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

Regulation Amendments in support of Sustainability and Access for the Ontario Drug Benefit Program

Questions and Answers for Pharmacists

Responsible management of health care is part of the government's plan to build a better Ontario through its Patients First: Action Plan for Health Care, providing patients with faster access to the right care, better home and community care, the information they need to live healthy and a health care system that's sustainable for generations to come.

The Ministry of Health and Long-Term Care (the "ministry") is making changes to pharmacy payments, fees and program policies under the Ontario Drug Benefit (ODB) program to make the program more efficient, effective and responsive to today's patients.

These initiatives represent a fair and balanced approach to generating savings and will contribute to the Province's efforts to identify short- and longer-term opportunities to ensure continued patient access to drugs. These changes will enable the government to achieve savings of over $200 million annually when fully implemented, as per the 2015 Ontario Budget.

Amendments to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* will come into force on October 1, 2015 to support these ODB program changes. Updates to the ministry's Health Network System (HNS) will support these changes, where applicable and available.

All initiatives will be enforced in the manner outlined below.

For more information please visit the Ministry website at:
http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx

You may also contact the ODB Pharmacy Help Desk at 1-800-668-6641 or email your questions to: PublicDrugPrgrms.moh@ontario.ca

Mark-up Reduction for High-Cost Drugs

1. What is the new mark-up amount paid on high-cost drugs?

Effective October 1, 2015, for claims on which the drug cost is equal to or greater than $1,000.00, the mark-up will be 6% of the drug benefit price of the product dispensed.

For claims on which the total drug cost is less than $1,000.00, pharmacies will continue to receive an 8% mark-up on the drug benefit price of the product dispensed.

2. How will this change affect ODB recipients?

This change will not impact ODB recipients.

3. What will happen if I dispense a lower quantity of a high-cost drug?

Pharmacies are not permitted to dispense smaller quantities to keep the total drug cost below $1,000.00 to receive 8% markup. Pharmacists are reminded that ODB claims data is used for clinical purposes through the Drug Profile Viewer and pharmacy records must accurately reflect dispensing activities.

Dispensing Fee Reduction for Claims for Residents of Long-Term Care Homes

4. How will this change affect pharmacies dispensing medications to residents of Long-Term Care Homes?

Effective October 1, 2015, the dispensing fee for pharmacies dispensing to residents of Long-Term Care homes (LTCH) will be reduced by $1.26 for each prescription dispensed.

5. My pharmacy currently dispenses weekly to residents of LTCH. Will this change affect this medication delivery schedule?

No. The Regulation changes do not affect frequency of dispensing for LTCH residents. LTCH pharmacy service providers can continue to claim weekly dispensing fees, where weekly dispensing for LTCH residents is deemed appropriate.

6. How will this change affect residents of LTCH?

The reduction to the ODB dispensing fee reimbursed to LTCH pharmacy service providers is not expected to impact LTCH residents. Residents of LTCH may be charged up to $2.00 co-payment for each prescription, although some LTCH may have established alternate arrangements with their pharmacy service providers.

Maximizing the Quantity Dispensed for Chronic-Use Medications

7. How will this change affect prescriptions for chronic-use medications?

Effective October 1, 2015, pharmacies will only be entitled to receive a maximum of five (5) dispensing fees per 365-day period, beginning with the first dispensing transaction for an identified chronic-use medication on or after October 1, 2015. Pharmacists are encouraged to provide most ODB recipients with a 100 days' supply of most chronic-use medications.

8. What are the 15 categories of chronic-use medications that are affected?

Table 1: Chronic-use medications list

Chronic-Use Drug Category	ODB Drug Product Examples*
ACE Inhibitors	Enalapril, ramipril, quinapril
Angiotensin II Receptor Blockers	Candesartan, irbesartan, valsartan
Beta-Blockers	Atenolol, metoprolol, sotalol
Calcium Channel Blockers	Amlodipine, diltiazem, nifedipine
Other Drugs Used for Hypertension	Methyldopa, prazosin, terazosin
Other Cardiac Drugs	Amiodarone, digoxin, isosorbide, pentoxifylline
Statin Drugs Used to Lower Cholesterol	Atorvastatin, lovastatin, rosuvastatin
Other Drugs Used to Lower Cholesterol	Bezafibrate, ezetimibe, gemfibrozil
Oral Anti-diabetic Agents	Glyburide, metformin, saxagliptin
Diuretics	Furosemide, hydrochlorothiazide, indapamide
Drugs Used for GI Conditions	Famotidine, misoprostol, omeprazole, sucralfate
Drugs Used to Prevent Gout	Allopurinol
Oral Iron Replacement Therapy	Ferrous fumarate, ferrous gluconate
Drugs Used for Osteoporosis	Alendronate, raloxifene, risedronate
Drugs Used for Prostate Conditions	Dutasteride, silodosin, tamsulosin

*List is not exhaustive

The full list of medications that fall under the 15 categories of chronic-use medications that are subject to the 5 dispensing fees per 365-day period rule is posted on the ministry website at: http://www.health.gov.on.ca/en/pro/programs/drugs/opdp_eo/eo_communiq.aspx. This list will be updated on an as-needed basis.

