GROUP BENEFITS special bulletin

Mosey&Mosey

Working *towards* better solutions

BILL 102: Transparent Drug System for Patients Act ... What the Employer needs to know

It's undeniable that the Ontario drug system needs reform to remain sustainable in the future. Our population is aging and baby boomers are about four years away from hitting the system, which will translate into further strain. The fact is, drug costs are escalating. The Ontario Drug Benefit program (ODB) costs $3.4 billion annually, an increase of over 140% since 1997. The ODB operates from a drug formulary that has approved more than 3,400 drug products for its recipients.

Certainly, drug cost containment and managed care initiatives are not new to employer groups. Costs have escalated over the years. Newer and more expensive drugs, an aging population, government downloading of services and of course, increased utilization are all factors driving the cost. Employers spend $2.6 billion annually on employee drug programs and Mosey & Mosey have long been helping our clients to be innovative in controlling costs, with managed formularies often involved.

The changes proposed in Bill 102 reflect the urgency of our government to act now to preserve our drug program, which is such a tremendous part of our well being and our economy. According to the Ministry, impetus for Bill 102 is partially attributed to the achievement of a "generics first" provision in the CAW and Big Three collective agreements.

WHAT IS BILL 102 ALL ABOUT?

Health and Long Term Care Minister George Smitherman

On April 13, 2006 Health and Long Term Care Minister George Smitherman introduced a controversial new plan to improve the efficiency of the provincial drug system. Based on recommendations from The Drug System Secretariat appointed to review the system in 2005, the Ministry of Health is touting this reform as long overdue and necessary to protect the future integrity of our drug plan.

Implications of such legislation are far reaching. Changes to the Drug Interchangeability and Dispensing Fee Act, as well as The Ontario Drug Benefit Act would be required. Naturally, much discussion and debate has erupted as concerned parties levy their interests. Pharmacists, patients, generic and brand name drug manufacturers have all come to the table in the legislature. The government is motivated to push the bill through to implementation by October of 2006 on the expectation of recouping over $222 million.

Bill 102 focuses on five key areas:

1) PATIENT ACCESS

The bill contains a Conditional Listing Category, which will allow patients to access new drugs on a conditional basis while they are being formally evaluated. This eliminates Limited Use and Section 8 Listings and the administration and paperwork that can impede access to needed drug therapies.

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The bill seeks to provide quick decisions on drugs considered to be a breakthrough for life-threatening conditions. In these cases, the review process will start before the drug is marketed in Canada.

2) TRANSPARENCY & DEMOCRACY

This legislation seeks to unveil some of the secrecy in the drug system, specifically in the management of the drug formulary. A recent Leger poll found only 36% of Canadians believe policy-making by our government reflects the will of the people. If the bill is passed, Ontario will be the first province to permit direct patient involvement in both decision-making and policy direction. The issues encountered in assessing clinical data will be public. How do drugs get added or on what basis are they declined? Is evidence supporting outcomes lacking? Are clinical definitions clearly presented? Is there potential for "off label" use? What is the difference in cost for new higher priced drugs? What is the anticipated benefit to be gained with the more expensive drug? Are the anticipated benefits clinically significant? If passed, there will be no secrecy around the cost benefit analysis that is undertaken for each drug under consideration.

Citizens' Council: A Citizens' Council will be created to give the public an opportunity to present their views on drug policy.

A Voice for Patients: A Committee to Evaluate Drugs (to be named) will appoint two seats to patient representatives for a role in drug listing decisions.

Executive Officer: This role will be established to manage the drug system and ultimately make listing decisions while working with stakeholders and to communicate listing decisions. It represents a significant shift in power, but one that can facilitate a faster process.

3) RECOGNIZING PHARMACISTS & PROMOTING PROPER USE OF MEDICATIONS

The legislation will promote appropriate use of medications by paying pharmacists for some of the direct patient care services they provide. The legislation speaks to the value that pharmacists can bring to patient outcomes as front line health providers. $50 million will be directed to cognitive services performed by pharmacists.

Bill 102 also refers to a Shared Care Network. Web-based independent best practice guidelines will be developed to ensure doctors make the best prescribing decisions and help patients adhere to drug therapies.

