

**The Right Prescription to
Reshape Drug System:
Transparent Drug System for
Patients Act, 2006**

**Submission to the Standing
Committee on Social Affairs**

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**The Registered Nurses' Association
of Ontario (RNAO)**

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Issues Summary & Recommendations

Governance: RNAO supports the creation of an Executive Officer position, as it has the potential to increase the efficiency and effectiveness of the drug system. We caution that no attempts should be made to transfer political accountability for Ontario's drug programs from the Minister to this position.

Transparency: RNAO supports the government's efforts to increase the transparency, responsiveness and accountability of the drug system. RNAO recommends that government establish, in regulation, a transparent process of appointment to the Committee to Evaluate Drugs and the Citizens' Council. RNAO also recommends that government establish, in regulation, timelines and minimum standards for reporting by the Committee to Evaluate Drugs, the Citizens' Council and the Pharmacy Council.

Access: RNAO welcomes removal of red tape; however, we caution that the safety of the drug system must not be compromised by making testing less rigorous. In the case of conditional listing and exceptional use, RNAO recommends a follow-up study to ensure safety standards are being maintained. In the interests of transparency and accountability, the public should have access to all information used for drug approvals.

Use of Generic Drugs: RNAO supports increased interchangeability between generics and patent drugs, and, supports the government continuing to fully reimburse "no substitution" prescriptions for clients with adverse reactions to substitutes.

Pricing of Drugs: RNAO supports the government's efforts to control drug costs, and recommends strengthening the Bill by empowering the Executive Officer to initiate a request to negotiate a price change when it is deemed to be in the public interest.

Appropriate Use of Drugs: RNAO supports efforts to ensure the appropriate use of drugs, and recommends adequate funding for the best practice guidelines and Innovation Research Fund to support these efforts.

Introduction

The Registered Nurses' Association of Ontario (RNAO) is the professional organization for registered nurses who practice in all roles and sectors across Ontario. Our mandate is to advocate for healthy public policy and for the role of nursing in shaping and delivering health services. It is in the context of this mandate that RNAO is pleased to make this submission on Bill 102, the Transparent Drug System for Patients Act, to the Standing Committee on Social Affairs.

Prescription drugs are an essential tool in health care, and with appropriate use and pricing, can make an important contribution to the sustainability of the health-care system and to the health of Ontarians. However, the cost of those drugs could become a threat to health-system sustainability. Drug expenditures by the Province rose from under \$400 million in 1985 to a forecast \$3.7 billion in 2005. This is an 830 per cent increase over the level in 1985 and 169 per cent above the level in 1995. Even on a per capita basis, forecast provincial drug expenditures for 2005 were 135 per cent above their 1995 levels. The growth in drug expenditures has outstripped other expenditures. As a result, prescription drugs are taking up a greater share of provincial health expenditures, rising from 4.0 per cent of the total in 1985 to 7.3 per cent in 1995 and to a forecast 10.1 per cent in 2005.¹

The cost of prescription drugs to the private sector is also a matter of concern as the sector has also faced sharp increases in expenditures for prescription drugs (rising 151 per cent per capita between 1995 and 2005). This represents a major cost burden for employers offering health plans, and is becoming prohibitively expensive for the many Ontarians who must pay out-of-pocket for their drugs.

There are a variety of problems with our current drug system:

- unequal access to essential drugs, due to the lack of a first-dollar pharmacare program covering all Ontarians;
- growing expenditures on prescription drugs and the implications for the sustainability of our publicly funded health-care system;
- lack of control over high prices set for essential drugs;
- inefficiency of the multiple-payer system for essential drugs;
- insufficient transparency in all dimensions of the system; and,
- insufficient measures to guarantee that drugs are prescribed in a safe, effective and cost-efficient manner.

Bill 102 addresses many of these problems. RNAO supports the proposed measures, while seeking to strengthen some of them.

The Bill has the potential to enhance public drug policy in a number of areas:

- Governance;
- Transparency;
- Access;
- Use of generic drugs;
- Pricing of drugs; and
- Appropriate use of drugs.

We will address these issues in turn.

