

## Ontario Public Drug Programs Division

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Proposal to amend Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* and Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act* to implement pharmacy reform initiatives and promote efficiencies for interchangeability listings on the Ontario Drug Benefit Formulary/Comparative Drug Index.

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July 23, 2015

### Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act*

The public drug program is facing continual demand for new drugs, rising costs related to pharmacy fees, and fewer opportunities to leverage savings through generic products. As a result, innovative solutions are required to keep the rate of program growth in check and ensure sustainable patient access to the highest quality of care in the long-term.

*Patients First: Ontario's Action Plan for Health Care* reflects a commitment on the part of the ministry to build a health-care system that is patient-centered. A sustainable drug system, working together with our partners, puts Ontario in the best position to ensure access for patients to drug products that they require.

The Ministry of Health and Long-Term Care (the “ministry”) is proposing to reform the Ontario Drug Benefit (ODB) program in order to make it more efficient, effective and sustainable.

Proposed amendments to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* are required to implement a number of changes to pharmacy payments and practices, as well as changes to particular programs, to reflect best evidence, increased value for money, and achieve better outcomes. The proposed initiatives would take effect on October 1, 2015. These initiatives are as follows:

- Reduce the mark-up percentage fee for high-cost drugs. The mark-up would be reduced from 8% to 6% for drug costs greater than or equal to \$1000 per claim.
- In the long-term care sector, reduce dispensing fees and enhance medication management to support appropriate prescribing, resulting in lower long-term care pharmacy costs. Dispensing fees paid to pharmacies for supplying listed drug products to long-term care home residents would be reduced by \$1.26 across all categories of pharmacies, including hospital outpatient dispensing pharmacies and community pharmacies in rural and remote areas.
- Optimize the quantity of medication dispensed for certain chronic care medications where patients have been on the same medication for years, in order to minimize unnecessary trips by patients to the pharmacy for the same prescription and reduce co-payment costs to patients. A limit on the number of dispensing fees would be established to allow for a maximum of 5 dispensing fees billed per year per patient per chronic therapy drug.

- Require patients to try more than one generic before the brand product is reimbursed by the ministry as a “no substitution” claim, in order to maximize the use of safe and effective generic alternatives.

### **Housekeeping changes to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act***

Housekeeping changes to Ontario Regulation 201/96 are included to clarify existing language relating to the current conditions for charging co-payments.

### **Regulation 935 made under the Drug Interchangeability and Dispensing Fee Act**

The ministry is also proposing to amend section 6 of Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act* to further streamline interchangeability designations for a small number of generic products. The proposed amendments would do the following:

- With respect to aqueous solutions that are currently exempt from the in vivo bioequivalence study requirement in section 6(1)(h) of the Regulation, remove the requirement that the aqueous solutions must be the “same volume” as the original product, and replace it with a requirement that the aqueous solution be the “same strength” as the original product.
- Exempt dermatological products from the in vivo bioequivalence study requirement in section 6(1)(h). To qualify for the exemption the product would have to contain one or more glucocorticoids as the only active ingredient(s), and have a declaration of equivalence from Health Canada with the original product or another listed interchangeable product with which it would be designated as interchangeable.
- Exempt products with a transdermal route of administration for systemic effect from the in vivo bioequivalence study requirement in clause 6(1)(h). To qualify for the exemption the product would have to have a declaration of equivalence from Health Canada with the original product or another listed interchangeable product with which it would be designated as interchangeable.

A copy of the draft regulations that propose to amend Ontario Regulation 201/96 and Regulation 935 are available on the Regulatory Registry website at:

<http://www.ontariocanada.com/registry/view.do?postingId=19202&language=en>

**The content of the final regulations are at the discretion of the Lieutenant Governor in Council (“LGIC”) who may make the regulations with any changes that the LGIC considers appropriate.**

Interested parties are invited to provide written comments on the proposed changes to the regulations as part of the review. The ministry will consider comments received on or before **August 24, 2015 at 5:00 p.m. EST** (“comment period.”). Please be advised that submissions received after the comment period may not be considered.

Please submit your written comments to:

Executive Officer, Ontario Public Drug Programs  
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: [PublicDrugPrgrms.moh@ontario.ca](mailto:PublicDrugPrgrms.moh@ontario.ca)

### **Statement about Comments**

Unless requested and otherwise agreed to by the ministry, all materials or comments received from organizations in response to the 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.