



October 14, 2010

HAND DELIVERED

Mr. Shafiq Qaadri, MPP
Chair, Standing Committee on Social Policy
Room 1405, 99 Wellesley Street West
Whitney Block, Queen's Park
Toronto, Ontario
M7A 1A2

Dear Mr. Qaadri:

Re: *Narcotics Safety and Awareness Act, 2010*

I would like to thank the Standing Committee on Social Policy for the opportunity to comment on Bill 101, the *Narcotics Safety and Awareness Act, 2010* ("the proposed *Act*").

As you are aware, the Office of the Information and Privacy Commissioner of Ontario is responsible for overseeing the public sector access and privacy legislation in force in the Province of Ontario, the *Freedom of Information and Protection of Privacy Act* and the *Municipal Freedom of Information and Protection of Privacy Act*, as well as the health sector privacy legislation, the *Personal Health Information Protection Act, 2004*. In exercising such oversight, our office is charged with the responsibility of protecting the privacy of individuals with respect to their personal information, including their personal health information. In addition, pursuant to section 59(a) of the *Freedom of Information and Protection of Privacy Act*, our office has been given the mandate to review and comment on the privacy implications of proposed legislative schemes or government programs.

It is further to these responsibilities and this statutory mandate that I am making these written submissions to the Standing Committee on Social Policy with respect to the proposed *Act*. In particular, the Office of the Information and Privacy Commissioner of Ontario has the following fundamental concerns with the proposed *Act*:

1. The lack of clarity as to how the collection, use and disclosure of personal information will achieve the stated purpose of the proposed *Act*.
2. Given the availability of less privacy intrusive measures, the proposed *Act* does not appear to be a necessary and proportionate means of achieving the stated purposes.

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3. The unjustified intrusion on the privacy of individuals resulting from the directed disclosure of sensitive personal information to the government.

In addition, the Office of the Information and Privacy Commissioner has comments on specific sections of the proposed *Act* to promote transparency and clarify and to minimize the personal information that would be collected, used and disclosed; to provide independent oversight of any directed disclosure of personal information; and to ensure adequate public consultation in respect of any regulations contemplated under the proposed *Act*. As well, comments are provided in relation to the additional provisions that are needed in order to protect the personal information collected by the Minister of Health and Long-Term Care (“the Minister”) and the executive officer under the *Ontario Drug Benefit Act* (“the Executive Officer”).

Overview and Purpose of the Proposed Act

The proposed *Act* requires every prescriber and dispenser of a monitored drug to collect and record on a prescription or to keep a record of certain information, including personal information. A prescriber, dispenser or operator of a pharmacy is further required to disclose this information as well as any other information required by the regulations, including personal information, to and upon the direction of the Minister or the Executive Officer. The proposed *Act* then authorizes the Minister or the Executive Officer to collect and use the personal information for the purpose of the proposed *Act* and to disclose the personal information if permitted by the proposed *Act*, the *Freedom of Information and Protection of Privacy Act* or the *Personal Health Information Protection Act, 2004*. Personal information is defined in the proposed *Act* to include personal health information.

The purpose of the proposed *Act*, as stated in section 1, is to improve the health and safety of Ontarians by permitting the monitoring, analysis and reporting of information, including personal information, related to the prescribing and dispensing of monitored drugs in order to:

- contribute to and promote appropriate prescribing and dispensing practices;
- identify and reduce the abuse, misuse and diversion of monitored drugs; and
- reduce the risk of addiction and death resulting from the abuse or misuse of monitored drugs.

