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) The definitions of "Formulary" and "Ministry" in subsection 1 (1) of Ontario Regulation 201/96 are revoked and the following substituted:

"Ministry" means the Ministry of Health and Long-Term Care;

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

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

(3) Subsections 1 (1.1), (1.2), (2), (3), (4) and (7) 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.

(3) The executive officer may enter into agreements for the purposes of carrying out his or her functions under clause 1.1 (2) (a) of the Act.

(4) The executive officer may, in writing, delegate his or her authority under clause 1.1 (2) (c), (f) or (g) of the Act or subsection 1 (3) of this Regulation to any person employed in the Ministry.

(5) For greater clarity, the power of the executive officer under clause 1.1 (2) (f) of the Act to negotiate agreements includes the power to enter into such agreements that have been negotiated.

(6) The executive officer shall commence paying operators of pharmacies for professional services under clause 1.1 (2) (j) of the Act no later than April 1, 2007.

(7) For the purposes of subsection 1.4 (2) of the Act,

"Association" means the Ontario Pharmacists' Association.

(8) For the purposes of section 11.5 of the Act,

"professional allowance", in the definition of "rebate", means, subject to subsections (9) and (10), a benefit, in the form of currency, services or educational materials that are provided by a manufacturer to persons listed in subsection 11.5 (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.

(9) Where the value of all of the benefits provided for in subsection (8) exceeds, with respect to all of a manufacturer's listed drug products or listed substances, the value of X in the formula below, then the benefits that are in excess of X are a rebate and not a professional allowance:

$$X = 20\% \text{ of } (P - V)$$

where,

"X" is the total dollar amount of professional allowances that may be provided by a manufacturer to persons listed in subsection 11.5 (1) of the Act;

"P" is the total dollar amount of a manufacturer's drug products reimbursed under the Act based on the number of units reimbursed at each product's drug benefit price;

"V" is the total dollar value of any volume discount or any other amount of payment that was made to the Minister of Finance under an agreement entered into under this Regulation or Regulation 935 of the Revised Regulation of Ontario, 1990 (General) made under the *Drug Interchangeability and Dispensing Fee Act* for those products reflected in P.

(10) A benefit is not a professional allowance if the contents of the Code of Conduct established under subsection 11.5 (15) of the Act, and as set out in Schedule 3, are not complied with.

(11) The executive officer shall, no later than October 1, 2008, begin a review of the Code of Conduct as set out in Schedule 3 and in Regulation 935 of the Revised Regulations of Ontario, 1990 (General) under the *Drug Interchangeability and Dispensing Fee Act*, and of the definition of "professional allowance" set out in this Regulation and in Regulation 935.

2. (1) Clause 2 (3) (b) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

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

(4) Information received by the Minister before October 1, 2006 shall be deemed to have been received by the executive officer.

3. (1) Paragraph 3 of subsection 3 (1) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

(2) Subsection 3 (3) of the Regulation is amended by striking out "Minister" in the portion before clause (a) and substituting "executive officer".

(3) Clause 3 (3.1) (a) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(4) Clause 3 (3.1) (b) of the Regulation is amended is amended by striking out "Minister" and substituting "executive officer".

(5) Clause 3 (3.1) (c) of the Regulation is amended is amended by striking out "Minister" and substituting "executive officer".

(6) Subsection 3 (3.3) of the Regulation is amended is amended by striking out "Minister" and substituting "executive officer".

(7) Subparagraph 1 ii of subsection 3 (4) of the Regulation is revoked and the following substituted:

ii. a product that is a facilitated access drug product funded under the Ontario Drug Benefit Program.

(8) Subparagraph 1 vi of subsection 3 (4) of the Regulation is amended by striking out "under paragraph 2 of subsection 9 (1)" at the end.

(9) Subparagraph 1 viii of subsection 3 (4) of the Regulation is amended by striking out "section 8" and substituting "section 16".

(10) Clause 3 (5) (a) of the Regulation is amended is amended by striking out "Minister" and substituting "executive officer".

(11) Clause 3 (5) (b) of the Regulation is amended by striking out "Director of the Drug Programs Branch of the Ministry" and substituting "executive officer".

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

(10) An application submitted to the Minister before October 1, 2006 shall be deemed to have been submitted to the executive officer for the purposes of this section.

