

**Ontario Public Drug Programs
Ministry of Health and Long-Term Care**

**Public Consultation to Review the definition of
Professional Allowance and the Codes of Conduct**

October 3, 2008

Background

In 2006, the Ministry made some key legislative reforms to its drug legislation. One key reform was a change to the pharmacy reimbursement structure to permit pharmacists to accept professional allowances from drug manufacturers, which are to be used exclusively to fund patient care initiatives. These allowances are capped at 20 per cent of a pharmacy's total Ontario Drug Benefit sales and are governed by the Code of Conduct set out in the regulations under the *Ontario Drug Benefit Act* (ODBA) and the *Drug Interchangeability and Dispensing Fee Act* (DIDFA). The Code of Conduct requires manufacturers and pharmacies to report specific information relating to the payment, receipt and use of professional allowances, to submit this information to the Ministry, and to retain this information for audit purposes.

Since implementing the professional allowances framework, the Ministry has regularly answered questions on acceptable professional allowance expenditures and on reporting requirements, through Executive Officer Communications or bulletin board notifications to stakeholders. Ontario Public Drug Programs (OPDP) has also established a process in collaboration with the Ontario Pharmacists' Association and the Canadian Association of Chain Drug Stores, to regularly review requests for clarification. The OPDP continues to work with stakeholders relating to the successful submission of professional allowance reports.

In accordance with the regulatory requirement, the Executive Officer, on behalf of the Ministry of Health and Long-Term Care (Ministry), has initiated a review of the Code of Conduct and the definition of "professional allowance" and is inviting public comment from interested parties.

Following the review of written submissions, the Executive Officer intends to hold a stakeholder meeting to discuss the written proposals. The Ministry will provide further notice about the meeting date following the submission closing date.

Invitation to Provide Written Comments

Interested parties are invited to provide written comments on the Code of Conduct and the definition of "professional allowance" for the Executive Officer's consideration as part of the review. The Executive Officer will consider comments received on or before **January 9, 2009 at 5:00 p.m. EST** ("comment period").

If your submission includes a proposal to change the Code or the definition of professional allowance, please include a detailed explanation and rationale for the proposed change.

When preparing your submission, please consider the following:

- Does the definition of “professional allowance” require further clarification?
- Are there any provisions in the Code that require further clarification? Please identify the provision that requires further clarification.
- Currently, permitted uses for professional allowances fall into four categories. Are there any categories that should be added or specific categories that should be excluded?
- Please provide comments on the current reporting framework for professional allowances and recommendations to improve and facilitate the reporting process.

Please provide any other relevant comments in your submission. Please be as specific as possible with your recommendations and provide a full explanation for any suggested changes or additions.

Submission of Written Comments

Please submit your written comments to:

Helen Stevenson
Assistant Deputy Minister and
Executive Officer, Ontario Public Drug Programs
Ministry of Health and Long-Term Care
80 Grosvenor Street, 9th Floor
Hepburn Block, Queen’s Park
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While all submissions are appreciated and will be considered by the Executive Officer as part of the review, the Executive Officer is in no way bound to act on any of the submissions put forward. If the Executive Officer proposes changes to the Code of Conduct or the definition of “professional allowance” as a result of the review, stakeholders will be notified in accordance with the requirements contained in section 18 of the ODBA.

Please be advised that submissions received after the comment period may not be considered.

Statement about Comments

Please note that unless requested and otherwise agreed to 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 as part of its review. The Ministry may disclose materials or comments, or summaries of them, to other interested parties during and after the comment period.

An individual who makes a submission and who indicates an affiliation with an organization in his or her submission will be considered to have made his or her submission on behalf of the affiliated organization.

The Ministry will not disclose any personal information contained in a submission of an individual who does not specify an organizational affiliation in his or her submission without the individual's consent unless required by law. However, the Ministry may use and disclose the content of the individual's submission to assist the Ministry in its review.

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.

Content of Current Regulations under the ODBA Regulation and the DIDFA Regulation (Reproduced from O. Reg. 201/96 made under the ODBA)

(a) Definition of Professional Allowance

1.(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.*

(b) Code of Conduct

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, 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. 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. Revoked: O. Reg. 559/06, s. 4 (2).*
- 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, 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.*
- 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.

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