Fundamental Concerns

1. *The lack of clarity as to how the collection, use and disclosure of personal information will achieve the stated purpose of the proposed Act*

The proposed *Act* does not provide an explanation as to how empowering the Minister or the Executive Officer to collect, use or disclose personal information and therefore to track and

monitor the personal information of individuals prescribed and dispensed a monitored drug, including the address, date of birth and gender of the individual and the name, strength and quantity of the monitored drug prescribed, will achieve the stated purpose of the proposed *Act*. For example, the proposed *Act* does not specify the circumstances in which the Minister or the Executive Officer will direct prescribers, dispensers and operators of pharmacies to disclose personal information and the criteria that will be used by the Minister or the Executive Officer in determining the actions that will be taken in respect of the personal information, including the circumstances in which, the purposes for which and to whom personal information will be disclosed.

The on-line management of prescription medications will allow the purposes of the proposed *Act* to be achieved, without the need to resort to the extraordinary measure of empowering the government, namely the Minister or the Executive Officer, to track and monitor the personal information of all individuals who have been prescribed and dispensed monitored drugs.

2. *Given the availability of less privacy intrusive measures, the proposed Act does not appear to be a necessary and proportionate means of achieving the stated purposes*

A press release dated August 27, 2010, entitled *Ontario Moving to Reduce Abuse of Prescription Narcotics*, states that prescriptions for monitored drugs will be collected by the Minister and the Executive Officer pursuant to the proposed *Act* and will be monitored through an electronic database. The electronic database will analyze and flag patterns of inappropriate or excessive prescribing and dispensing of monitored drugs. The Minister also indicated that a province-wide system of alerts will be implemented to detect attempts to visit multiple prescribers or multiple dispensers.

Despite this explanation, it is open to serious question whether requiring prescribers, dispensers and operators of pharmacies to disclose personal information to and upon the direction of the Minister or the Executive Officer and permitting the Minister or the Executive Officer to collect and use this personal information, is necessary to achieve the stated purpose of the proposed *Act*; is a proportionate response in relation to the stated purpose; and that other less privacy intrusive measures are either not available or would not achieve the stated purpose.

More specifically, it is not clear that personal information is required to contribute to and promote appropriate prescribing and dispensing practices for monitored drugs. This is because other more proportionate and less privacy intrusive measures that do not involve the collection, use and disclosure of personal information by the Minister or the Executive Officer would appear to be available, including:

- The development, implementation and enforcement of standards of practice to assure the quality of practice of health professionals in prescribing and dispensing monitored drugs;
- The development and implementation of clinical practice and other guidelines in relation to the quantity, duration and dose of monitored drugs that are prescribed and dispensed;

- Education and training to develop, establish and maintain the required standards of knowledge and skill and to promote continuing competence among health professionals in prescribing and dispensing monitored drugs; and
- Stronger enforcement of the *Drug and Pharmacies Regulation Act*, the *Regulated Health Professions Act, 1991* and other relevant statutes.

In addition, it is important to note that the government already has a broader e-health strategy and legislation in place that will achieve the stated purpose of the proposed *Act*. As a result, the proposed *Act* would appear to be redundant.

On-line management of prescription medications has been identified by eHealth Ontario as one of three clinical priorities and therefore forms part of the broader e-health strategy. According to *Ontario's eHealth Strategy 2009 – 2012*, released on March 19, 2009, province-wide rollout will commence in 2011 – 2012 and will include an electronic prescribing solution, a drug information system, a drug profile viewer and computerized physician order entry systems. Once implemented, dispensers will have access to electronic records of personal health information to view pending prescriptions and prescribers will have access to a comprehensive medication record for individuals, as well as their pending prescriptions. In a document entitled, *Ontario's Narcotics Strategy: Frequently Asked Questions*, the Ministry of Health and Long-Term Care states that the database in support of the proposed *Act* is “expected to be operational in 2011.” Therefore, by the time the database in support of the proposed *Act* would be operational, according to the e-health strategy, the on-line management of prescription medications would be rolling out province-wide.

As a result, even in the absence of the proposed *Act*, prescribers, dispensers and operators of pharmacies would have the information necessary to appropriately prescribe and dispense monitored drugs and to identify and thereby reduce the abuse, misuse or diversion of monitored drugs. Additionally, they would be permitted to disclose this information in appropriate circumstances pursuant to the *Personal Health Information Protection Act, 2004*. This demonstrates further the redundancy of the proposed *Act*.

