

April 8, 2010

Notice of Proposed Regulations to Amend 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 (the “Minister”) on behalf of the Government of Ontario invites public comments on proposed regulations to amend Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) and Ontario Regulation 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 Regulation 935 made under the DIDFA (the “DIDFA Regulation”) and the other which proposes to amend Ontario Regulation 201/96 made under the ODBA (the “ODBA Regulation”).

These proposed regulations are part of a comprehensive drug system reform initiative which was announced by the Government of Ontario on April 7, 2010 and posted on the Ministry of Health and Long-Term Care website at <http://ontario.ca/drugreforms>.

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 the DIDFA Regulation and the ODBA Regulation as follows:

Summary of the proposed regulation to amend the DIDFA Regulation

Section 1:

- would revoke section 1(3) of the DIDFA Regulation so that, under section 7(2) of the Act, “the lowest amount” that a dispenser can charge for a drug product would be determined in reference to the drug benefit price published in the Formulary. This amendment would come into force on April 1, 2012.

Section 2:

- Subsection (1) would amend section 2 of the DIDFA Regulation by introducing a 50% cap on professional allowances provided by manufacturers in respect of interchangeable products that are not reimbursed under the *Ontario Drug Benefit Act* (ODBA). This amendment would come into force on May 15, 2010.
- Subsection (2) would reduce the cap on professional allowances to 35%. This amendment would come into force on April 1, 2011.
- Subsection (3) would reduce the cap on professional allowances to 25%. This amendment would come into force on April 1, 2012.
- Subsection (4) would amend section 2 of the DIDFA Regulation by introducing a new subsection to exclude “ordinary commercial terms” from the prohibition against rebates under section 12.1 of the Act, and to establish the following conditions that must be met in order for a benefit to be considered ordinary commercial terms: (1) the benefit must be provided in the ordinary course of business; (2) the value of the benefit must be set out in a written agreement; and (3) the benefit must relate to an ordinary commercial relationship that is any of the following: (i) a prompt payment discount; (ii) a volume discount; or (iii) a distribution service fee . This amendment would come into force on May 15, 2010.

Section 3:

- would revoke and replace section 7 of the DIDFA Regulation to provide that, where it is proposed that a product be designated as both interchangeable under the DIDFA and a listed drug product (i.e. a benefit) under the ODBA, the product cannot be designated unless the proposed drug benefit price is no greater than the price permitted under the ODBA. This amendment would come into force on May 15, 2010.

Section 4:

- Subsection (1) would revoke paragraphs 4, 5, 5.1, 5.2 and 6 of subsection 8(1) of the DIDFA Regulation and replace them with paragraphs setting out the following conditions that must be met for a drug product that has been designated as interchangeable to continue to be designated as interchangeable:
 - if the product is a benefit under the ODBA and it is being supplied to a person who is eligible to receive benefits under the ODBA, the price of the product cannot be more than the drug benefit price permitted under the ODBA (proposed new paragraph 4);
 - if the product is a benefit under the ODBA but the manufacturer is not selling the product for the purpose of supplying it to an eligible person under the ODBA, the manufacturer shall not sell the product at a price higher than 50% of the drug benefit price of the original product as of the

date on which the product was first proposed for an interchangeability designation (proposed new paragraph 5). However, if this price would be lower than the drug benefit price permitted under the ODBA, then the manufacturer shall not sell the product at a price higher than the drug benefit price permitted under the ODBA (proposed new paragraph 6). These amendments would come into force on May 15, 2010.

