

# **Notice: Amendments to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* and Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act* to reduce Administrative Burden to Drug Manufacturers and Pharmacies**

**December 23, 2019**

The government is committed through the Open for Business/Red Tape Reduction initiative to provide timely access to new clinically proven medicines and reduce the administrative burden for businesses and red tape for the industry.

The Ministry of Health proposed a number of opportunities in response to feedback from stakeholders that would reduce technical requirements, address discrepancies and improve alignment with industry standards and policies in other provinces, territories (P/Ts) and nationally, and modernize existing processes for drug manufacturers and Ontario pharmacies.

Stakeholders were invited to provide written feedback through the Regulatory Registry on the proposed changes in fall 2019.

Following public consultations, the following changes are being made to Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* (ODBA) and Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA).

## **Effective January 1, 2020:**

1. Removal of the Drug Notification Form (DNF) for all submissions under the ODBA and DIDFA.
2. Simplified requirements for biosimilar drug product submissions.
3. Simplified requirements for generic line extension product submissions.
4. Revocation of provisions authorizing Ontario to conduct a price review of certain single-source generic products.
5. Amendment of the definition of the Ontario Drug Programs Reference Manual.

**Effective April 1, 2020:**

6. Extension of the period for electronic Ontario Drug Benefit (ODB) program claim reversals by pharmacies, through the province's Health Network System (HNS), from seven (7) days to ninety (90) days.

**Retroactive to April 1, 2018:**

7. Permittance of generic drug price adjustments due to price tier changes in accordance with the pan-Canadian generic pricing framework.

**Retroactive to November 1, 2019:**

8. Facilitation of the management of drug shortages by allowing the ministry to provide short-term public funding, through the exemption of certain drug submission requirements, for clinically-appropriate alternate drugs that are not currently funded.

**Additional Information****For drug manufacturers:**

- Manufacturers must continue to make submissions to the Drugs and Devices Division to have their products considered by the Executive Officer for listing and funding, in accordance with Ontario Regulation 201/96 under the ODBA and Regulation 935 under the DIDFA, as applicable.
- For more information on the specific submission requirements as a result of the amendments to the ODBA and DIDFA, please visit the ministry's website at: [Drug Submissions](#)
- Drug shortages are characterized based on various conditions including reported shortage status on Canada's drug shortage website, engagement with provincial stakeholders and national dialogue with the provinces and territories on the impact of the shortage. Alternative options are identified through provincial and national discussions, clinical consultation and literature review.
- The ministry considers the characteristics of the shortage when assessing a supply interruption: appropriate alternatives, temporary coverage timeline of the alternative product, communication with patients and stakeholders, financial impact and funding options of the

program, and impact to Ontarians. If deemed necessary, the ministry may list a product under the “Temporary Benefit Status” of the formulary for a limited period of time.

**For pharmacies:**

- The Ontario Drug Programs Reference Manual (the ‘Manual’) is a collection of approved policies, procedures and technical directions for pharmacies relating to Ontario Public Drug Programs. The updated Manual dated November 27, 2019 and posted on the Ministry’s website, reflects program and policy changes that have occurred and have been communicated through Executive Officer (EO) Notices, website postings and direct emails to pharmacies, since the last version of the Manual was published in September 2005.
  - The online updated version of the Manual dated November 27, 2019 [Ontario Drug Programs Reference Manual](#) will enable pharmacies to have timely access to current Ministry requirements and policies in a single document.
- The Extemporaneous Preparations policy changes from 2006 have been included in the updated Ontario Drug Programs Reference Manual to provide greater clarity for pharmacies in understanding what is eligible for funding under the Extemporaneous Preparations policy.
  - For further details regarding the entire Extemporaneous Preparations policy, please refer to Section 6.1 of the Manual dated November 27, 2019.
  - Overpayments due to claim submissions that do not comply with the updated Manual or Extemporaneous Preparations policy are subject to recovery, as of January 1, 2020.
- The electronic submission period extension is strictly an administrative and billing requirement for pharmacy payments. There is no impact to patients or patient care, as claim reversals occur at the pharmacy when a claim for a drug/product is no longer required or is processed in error and, prior to this change, were required to be submitted on paper.
- For additional information, please call ODB Pharmacy Help Desk at: 1-800-668-6641

**For all other Health Care Providers and the Public:**

- Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282