The *Personal Health Information Protection Act, 2004* already permits prescribers, dispensers and operators of pharmacies to disclose personal health information without the consent of the individual to whom the personal health information relates, if there are reasonable grounds to believe that the disclosure is necessary for the purpose of eliminating or reducing a significant risk of serious harm. In addition, they are also given the discretion to disclose personal health information without consent to a person carrying out an inspection, investigation or similar procedure that is authorized by a warrant or by or under any Act of Ontario or Canada. Finally, note that prescribers, dispensers and operators of pharmacies are permitted to disclose personal health information to a college within the meaning of the *Regulated Health Professions Act, 1991* for the purpose of administering and enforcing certain legislation, including the *Drug and Pharmacies Regulation Act*.

The on-line management of prescription medications will allow the purposes of the proposed *Act* to be achieved, without the need to resort to the extraordinary measure of empowering the government, namely the Minister or the Executive Officer, to track and monitor the personal information of all individuals who have been prescribed and dispensed monitored drugs.

3. *The unjustified intrusion on the privacy of individuals resulting from the directed disclosure of sensitive personal information to the government*

The requirement imposed on prescribers, dispensers and operators of pharmacies under section 8 of the proposed *Act*, namely to disclose sensitive personal information to and upon the direction of the government through a direction issued by the Minister or the Executive Officer, has serious privacy implications.

The privacy implications arise from the fact that personal health information, which is among the most sensitive types of information, is routinely provided by individuals to their health care providers in the context of a trust relationship. Empowering the government to direct prescribers, dispensers and operators of pharmacies to disclose personal health information, which has been collected or provided in the course of this relationship may not only undermine trust in this relationship, but may also deter individuals from seeking necessary care and treatment and cause individuals to withhold or falsify information provided to their health care providers.

The intrusiveness of the proposed *Act* is even more pronounced when, as in section 14 of the proposed *Act*, a person is guilty of an offence for failing to disclose information as directed by the Minister or the Executive Officer and on conviction is liable to a fine and/or to a term of imprisonment.

It is important to note that the directed disclosure of personal information mandated by the proposed *Act* would remove all clinical and professional judgement that is generally required to be exercised by health care providers in determining whether to disclose personal health information in any particular circumstance. Disclosure, as opposed to the protection of privacy, would become the default.

Others have also acknowledged the need for health care providers to exercise discretion prior to any disclosure of personal health information in the context of monitored drugs. In its report entitled *Avoiding Abuse, Achieving A Balance: Tackling the Opioid Public Health Crisis*, the College of Physicians and Surgeons of Ontario states:

Of course, not all potential contraventions of the law will be intentional or done with criminal intent. For example, an elderly patient may seek to refill a prescription accidentally, not realizing that he/she already has sufficient pills. Also, there may be cases where a patient approaches a doctor for treatment of his/her drug

addiction and shares information that might otherwise be reportable. *It is not in the patient's or the community's interest to disclose information provided by patients who are seeking to overcome their drug addiction. Health-care professionals and health information custodians will be expected to exercise professional judgment, as they commonly do in other aspects of their work. [Emphasis added]*

Previously, the Government of Ontario was strongly criticized when it attempted to enact a provision that would provide the Minister with the broad power to compel health care providers to disclose personal health information to the Minister for the purposes of planning and managing the health system in the context of Bill 159, the predecessor to the *Personal Health Information Protection Act, 2004*. For example, in its submission to the Standing Committee reviewing Bill 159, the former President of the Ontario Medical Association (“OMA”) stated that the OMA did not support the provision in Bill 159 that “would allow the government to force the disclosure of patient charts that are held by physicians” and requested that the provision be deleted in its entirety. Thereafter, this provision was removed from Bill 159 and an alternate framework was developed and now appears in the *Personal Health Information Protection Act, 2004*.

