



Psychiatric Patient Advocate Office

*Submission Regarding
Bill 102
Transparent Drug System for Patients Act,
2006*

June 2006

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PROMOTING PATIENTS' RIGHTS



Psychiatric Patient Advocate Office

Bureau de l'intervention en faveur des patients des établissements psychiatriques

June 2, 2006

Shafiq Qaadri, MPP
Chair
Standing Committee on Social Policy
Room 184
Main Legislative Building
Toronto, Ontario
M7A 1A4

Dear Dr. Qaadri:

RE: Submission on Bill 102, the *Transparent Drug System for Patients Act*, 2006

I am pleased to submit the response of the Psychiatric Patient Advocate Office (PPAO) regarding the current consultation on Bill 102.

The PPAO is an arm's length office of the Ministry of Health and Long-Term Care. Since 1983 the PPAO has provided individual advocacy, rights protection and rights advice to clients of tertiary care psychiatric facilities in Ontario. Through our community rights advice service, we also provide rights in nearly psychiatric units of Schedule 1 and 2 hospitals throughout Ontario. For more than two decades the PPAO has advocate strenuously on behalf of consumers of mental health services in an effort to address significant local, regional and provincial systemic issues.

We believe the proposed legislation in concert with other government initiatives promises to reduce escalating drug costs and maintain the viability of the current public drug program. In general, the PPAO supports Bill 102 in the context of the government's overall strategy to increase reliance on generic drugs, broaden the array of effective, interchangeable medications, increase consultation with consumers and other stakeholders, and improve transparency through public reporting mechanisms.

In this submission, we review Bill 102 and highlight areas that we believe require clarification or strengthening.

Please contact me at (416) 327-7004 should you have any questions regarding this submission.

Sincerely,

David Simpson
Director (A)

Introduction and Background

The Psychiatric Patient Advocate Office (PPAO) is an arm's length office of the Ministry of Health and Long-Term Care. The PPAO provides individual advocacy, rights protection and rights advice to clients in the current and former provincial psychiatric hospitals in Ontario. Through its community rights advice service, the PPAO provides rights advice to nearly all psychiatric units of Schedule 1 and Schedule 2 hospitals throughout Ontario. For more than two decades the PPAO has advocated strenuously on behalf of consumers of mental health services in an effort to address significant local, regional and provincial systemic issues.

As a rights protection organization, the PPAO is particularly concerned about the protection of vulnerable individuals who are consumers of mental health and other health care services. This submission is in response to the consultation on Bill 102, An Act to amend the *Drug Interchangeability and Dispensing Fee Act* and the *Drug Benefit Act*, being conducted by the Standing Committee on Social Policy of the Ontario legislature. The current legislation flows from the recommendations of the Drug System Secretariat and is part of a comprehensive strategy to ensure the cost-effectiveness and sustainability of Ontario's drug program. Proposed changes to existing legislation target areas of drug access and interchangeability; drug pricing and reimbursement; and system management, transparency and accountability. Access to needed drug therapies is of paramount importance to individuals diagnosed with mental illness, who are recipients of drug program benefits, and for whom drug treatment is an essential ingredient in their recovery and continued well-being. We are hopeful that the proposed legislation will never erect barriers to access for our clients and that cost will never be the determining factor when deciding if clients should have a particular medication. Clients must be able to access the medications that work best for them and achieves the best results.

The proposed *Transparent Drug System for Patients Act, 2006* (Bill 102) represents an enabling legislative component in a larger scheme of drug system reform which strives to:

- improve access through emphasis on the use of generic and interchangeable drugs;
- reduce costs through competitive pricing and reimbursement;
- prohibit and sanction drug company rebates; and
- streamline system management and create a transparent and publicly accountable administrative process.

The planned strategy has the potential to reduce rising drug costs and benefit consumers through specific procedural changes and increased public involvement and scrutiny. Bill 102, as a first step in the direction of reform, begins to lay a framework that requires further development to be fully realized.

The PPAO applauds the government's efforts to stem rising drug costs and develop a system that more effectively meets the needs of consumers. It is

anticipated that any savings realized by an overhaul of the existing system may be reallocated to others areas of need within the health care system, providing both immediate and long-term dividends to consumers and the public at large. However, a number of questions arise regarding the procedural and structural changes captured in the proposed amendments. This submission reviews Bill 102 and highlights areas that require clarification or strengthening.

The Executive Officer

Bill 102 transfers the authority and responsibilities of the Minister for managing and overseeing the public drug system to an executive officer, who will be appointed by the Lieutenant Governor in Council. This represents a significant shift in the administration of this program, giving considerable and broad authority to the executive officer. The powers of the executive officer include, for example: maintaining and publishing the Formulary, designating interchangeable products, listing and de-listing drug products, negotiating agreements with drug manufacturers and ensuring compliance with the legislation. While the Lieutenant Governor in Council may make a regulation “clarifying, modifying, or restricting the functions and powers of the executive officer,” the legislation is silent on the qualifications and criteria for appointment of the executive officer. Given the scope and authority of this position and the stated goals for reforming the drug program, the PPAO believes that it is critical that qualifications and appointment criteria be articulated within the legislation. Successfully implementing comprehensive reform to Ontario’s drug program hinges on selecting the right individual for this important role.

Recommendation:

The PPAO recommends that Bill 102 identify qualifications and appointment criteria for the executive officer.