4) RESEARCH & DEVELOPMENT

$5 million will be directed to the creation of an Innovation Research Fund. The intent is to support drug policy by investigating value of medicines across the entire health care system. Ultimately, the research will illustrate concrete evidence of better health outcomes.

5) VALUE FOR TAXPAYERS

Marketing for Bill 102 is strongly routed in attaining value for the money that taxpayers spend. Without question this is where the majority of stakeholders are weighing in. Several pieces of the legislation are worth noting:

Secondary Payer: The legislation is clear that Ontario will be second payer for those covered under the Public Service Health Plan, but is somewhat vague on working seniors with private plans.

Volume Discounts: Getting back to business basics, the government will attempt to leverage its purchasing power to negotiate with manufacturers for better prices. The legislation speaks to developing a partnership for brand name drugs to secure more competitive prices in the marketplace. This will allow more brand name drugs listed with lower prices.

Lower prices for generic drugs: The price for generic drugs will be lowered by 20% to 50% of the brand name.

Dispensing Fees: The bill will seek to increase the ODB dispensing fee by 7% to $7.

Mark Up: Allowable mark up will decrease from 10% to 8% with a $25 dollar cap per prescription.

Rebates: Present practice allows generic drug companies to pay huge rebates to pharmacies in exchange for shelf space. Bill 102 will eliminate these rebates in an effort to reduce the price of generic drugs and develop a partnership with generic manufacturers to develop a Code of Conduct for marketing.

Off Formulary Interchangeability (OFI): Perhaps the most significant change is that employers will have greater access to generic substitution, which will reduce costs. The idea behind OFI is to dispense less expensive, but equally effective generic drugs in place of brand names.

Currently, after Health Canada approves a generic version of a brand name drug for which the patent has expired, the generic version is considered for inclusion in the ODB formulary. Health Canada approval means the generic drug is "bioequivalent" or as safe and effective as the brand name equivalent.

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Once the drug is listed in the formulary, it is designated as "interchangeable" with the brand name drug. The problem is that there are thousands of drugs considered interchangeable, but they are not in the formulary.

Controversy exists because the current wording requires that only the "same'" active ingredient in the "same" dosage form can be interchangeable. Many feel this has contributed to "evergreening." This is a process where brand name companies exploit the wording by making small changes to a drug product that provide no added benefit for patients. It simply prolongs their patent protection.

This practice was highlighted when AstraZebeca avoided generic competition by switching its Losec ulcer drug from a capsule to a tablet. This did nothing to change the therapeutic value for patients, yet forced the Ontario Government to spend an extra $85 million over the past two years and employer-sponsored plans to spend an extra $45 million in the same period.

A pharmacist is only permitted to substitute generic for brand if a medication exists in the formulary list of over 3,400 drugs. Of importance here are the thousands of drugs that are NOT on that list and therefore not considered "interchangeable." Today, the pharmacist would be required to call the doctor for permission before dispensing the generic. This legislation proposes to rely on the expertise of pharmacists as frontline providers and make the substitution automatic.

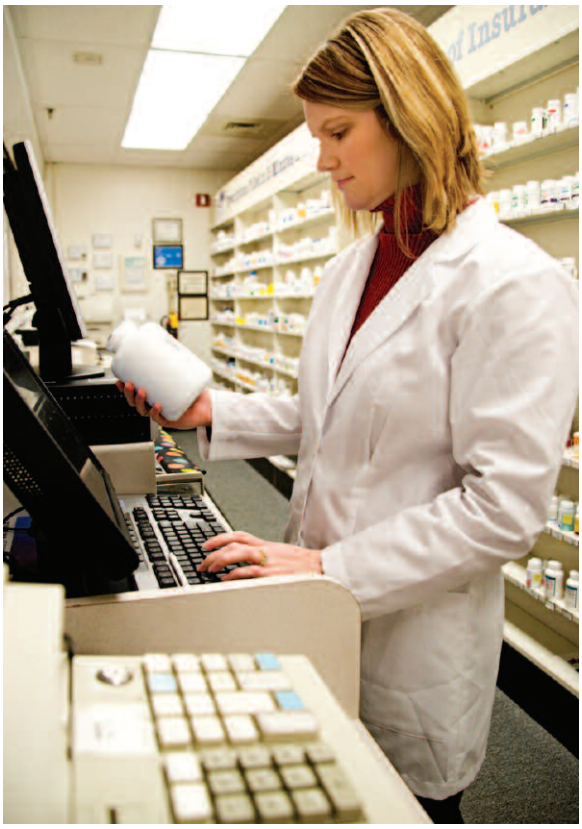
What are the stakeholders saying?

