Questions and Answers Ontario Public Drug Programs Amendments to Ontario Drug Benefit Act regulation regarding the Payment of Dispensing Fees Effective Date: August 1, 2008

1. What is the rationale for setting conditions on the payment of dispensing fees under the Ontario Drug Benefit (ODB) Program?

A review of ODB claims data has revealed that, over the past several years, the rate of growth in the number of dispensing fee claims has greatly exceeded the growth in the number of ODB recipients and growth in the number of drugs per recipient. In particular, the number of chronic medications dispensed weekly and more frequently has increased dramatically over the past several years despite a lack of evidence that such increases in reduced quantity dispensing are necessary based on patient need or changes in clinical circumstances. More specifically, both weekly and daily dispensing have increased by 26% and 25% respectively since 2006. In 2007, the Ministry paid almost \$170 million in weekly dispensing fees and \$7 million in fees for medications dispensed on a daily basis.

The public drug system aims to meet the needs of Ontarians as patients, consumers and taxpayers. The Ministry has a responsibility to consistently achieve value-for-money and to ensure the best use of resources at every level of the system. To this end, changes have been made to O. Reg. 201/96 made under the *Ontario Drug Benefit Act* (the "ODBA Regulation") as further described below.

2. Do the regulation amendments place limits on the number of dispensing fees that may be paid under the ODB Program?

Yes. As a condition for payment of a dispensing fee for dispensing listed drug products to ODB recipients, dispensers are required to dispense at one time the entire quantity of the product that is specified on the prescription to be dispensed at one time, up to the maximum quantity permitted under the ODBA Regulation ("Maximum Quantity").

In most cases, the Maximum Quantity would be a supply sufficient for a 100-day course of treatment. For recipients who are eligible for ODB benefits under the Ontario Works program, the Maximum Quantity permitted is a 35-day supply. In the case of medications to which the Trial Prescription Program applies, the Maximum Quantity that may be dispensed is a quantity sufficient for 30 days.

For the majority of listed drug products dispensed to ODB recipients, dispensers may receive payment for a maximum of 2 dispensing fees per medication per patient in any calendar month. Some exceptions will be allowed, where reduced quantity dispensing is warranted for reasons related to patient care and safety.

3. What if a prescriber directs the dispensing of a prescription on a weekly or daily basis?

Subject to the list of exempted medications (see #7below), if a prescriber directs that a medication is to be dispensed in a reduced quantity (i.e. less than the Maximum Quantity), the dispenser will be reimbursed a maximum of two (2) dispensing fees per medication per recipient per calendar month. Dispensers, therefore, are encouraged to work with prescribers to facilitate the dispensing of the Maximum Quantity allowed under the ODBA Regulation.

4. What if the ODB recipient is incapable of managing his/her medication regimen as a result of cognitive, sensory or physical impairment?

If a prescriber directs that a medication is to be dispensed in a reduced quantity or a dispenser has determined that the ODB recipient is incapable of managing his/her medication regimen as a result of cognitive, sensory or physical impairment, dispensers will be reimbursed a maximum of 2 dispensing fees per medication per recipient per calendar month.

In cases where the dispenser has determined that reduced quantity dispensing is warranted due to patient impairment, the dispenser must:

- (1) make a written record of the rationale for reduced quantity dispensing; and
- (2) obtain written authorization from the patient (or person presenting the prescription) for the dispensing of a reduced quantity. The Ministry requires that the authorizing person sign the original prescription to indicate that s/he has authorized reduced quantity dispensing, specify the quantity they have authorized, and the reason why.

The foregoing records must be maintained by the pharmacy for a minimum period of 2 years for audit purposes.

5. What if an ODB recipient (or the person presenting the prescription) requests that a medication be dispensed in a reduced quantity?

Unless (a) the prescriber has directed on the prescription that quantity less than the maximum quantity is to be dispensed, or (b) the dispenser has determined, in the dispenser's professional judgment, that the patient is incapable of managing his or her medication as a result of physical, cognitive

or sensory impairment, the dispenser is required to dispense the Maximum Quantity. In cases where the dispenser has determined that the patient has an impairment which warrants reduced quantity dispensing, the dispenser would be reimbursed under the ODB Program a maximum of 2 dispensing fees per medication, per recipient, per calendar month, and must meet the consent and record-keeping requirements described above (see #4).

