

an overview of Ontario's proposed drug pricing regulatory reforms

Recently announced changes to Ontario's drug pricing laws will potentially have a significant impact on the bottom line of many stakeholders in the Ontario generic drug industry. Pharmacies have been quite vocal against these reforms, from national franchised chains to independent stores. For example, Shoppers Drug Mart Inc.'s President and Chief Executive Officer announced that the chain will layoff staff at its Ontario stores (including eliminating intern positions for over 300 pharmacy students), reduce the hours of operation of some of its Ontario pharmacies, cut services such as deliveries of medications and re-evaluate investment and expansion opportunities in the province the day after the much anticipated proposed regulations were released by the Ministry of Health and Long-Term Care.

The reforms are detailed in both the Ontario budget bill C-16, *Creating the Foundation for Jobs and Growth Act, 2010* and the proposed amendments to regulations under the *Drug Interchangeability and Dispensing Fee Act* (the "DIDFA") and the *Ontario Drug Benefit Act* (the "ODBA") that were announced on April 8, 2010. Bill C16 went through first reading on March 25, 2010. The amendments to the DIDFA and ODBA and regulations will take effect on May 15, 2010.

phase-out and elimination of professional allowances

Generic drug manufacturers often offer lucrative financial incentives to pharmacies in order to be retained as the pharmacy's exclusive generic supplier for a variety of medications. In 2006, the Ontario Government took steps to curb this practice by banning the provision and receipt of rebates (defined broadly to include currency, discounts, refunds, trips, free goods and other benefits provided by the manufacturer to the pharmacy in exchange for stocking their products) and requiring any such rebates to be flowed through to the government's coffers. The only exceptions to the rebate prohibition are a discount for prompt payment to the manufacturer offered in the ordinary course of business (not greater than 2% of the invoiced price) and professional allowances. The professional allowances received by a pharmacy may only be used for direct patient care expenditures listed in the regulations under the ODBA, such as producing disease management brochures for patients and holding smoking cessation clinics at the pharmacy.

The professional allowances a manufacturer may provide to a pharmacy may not exceed 20% of the value of the publically-reimbursed drugs dispensed by the pharmacy in a given period. There is no limit on the amount of professional allowances a manufacturer may provide to a pharmacy customer for drugs dispensed to cash paying customers or individuals covered by employer drug plans though the allowances must be used for the same direct patient care purposes as for the public professional allowances. Large pharmacy chains with buying power were able to negotiate massive professional allowances from manufacturers in amounts the approached the amount of the acquisition cost of the drugs purchased for the private market.

The Government's policy rationale for the 2006 ban on rebates and regulation of professional allowances was three-fold:

1. It should only be liable to reimburse pharmacies for its actual acquisition cost of the drugs, net of all financial discounts, plus a prescribed mark-up and dispensing fees, in order to limit public spending to the actual cost of the product factoring in reasonable compensation to the pharmacies.
2. Manufacturers incorporate the value of the professional allowances into its pricing of products that are eventually paid for by either the Ontario Drug Benefit Plan, cash paying customers or employer-sponsored benefit plans, resulting in higher prices for all purchasers.
3. If professional allowances are provided, the money should be used to fund programs that have a positive effect on patient care and reduce other public health costs through a greater involvement by pharmacists in direct patient care.

Manufacturers and pharmacies were required to report the amount and intended use of the professional allowances on a semi-annual basis (\$750 million in professional allowances were reported to be paid to pharmacies in 2009). According to the Ontario Government, some pharmacies failed to submit reports and others produced either incomplete documentation or provided information that the payments were being used for paying employee salaries, bonuses and other working capital expenses instead of segregating those amounts for direct patient care initiatives. As a result of the perceived widespread non-compliance with the professional allowance regulations, the Ontario Government is now seeking to phase out and eventually eliminate the professional allowance exception to the ban on rebates. If any such payments are made and discovered by the Executive Officer of the Ontario Public Drug Program, they will be treated as illegal rebates and the amounts must be directed to the Ontario Government.