- Subsection (2) would reduce the aforementioned 50% price limit in the proposed new paragraph 5 to 35%. This amendment would come into force on April 1, 2011.
- Subsection (3) would revoke the pricing rules in the proposed new paragraphs 4, 5 and 6 of subsection 8(1) of the DIDFA Regulation, and replace them with a new paragraph 4 which would provide that, where a product is listed as a benefit under the ODBA, the manufacturer shall not sell that product at a price higher than the drug benefit price permitted under the ODBA whether or not it is being supplied to an eligible person under the ODBA. This amendment would come into force on April 1, 2012.
- Subsection (4) would amend subsection 8(1) of the DIDFA Regulation by adding a new condition that must be met for a drug product that has been designated as interchangeable to continue to be designated as interchangeable. This condition would be that, if required by the Executive Officer of Ontario Public Drug Programs (the "EO"), the manufacturer of a product would have to inform the EO of the price that the manufacturer receives for the product, net of the value of any professional allowances or ordinary commercial terms. This amendment would come into force on May 15, 2010.
- Subsection (5) would revoke subsection 8(3) of the DIDFA Regulation. This amendment would come into force on May 15, 2010.

Section 5:

- would amend the DIDFA Regulation by adding a new section 9 to prohibit interchangeability designations in respect of "private label products". A "private label product" would be defined as including a drug product in respect of which (a) the manufacturer applying for the interchangeability designation does not directly fabricate the product itself (and is not controlled by a person that directly fabricates the product or does not control the person that directly fabricates the product); (b) the manufacturer does not have an arms length relationship with an operator of a pharmacy or a company that owns, operates or franchises pharmacies; and (c) the product is to be supplied under a marketing arrangement associating the product with one or more operators of pharmacies or companies that own, operate or franchise pharmacies. This amendment would come into force on May 15, 2010.

Section 6:

- would amend Schedule 1 to the DIDFA Regulation by striking out the second paragraph of the section entitled "Reporting" which concerns the reporting obligations of pharmacy operators in respect of professional allowances. This amendment would come into force on May 15, 2010.

Section 7:

- would provide that the foregoing amendments would come into force on the dates indicated above.

Summary of proposed regulation to amend the ODBA Regulation

Section 1:

- Subsection (1) would amend subsection 1(9) of the ODBA Regulation to reduce the cap on professional allowances provided in respect of a manufacturer's drug products that are reimbursed under the ODBA from 20% to 5%. This amendment would come into force on May 15, 2010.
- Subsection (2) would delete subsection 1(11) of the ODBA Regulation and introduce a new provision to exclude "ordinary commercial terms" from the prohibition against rebates under section 11.5 of the Act, and to establish the following conditions that must be met in order for benefits provided in respect of an interchangeable listed drug product to qualify as ordinary commercial terms: (1) the benefit must be provided in the ordinary course of business; (2) the value of the benefit must be set out in a written agreement; and (3) the benefit must relate to an ordinary commercial relationship that is any of the following: (i) a prompt payment discount; (ii) a volume discount; or (iii) a distribution service fee. These amendments would come into force on May 15, 2010.
- Subsection (2) would also introduce a new subsection 1(12) to the ODBA Regulation to clarify that the rebate prohibition does not apply to ordinary commercial terms in the form of a prompt payment discount where such discount is provided in respect of a listed drug product that is not interchangeable. This amendment would come into force on May 15, 2010.

Section 2:

- This section would amend subsection 11(1) of the ODBA Regulation to change the conditions that must be met in order for a product that is being proposed for designation as interchangeable under the DIDFA to also be designated as a listed drug product (i.e. a benefit) under the ODBA. Specifically:
 - Subsection (1) would amend paragraph 1 of subsection 11(1) of the ODBA Regulation to provide that the maximum drug benefit price that may be

proposed in respect of a product (where the original product is still listed on the Formulary as a benefit) is reduced from 50% to 25% of the drug benefit price of the original product as set out in the Formulary on the date that the product is first proposed for designation as a benefit (the “25% Pricing Rule”).

- Subsection (2) would amend paragraph 2 of subsection 11(1) to apply the 25% Pricing Rule to products that are being proposed for listing where the original product was but is no longer listed on the Formulary as a benefit.
- Subsection (3) would revoke paragraph 3 of subsection 11(1) of the ODBA Regulation.
- Subsection (4) is a technical change that would update the aforementioned paragraph references within paragraph 4 of subsection 11(1) of the ODBA Regulation.
- Subsection (5) is also a technical change that would update the aforementioned paragraph references within subsection 11(2) of the ODBA Regulation.

All of the foregoing amendments would come into force on May 15, 2010.

