

Notice: Proposal to Reduce Administrative Burden to Drug Manufacturers and Pharmacies

October 28, 2019

On April 11, 2019 the government tabled its 2019 Budget. In the budget, the government committed to provide timely access to new clinically proven medicines and reduce the administrative burden for businesses and red tape for the industry wherever possible.

The purpose of this notice is to provide you with information on several opportunities that have been identified that, if approved, would reduce technical requirements, address discrepancies and misalignments with industry standards and policies in other provinces, territories (P/Ts) and nationally, and modernize existing processes for drug manufacturers and Ontario pharmacies. Specifically, the ministry is proposing a series of amendments to Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* (ODBA) and Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) to:

1. Remove the requirement for the Drug Notification Form (DNF) from all Ontario Drug Benefit Formulary drug submissions
2. Reduce requirements for biosimilar drug submissions to simplify and align with national processes
3. Permit generic drug price adjustments in accordance with the pan-Canadian generic pricing framework
4. Streamline drug submission requirements for generic line extension
5. Revoke provisions authorizing Ontario to conduct price review of certain single source generic products as the required pricing assessment is

already conducted through the current pan-Canadian generic pricing framework

6. Facilitate the management of drug shortages by allowing Ontario to provide short-term public funding, through the exemption of certain drug submission requirements, for clinically-appropriate alternate drugs that are not currently funded
7. Extend the submission window for electronic drug claim reversals from 7 days to 90 days
8. Amend the definition of the Ontario Drug Programs Reference Manual to facilitate the publication of future versions of the Manual
9. Modify the cap on ordinary commercial term (OCT) payments from 10% to 25%

A summary of the proposal and text of the draft amendments to the regulations are available on the Regulatory Registry website at:

<https://www.ontariocanada.com/registry/view.do?postingId=30831&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 **November 27, 2019 at midnight EST**. Please be advised that submissions received after this date may not be considered.

Please submit your written comments to:

Drugs and Devices Division
Ministry of Health
5700 Yonge Street, 3rd Floor
Toronto ON
M2M 4K5

Fax: 416-325-6647

E-mail: 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.