9. Do the Regulation changes apply to all ODB recipients and all prescriptions?

ODB recipients who require more frequent dispensing due to an established physical, cognitive or sensory impairment, or because they are on a complex medication regimen where their safety is at risk, can continue to receive their chronic-use medications at more frequent intervals.

Where the dispenser has determined, in his or her professional opinion, that the ODB recipient is incapable of managing his/her medication regimen as a result of physical, cognitive or sensory impairment or a complex medication regimen where the recipient's safety is at risk, the dispenser is required to notify the prescriber with the rationale for the decision.

Documentation must include the reason for this opinion, the dispenser's notification to the prescriber, as well as a record of the authorization received from the ODB recipient (or person presenting the prescription) for dispensing in reduced quantities. The nature of the physical,

cognitive or sensory impairment or complex medication regimen must be clearly documented, including clinical or safety risks to the patient if larger quantities were dispensed.

These authorizations are valid for a period of 365 days and are required to be updated annually, and maintained as part of the ODB recipient's permanent pharmacy health record.

ODB recipients who are deemed to require more frequent dispensing will need to be assessed regularly to verify an ongoing need for more frequent dispensing. For example, a patient on a complex medication regimen may require assistance for a short period of time, in order to learn to manage their medications as directed, but once stabilized, may be capable of managing 100 day supplies.

The conditions for payment of a dispensing fee for chronic-use medications do not apply to Ontario Works (OW) recipients, LTCH residents and residents of publicly-funded residential care facilities listed on the ministry's website (i.e. Homes for Special Care). All extemporaneous preparations of chronic-use medications are also exempt from this change.

10. In cases where an ODB recipient does not meet the established exception criteria to the 5 fees per 365-day period policy but currently receives their medications in compliance packaging, are pharmacists able to charge the ODB recipient to continue receiving this service?

ODB recipients who require more frequent dispensing for a valid clinical reason will be able to qualify under the established exemptions. For all other ODB recipients who do not meet the established exemption criteria, the pharmacist shall not pass on any ODB-ineligible dispensing fees – that is, beyond the fifth dispensing transaction – to either the ODB recipient or their private insurer (if applicable). Passing new costs to ODB recipients is not the intent of this initiative.

11. Why are residents of registered retirement homes not exempt from this change?

Residents of retirement homes are not identified separately from other seniors receiving benefits under the ODB program. Retirement home residents who require compliance packaging to support more frequent dispensing for a valid clinical reason will qualify for more frequent dispensing under the established exemptions.

12. How does this change affect recipients of the Trillium Drug Program?

The limit of 5 annual dispensing fees on the 15 chronic-use drug categories applies to Trillium recipients once they have reached their deductible. To clarify, only claims submitted after the deductible has been met will be counted towards the 5 fee per 365 day period limit.

13. What technical support will be in place to support this change?

It is anticipated that Health Network System (HNS) changes will be implemented mid-2016, and at that time, **patient profiles will be reviewed back to October 1, 2015. Where 5 dispensing fees have been paid for a chronic-use medication, pharmacies will not be**

entitled to receive additional fees for 365 days after the first claim for that chronic-use medication. Until the HNS changes are implemented in 2016, it will be the responsibility of pharmacists and pharmacy staff to ensure their dispensing practices are in compliance with this initiative. Further information regarding the HNS changes will be provided prior to implementation of the changes.

14. How can pharmacists know if an ODB recipient has already had a chronic-use medication filled 5 or more times if they visit different pharmacies?

In accordance with the changes, all pharmacies are expected to dispense 100 day supplies of the included chronic-use medications for ODB recipients who are capable of managing a 100 days' supply. Pharmacists should counsel their patients and determine if and when prescriptions for chronic-use medications have been filled at other pharmacies. ODB recipients receiving 100 day supplies of chronic-use medications will not generate more than 5 fees in a 365 day period. Once the HNS changes are implemented, the number of fees for each ODB recipient for each chronic-use medication will be tracked and reviewed back to October 1, 2015, regardless of which pharmacy the ODB recipient has attended to receive their medications. Pharmacies submitting claims for ODB recipients for whom 5 dispensing fees have been paid for a chronic-use medication will not be entitled to receive additional fees until 365 days after the initial claim for that chronic-use medication.

15. What measures will be put in place to monitor this change in the absence of Health Network System changes?

After October 1, 2015, the ministry will actively monitor claims data for the 15 categories of chronic-use medications. The Ministry will retain the discretion to audit and recover dispensing fees paid in excess of the established limit. In exercising this discretion, consideration will be given where ODB recipients have attended multiple pharmacies. Pharmacies that are continually non-compliant with this change after a three-month period will be subject to audit and recoveries.