The new regulations will result in the following specific changes to professional allowances:

- the current cap on professional allowances in the public system will be reduced from 20% to 5% of public reimbursed sales on May 15th;
- a cap of 50% on professional allowances of sales by manufacturers to pharmacists for private sales will commence on May 15, 2010, to be reduced to 35% (beginning on April 1, 2011), and then 25% (beginning on April 1, 2012)
- it is believed that professional allowances will be prohibited completely by 2014 as Bill C-16 removed the professional allowance exception from the rebate prohibition in the legislation, while the Regulations gradually reduced the allowable professional allowance limits over the next three years

- only manufacturers and not pharmacies will be required to continue submitting reports on professional allowances to the Executive Officer
- a new “ordinary commercial terms” exception to the ban on rebates will expand on the current prompt payment discount exception. In order to receive this benefit the following must conditions must be met:
 - the benefit must be provided in the ordinary course of business;
 - the value of the benefit must be set out in a written agreement; and
 - the benefit must relate to an ordinary commercial relationship that is any of the following:
 - a prompt payment discount;
 - a volume discount; or
 - a distribution service fee.

There are currently no definitions, limits or other guidelines on what constitutes an ordinary commercial relationship, a volume discount or a distribution service fee. Consequently, this exception for the time being presents an opportunity for manufacturers and pharmacies to reconstitute some of the professional allowance payments as volume discounts or distribution service fees.

price of generic drugs

The Ontario Government will also reduce the maximum prices for generic products listed on the Ontario Drug Benefit Formulary to a maximum of 25% of the price of the corresponding brand name drug (currently the maximum is 50%), commencing on May 15, 2010. The price reduction for cash paying customers or private employer insurance plan covered drug sales will be staggered. A 50% maximum is proposed beginning on May 15, 2010, to be reduced to 35% (beginning on April 1, 2010) and 25% (beginning on April 1, 2012). New exceptions to these caps will apply where the brand name drug has been listed as a benefit and one or more generic products has been available for more than 10 years and where the brand name drug has been listed as a benefit in the past but have not been listed for more than 5 years. The “Single Source Pricing Exemption”, which applies to drugs where there is a single generic source available and the “Raw Material Cost Increase Exemption”, which applies when substantial raw material costs have increased for the manufacturer are still available for manufacturers.

other proposed reforms

Some other proposed regulatory changes include the following:

“Private label” prescription products will not be reimbursed under the ODBA nor eligible for designation as interchangeable under the DIDFA.

- A change in the maximum permitted pharmacy mark-up depending on the location of the pharmacy
- An increase in the dispensing fees paid by the government to the pharmacists directly for the services they provide. This includes:
 - an immediate increase for every Ontario Drug Benefit Plan prescription filled of at least \$1 (up to \$4 in rural and underserved areas);

- an annual increase in the dispensing fees; and
- \$100 million to compensate pharmacy owners for the professional services pharmacists provide to Ontario residents (including new services allowed in conjunction with the expansion of the scope of practice of pharmacists in Ontario, which will allow them to prescribe certain drugs, authorize refills, and modify prescriptions without the need for physician involvement or consult patients via videoconferencing technology installed on drug dispensing machines which will increase service opportunities in rural areas).

next steps

If the proposed regulations are passed as currently drafted, manufacturers, wholesalers and pharmacies will need to review and update their business models and supply arrangements to comply with the new regulatory framework. The association representing generic manufacturers in Canada announced that the regulations will impact on the ability of generic manufacturers to profitably supply the Ontario market and constrain the introduction of new products through a loss of R&D in the market. Some pharmacies have argued that this will impact on their financial viability and have hinted that they may shut down their stores or reduce services significantly. A consultation period on the new regulations remains open until May 8, 2010, presenting an opportunity for all affected stakeholders to write to the Executive Officer of the Ontario Public Drug Programs to present their case and a widespread response is indeed expected. However, the Ontario Government feels strongly that drug purchasers have been overpaying for generic drugs in the Province, and it's not expected that the regulations will change much (especially as these reforms are viewed as the first battle in a series of upcoming significant changes to the funding of the public health care system in Ontario and the Government cannot show its weakness on this front). As other provinces are watching what happens in Ontario and may in fact follow suit, the outcome of these regulatory changes may have a massive impact on the future of the generic pharmaceutical and retail pharmacy industries in Canada. Stay tuned.

by: Les Chaiet ¹

¹ The assistance of Jessica Young, Student-at-Law, in preparing this bulletin is greatly appreciated.

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a cautionary note

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