Governance

The Bill would create the position of Executive Officer in charge of the Ontario drug programs. It provides this Officer with considerable powers to conduct public drug policy, and to negotiate in the public interest. These include the powers to:

- administer Ontario's public drug programs;
- maintain and publish the Ontario Drug Benefit Formulary, which will include listed drugs, drug benefit prices, and interchangeability of products;
- designate products as interchangeable, or to remove such designations;
- list or delist products, without requiring regulations (conditions for listing are set out in regulations, but the Executive Officer would have the authority to specify clinical criteria for reimbursement for drugs listed as "Limited Use");
- set payment amounts and disburse payments for professional services delivered by pharmacists;
- negotiate drug-benefit prices with manufacturers, as they are being listed. Also, set drug benefit prices for non-formulary items under the exceptional access program;
- make payments under the Ontario drug programs; and
- require drug suppliers to provide information to determine compliance with the relevant drug legislation.

RNAO supports the creation of this position, as it has the potential to increase the efficiency and effectiveness of the drug system. We caution that no attempts should be made to transfer political accountability for Ontario's drug programs from the Minister to this position.

Transparency

In the Bill and in its plan to improve the drug system, the government has proposed a number of steps that have the potential to enhance transparency, responsiveness and accountability.

The creation of a separate Executive Officer position independent of Cabinet and the Minister could improve transparency and accountability. This will require a transparent appointment process. It will also require independence and transparency on the part of the Executive Officer. The publicly available Formulary will continue to act as a vehicle for reporting and accountability.

The Bill would also introduce greater transparency in drug pricing by banning rebates from manufacturers to pharmacies, wholesalers, and their representatives.

Supporting these measures in the Bill is a series of proposed initiatives in the government's plan for the drug system. One is the appointment of two patient representatives to the Committee to Evaluate Drugs, which could increase transparency, accountability and responsiveness. It is crucial that these appointees are truly arm's-length from government and industry, and able to represent the broader public. The government also proposes to create a Citizens' Council to help guide public drug policy. The government must ensure that this Council is effective and representative.

Finally, the government has promised to report on drug reviews, on the work of the above two bodies, and on the work of a proposed Pharmacy Council. Reporting is an essential component of accountability and transparency. We would expect such reporting to be comprehensive and timely.

Recommendations: RNAO supports the government's efforts to increase the transparency, responsiveness and accountability of the drug system. RNAO recommends that government establish, in regulation, a transparent process of appointment to the Committee to Evaluate Drugs and the Citizens' Council. RNAO also recommends that government establish, in regulation, timelines, and minimum standards for reporting by the Committee to Evaluate Drugs, the Citizen's Council and the Pharmacy Council.

Access

This Bill addresses one dimension of access. It streamlines the approval process for extraordinary use of drugs not yet on the Formulary by reducing paperwork required of physicians making extraordinary use prescriptions.

Recommendations: As part of the government's plan to change the drug system, it has indicated it may take other steps to expedite funding decisions for breakthrough drugs addressing life-threatening conditions. While RNAO welcomes removal of red tape, we caution that the safety of the drug system must not be compromised by making testing less rigorous. In the case of conditional listing and exceptional use, RNAO recommends a follow-up study to ensure safety standards are being maintained. In the interests of transparency and accountability, the public should have access to all information used for drug approvals.

Use of Generic Drugs

The Bill would expand the scope for interchangeability between generics and patent drugs. All interchangeabilities would be listed in the Formulary. Pharmacists could then substitute drugs with ingredients and dosage forms that are similar but not necessarily identical, according to the Formulary. Under existing legislation, both the ingredients and the dosage forms must be identical.

Increased access to generic drugs introduces a welcome element of competition that helps to lower prices that are kept high by very strong patent protection.

Recommendation: RNAO supports increased interchangeability between generics and patent drugs; and, supports the government continuing to fully reimburse "no substitution" prescriptions for clients with adverse reactions to substitutes.

Pricing of Drugs

Given the long periods of patent protection afforded to pharmaceuticals, there is a strong argument to regulate prices for those drugs that are essential for health and well-being. The Bill would introduce a number of measures to control drug prices.

First, the Executive Officer may negotiate the drug-benefit price with manufacturers. This would occur when the drug is first listed on the Formulary, and would allow the Province to use its purchasing power to reduce prices. Manufacturers would be barred from selling the listed drugs above the drug-benefit price. Evidence from other jurisdictions suggests that using public-bulk purchasing power can reduce drug costs. For example, Australia has drug costs about 9 per cent lower than Canada's, due to using its bargaining power with drug companies.²

As the Bill is presently written, a request to negotiate a price change after a drug has been listed on the Formulary could only be initiated by the manufacturer. Thus, a listed drug would only come down in price if it were in the interest of the manufacturer to do so.