Section 3:

- would amend the ODBA Regulation by adding a new section 12.0.2 to prohibit benefit designations in respect of “private label products”. A “private label product” would be defined as including a drug product in respect of which (a) the manufacturer applying for the benefit designation does not directly fabricate the product itself (and is not controlled by a person that directly fabricates the product or does not control the person that directly fabricates the product); (b) the manufacturer does not have an arms length relationship with an operator of a pharmacy or a company that owns, operates or franchises pharmacies; and (c) the product is to be supplied under a marketing arrangement associating the product with one or more operators of pharmacies or companies that own, operate or franchise pharmacies. This amendment would come into force on May 15, 2010.

Section 4:

- Subsection (1) is a technical change that would include a reference to the new paragraph 6.3 under subsection 12.1(1) of the ODBA Regulation.
- Subsection (2) would revoke paragraph 6 of subsection 12.1(1) of the ODBA Regulation.

- Subsection (3) would amend the conditions that must be met for an interchangeable product that has been listed as a benefit under the ODBA to continue to be listed as a benefit, by providing that the 25% Pricing Rule (described in Section 2 above) does not apply to the product if:
 - the original product is listed as a benefit and one or more products have been designated as interchangeable with it for more than ten (10) years; or
 - the original product was but is no longer listed as a benefit and has not been listed as a benefit for more than five (5) years (the “New Pricing Exemption for Older Products”).
- Subsection (4) would amend subsection 12.1(1) of the ODBA Regulation by adding a new condition that must be met for a drug product that has been listed as a benefit under the ODBA to continue to be listed as a benefit. This condition would be that, if required by the EO, the manufacturer of a listed drug product would have to inform the EO of the price that the manufacturer receives for the product, net of the value of any professional allowances or ordinary commercial terms.
- Subsection (5) would update subsection 12.1(2) of the ODBA to provide that the conditions for continued listing under subsection 12.1(1) apply to a product irrespective of whether the product was designated as a benefit under the ODBA or as an interchangeable product under the DIDFA on or after May 15, 2010.
- Subsection (6) would revoke subsection 12.1(3) of the ODBA Regulation and replace it with a new subsection 12.1(3) that provides that, where one of the exemptions to the 25% Pricing Rule apply to a listed drug product, then the EO may negotiate an agreement with the manufacturer for any drug benefit price for that product, but:
 - if the product is a product to which only paragraph 6.1 (the “Single Source Pricing Exemption”) or paragraph 6.2 (the “Raw Materials Cost Increase Exemption”) applies, then the negotiated price cannot be higher than the drug benefit price of the original product;
 - if the product is priced under the Single Source Pricing Exemption but circumstances change such that the Single Source Pricing Exemption no longer applies, then the product must be priced in accordance with the 25% Pricing Rule;
 - if the product is subject to the New Pricing Exemption for Older Products and that is the only applicable exemption, the negotiated price may be higher than the price of the original product but only where the EO considers such a drug benefit price to be in the public interest;

- if the product is subject only to the Single Source Pricing Exemption or the New Pricing Exemption for Older Products, the EO shall not increase the drug benefit price more than once every five years.

All of the foregoing amendments would come into force on May 15, 2010.

Section 5:

- Subsection (1) would revoke subsection 13(2) of the ODBA Regulation and replace it with a provision that provides for the payment by the EO of differential mark-ups under different circumstances. For the purpose of paragraph 3 of subsection 6(1) of the Act, the mark-up on the drug benefit price of a listed drug product would be determined as follows:
 1. 10% for a Category 2, 3 or 4 pharmacy, unless paragraph 3 or 4 applies
 2. 8% for a Category 1 pharmacy, unless paragraph 3 or 4 applies
 3. 5% if the pharmacy has not purchased at least 75% of the products it supplies under the Act from a comprehensive wholesaler
 4. if the value of the mark-up applying paragraph 1, 2 or 3 is greater than \$125, then the mark-up is \$125.

This amendment would come into force on May 15, 2010.