We can learn a lot about the implications of policy change from the concerns voiced by the stakeholders. As both proponents and opponents of Bill 102 weigh in, it is important the government carefully consider all submissions.

Although the issues are tremendously complex and there are many stakeholders, a snapshot of some of the major concerns is provided below:

Generic Drug Companies: Clearly supportive of the move to promote effective generic therapies, yet concerned over the 20% reduction in price allowance to 50% of the brand name equivalent.

Brand Name Drug Companies: Perhaps the single biggest source of opposition is coming from the brand name drug companies who have been lobbying hard against Bill 102. Certainly, the move to use generic drugs more often impacts their bottom line, some estimates suggest by at least $1 billion. The government needs to tread carefully given the level of research investment generated by drug companies and even the entire research and development sector. It will be crucial for our economy that the bill does not deter new and existing investment in the province.



Pharmacists: The recognition of pharmacists as front- line health care providers and payment for these professional services is a win for pharmacists. At the same time, substantial concerns exist around the elimination of rebates from generic companies, to the point that some pharmacists are worried they will be put out of business.

Patient Advocates: Supportive of the move to provide a voice for patients in the formulary decision making, as well as the potential for drugs – particularly those considered breakthrough – to hit the market faster. At the same time, there is significant concern about pharmacists having the power to substitute generic drugs without express consent from the attending physician.

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"Our drug system has been failing us. It hasn't served patients as well as it should. It hasn't been serving tax-payers. It hasn't been serving professionals who work within the system day after day."

HONOURABLE
GEORGE SMITHERMAN

MINISTER OF HEALTH
AND LONG TERM CARE

MAY 15, 2006

What does Bill 102 mean for employers?

Of special interest to Mosey & Mosey is the implication such reform may have on our clients' employer-sponsored benefit programs. With October slated for implementation, the Ministry is motivated to pass this bill prior to the summer break. Stakeholders, however, are looking for more time to table their concerns. Late this week, we expect George Smitherman to release a series of amendments to the bill as a result of June committee hearings.

We are hopeful the proposed Shared Care Network will eventually influence the prescribing habits of physicians. We strongly believe that although there are many players in the health care economy, doctors with their knowledge and expertise are central to the success of any managed care initiatives. We are supportive of any tools that will help doctors prescribe the most appropriate, cost-effective therapies for their patients.

Rules on the second payer are somewhat vague. Will they apply to those age 65 and over who have another plan? If this happens, there would be an impact on employer-sponsored plans offering benefits beyond age 65, whether for working seniors or retired employees. Assuming the reduction in mark up, particularly the $25 cap that applies to all drug plans, it is likely there will be a corresponding decrease in the cost of prescription claims.

Clearly, Mosey & Mosey is supportive of the move to require more substitution of less expensive generic drugs. The government estimates OFI savings for employers and out-of-pocket purchasers at $30 million annually. This figure is based on prices charged by brand name drug companies versus prices charged by generic medicines.

At the same time, employers need to be aware that some patient advocates have voiced concern with the impact of OFI because of the subtle differences that can exist between the brand and generic that can cause side effects/discomfort. Striking that delicate balance will be critical.

The criteria to determine eligible services and rate structures for pharmacists are not clear. This vagueness may eventually result in pressure on plan sponsors to include cognitive services in their plan design. We will be following this closely. At the same time, we support the recognition of pharmacists as front line health care providers and we feel potential exists to utilize the expertise of pharmacists in disease state management.

While it may be too soon to assess the full impact, we believe it will be positive and we welcome efforts for more effective drug plan management. Mosey & Mosey will be closely monitoring the status of Bill 102. We will provide an updated bulletin as this bill moves through the legislative process.

We're Moving!

Effective July 4th, 2006 Mosey & Mosey (Mississauga office) will be located at: 100 Milverton Drive, Ste. 604, Mississauga, Ontario L5R 4H1

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