The broad scope of the proposed directed disclosure of personal information in the proposed *Act*, which is reminiscent of the directed disclosure provision in Bill 159, further exacerbates our concern. Specifically, the personal information of *all* individuals prescribed or dispensed monitored drugs will be disclosed to and will be collected, monitored and analyzed by the Minister or the Executive Officer, rather than just the personal information of the small minority of individuals who are allegedly abusing, misusing or diverting monitored drugs.

Further, a monitored drug is broadly defined in section 2 of the proposed *Act* to mean a controlled substance under the *Controlled Drugs and Substances Act*, unless the controlled substance has been excluded by the regulations, and any other drug designated in the regulations to the proposed *Act*. Therefore, the Minister or the Executive Officer will be authorized to direct the disclosure of and to collect, monitor and analyze the personal information of all individuals prescribed and dispensed such drugs as Tylenol 3 and Ritalin unless these are specifically excluded by the regulations.

Monitoring the prescription, dispensing and use of monitored drugs may also have a chilling effect on the willingness of individuals to be prescribed, and of health care providers to prescribe, monitored drugs. This may, in turn, impact the ability of the proposed *Act* to achieve one of its stated purposes – to support access to monitored drugs for medically appropriate treatment. Monitoring and tracking the prescription and dispensing of monitored drugs may also have unintended consequences, such as increasing the abuse and misuse of illegal drugs or other addictive substances, thereby displacing one identified problem with other, perhaps more serious, problems.

Comments on Specific Sections of the Proposed Act

Should the government decide to proceed with the proposed *Act* despite our overarching concerns related to the need for and the proportionality of the framework established by the proposed *Act*, we offer the following comments on specific sections of the proposed *Act*.

1. Section 6 – Notice Requirements

Given the nature and sensitivity of the personal information that will be collected by the Minister or the Executive Officer, transparency about the collection, use and disclosure of personal information is essential. It is therefore recommended that section 6 of the proposed *Act* be amended to prescribe the minimum content of the notice that is required to be made available to prescribers, dispensers, operators of pharmacies and the public and to require that the notice be posted or be made readily available where it is likely to come to the attention of the public. In particular, it is recommended that the proposed *Act* be amended to include the following section:

6.1 (1) The notice that is required to be made available under section 6 shall set out:

- (a) the personal information that the prescriber, dispenser or operator of a pharmacy is required to disclose to the Minister or the executive officer under this Act;
- (b) the purposes for which the Minister or the executive officer may use personal information for the purpose of this Act;
- (c) the purposes for which and the circumstances in which personal information may be disclosed by the Minister or the executive officer and the persons or organizations to which the personal information may be disclosed;
- (d) the length of time that the personal information will be retained by the Minister or the executive officer;
- (e) the administrative, technical and physical safeguards that have been implemented by the Minister or the executive officer to protect the privacy of individuals whose personal information is collected and to maintain the confidentiality of that information, and
- (f) the name and/or title and contact information of the person to whom inquiries or concerns may be directed.

(2) Prescribers, dispensers and operators of pharmacies are required to post or make readily available the notice required under section 6 where it is likely to come to the attention of the public.

2. *Section 8 – Directed Disclosures by Prescribers, Dispensers or Pharmacy Operators*

Subsection 8(1) lacks clarity as to the scope of the personal information that is properly the subject matter of a direction to disclose personal information to the Minister or the Executive Officer. Subsection 8(1)1 of the proposed *Act* authorizes the Minister or the Executive Officer to direct a prescriber, dispenser or operator of a pharmacy to disclose information, including personal information, “required under section 10 or 11” of the proposed *Act*. Subsection 10(2) and subsection 11(5) of the proposed *Act* state that nothing in section 10 or section 11 limits or replaces the application of any other Act with respect to the information that must be recorded on a prescription or for which a record must be kept.