- Subsection (2) would revoke subsection 13(4) of the ODBA Regulation and replace it with a provision that provides for the payment by the EO of differential dispensing fees based on the classification of a pharmacy as either a Category 1, 2, 3, or 4 pharmacy. For the purpose of subclause 6(2)(c)(i) of the Act, the dispensing fee for a listed drug product would be:
 - (a) for a product dispensed in a Category 1 pharmacy, \$8.00;
 - (b) for a product dispensed in a Category 2 pharmacy, \$9.00;
 - (c) for a product dispensed in a Category 3 pharmacy, \$10.00; and
 - (d) for a product dispensed in a Category 4 pharmacy, \$11.00.

This amendment would come into force on May 15, 2010.

- Subsection (2) would also introduce a new subsection 13(5) to the ODBA Regulation which would provide that pharmacies shall be classified as Category 1, 2, 3 or 4 pharmacies based on criteria that include: (a) the Rurality Index of Ontario; (b) the number of pharmacies within the geographic area served by the pharmacy; (c) the distance between the pharmacy and other pharmacies; and (d) the volume of claims submitted for payment under the Act by the operator of the pharmacy. This amendment would come into force on May 15, 2010.

Note: It is proposed that pharmacies in rural and under-serviced areas of the province would be classified as Category 2, 3 or 4 pharmacies. The Minister invites comments on the criteria by which a pharmacy operator would be classified as a Category 1, 2, 3 or 4 pharmacy for the purpose of determining the applicable mark-up and dispensing fee.

- Subsection (2) would also introduce a new subsection 13(6) to the ODBA Regulation in which the term “comprehensive wholesaler” is defined as a wholesaler that:
 - (a) has as its principal business the business of distributing pharmaceutical and other consumer products;
 - (b) carries in stock and has available for sale to an operator of a pharmacy at least 80% of the listed drug products and listed substances in the Formulary;
 - (c) is prepared to supply products to any operator of a pharmacy in Ontario that regularly orders from the wholesaler and pays the wholesaler; and
 - (d) has an arms-length relationship with all manufacturers, operators of pharmacies and companies that own, operate or franchise pharmacies.
 This amendment would come into force on May 15, 2010.

- Subsection (3) would increase the dispensing fees payable in respect of listed drug products dispensed in each category of pharmacy as follows:
 - (a) for a Category 1 pharmacy, from \$8.00 to \$8.20;
 - (b) for a Category 2 pharmacy, from \$9.00 to \$9.22;
 - (c) for a Category 3 pharmacy, from \$10.00 to \$10.25; and
 - (d) for a Category 4 pharmacy, from \$11.00 to 11.28.
 This amendment would come into force on April 1, 2011.

- Subsection (4) would increase the dispensing fees payable in respect of listed drug products dispensed in each category of pharmacy as follows:
 - (a) for a Category 1 pharmacy, from \$8.20 to \$8.40;
 - (b) for a Category 2 pharmacy, from \$9.22 to \$9.45;
 - (c) for a Category 3 pharmacy, from \$10.25 to \$10.50; and
 - (d) for a Category 4 pharmacy, from \$11.28 to 11.55.
 This amendment would come into force on April 1, 2012.

- Subsection (5) would increase the dispensing fees payable in respect of listed drug products dispensed in each category of pharmacy as follows:
 - (a) for a Category 1 pharmacy, from \$8.40 to \$8.62;
 - (b) for a Category 2 pharmacy, from \$9.45 to \$9.69;
 - (c) for a Category 3 pharmacy, from \$10.50 to \$10.77; and
 - (d) for a Category 4 pharmacy, from \$11.55 to 11.85.
 This amendment would come into force on April 1, 2013.

- Subsection (6) would increase the dispensing fees payable in respect of listed drug products dispensed in each category of pharmacy as follows:
 - (a) for a Category 1 pharmacy, from \$8.62 to \$8.83;
 - (b) for a Category 2 pharmacy, from \$9.69 to \$9.93;
 - (c) for a Category 3 pharmacy, from \$10.77to \$11.04; and
 - (d) for a Category 4 pharmacy, from \$11.85 to 12.14.
 This amendment would come into force on April 1, 2014.