Public Interest

Bill 102 permits the executive officer to designate a product in the Formulary as a listed drug product or to designate a product as being interchangeable with another product if it is in the “public interest” to do so. Given the broad powers of the executive officer, there should be a definition for “public interest”. It is a well-established principle of statutory interpretation that words or phrases be precise and unambiguous.

Recommendation:

The PPAO recommends that the phrase “public interest” be defined in the legislation.

Governance Principles

The proposed legislation articulates five governance principles in the preamble to the *Ontario Drug Benefit Act* intended to enhance both accountability and transparency. In summary, these include:

- serving the needs of consumers and taxpayers;
- involving consumers and patients in a meaningful way;
- transparent operations for all stakeholders;
- ensuring the most effective use of resources at all levels; and
- basing funding decisions on the best clinical and economic evidence and openly communicating these decisions.

The inclusion of these principles underscores a commitment to building a system that clearly works in the interest of consumers and taxpayers, involves and informs stakeholders, and makes evidence-based economic decisions. Yet, the legislation fails to operationalize these principles and this is an important omission. That the Minister and executive officer “may” consult stakeholders with respect to matters arising from the legislation falls somewhat short of the mark, where a requirement for regular consultation might be expected.

Elsewhere, the government has made a commitment to involving patients in the drug listing decision-making process through representation on the Committee to Evaluate Drugs. In addition, a Citizens’ Council has been proposed to provide the public with an opportunity to shape drug policy. A Pharmacy Council has also been proposed to assist in the development of policy and reimbursement models for pharmacists.

The PPAO is supportive of the inclusion of patient representatives in the drug evaluation process and would recommend further that a subcommittee be formed to specifically address mental health related medication issues. We would also recommend that guidelines be established for committee and council membership to ensure equitable representation.

We believe that it is fundamental to define mechanisms for the inclusion of stakeholders in decision-making processes within the statute. Similarly, the legislation should outline mechanisms and guidelines for public reporting of relevant committee work and drug reviews. This will help to ensure system transparency and accountability.

Regular reporting on medication usage in Ontario should be established and will contribute significantly to heightened public awareness and support the aim of meaningful involvement of consumers. In keeping with efforts to promote the appropriate and safe use of medication, the creation of a database that advises the public about adverse medication events should be considered.

Recommendations:

The PPAO recommends that:

- the proposed legislation operationalize governance principles;
- Bill 102 define mechanisms for stakeholder inclusion in decision-making;
- Bill 102 establish guidelines for committee and council membership;
- the legislation establish guidelines for reporting on the work of councils and committees;
- the public be informed about medication usage; and
- a database be established advising the public about adverse medication events.

Improved Accessibility

Under the proposed legislation, the executive officer will have the authority to add or remove drugs from the Formulary without the introduction of a regulation. This will, to an extent, streamline the process of adding and removing drugs from the Formulary. Access to interchangeable drugs will be improved insofar as drugs may now have the “same amounts of the same or similar active ingredients in the same or similar dosage form.”

The PPAO supports initiatives to streamline the process of drug inclusion in the Formulary and to broaden the scope of what might be considered equivalent and interchangeable providing mechanisms for the inclusion of consumer feedback in the decision-making process are established. Some consumers have expressed concern that generic products considered to be biologically equivalent to brand name medications may prove less effective. Though we understand that empirical findings do not support this concern regarding reduced efficacy for generic medications, we believe that anecdotal evidence from consumers, physicians and pharmacists should be considered.

Many clients of the PPAO have very low or limited incomes as they are in receipt of some form of social assistance, either Ontario Disability Support Program or Ontario Works. We would recommend that clients whose only source of income is provided by the provincial government be exempt from paying any co-payment when having their prescriptions filled. This legislation also allows public hospitals to charge the same dispensing fees as pharmacies in the community and we are concerned that this may become a barrier to access for some clients.

Recommendations:

The PPAO recommends the inclusion of anecdotal evidence from consumers, physicians and pharmacists in drug listing decision-making.

The PPAO recommends that clients whose only source of income is government assistance be exempt from paying any co-payment fee.

Complaint Process

Neither this legislation nor announced government initiatives have identified a complaint or appeal process respecting decisions of the executive officer. In our opinion, this is a critical omission. There needs to be some avenue to address concerns arising from particular decisions, policies or the management of the public drug program in general. There is a potential advantage in having a single, dedicated individual, such as the executive officer, administer the public drug program, providing he or she has the appropriate background and expertise. The overarching authority of this role in decision-making may significantly simplify and streamline decision-making. However, with the delegation of the Minister's authority, there is a potential loss of political accountability. The Lieutenant Governor in Council could potentially change or limit the function and power of the executive officer through the introduction of regulations.

The PPAO holds that there is a need to establish a complaint resolution process as an additional and more immediate accountability mechanism. Without such a process, stakeholders are deprived of a means of addressing their concerns and tempering the authority of the executive officer.

Recommendations:

The PPAO recommends the development of a transparent complaint resolution process to address stakeholder concerns.

The PPAO recommends that the Ministry provide education to consumers and stakeholders regarding the complaints resolution process and how to make a complaint.

Conclusions

Bill 102 represents an enabling legislative element in the government's comprehensive strategy to overhaul the public drug program. The proposed legislation in concert with other initiatives promises to reduce escalating drug costs and maintain the viability of the current system. This framework calls for increased accountability to consumers and taxpayers. In general, the PPAO supports the proposed legislation in the context of the government's overall strategy to increase reliance on generic drugs, broaden the array of effective, interchangeable medications, increase consultation with consumers and other stakeholders, and improve transparency through public reporting mechanisms.