Given the information that must be recorded on a prescription or for which a record must be kept pursuant to another Act is not “required under section 10 or 11” of the proposed *Act*, it appears that this information would not properly be the subject of a directed disclosure. It is recommended that this be clarified in section 8 of the proposed *Act*. In particular, it is recommended that subsection 8(1)1 of the proposed *Act* be amended as follows:

8. (1) If directed by the Minister or the executive officer, a prescriber, dispenser or operator of a pharmacy shall disclose the following information to the Minister or the executive officer for the purpose of this Act:

1. The information, including personal information, required under *subsection 10(1) or 11(1)* ~~section 10 or 11~~.

In addition, due to the privacy implications associated with directed disclosures, it is recommended that the proposed *Act* be amended to subject any direction to disclose personal information to independent oversight by requiring the Minister or the Executive Officer, as the case may be, to submit a proposal to the Information and Privacy Commissioner of Ontario for review and comment prior to directing any disclosure of personal information. In particular, it is recommended that section 8 of the proposed *Act* be amended to add the following subsections:

8. (5) Prior to issuing a direction to disclose personal information pursuant to subsection 8 (1), the Minister or the executive officer shall submit a proposal to and allow the Information and Privacy Commissioner of Ontario to review and comment on the proposal.

(6) Within 30 days after the Information and Privacy Commissioner of Ontario receives the proposal, the Information

and Privacy Commissioner of Ontario shall review the proposal and may comment in writing on the proposal.

(7) In reviewing the proposal, the Information and Privacy Commissioner of Ontario shall consider the public interest in directing the disclosure and the privacy interest of the individuals to whom the personal information relates in the circumstances.

(8) The Minister and the executive officer shall consider the comments, if any, made by the Information and Privacy Commissioner of Ontario within the time specified in subsection (6), and may amend the proposal if the Minister and the executive officer consider it appropriate.

Similar provisions exist in section 47 of the *Personal Health Information Protection Act, 2004*, the only provision authorizing the directed disclosure of personal health information. Section 47 of the *Personal Health Information Protection Act, 2004* states that prior to directing health information custodians to disclose personal health information to a health data institute for analysis, the Minister must submit a proposal to the Information and Privacy Commissioner of Ontario for review and comment.

In order to limit the personal information that would be disclosed pursuant to a direction of the Minister or the Executive Officer, it is further recommended that section 8 of the proposed *Act* be amended to prohibit the Minister and the Executive Officer from requiring a prescriber, dispenser or operator of a pharmacy to disclose personal information if other information will serve the purpose and from disclosing more personal information than is reasonably necessary to meet the purpose. In particular, it is recommended that section 8 of the proposed *Act* be amended to include the following subsections:

8. (9) The Minister or the executive officer shall not issue a direction to disclose personal information pursuant to subsection 8 (1) if other information will serve the purpose of the disclosure.

(10) The Minister or the executive officer shall not issue a direction pursuant to subsection 8(1) to disclose more personal information than is reasonably necessary to meet the purpose of the disclosure.

In our opinion, this amendment is especially important because the general limiting principles in section 30 of the *Personal Health Information Protection Act, 2004*, which prohibit prescribers, dispensers and operators of pharmacies from disclosing personal health information if other information will serve the purpose and from disclosing more personal health information than is reasonably necessary to meet the purpose, do not apply to disclosures that are required by law. It is also important given the Lieutenant Governor in Council may make regulations pursuant to

section 17 of the proposed *Act* to expand the personal information that the Minister or Executive Officer may direct to be disclosed.

3. *Section 17 – Regulations*

Section 17 of the proposed *Act* provides the Lieutenant Governor in Council with substantial power to make regulations under the proposed *Act*, including regulations specifying the requirements or conditions in respect of the collection, use or disclosure of personal information by the Minister or the Executive Officer and respecting the information, including personal information, which is required to be disclosed to the Minister or Executive Officer.

