Health Law Bulletin

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Ontario Drug System Faces Major Reform

It's no secret that drug costs have been going up. In fact, over the past ten years, Ontario drug costs have increased by over 140%. Ontario government spending on the province's Drug Benefit Program is up to $3.4 billion, with an additional $280 million going to other specialized programs, each year. Ontario employers are also grappling with dramatic increases, with annual spending now at $2.6 billion a year. To combat this, Ontario's Minister of Health and Long-Term Care introduced new legislation April 13, 2006, as part of his comprehensive plan for Ontario drug system reform.

The proposed *Transparent Drug System for Patients Act, 2006*, Bill 102 (the Bill), follows recommendations from the Drug System Secretariat, which the Minister directed to review Ontario's whole drug system. During its review, the Secretariat joined global experts to study other jurisdictions' best practices and consulted with a full range of stakeholders, including patients, professional organizations, industry organizations, brand name and generic manufacturers, hospitals, wholesalers, private insurers, major employers, and the public. The Minister is now acting on the significant opportunities to improve the provincial drug system that the Secretariat identified.

The Minister proposes an aggressively managed provincial drug system framework built on integrated policy, legislative and regulatory change. The framework's five key areas are:

- the drug system's governance and operations,
- access to drug products,
- drug product pricing and reimbursement,
- appropriate use of partnerships, and
- innovation.

The Bill's Highlights

To implement the Minister's drug system strategies, Bill 102 amends the *Drug Interchangeability and Dispensing Fee Act* and the *Ontario Drug Benefit Act*. Fundamentally, the Bill contemplates the following changes to the law.

Stronger Governance and Operations of Ontario's Drug System

The Bill creates an Executive Officer to take charge of Ontario's public drug programs and outlines the associated functions and powers. The Lieutenant Governor in Council will appoint the Executive Officer, who will assume responsibilities that had rested with the Minister.

Next, the Bill simplifies how drug products are designated as interchangeable and how these designations may be removed. The new Executive Officer will be responsible for setting and removing interchangeable designations and maintaining the Formulary published on the Ministry's website. Although this replaces the current process where the Minister or Lieutenant Governor in Council introduces a regulation, conditions for designating products interchangeable will still be outlined in regulations and the Executive Officer will apply the same interchangeability requirements that the Minister and Lieutenant Governor in Council applied.

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The Bill also streamlines how drug products are added to and taken off of the Formulary. The Executive Officer will be able to add and remove drug products listed on the Formulary without a regulation (as needed now) and establish clinical criteria required for payment regarding certain drug products or classes. Along with listing drug products and substances, the Formulary will include drug benefit prices, interchangeable products, other information required by law, and any other information the Executive Officer chooses to add.

Better Access to Drug Products

The Bill also expands the range of drug products that may be designated as interchangeable to include products with the same or similar active ingredients in the same or similar dosage form. In the past, drugs had to have the same active ingredients in the same dosage form to be interchangeable. The Minister will be authorized to make regulations designating products with similar active ingredients and in similar dosage form as interchangeable when the Bill receives Royal Assent, with the Minister's power on this point ending once the Executive Officer is in place.

Drug Product Pricing and Reimbursement

The Bill stops manufacturers from giving rebates to wholesalers, pharmacy operators, companies owning, operating or franchising pharmacies, and their directors, officers, employees or agents for:

1 interchangeable products,

2 any products the manufacturer has applied to the Executive Officer for an interchangeable designation,

3 listed drug products and substances and designated pharmaceutical products, or

4 any drugs the manufacturer has applied to the Executive Officer for designation as a listed drug product.

The Bill defines prohibited rebates to include money, discounts, refunds, trips, free goods and any other prescribed benefits. Discounts offered in the ordinary course of business for prompt payment are not rebates. The regulations (not released at the time of writing) may well explain exactly what else will not fall within rebate's fairly broad definition. For added bite, the Bill also prohibits anyone from directly or indirectly accepting a rebate.

If the Executive Officer believes on reasonable grounds (a pretty low threshold) that a manufacturer has provided rebates, the Executive Officer may order the manufacturer to refund the government for the rebate's value. The Bill also lays out how the amount owed will be calculated, the manufacturer will be notified, the amount owed may be reconsidered, and the manufacturer will be sanctioned for not paying. Manufacturers will have fourteen days to pay. If they do not pay, the Executive Officer may issue an unappealable order for further payment or:

1 remove the drug product's interchangeability or listed drug product designation,

2 with no less than 30 days' notice, refuse to designate the manufacturer's other drug products as interchangeable or listed drug products or approve any of the manufacturer's products under the exceptional access program until the Executive Officer believes the manufacturer has stopped offering rebates, and

3 publish the offending manufacturer's corporate name and details of the offence and Executive Officer's actions.

The Bill also contains some rules on how the Executive Officer must make an order or notify the manufacturer. Because the *Statutory Powers Procedure Act* will not apply to the Executive Officer's orders, the Executive Officer need not follow statutory rules of due process other Ontario proceedings must apply. However, common law due process

rules will apply. Since manufacturers will have no right to appeal, their only recourse will be to apply for judicial review, which is available on only limited grounds.

The Bill eliminates the power to set different dispensing fees for hospital pharmacies than those set for other community pharmacies.

To determine compliance with the *Ontario Drug Benefit Act* and *Drug Interchangeability and Dispensing Fee Act*, the Bill allows both the Minister and Executive Officer to require manufacturers, wholesalers, listed substance suppliers, pharmacy operators, companies owning, operating or franchising pharmacies, physicians and eligible persons (and their representatives) to provide information (other than personal information) to the Executive Officer in response to a specific request or at regular intervals.

Under the new law, inspectors will be permitted to examine records pharmacy operators, companies owning, operating or franchising pharmacies and listed substance suppliers hold. This adds to their current ability to examine records in a wholesaler's or manufacturer's possession or control to determine whether a claim or information that must be submitted under the *Ontario Drug Benefit Act* is accurate and complete or whether a wholesaler or manufacturer has complied with the *Ontario Drug Benefit Act* and its regulations.

No specific provisions in the Bill specify sanctions for people who accept rebates or refuse to provide information the Minister or Executive Officer requires.

New rules on the drug benefit price of listed drug products (and other products not on the Formulary that are subject to an exceptional access program) are included in the Bill. This includes so-called partnership agreements between the Executive Officer and the manufacturer. The Bill prohibits manufacturers from selling listed drug products at prices higher than their drug benefit price in the Formulary.

The Bill's Status

Bill 102 received first reading April 13, 2006. The Bill may be revised before being passed into law, although the Drug System Secretariat apparently has already conducted significant public consultation. The Ministry seems to be fast-tracking the Bill because amendments to the *Drug Interchangeability and Dispensing Fee Act* and *Ontario Drug Benefit Act* (other than a few that come into force on Royal Assent) are intended to come into force October 1, 2006.

THE PEOPLE WHO CAN HELP

For help to better understand the Bill's implications or to make submissions to the Standing Committee the Bill may be referred to, please contact your McMillan Binch Mendelsohn LLP lawyer or the Chair of our Health Law Group:

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