Section 6:

- would amend Schedule 3 to the ODBA Regulation by striking out the second paragraph of the section entitled “Reporting” which concerns the reporting obligations of pharmacy operators in respect of professional allowances. This amendment would come into force on May 15, 2010.

Section 7:

- provides that the foregoing proposed amendments would come into force on the dates indicated above.

Invitation to Provide Written Comments

The DIDFA and the ODBA require a 30-day consultation period from the date of the publication of the notice during which the public may submit written comments on the proposed regulations.

Interested parties are invited to provide written comments on the proposed regulations to amend the DIDFA Regulation and the ODBA Regulation **before 5 p.m. on May 8, 2010.**

When preparing your response, please consider whether you agree with the proposed regulations to amend the DIDFA Regulation and the ODBA Regulation 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:

Helen Stevenson
Executive Officer of Ontario Public Drug Programs and Assistant Deputy Minister
Ministry of Health and Long-Term Care
80 Grosvenor Street, 9th Floor
Hepburn Block, Queen’s Park
Toronto ON M7A 1R3
Fax: 416-325-6647
E-mail: helen.stevenson@ontario.ca

All comments and submissions received during the consultation period will be considered during the preparation of the final regulations. Comments and submissions received after the consultation period will not be considered. The content, structure, and form of the proposed regulations may be changed following the consultation

process at the discretion of the Lieutenant Governor in Council who has the final decision on the content of any final regulations. The final amending regulations may, therefore, be different from those posted in this notice.

Copies of the DIDFA, the ODBA, and the regulations made respectively thereunder are available from Publications Ontario, 50 Grosvenor St., Toronto, Ontario, M7A 1N8, (416) 326-5300. They can also be accessed on-line at: www.e-Laws.gov.on.ca.

The content of the final regulations amending the DIDFA Regulation and the ODBA Regulation 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 Deb Matthews
Minister of Health and Long-Term Care

PROPOSED REGULATION AMENDING REG. 935 UNDER THE DIDFA

1. Subsection 1 (3) of Regulation 935 of the Revised Regulations of Ontario, 1990 is revoked.

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

(1.1) Where the value of all of the benefits provided under subsection (1) exceeds the value of X in the formula below, in respect of all of a manufacturer's interchangeable products that are not reimbursed under the *Ontario Drug Benefit Act*, then the benefits that are in excess of X are a rebate and not a professional allowance:

$$X = 50\% \text{ of } P$$

Where,

“X” is the total dollar amount of professional allowances that may be provided by a manufacturer to persons listed in subsection 12.1 (1) of the Act, and

“P” is the total dollar amount of a manufacturer's interchangeable products that are not reimbursed under the *Ontario Drug Benefit Act* and that are sold to pharmacies in Ontario based on the number of units reimbursed at each product's drug benefit price.

(2) The formula set out in subsection 2 (1.1) of the Regulation is amended by striking out “50%” and substituting “35%”

(3) The formula set out in subsection 2 (1.1) of the Regulation is amended by striking out “35%” and substituting “25%”

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

(11) For the purposes of section 12.1 of the Act, a “rebate” does not include the value of a benefit that is provided in accordance with ordinary commercial terms that meet all of the following conditions:

1. The benefit is provided in the ordinary course of business in the supply chain system of interchangeable products between any of a manufacturer, a wholesaler, an operator of a pharmacy or a company that owns, operates or franchises pharmacies.
2. The value of the benefit is set out in a written agreement between any of a manufacturer, a wholesaler, an operator of a pharmacy and a company that owns, operates or franchises pharmacies.
3. The benefit relates to an ordinary commercial relationship that is any of the following:

- i. a prompt payment discount,
- ii. a volume discount,
- iii. a distribution service fee.

3. Section 7 of the Regulation is revoked and the following substituted:

7. Where it is proposed that the strength and dosage form of a product be designated as interchangeable and it is proposed that it also be designated as a listed drug product under the *Ontario Drug Benefit Act*, an additional condition to be met in order for it to be designated as interchangeable is that the proposed drug benefit price must be no greater than the price permitted under that Act for the strength and dosage form of the product.

