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.

1. (1) The definition of "Formulary" in subsection 1 (1) of Regulation 935 of the Revised Regulations of Ontario, 1990 is revoked.

(2) The definition of "original product" in subsection 1 (1) of the Regulation is revoked and the following substituted:

"original product" means the original source of a drug product in a particular strength and dosage form that is or was designated on or after October 1, 2006 as a listed drug product by the executive officer or under Ontario Regulation 201/96 (General) under the *Ontario Drug Benefit Act* before October 1, 2006 or that was listed as a drug product under Regulation 868 of the Revised Regulations of Ontario, 1990 (General) or the Parcost C.D.I. prescribed under Ontario Regulation 839/84 as it read on November 30, 1986;

(3) The definition of "original product" in subsection 1 (1) of the Regulation is revoked and the following substituted:

"original product" means the original source of a drug product in a particular strength and dosage form;

(4) Subsections (1.2), (1.3), (2), (3), (4) , (5) and (6) of the Regulation are revoked and the following substituted:

(2) For the purposes of subsection 1 (2) of the Act,

"therapeutic substitution" means the substitution of a drug that contains chemically different active ingredients that are considered to be therapeutically equivalent, without authorization from a person authorized to prescribe drugs within the scope of his or her practice of a health profession.

2. Sections 2 and 3 of the Regulation are revoked and the following substituted:

2. (1) For the purposes of section 12.1 of the Act,

"professional allowance", in the definition of "rebate", means, subject to subsection (2), a benefit, in the form of currency, services or educational materials that are provided by a manufacturer to persons listed in subsection 12.1 (1) of the Act for the purposes of direct patient care as set out in paragraphs 1 to 8 of this subsection:

1. Continuing education programs that enhance the scientific knowledge or professional skills of pharmacists, if held in Ontario.

2. Continuing education programs for specialized pharmacy services or specialized certifications, if held in North America.

3. Clinic days provided by pharmacists to disseminate disease or drug-related information targeted to the general public including flu shot clinics, asthma clinics, diabetes management clinics, and similar clinics. For this purpose, a "clinic day" includes any additional staff to support the clinic day or the regular pharmacy business while the pharmacist is hosting a clinic day, during that day.

4. Education days provided by pharmacists that are targeted to the general public for health protection and promotion activities. Such education days must be held in the pharmacy, or a school, long-term care home, community centre, place of worship, shopping mall, or a place that is generally similar to any of these. For this purpose, an "education day" includes any additional staff to support the education day or the regular pharmacy business while the pharmacist is hosting an education day, during that day.

5. Compliance packaging that assists their patients with complicated medication regimes.

6. Disease management and prevention initiatives such as patient information material and services, blood pressure monitoring, blood glucose meter training, asthma management and smoking cessation, used in their pharmacy. For this purpose, "disease management and prevention initiatives" includes any additional staff required to support these initiatives or the regular pharmacy business while the pharmacist is hosting a disease management and prevention initiative, during the time it is being held.

7. Private counselling areas within their pharmacy.

8. Hospital in-patient or long-term care home resident clinical pharmacy services, such as medication reconciliation initiatives or other hospital or long-term care home-

identified clinical pharmacy priorities. For this purpose, “clinical pharmacy services” includes the costs of any additional staff required to support these services or the regular pharmacy business while the pharmacist is hosting a clinical pharmacy service, during the time it is being held.

(2) A benefit is not a professional allowance if the contents of the Code of Conduct established under subsection 11.5 (15) of the *Ontario Drug Benefit Act*, and as set out in Schedule 1, are not complied with.

3. (1) Subsection 6 (1) of the Regulation is amended by striking out “Minister” in the portion before clause (a) and substituting “executive officer”.