Second, the enhanced interchangeability between generics and patent drugs would introduce cost savings through greater substitution. It would also put downward competitive pressure on high, brand-name prices. The Minister has suggested that the Ministry could save \$222 million through the government drug reform package.

The government's plan includes using its bargaining power to negotiate lower prices for patent drugs and substantially reducing the prices of generics. It is important to address high prices of both patent and generic drugs.

Recommendation: RNAO supports the government's efforts to control drug costs, and recommends strengthening the Bill by empowering the Executive Officer to initiate a request to negotiate a price change when it is deemed to be in the public interest.

Appropriate Use of Drugs

Drug expenditures are high not only because of prices, but also because of rising use. This use may be justified when health outcomes are enhanced and/or when they result in decreases in other health-care costs. However, there is evidence that safe, effective, and efficient prescribing and use has not always been followed.

The Bill proposes to pay pharmacists to deliver professional services, which would include management of medications. Providing this kind of an incentive for pharmacists could enhance the quality of drug prescribing and use.

The government's drug plan includes the development of independent best practice guidelines for prescribing through the Shared Care Network. Ontario's pioneering work in best practice guidelines for nursing practice has received global praise, and similar high-quality guidelines for prescribing would be most welcome. These could enhance health outcomes and save both the public and private sectors the money spent on medications that were being used inappropriately.

The proposed Innovation Research Fund investigating the value of drugs would deliver data that could both inform best practice guidelines and public policy. In order to be effective, such an initiative must be adequately funded.

Recommendation: RNAO supports efforts to ensure the appropriate use of drugs, and recommends adequate funding for the best practice guidelines and Innovation Research Fund to support these efforts.

Conclusion

With Bill 102 and its proposals to improve the drug system, the government has taken important steps to make the drug system and the health-care system more effective and sustainable.

RNAO supports and applauds the proposed measures to control drug prices, and urges the government to strengthen the capacity of the Executive Officer to control prices.

RNAO also supports the proposed measures to expand the use of generic drugs. The Association supports the continued accommodation of the “no substitution” needs of those few patients who have adverse reactions to substitute drugs.

RNAO supports and applauds the measures to enhance governance and transparency. In particular, RNAO recommends transparent appointment processes for the Executive Officer, members of the Committee to Evaluate Drugs and the Citizens’ Council. RNAO also recommends that government establish timelines and minimum standards for reporting by the Committee to Evaluate Drugs, the Citizens’ Council and the Pharmacy Council. These will ensure transparency and independence from the pharmaceutical industry.

RNAO supports the measures to enhance appropriate prescribing and use of drugs. RNAO calls upon the government to invest sufficient resources to ensure that best practice guidelines and the Innovation Research Fund are able to deliver high-quality products on a timely basis.

RNAO gives qualified support to the measures to improve access. The streamlining of approval for extraordinary use of non-listed drugs will save doctors time and widen access to potentially beneficial drugs. However, follow-up studies must ensure that this expanded access is, in fact, safe and effective. Similarly, we endorse the expedited approval of breakthrough drugs for the Formulary only if the rigor of testing is not compromised. RNAO does not endorse expedited approval of drugs with marginal or no therapeutic gain.

The Bill does not, however, address the major obstacle to access: cost to individuals. Many Ontarians do not have access to drug benefit plans. Inadequate access to essential medication based on ability to pay is inequitable and compromises health. The only solution is a first-dollar pharmacare program. Bill 102 would make medicare and the public drug system more sustainable, but it is not a substitute for a pharmacare program. As a start, RNAO asks that all savings accrued through Bill 102 (expected to be over \$220 million in the first fiscal year), be reinvested to expand universal drug coverage for low-income persons.

In sum, the government has taken a number of significant steps forward with Bill 102 and its plan of action to improve the drug system. RNAO offers the above recommendations to help realize the full potential of the government’s plan to enhance drug system affordability, sustainability, effectiveness, safety, transparency and access.

¹ Canadian Institute for Health Information (2006), *Drug Expenditure in Canada 1985 to 2005*, released May 2006.

² Dr. Joel Lexchin, cited by Tammy Horne in “Canada Should Learn From Public Health Care Successes,” *Globe and Mail*, April 26, 2005.