4. (1) Paragraphs 4, 5, 5.1, 5.2 and 6 of subsection 8 (1) of the Regulation are revoked and the following substituted:

4. If the product is a listed drug product under the *Ontario Drug Benefit Act*, the price of the product may not be more than the drug benefit price permitted under that Act where it is supplied to an eligible person under that Act.
5. Subject to paragraph 6, if the product is a listed drug product under the *Ontario Drug Benefit Act*, but the manufacturer is not selling the product for the purpose of supplying it to an eligible person under that Act, the manufacturer shall not sell the product at a price higher than 50 per cent of the drug benefit price of the original product as set out in the Formulary on the date the product was first proposed for designation as interchangeable with the original product.
6. If the price set out in paragraph 5 is lower than the drug benefit price permitted under the *Ontario Drug Benefit Act*, then the manufacturer shall not sell the product at a price higher than the drug benefit price permitted under the *Ontario Drug Benefit Act*.

(2) Paragraph 5 of subsection 8 (1) of the Regulation is amended by striking out “50 per cent” and substituting “35 per cent”.

(3) Paragraphs 4, 5 and 6 of subsection 8 (1) of the Regulation are revoked and the following substituted:

4. If the product is a listed drug product under the *Ontario Drug Benefit Act*, the manufacturer shall not sell the product at a price higher than the drug benefit price permitted under that Act whether or not the product is supplied for the purposes of that Act.

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

9. If required by the executive officer, the manufacturer of a product that has been designated as interchangeable shall inform the executive officer of the price that the manufacturer receives for the product, net of the value of any professional allowances or ordinary commercial terms.

(5) Subsection 8 (3) of the Regulation is revoked.

5. The Regulation is amended by adding the following section:

9. (1) A drug product that is a private label product shall not be designated as interchangeable.

(2) In this section,

“private label product” includes a drug product in respect of which,

- (a) the manufacturer applying for the designation of the product as interchangeable does not directly fabricate the product itself, and
 - (i) is not controlled by a person that directly fabricates the product, or
 - (ii) does not control the person that directly fabricates the product;
- (b) the manufacturer does not have an arms length relationship with an operator of a pharmacy or a company that owns, operates or franchises pharmacies; and
- (c) the product is to be supplied under a marketing arrangement associating the product with one or more operators of pharmacies or companies that own, operate or franchise pharmacies.

6. Schedule 1 to the Regulation is amended by striking out the paragraph that begins “Operators of pharmacies” under the heading “Reporting”.

7. (1) Subject to subsections (2) and (3), this Regulation comes into force on May 15, 2010.

(2) Subsection 2 (2) and subsection 4 (2) come into force on April 1, 2011.

(3) Section 1 and subsections 2 (3) and 4 (3) come into force on April 1, 2012.

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

1. (1) The formula set out in subsection 1 (9) of Ontario Regulation 201/96 is amended by striking out “20%” and substituting “5%”.

(2) Subsection 1 (11) of the Regulation is revoked and the following substituted:

(11) For the purposes of section 11.5 of the Act, a “rebate” does not include the value of a benefit that is provided in accordance with ordinary commercial terms that meet all of the following conditions:

1. The benefit is provided in the ordinary course of business in the supply chain system of listed drug products that are designated as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* between any of a manufacturer, a wholesaler, an operator of a pharmacy or a company that owns, operates or franchises pharmacies.
2. The value of the benefit is set out in a written agreement between any of a manufacturer, a wholesaler, an operator of a pharmacy and a company that owns, operates or franchises pharmacies.
3. The benefit relates to an ordinary commercial relationship that is any of the following,
 - i. a prompt payment discount,
 - ii. a volume discount,
 - iii. a distribution service fee.

(12) For the purposes of section 11.5 of the Act, a “rebate” does not include the value of a benefit provided in accordance with ordinary commercial terms with respect to a listed drug product that is not interchangeable where the ordinary commercial terms are a discount for prompt payment.