(2) Clause 6 (1) (b) of the Regulation is revoked and the following substituted:

(b) a letter authorizing the executive officer to gain access to all information with respect to the product in the possession of Health Canada, the Patented Medicine Prices Review Board established under section 91 of the *Patent Act* (Canada), the government of any province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health and authorizing the executive officer to disclose any information with respect to the product in the possession of the Ministry to Health Canada, the Patented Medicine Prices Review Board, the government of a province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health;

(3) Clauses 6 (1) (d) and (e) of the Regulation are revoked and the following substituted:

(d) the proposed drug benefit price of the product, where it is proposed that the product be designated as a listed drug product under the *Ontario Drug Benefit Act*, and a proposed manufacturer’s list price where it is not proposed that the product be so designated;

(e) evidence that the manufacturer is able to supply the product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the product where it is proposed that the product be designated as a listed drug product under the *Ontario Drug Benefit Act*;

(4) Subsection 6 (2) of the Regulation is amended by striking out “Minister” in the portion before paragraph 1 and substituting “executive officer”.

(5) Section 6 of the Regulation is amended by adding the following subsection:

(8) Anything submitted to the Minister under this section before October 1, 2006 shall be deemed to have been submitted to the executive officer, and any authorization given to the Minister shall be deemed to have been given to the executive officer.

4. (1) Subsection 7 (1) of the Regulation is amended by adding "where it is proposed that the product be designated as a listed drug product under the *Ontario Drug Benefit Act*" at the end.

(2) Subsection 7 (2) of the Regulation is revoked and the following substituted:

(2) A strength and dosage form of a product shall not be designated as interchangeable with other products unless it meets the following conditions:

1. If the original product is a listed product the drug benefit price proposed to the executive officer under clause 6 (1) (d) must be less than or equal to 50 per cent of the drug benefit price, as set out in the Formulary, of the product with which it would be interchangeable.

2. Subject to paragraph 3, if the original product was but is no longer a listed drug product, the drug benefit price of the product proposed to the executive officer under clause 6 (1) (d) must be less than or equal to 50 per cent of the drug benefit price of the original product that was set out in the Formulary immediately before its removal.

3. If the original product was removed from the Formulary as a listed drug product before May 27, 1996, the drug benefit price of the product proposed to the executive officer under clause 6 (1) (d) must be less than or equal to 50 per cent of the best available price that was set out in the Formulary immediately before the removal of the original product.

4. In addition to the applicable conditions under paragraphs 1, 2 and 3, where the product is to be designated as a listed product under the *Ontario Drug Benefit Act*, and if required by the executive officer, the manufacturer of the product shall enter into an agreement with the executive officer that specifies any volume discount or other amount that may be payable by the manufacturer to the Minister of Finance, and shall agree that the executive officer may make public the following information, and that information only, with respect to the agreement:

    i. The name of the manufacturer.

    ii. The subject-matter of the agreement.

    iii. The fact of entering into or terminating the agreement.

5. (1) Paragraph 1 of section 8 of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(2) Paragraph 3 of section 8 of the Regulation is amended by adding "where the product is designated as a listed drug product under the *Ontario Drug Benefit Act*" at the end.

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

4. Subject to paragraph 5, if the product is a listed drug product under the *Ontario Drug Benefit Act*, the drug benefit price of the product may not be more than the price that could be proposed to the executive officer under subsection 7 (2).

5. Paragraph 4 does not apply to a product that is designated as interchangeable with an original product where the original product has the same drug benefit price on the Formulary as the interchangeable product, or has no drug benefit price on the Formulary but in no case may the interchangeable product be priced higher than the original product.

6. Where a product is designated as a listed drug product under the *Ontario Drug Benefit Act*, and if required by the executive officer, the manufacturer of the product shall enter into and remain a party to an agreement with the executive officer that specifies any volume discount or other amount that may be payable by the manufacturer to the Minister of Finance, and shall agree that the executive officer may make public the following information, and that information only, with respect to the agreement:

    i. The name of the manufacturer.

    ii. The subject-matter of the agreement.

    iii. The fact of entering into or terminating the agreement.

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

7. If the drug product has not been designated as a listed drug product under the *Ontario Drug Benefit Act*, the manufacturer of the product shall give the executive officer notice of every change in the manufacturer's list price for the drug product.

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

(2) For greater certainty, the conditions set out in subsection (1) apply whether the designation of the product as an interchangeable product took place before, on or after October 1, 2006.

6. The Regulation is amended by adding the following Schedule:

SCHEDULE 1
CODE OF CONDUCT

The Code of Conduct is intended to establish system-wide guidance governing the use of professional allowances to be paid by manufacturers to operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents.