4. (1) Subsection 4 (6) of the Regulation is amended,

(a) by striking out "Minister" in the portion before clause (a) and substituting "executive officer";

(b) by striking out "Minister's" in clause (a) and substituting "executive officer's"; and

(c) by striking out "Minister's" in clause (b) and substituting "executive officer's".

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

(6.1) For the purposes of subsection (6), a written notification submitted to the Minister before October 1, 2006 shall be deemed to have been submitted to the executive officer.

5. Sections 7, 7.2, 8, 9 and 10 of the Regulation are revoked.

6. Section 11 of the Regulation is revoked and the following substituted:

CONDITIONS FOR DESIGNATION OF LISTED DRUG PRODUCTS

11. A strength and dosage form of a product that has been submitted for designation as an interchangeable product under the *Drug Interchangeability and Dispensing Fee Act* shall not be designated as a listed drug product unless the manufacturer submits the information required under section 12 and the following conditions are met:

1. If the original product is a listed drug product, the drug benefit price of the product proposed to the executive officer under clause 12 (1) (d) must be less than or equal to 50 per cent of the drug benefit price of the original product as set out in the Formulary.

2. Subject to paragraph 3, if the product is an original product that was but is no longer a listed drug product, the drug benefit price of the product proposed to the executive officer under clause 12 (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 it existed by regulation at the time, as a listed product before May 27, 1996, the drug benefit price of the product

proposed to the executive officer under clause 12 (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, 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.

7. (1) Subsection 12 (1) of the Regulation is amended by striking out "Minister" in the portion before clause (a) and substituting "executive officer".

(2) Clause 12 (1) (a) of the Regulation is revoked and the following substituted:

(a) either,

(i) evidence that Health Canada has approved the product for sale in Canada, a copy of the product's drug notification form issued by Health Canada and, subject to subsection (2), a copy of the product monograph approved by Health Canada, or

(ii) evidence that an application has been made to Health Canada to approve the product for sale in Canada, and evidence satisfactory to a panel of experts established for the purpose that the product meets at least one of the following criteria:

A. The product is a new chemical entity that is effective for the treatment of an immediately life-threatening disease or other serious disease for which it offers substantial improvements on significant outcomes, including improved efficacy, safety and tolerability and quality of life over other available drug therapies in Canada, or for which no treatment or no other effective drug therapy is currently available in Canada.

B. The product is a new chemical entity that would have, if designated as a listed drug product, the effect of saving or creating efficiencies

for the Government of Ontario, an average of at least $2,500,000 per year for the first three years the product is marketed in Ontario.

C. The product is a new chemical entity that would have, if designated as a listed drug product, the effect of saving the Ontario Drug Benefit Program an average of at least $250,000 per year for the first three years the product is marketed in Ontario;

(3) Clause 12 (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;

(4) Subsection 12 (1) of the Regulation is amended by adding the following clause:

(c) an estimate of the net costs to the Ontario Drug Benefit Program in a three-year period;

(5) Subsection 12 (2) of the Regulation is amended by striking out "Minister" in the portion before paragraph 1 and substituting "executive officer".

(6) Subsection 12 (4) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

(7) Section 12 of the Regulation is amended by adding the following subsections:

(7) 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:

1. The name of the manufacturer.

2. The subject-matter of the agreement.

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

(8) Despite subclause (1) (a) (ii), but subject to subsection (6), a product may not be designated as a listed drug product until evidence that satisfies subclause (1) (a) (i) is also received.

(9) 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, but where a decision on designation has not been made before October 1, 2006 and the estimate required by clause (1) (c) has not been submitted, a decision shall not be made until the estimate is submitted.

(10) In clause (1) (a),

"Government of Ontario" includes all ministries of the Government of Ontario, all programs and agencies funded by the Government of Ontario and all agencies that are established by Ontario statute or regulation but are not necessarily funded by the Government of Ontario.

8. Section 12.0.1 of the Regulation is revoked and the following substituted:

12.0.1 An agreement that was entered into under this section as it existed before October 1, 2006 continues in force until it expires according to its terms.