2. (1) Paragraph 1 of subsection 11 (1) of the Regulation is amended by striking out “50 per cent” and substituting “25 per cent”.

(2) Paragraph 2 of subsection 11 (1) of the Regulation is amended,

- (a) by striking out “Subject to paragraph 3, if” at the beginning and substituting “If”.**
- (b) by striking out “50 per cent” and substituting “25 per cent”.**

(3) Paragraph 3 of subsection 11 (1) of the Regulation is revoked.

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

(5) Subsection 11 (2) of the Regulation is amended by striking out “Paragraphs 1, 2 and 3” at the beginning and substituting “Paragraphs 1 and 2”.

3. The Regulation is amended by adding the following section:

12.0.2 (1) A drug product that is a private label product shall not be designated as a listed drug product.

(2) In this section,

“private label product” includes a drug product in respect of which,

- (a) the manufacturer applying for the designation of the product as a listed drug product does not directly fabricate the product itself, and
 - (i) is not controlled by a person that directly fabricates the product, or
 - (ii) does not control the person that directly fabricates the product;
- (b) the manufacturer does not have an arms length relationship with an operator of a pharmacy or a company that owns, operates or franchises pharmacies; and
- (c) the product is to be supplied under a marketing arrangement associating the product with one or more operators of pharmacies or companies that own, operate or franchise pharmacies.

4. (1) Paragraph 5 of subsection 12.1 (1) of the Regulation is amended by striking out “paragraphs 6, 6.1 and 6.2” and substituting “paragraphs 6.1, 6.2 and 6.3”.

(2) Paragraph 6 of subsection 12.1 (1) of the Regulation is revoked.

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

6.3 Paragraph 5 does not apply with respect to a product that has been designated as interchangeable with an original product where,

- i. the original product is a listed drug product and one or more products have been designated as interchangeable with it for more than 10 years, or

- ii. the original product was but is no longer a listed drug product and has not been a listed drug product for more than five years.

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

- 8. If required by the executive officer, the manufacturer of a product that has been designated as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* shall inform the executive officer of the price that the manufacturer receives for the product, net of the value of any professional allowances or ordinary commercial terms.

(5) Subsection 12.1 (2) of the Regulation is amended by striking out “October 1, 2006” at the end and substituting “May 15, 2010”.

(6) Subsection 12.1 (3) of the Regulation is revoked and the following substituted:

- (3) Where the circumstances described in paragraph 6.1, 6.2 or 6.3 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,
 - (a) in respect of a product for which the only applicable circumstances are those set out in paragraph 6.1 or 6.2 of subsection (1), in no case may the interchangeable product be priced higher than the original product;
 - (b) in respect of a product for which the only applicable circumstances are those set out in paragraph 6.1 of subsection (1), if the circumstance set out in subparagraph 6.1 i no longer applies, the drug benefit price of the product shall revert to a price that is less than or equal to 25 per cent of the drug benefit price of the original product as set out in the Formulary on the date that the product was first proposed for designation as a listed drug product;
 - (c) in respect of a product for which the only applicable circumstances are those set out paragraph 6.3 of subsection (1), the drug benefit price may only be higher than the price of the original product where the executive officer considers such a price to be in the public interest, having regard to the matters set out in subsection 22 (2) of the Act and anything else the executive officer considers relevant; and
 - (d) in respect of a product for which the only applicable circumstances are those set out in paragraph 6.1 or 6.3 of subsection (1), the executive officer shall not increase the drug benefit price more than once every five years.

5. (1) Subsection 13 (2) of the Regulation is revoked and the following substituted:

(2) 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 shall be determined as follows:

1. Ten per cent if the pharmacy is a Category 2, 3 or 4 pharmacy, unless paragraph 3 or 4 applies.
2. Eight per cent if the pharmacy is a Category 1 pharmacy, unless paragraph 3 or 4 applies.
3. Five per cent if the pharmacy has not purchased at least 75 per cent of the products it supplies under the Act from a comprehensive wholesaler.
4. If the value of the mark-up applying paragraphs 1, 2 or 3 is greater than \$125, then the mark-up is \$125.