Upon implementation of HNS changes in mid-2016, the system will employ a look-back function to October 1, 2015 and will not allow further dispensing fees for claims that have been processed with ≥5 dispensing fees for ODB recipients on an eligible chronic-use medication.

Reimbursement of Medically Necessary "No Substitution" Claims

16. Why is the ministry making changes to the current "no substitution" policy?

The ministry is making changes to the current "no substitution" policy in order to increase the use of safe and effective generic alternatives to brand name products.

Generic drugs are as good as brand name drugs, and have enormous cost saving potential for our health care system. Health Canada has stringent regulations in place to ensure only safe and effective products are marketed, regardless of whether they are brand or generic drugs.

17. How do the Regulation changes affect “no substitution” claims?

Effective October 1, 2015, ODB recipients will be required to try two (2) generic interchangeable products and have a documented Adverse Drug Reactions (ADR) for each generic, before being eligible to receive the brand name medication at no additional charge (other than any applicable co-payment amount).

18. How will a “no substitution” prescription be reimbursed where two or more lower-cost interchangeable drug products are not available?

Where only one lower-cost interchangeable generic product is listed as a benefit, the ministry will reimburse the higher-cost brand product, provided the ODB recipient has tried the one lower-cost generic and has experienced a significant adverse reaction. Prescribers will still be required to indicate “no sub” (either hand written in the case of a written prescription or verbally in the case of a verbal prescription) and complete a copy of the Health Canada’s Canada Vigilance Adverse Reaction Reporting Form.

19. What additional documentation is required to support this change?

Prescribers are required to complete, sign and forward to the pharmacist a copy of the Health Canada Canada Vigilance Adverse Reaction Reporting Form for **each** lower-cost interchangeable drug product trialed, and will continue to be required to write a “no substitution” or “no sub” on a written prescription or indicate “no substitution” to the pharmacist in the case of a verbal prescription. The form(s) must be completely filled out noting the details of the adverse reaction(s) and signed by the prescriber.

Upon receipt of a “no substitution” prescription, the pharmacist will continue to:

- Clearly note on each adverse drug reaction form(s) - “**ODB NO SUBSTITUTION**”; and
- Fax or mail the completed and signed form(s) to Health Canada’s Canada Vigilance Program if not already submitted by the prescriber; and
- Retain copies of the completed and signed adverse drug reaction form(s) in a readily retrievable format at the pharmacy.

Health Canada adverse drug reaction forms do not have an expiry date and serve as a permanent record.

The pharmacist will continue to be required to mail or fax the completed form(s), where it has not been submitted by the prescriber, to:

Canada Vigilance Program, Marketed Health Products Directorate, Health Canada, Postal Locator 0701E, Ottawa, Ontario K1A 0K9 Fax: 1-866-678-6789

In accordance with sections 19 and 29 of O. Reg. 201/96 made under the *Ontario Drug Benefit Act*, the dispensary is required to retain a copy of the prescription and the required Health Canada adverse drug reaction form(s) (completed and signed by the prescriber) in a readily retrievable format.

20. What system changes will be in place to support this change?

At this time, the ministry will not be making changes to the HNS to support this policy change. All claims will be submitted as per the current requirements for “no sub” claims outlined in the ODB Formulary and the Ontario Drug Programs Reference Manual, ensuring two lower-cost generic products have been trialed (where available) for each ODB recipient presenting with a medically necessary “no substitution” prescription.

The dispenser is required to document how prior therapy was determined, whether that be with the patient or prescriber, and ensure the required ADR form is completed (or if previously completed, shared with the dispenser) and kept on file to support the claim for the brand product.

21. How will this change affect ODB recipients?

Under the new policy, the ministry will require ODB recipients to try at least two lower-cost generic drug products (where available) before a “no substitution” prescription for a brand name drug will be reimbursed under the ODB program. This will maximize the use of safe and effective generic alternatives and provide better value to taxpayers and the government.

ODB recipients with a valid “no substitution” prescription that was filled **prior** to October 1, 2015 will be permitted to renew and refill their brand therapy as directed, as long as the appropriate documentation remains on file.

If an ODB recipient chooses to exercise their personal preference for the brand therapy without trying one or more lower-cost generic drug products, pharmacists may continue to provide them with their choice and it will be the responsibility of the recipient to pay for any cost difference as per the usual process. The same will apply if the recipient’s prescriber does not provide the appropriate adverse reaction reporting forms to the pharmacy.

Pharmacists are encouraged to discuss alternative lower-cost treatment options, where available, with these patients and their prescribers.

22. For more information on generic drug products

If you would like more information on interchangeability of generic drugs, please visit:

http://www.rxfiles.ca/rxfiles/uploads/documents/Bioequivalency-QandA-Links.pdf

https://www.cadth.ca/sites/default/files/pdf/similarities_differences_brandname_generic_drugs_e.pdf