Given that such regulations may have significant privacy implications, we are pleased that the proposed *Act* contemplates public consultation. However, we are concerned that the proposed *Act* may not provide sufficient notice and time for interested members of the public to comment on the proposed regulations.

The notice of the proposed regulation will only be published on the website of the Ministry of Health and Long-Term Care and “in any other format the Minister considers advisable.” Publication in *The Ontario Gazette* is not specifically mentioned. Further, members of the public will be given a minimum of thirty days to comment on the proposed regulation and this may be further abridged in accordance with subsection 17(5) of the proposed *Act*.

Due to the scope of the regulations contemplated and their associated privacy implications, it is recommended that the proposed *Act* be amended to require that the notice of proposed regulation be published in *The Ontario Gazette* and that members of the public be given at least sixty days to comment on the proposed regulation, calculated from the date that the Minister has published the notice. The requirement for publication of the proposed regulations in *The Ontario Gazette* and the general requirement for a sixty-day public consultation period would be consistent with the provisions in the *Personal Health Information Protection Act, 2004*.

It is therefore recommended that subsections 17(2) and 17(4) of the proposed *Act* be amended as follows:

17. (2) The Lieutenant Governor in Council shall not make any regulations under clause (1) (b), (d), (f), (g), (h) or (i) unless,
 - (a) the Minister has published a notice of the proposed regulation in *The Ontario Gazette*, on the website of the Ministry and in any other format the Minister considers appropriate for the purpose of providing notice to the persons who may be affected by the proposed regulation advisable;
 - (b) the notice complies with the requirements of this section;

- (c) the time periods specified in the notice, during which members of the public may exercise a right described in clause (3) (b) or (c), have expired; and
- (d) the Minister has considered whatever comments and submissions that members of the public have made on the proposed regulation in accordance with clause (3) (b) or (c) and has reported to the Lieutenant Governor in Council on what, if any, changes to the proposed regulation the Minister considers appropriate.
- (e) all other information that the Minister considers appropriate.

[...]

- (4) The time period mentioned in clauses (3) (b) and (c) shall be at least ~~60~~ 30 days after the Minister gives the notice mentioned in clause (2) (a) unless the Minister shortens the time period in accordance with subsection (5).

Other Recommended Provisions in the Proposed Act

The proposed *Act* contemplates broad collection of personal information by the Minister or the Executive Officer in relation to individuals that have been prescribed and dispensed monitored drugs. However, the proposed *Act* does not address how the Minister and the Executive Officer will protect the privacy of individuals with respect to this personal information.

In particular, it is recommended that the proposed *Act* specify the maximum length of time that the personal information will be retained by the Minister or the executive officer in identifiable form; the persons who will have access to the personal information; the purposes for which they are permitted to access this personal information; and the administrative, technical and physical safeguards that must be implemented to protect the personal information from unauthorized use or disclosure.

Conclusion

The Office of the Information and Privacy Commissioner of Ontario has fundamental concerns with respect to the need for and the proportionality of the proposed *Act*, especially given the availability of less privacy intrusive measures and given impeding e-health initiatives and current legislation that would appear to render the proposed *Act* redundant.

However, should the government decide to proceed with the proposed *Act* despite these concerns, we urge the Standing Committee on Social Policy to consider our comments and recommendations on specific sections of the proposed *Act*. These comments and recommendations are aimed at promoting transparency and clarifying and minimizing the personal information being collected, used and disclosed; providing independent oversight of any directed disclosure of personal information; and ensuring adequate public consultation in respect of any regulations contemplated under the proposed *Act*.

Thank you for providing the Office of the Information and Privacy Commissioner of Ontario with the opportunity to comment on the proposed *Act* and for considering our views in this matter. We would be pleased to provide the Standing Committee on Social Policy or the Ministry of Health and Long-Term Care with any further information or clarification necessary.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Ken Anderson', with a long horizontal flourish extending to the right.

Ken Anderson
Assistant Commissioner (Privacy)