(2) Subsection 13 (4) of the Regulation is revoked and the following substituted:

(4) For the purpose of subclause 6 (2) (c) (i) of the Act, the dispensing fee for a listed drug product is,

- (a) for a product dispensed in a Category 1 pharmacy, \$8.00;
- (b) for a product dispensed in a Category 2 pharmacy, \$9.00;
- (c) for a product dispensed in a Category 3 pharmacy, \$10.00; and
- (d) for a product dispensed in a Category 4 pharmacy, \$11.00.

(5) For the purposes of this section, pharmacies shall be classified as Category 1, 2, 3 or 4 pharmacies based on criteria that include,

- (a) the Rurality Index of Ontario;
- (b) the number of pharmacies within the geographic area served by the pharmacy;
- (c) the distance between the pharmacy and other pharmacies; and
- (d) the volume of claims submitted for payment under the Act by the operator of the pharmacy.

(6) In this section,

“comprehensive wholesaler” means a wholesaler that,

- (a) has as its principal business the business of distributing pharmaceutical and other consumer products;
- (b) carries in stock and has available for sale to an operator of a pharmacy at least 80% of the listed drug products and listed substances in the Formulary;
- (c) is prepared to supply products to any operator of a pharmacy in Ontario that regularly orders from the wholesaler and pays the wholesaler; and
- (d) has an arms-length relationship with all manufacturers, operators of pharmacies and companies that own, operate or franchise pharmacies.

(3) Subsection 13 (4) of the Regulation is revoked and the following substituted:

(4) For the purpose of subclause 6 (2) (c) (i) of the Act, the dispensing fee for a listed drug product is,

- (a) for a product dispensed in a Category 1 pharmacy, \$8.20;
- (b) for a product dispensed in a Category 2 pharmacy, \$9.22;
- (c) for a product dispensed in a Category 3 pharmacy, \$10.25; and
- (d) for a product dispensed in a Category 4 pharmacy, \$11.28.

(4) Subsection 13 (4) of the Regulation is revoked and the following substituted:

(4) For the purpose of subclause 6 (2) (c) (i) of the Act, the dispensing fee for a listed drug product is,

- (a) for a product dispensed in a Category 1 pharmacy, \$8.40;
- (b) for a product dispensed in a Category 2 pharmacy, \$9.45
- (c) for a product dispensed in a Category 3 pharmacy, \$10.50; and
- (d) for a product dispensed in a Category 4 pharmacy, \$11.55.

(5) Subsection 13 (4) of the Regulation is revoked and the following substituted:

(4) For the purpose of subclause 6 (2) (c) (i) of the Act, the dispensing fee for a listed drug product is,

- (a) for a product dispensed in a Category 1 pharmacy, \$8.62;
- (b) for a product dispensed in a Category 2 pharmacy, \$9.69;
- (c) for a product dispensed in a Category 3 pharmacy, \$10.77; and
- (d) for a product dispensed in a Category 4 pharmacy, \$11.85.

(6) Subsection 13 (4) of the Regulation is revoked and the following substituted:

(4) For the purpose of subclause 6 (2) (c) (i) of the Act, the dispensing fee for a listed drug product is,

- (a) for a product dispensed in a Category 1 pharmacy, \$8.83;
- (b) for a product dispensed in a Category 2 pharmacy, \$9.93
- (c) for a product dispensed in a Category 3 pharmacy, \$11.04; and
- (d) for a product dispensed in a Category 4 pharmacy, \$12.14.

6. Schedule 3 to the Regulation is amended by striking out the paragraph that begins “Operators of pharmacies” under the heading “Reporting”.

7. (1) Subject to subsections (2) to (6), this Regulation comes into force on the day it is filed.

(2) Sections 1, 2, 3 and 4, subsections 5 (1) and (2) and section 6 come into force on May 15, 2010.

(3) Subsection 5 (3) comes into force on April 1, 2011.

(4) Subsection 5 (4) comes into force on April 1, 2012.

(5) Subsection 5 (5) comes into force on April 1, 2013.

(6) Subsection 5 (6) comes into force on April 1, 2014.