6. What are the exemptions to the new dispensing fee conditions?

The dispensing fee limitations described above do not apply to:

- residents of long-term care homes;
- drug products or categories of drug products that have been designated by the Executive Officer (EO) and posted on the Ministry website. The products which have been designated as exemptions by the EO include medications that are normally prescribed for periods of short duration (e.g. antibiotics) or products where there is risk of abuse or diversion (e.g. narcotics and controlled drugs) ("Exempted Medications")

7. Where can I find a list of the Exempted Medications?

Please refer to the ministry's website for a complete list of products and classes of medications which are exempted from the dispensing fee conditions described above:

http://www.health.gov.on.ca/english/providers/program/drugs/odbf/dispensing_fees_drug.pdf

8. What happens if more than 2 dispensing fees are claimed in respect of a medication that does not qualify under one of the exemptions?

If more than 2 claims for the same medication for the same patient are submitted in a calendar month, the dispenser would be reimbursed for the drug cost plus any applicable markup, but will not receive payment for a dispensing fee.

Currently, the new conditions on dispensing fee payments cannot be enforced on the Health Network System (HNS). Therefore, if more than 2 claims for the same medication for the same recipient are submitted in the same calendar month, the dispenser is responsible for ensuring that no dispensing fee is claimed. HNS changes will be introduced in the fall of 2008, at which time further communication and an implementation date will be provided. Until that time, all claims are subject to audit and inspection by the Ministry. Dispensers are reminded that payments made by the Ministry for claims that have been submitted inappropriately are subject to recovery.

9. If a third claim is put through and the pharmacy is only reimbursed the drug cost and mark up, can the dispensing fee be collected from the patient?

No. Other than the permitted co-payment, a dispenser may not charge, or accept payment from, a person other than the Executive Officer of Ontario Public Drug Programs, except in those circumstances described under section 21 of the ODBA Regulation.

The dispenser is permitted to charge an ODB-eligible person for the supply of a listed drug product only if: (a) the person elects to pay the full amount that would otherwise be payable by the Executive Officer for supplying the product; and (b) before supplying the product, the dispenser advises the person that, subject to any co-payment, the product would be available free of charge under the ODB Program.

10. What if an ODB recipient needs to have his/her medication replaced due to loss/theft/damage/recall of product?

In the majority of cases, a claim for a medication in such situations would not be impacted by the new dispensing fee billing rules. For example, if an ODB recipient receives a prescription for the Maximum Quantity permitted under the ODB program (100 days in most cases), and then the medication is lost within the same calendar month, the second claim would be fully reimbursed, including a dispensing fee. As per usual processes, however, the dispenser must clearly document on the prescription hardcopy why an early refill was issued. By the time the next refill is due, enough time should have elapsed so that a dispensing fee would be payable.

11. What happens if a medication dosage is changed by the prescriber and an early refill is required?

A claim which is required as the result of a dosage change should not be impacted by the new dispensing fee conditions as a different drug product is being dispensed.

12. What happens if a medication dosage changes several times in a month, as may occur with anticoagulant therapy?

Anticoagulants, during periods of dosage adjustment, are excluded from the new dispensing fee billing rules. However, when a dosage has been stabilized, the dispenser is expected to dispense the entire quantity prescribed, up to the Maximum Quantity allowed under the ODB Program. Please refer to the Ministry website for a complete list of Exempted Medications (see #7 above).

13. How often will the Ministry revise/update the list of Exempted Medications?

The Ministry will review and update the list on a regular basis.

14. Are claims submitted for reimbursement under the Individual Clinical Review/Exceptional Access Program (ICR/EAP) subject to the new dispensing fee billing rules?

Claims submitted for products approved for reimbursement under the ICR/EAP are subject to the same criteria and conditions as listed drug products on the Formulary.

15. Will the Ministry audit pharmacies and process recoveries when overpayments are identified?

Yes. Dispensers are required to submit all claims to the Ministry in accordance with all applicable legislation and policies. Any claims that have been improperly submitted are subject to audit and recovery.

If you have additional questions, please contact the Ministry's Help Desk at telephone 1(800) 668-6641.

Note: This document is intended to provide a summary description of the regulations for convenience only, and is not an authoritative version of the regulations. A copy of the regulation is available on the Government of Ontario e-Laws website at www.e-laws.gov.on.ca and official copies of regulations are printed and distributed by the Queen's Printer (Publications Ontario).