9. Section 12.1 of the Regulation is revoked and the following substituted:

CONDITIONS TO CONTINUE TO BE A DESIGNATED LISTED DRUG PRODUCT

12.1 (1) The following conditions must be met in order for a designated listed drug product to continue to be designated as a listed drug product:

1. The manufacturer of the product shall give the executive officer notice of any change made to the product, including a formulation change, and of any change in the ownership of the manufacturer.

2. The product must be authorized for sale under the *Food and Drugs Act* (Canada).

3. The manufacturer of the product must continue to be able to supply the product at the drug benefit price in a quantity that is sufficient to meet the demand for the product.

4. Where the manufacturer was a party to an agreement to which this paragraph, as it read before October 1, 2006, applied, the manufacturer shall continue to be a party to that agreement until it expires according to its terms.

5. Subject to paragraph 6, if the product has been designated as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* the drug benefit price of the

product may not be more than the price that could be proposed to the executive officer under section 11.

6. Paragraph 5 does not apply with respect to a product that has been 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.

7. 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.

(2) For greater certainty, the conditions set out in subsection (1) apply whether the designation as a listed drug product or as an interchangeable product under the *Drug Interchangeability and Dispensing Fee Act* took place before, on or after October 1, 2006.

10. (1) Subsection 13 (1) of the Regulation is amended by striking out "Part III of".

(2) Subsection 13 (2) of the Regulation is amended by striking out "10 per cent" and substituting "8 per cent".

(3) Subsection 13 (3) of the Regulation is revoked.

(4) Subsection 13 (4) of the Regulation is amended by striking out "$6.54" at the end and substituting "$7".

11. (1) Clause 14 (1) (a) of the Regulation is amended by striking out "subsections (2) and (3)" and substituting "subsection (2)".

(2) Subsections 14 (2) and (3) of the Regulation are revoked and the following substituted:

(2) The amount payable referred to in clause (1) (a) shall be the full amount payable for a shipment or order of a listed drug product less any amount charged for shipping and handling of the listed drug product.

12. Sections 15 and 16 of the Regulation are revoked and the following substituted:

15. (1) The drug benefit price of a drug for which there is not a listed drug product, and to which the executive officer has made the Act apply under section 16 of the Act, shall be the price agreed to by the manufacturer and the executive officer.

(2) The amount that the executive officer shall pay under subsection (1) shall be the amount as determined in section 6 of the Act and, if applicable, includes a compounding fee determined by the executive officer under subsection 17 (2) of the Act.

(3) The executive officer shall publish the price agreed to under subsection (1) on the Ministry's website.

13. (1) Section 17 of the Regulation is revoked and the following substituted:

17. (1) The amount the executive officer shall pay a physician under subsection 5 (3) of the Act is the amount calculated by adding the amounts determined under paragraphs 1, 2 and 3 and subtracting from that total the maximum co-payment that may be charged in respect of the supplying of a listed drug product for an eligible person:

1. The dispensing fee determined under subsection (2).

2. The drug benefit price set out opposite the listed drug product in the Formulary but, if there are other listed drug products that are interchangeable with the drug product, the drug benefit price shall be deemed to be the lowest of the drug benefit prices for the drug product and the listed drug products that are interchangeable with it.

3. A mark up equal to 10 per cent of the drug benefit price.

(2) The dispensing fee referred to in paragraph 1 of subsection (1) shall be,

(a) in the case of a physician whose office is within 20 kilometres of an accredited pharmacy, $4.28; and

(b) in any other case, $5.10.

(3) Subsections 6 (3), (4) and (5) of the Act and sections 14 and 15 of this Regulation apply with necessary modifications with respect to amounts payable by the executive officer to physicians under subsection 5 (3) of the Act.

(2) Paragraph 3 of subsection 17 (1) of the Regulation is revoked and the following substituted:

3. A mark up equal to 8 per cent of the drug benefit price.

14. (1) Subsection 18 (1) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(2) Subsection 18 (2) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(3) Subsection 18 (3) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(4) Subsection 18 (4) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(5) Subsection 18 (5) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(6) Paragraph 1 of subsection 18 (6) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

15. Subsection 19 (1) of the Regulation is amended by striking out "Minister" in the portion before clause (a) and substituting "executive officer".

16. Section 20 of the Regulation is revoked and the following substituted:

20. The amount payable by the executive officer to the operator of a pharmacy in respect of methadone provided to an eligible person is an amount determined by an agreement between the operator and the executive officer.