Where the term "representative" is used in this Code of Conduct, it means an officer, director, employee, or agent.

FUNDAMENTAL PRINCIPLES

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 the definition of "professional allowance" in subsection 2 (1) of the regulation.

2. All persons involved in the drug distribution system must operate transparently. To act transparently, manufacturers, operators of pharmacies, or companies that own, operate or franchise pharmacies, including their directors, officers, employees or agents must make the executive officer and other stakeholders knowledgeable of, and fully understand, the flow of funds in the drug products supply chain. This includes recording and reporting all such payments as required by the executive officer, and being subject to audit by the Ministry or a third party.

3. All suppliers of drug products as well as operators of pharmacies, or companies that own, operate or franchise pharmacies, including their directors, officers, employees or agents, must commit to abide by this Code of Conduct. Any breach of the Code will be subject to enforcement as set out in the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*.

USE OF PROFESSIONAL ALLOWANCES

Operators of pharmacies or companies that own, operate or franchise pharmacies may use professional allowances. Programs and information contained in educational materials must be full, factual and without intent to mislead.

Professional allowances may never be used for:

1. Advertising or promotional materials, such as store flyers, except in association with clinic days or education days mentioned in paragraphs 3 and 4 of the definition of “professional allowance” in subsection 2 (1) of the regulation.

2. Entertainment, social and sporting events.

3. Meals and travel not directly associated with a program referred to in paragraphs 1 to 4 of the definition of “professional allowance” in subsection 2 (1) of the regulation.

4. Convention displays.

5. Personal gifts provided to operators of pharmacies, or companies that own, operate or franchise pharmacies, including their directors, officers, employees or agents.

6. Staff wages and benefits, except as provided for in paragraphs 3 and 4 of the definition of “professional allowance” in subsection 2 (1) of the regulation.

7. Packaging costs and delivery services in respect of a prescription and dispensing fees.

8. Taxes.

9. Inventory costs.

10. Fees or penalties for inventory adjustments.

11. Purchases of sales and prescription-related data.

12. Fees for listing products in inventory.

13. Renovations, leasehold improvements and similar matters.

14. Store fixtures.

15. Real estate purchases or sales, encumbrances, leases or rent.

Professional allowances are to be calculated based on the following criteria:

1. Reasonable costs to provide direct patient care as set out in paragraphs 1 to 8 of the definition of “professional allowance” in subsection 2 (1) of the regulation.

2. Reasonable frequency of providing direct patient care as set out in paragraphs 1 to 8 of the definition of “professional allowance” in subsection 2 (1) of the regulation.

3. A reasonable number of patients per pharmacy.

MANUFACTURERS' REPRESENTATIVES

Manufacturers' representatives shall conduct business ethically and in a manner that is in the best interest of patients.

Any information provided by manufacturers' representatives, whether written or oral, must be full, factual and without misrepresentation.

Manufacturers shall be held responsible for the behaviour of their representatives.

PHARMACY REPRESENTATIVES

Pharmacy representatives shall conduct business ethically and in a manner that is in the best interest of their patients.

Pharmacies must not make procurement and purchasing decisions based solely on the provision of professional allowances.

REPORTING

Manufacturers will report to the executive officer the amount of professional allowance paid to each operator of a pharmacy, or company that owns, operates or franchises pharmacies, including their directors, officers, employees or agents, in as much detail as is required by the executive officer and at times required by the executive officer. The report must be signed by two officers of the manufacturer or by the manufacturer's auditors, as may be required by the executive officer.

Operators of pharmacies, or companies that own, operate or franchise pharmacies will report to the executive officer the amount of professional allowance received from each manufacturer in as much detail as is required by the executive officer and at times required by the executive officer. The report must be signed by two officers of the operator of the pharmacy, or company that owns, operates or franchises pharmacies, or by their auditors, as may be required by the executive officer.

7. (1) Subject to subsection (2), this Regulation comes into force on October 1, 2006.

(2) Subsections 1 (3), 3 (3) and 5 (2) and (4) come into force on April 1, 2007.