising or promotional materials, and staff wages and benefits, in respect of disease management and prevention initiatives and clinical pharmacy services mentioned in paragraphs 6 and 8 of the definition of "professional allowance"; and
  2. renovations, leasehold improvements and similar matters where they are directly related to a private counselling area within the pharmacy.

Section 5 would

- provide that the amending regulation is deemed to come into force on October 1, 2006, except for s.2 which comes into force on filing.

Summary of proposed regulation amending O. Reg. 201/96 under the ODBA

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Section 1 would

- amend s.11 of O. Reg. 201/96 to permit the executive officer to negotiate an agreement in respect of a product with a manufacturer for a drug benefit price that is different from the flat 50% price rule as set out in paragraphs 1, 2 and 3 of s. 11(1) of O. Reg. 201/96, 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. In no case may the drug benefit price for the interchangeable product be higher than the price of the original product. For greater certainty, where the executive officer and the manufacturer cannot agree as to a drug benefit price, the executive officer may not list the drug product.

Section 2 would

- amend s.12.1 of O. Reg. 201/96 to provide that the condition that an interchangeable product's drug benefit price (where that product is a listed drug product under the ODBA, may not be more than the price that could be proposed to the executive officer under s.11 of O. Reg. 201/96 in order for the product to continue to be designated as interchangeable) does not apply where there is evidence satisfactory to the executive officer that:
    1. the product is the only drug product of its type that is designated as interchangeable with an original product, and has been so designated for at least two years; and
    2. removing the product's designation would result in significant patient safety or access concerns, or significant increased costs to the Government of Ontario.

- amend s.12.1 of O. Reg. 201/96 to permit the executive officer to negotiate an agreement with a manufacturer in respect of the designated interchangeable product, where an exception to the flat 50% price rule exists, for a drug benefit price that is different from the flat 50% price rule. In no case may the drug benefit price for that product be higher than the drug benefit price of the original product.

Section 3 would

- amend s. 14 of O. Reg. 201/96 to permit the operator of a pharmacy to submit a claim for payment in accordance with s. 6 (3) of the ODBA where: a) the executive officer is satisfied that either 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; or b) the operator of a pharmacy is unable to acquire an interchangeable drug product and must dispense the original product. Clause (a) above is revoked on January 1, 2007.

Section 4 would

- make a technical amendment to paragraph 1 under the heading "Fundamental Principles" in Schedule 3 of O. Reg. 201/96 [the Code of Conduct] to refer to activities set out in paragraphs 1 to 8 of the definition of "professional allowance" in s. 1(8) of O. Reg. 201/96.

- clarify in the Code of Conduct that professional allowances may also be used for:
    1. advertising or promotional materials, and staff wages and benefits, in respect of disease management and prevention initiatives and clinical pharmacy services mentioned in paragraphs 6 and 8 of the definition of "professional allowance"; and
    2. renovations, leasehold improvements and similar matters where they are directly related to a private counselling area within the pharmacy.

Section 5 would

- provide that the amending regulation is deemed to come into force on October 1, 2006, except for s.1 which comes into force on filing.

Invitation to Provide Written Comments

While the DIDFA and the ODBA require at least 30 days from the date of the publication of the notice during which the public may submit written comments on the proposed regulations, the legislation authorizes the Minister to shorten the time period for public comment if the Minister is of the opinion that the urgency of the situation requires it or the proposed regulations clarify the intent or operation of the DIDFA, the ODBA or their regulations.

As there is urgency to the matters addressed in the proposed regulations and they clarify the intent and operation of the regulations they propose to amend, the time period for members of the public to make written submissions on the proposed regulations has been accordingly shortened and interested parties are invited to provide written comments on the proposed regulations to amend Reg. 935 and O. Reg. 201/96 on or before **5 p.m. on Thursday, November 23, 2006** [comment period].

When preparing your response, please consider whether you agree with the proposed regulations to amend Reg. 935 and O. Reg. 201/96 and/or whether the proposed regulations should be changed. Please provide any other relevant comments you think might be useful. Please be as specific as possible and provide a full rationale for any suggested changes or additions.

Submission of Written Comments

Please submit your written comments to:

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Ontario Ministry of Health and Long-Term Care
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All comments and submissions received during the comment period will be considered during the preparation of the final regulations. Comments and submissions received after the comment period will not be considered. The content, structure, and form of the proposed regulations may be changed as a result of the comment process in the discretion of the Lieutenant Governor in Council, who has the final decision on the contents of any final regulations. The final amending regulations may, therefore, be different from those posted in this notice.

Copies of the DIDFA, the ODBA, Reg. 935 and O. Reg. 201/96 are available from Publications Ontario, 50 Grosvenor St., Toronto, Ontario, M7A 1N8, (416) 326-5300. They are also available from www.e-Laws.gov.on.ca.

The content of the final regulations amending Reg. 935 and O. Reg. 201/96 would be published in the Ontario Gazette at www.ontariogazette.gov.on.ca and on e-laws at www.e-Laws.gov.on.ca.

Statement about Comments

Please note that unless requested and agreed otherwise by the ministry, all materials or comments received from organizations in response to this notice will be considered public information and may be used and disclosed by the ministry to assist in evaluating and revising the proposed regulations. This may involve disclosing materials or comments, or summaries of them, to other interested parties during and after the comment period.

An individual who provides materials or comments and who indicates an affiliation with an organization will be considered to have submitted those comments or materials on behalf of the organization so identified.

Materials or comments received from individuals who do not indicate an affiliation with an organization will not be considered public information unless expressly stated otherwise by the individual. However, the ministry may use and disclose materials or comments provided by individuals to assist the ministry in evaluating and revising the

proposed regulations. The ministry will not disclose personal information of those who do not specify an organizational affiliation, such as an individual's name and contact details, without the individual's consent unless required by law.

If you have any questions about the collection of this information, you can contact the ministry's Freedom of Information and Privacy Coordinator at (416) 327-7040.

The Honourable George Smitherman
Minister of Health and Long-Term Care

PROPOSED REGULATION AMENDING REG. 935 UNDER THE DIDFA

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. 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 may 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) Schedule 1 to the Regulation is amended by revoking paragraph 1 under the subheading "Professional allowances may never be used for" and substituting the following:

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 subheading "Professional allowances may never be used for" in Schedule 1 to the Regulation is amended by striking out "paragraphs 3 and 4" and substituting "paragraphs 3, 4, 6 and 8".

(4) Paragraph 13 under the 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 filing.

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

PROPOSED REGULATION AMENDING O. REG. 201/96 UNDER THE ODBA

1. 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 may 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 paragraphs 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 section 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; or

(b) the operator of a pharmacy is unable to acquire an interchangeable drug product and must dispense the original product.

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

4. (1) Schedule 3 to the Regulation is amended by revoking paragraph 1 under the subheading "Professional allowances may never be used for" and substituting the following:

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 subheading "Professional allowances may never be used for" in Schedule 3 to the Regulation is amended by striking out "paragraphs 3 and 4" and substituting "paragraphs 3, 4, 6 and 8".

(3) Paragraph 13 under the 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 filing.

(2) Sections 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 January 1, 2007.