17. Section 20.1 of the Regulation is amended by striking out "Minister" and substituting "executive officer".

18. (1) Clause (b) of the definition of "allowable drug costs" in subsection 20.2 (2) of the Regulation is amended by striking out "under Part IX of the Formulary" and substituting "as specified in the Formulary".

(2) Paragraph 1 of subsection 20.2 (5) of the Regulation is revoked and the following substituted:

1. Until the eligible person's allowable drug costs for the fiscal period reach the deductible amount, the maximum co-payment that may be charged shall be the amount equal to the full amount otherwise payable by the executive officer under section 6 of the Act in respect of the supply of the drug product less,

i. if the drug product is supplied in a pharmacy operated in a hospital approved as a public hospital under the *Public Hospitals Act*, $4.17,

ii. if the drug product is supplied by a physician whose office is within 20 kilometres of an accredited pharmacy, 23 cents,

iii. if the drug product is supplied by a physician whose office is more than 20 kilometres from an accredited pharmacy, 27 cents, and

iv. in all other cases, the amount, if any, by which the dispensing fee exceeds $6.11.

(3) Subparagraph 3 ii of subsection 20.2 (5) of the Regulation is revoked.

19. (1) Subsection 21 (1) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(2) Subsection 21 (2) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

(3) Clause 21 (3) (b) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(4) Subsection 21 (4) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

(5) Subsection 21 (5) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

20. Section 22 of the Regulation is amended by striking out "Minister" and substituting "executive officer".

21. (1) The definition of "claim reversal" in subsection 23 (1) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

(2) Section 23 of the Regulation is amended by adding the following subsection:

(3) For the purposes of sections 24 to 30, anything submitted to or done by the Minister before October 1, 2006 shall be deemed to have been submitted to or done by the executive officer.

22. (1) Subsection 24 (1) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

(2) Paragraph 1 of subsection 24 (2) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(3) Paragraph 4 of subsection 24 (2) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

23. (1) Subsection 25 (1) of the Regulation is amended by striking out "Minister" in the portion before paragraph 1 and substituting "executive officer".

(2) Paragraph 6 of subsection 25 (1) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(3) Paragraph 9 of subsection 25 (1) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(4) Subsection 25 (2) of the Regulation is amended by striking out "Minister" in the portion before paragraph 1 and substituting "executive officer".

(5) Paragraph 3 of subsection 25 (2) of the Regulation is amended by striking out "Minister" in the portion before subparagraph i and substituting "executive officer".

(6) Subparagraph 3 ii of subsection 25 (2) of the Regulation is amended by striking out "Minister" and substituting "executive officer".

(7) Subsection 25 (4) of the Regulation is amended,

(a) by striking out "Minister" and substituting "executive officer"; and

(b) by striking out "section 8" and substituting "section 16".

in the portion before paragraph 1.

(8) Paragraph 1 of subsection 25 (4) of the Regulation is revoked and the following substituted:

1. The drug benefit price of the drug as determined under section 15 of this Regulation.

(9) Paragraph 2 of subsection 25 (4) of the Regulation is amended by striking out "Minister" at the end and substituting "executive officer".

24. Subsection 26 (3) of the Regulation is amended by striking out "Minister" in the portion before clause (a) and substituting "executive officer".

25. Section 27 of the Regulation is amended by striking out "Minister" wherever it appears in the portion before paragraph 1 and substituting in each case "executive officer".

26. Subsection 28 (1) of the Regulation is amended is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

27. Subsection 28.1 (1) of the Regulation is amended by striking out "Minister" wherever it appears and substituting in each case "executive officer".

28. Column 1 of the Table to subsection 29 (1) of the Regulation is amended,

(a) by striking out "Minister" and substituting "executive officer"; and

(b) by striking out "Part III of the Formulary" wherever it appears and substituting in each case "the Formulary".

29. Schedules 3 and 4 to the Regulation are revoked and the following substituted:

SCHEDULE 3
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 paragraphs 1 to 8 of the definition of "professional allowance" in subsection 1 (8) 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 1 (8) 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 1 (8) 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 1 (8) 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 1 (8) 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 1 (8) 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.

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

(2) Subsections 1 (2), 10 (2) and 13 (2) come into force on April 1, 2007.