



**ISMP Canada's Guidance for
Sharing Medication Incident Data
in the Era of Ontario's
PHIPA, QCIPA and FIPPA**

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The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national, and international patient safety organizations, the pharmaceutical industry, and the public to promote safe medication practices.

ISMP Canada's mandate includes review and analysis of medication incident and near-miss reports, identifying contributing factors and causes and making recommendations for the prevention of harmful medication incidents. Information on safe medication practices for knowledge translation is published and disseminated.

Additional information about ISMP Canada, and its products and services, is available on the website: www.ismp-canada.org

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**ISMP Canada's Guidance for Sharing Medication Incident Data
in the Era of Ontario's *Personal Health Information Protection Act, 2004* (PHIPA) and the *Quality of Care Information Protection Act, 2004* (QCIPA); updated October 2011 to reflect changes to the *Freedom of Information and Protection of Privacy Act* (FIPPA)**

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent, national, not-for-profit organization established to analyze medication error reports and develop recommendations for the enhancement of patient safety. ISMP Canada is committed to promoting the safe use of medications.

To fulfill this commitment, ISMP Canada collects information regarding preventable adverse drug events from individual healthcare practitioners and institutions on a voluntary basis. The information is received by ISMP Canada via telephone, email, mail, fax, a web-based reporting function and through "Analyze-ERR", a software documentation tool designed by ISMP Canada to track and analyze medication errors at participating healthcare institutions.

In May 2006, ISMP Canada posted the first version of this Guidance document on its website. It was created to confirm that medication incident information received by ISMP Canada does not fit within the definitions of "personal health information" (health information that is individual-identifying and protected in Ontario under PHIPA) or "quality of care information" (opinions and conclusions that arise during a committee review and protected in Ontario under QCIPA.) In our view, neither PHIPA nor QCIPA limits the ability of practitioners and hospitals to voluntarily share non-identifying facts about a medication incident with ISMP Canada.

On January 1, 2012, Ontario hospitals will be "institutions" under the *Freedom of Information and Protection of Privacy Act* (FIPPA.) FIPPA governs institutions with regard to collection, use and disclosure of "personal information" and provides rights of access to information within the custody or control of the institution.

This updated version of the Guidance document includes ISMP Canada's review of rules that relate to disclosure of information under FIPPA, considers some of the impacts on hospitals that report medication incident information to ISMP Canada and shows that reporters can continue to share incident information that consists of non-identifying facts about the incident.

Personal Health Information Protection Act, 2004

In November of 2004, Ontario's *Personal Health Information Protection Act* ("PHIPA") came into force. PHIPA governs how health care practitioners and institutions collect, use and disclose personal health information. The underlying principle of the legislation is that consent is required for the use, collection or disclosure of personal health information. "Personal health information" is defined as any "identifying information about an individual in oral or recorded form" that is related to the provision of health care. The Act defines "identifying information" as being any information that identifies, or could be reasonably foreseen to identify, an individual.

In the process of fulfilling its mandate, ISMP Canada requests healthcare practitioners and institutions to provide it with information regarding adverse events involving medication errors. Specifically, ISMP Canada asks for the following information to be shared:

- a description of the incident or preventable adverse drug event
- information about the patient's medical condition
- the outcome of the adverse drug event and the patient's status
- the type of healthcare facility where the incident occurred
- the type and dosage of medication involved
- a description of how the incident was discovered
- any recommendations the practitioner or institution may have as to how the institution intends to prevent similar incidents in the future
- a description of the healthcare practitioners involved in the incident
- information which identifies the institution
- contact information for the person reporting to ISMP Canada

ISMP Canada does not require any information that identifies or may reasonably be foreseen to identify an individual. More specifically, ISMP Canada requests that all identifying information about patients be removed prior to it being shared.

As a way to assist practitioners or institutions in ensuring that personal health information is not disclosed during the collection process, ISMP Canada uses the "Analyze ERR" software that is designed to restrict collection to non-identifying information.

Despite the above-mentioned precautions, it is possible that, on occasion, information submitted to ISMP Canada may inadvertently include identifying information as defined in PHIPA. ISMP Canada has a privacy policy that covers this type of situation. Accordingly, where identifiable personal information is inadvertently disclosed in an incident report, ISMP Canada has practices and procedures in place to de-identify the information and inform reporters that identifiable information is not required for incident reporting. The identifying information is securely destroyed and the only information kept is de-identified.

Quality of Care Information Protection Act, 2004

Alongside the arrival of PHIPA was the arrival of the *Quality of Care Information Protection Act, 2004* ("QCIPA"). QCIPA provides for the collection, use and disclosure of information in the context of a quality assurance review process conducted by an institution in the wake of an adverse event. "Quality of care information" is defined by the Act as information collected by or prepared for a quality of care committee for the purposes of the committee. These purposes are for the improvement and maintenance of the provision of health care. The Act restricts the disclosure of quality of care information to limited circumstances in order to facilitate open and honest communication during the review process.

Given that QCIPA reviews often follow an adverse event, information that is collected during the review may be a component of the information that a health care provider or hospital wishes to report to ISMP Canada. ISMP Canada does not expect practitioners and institutions to share quality of care information in their reporting of adverse events involving medication errors. The majority of information requested by ISMP Canada (as noted above) is information that QCIPA does not include in its definition of quality of care information. While QCIPA protects opinions and conclusions shared during the review, it does not protect any of the facts uncovered. The Act stipulates that the following information is outside the scope of quality of care information:

- information found in a patient's health record;
- new facts learned during the course of a QCIPA review; and
- the fact that a quality of care committee met and conducted a review and when it took place

In light of this allowance in the Act, the restrictions under QCIPA should not effect the sharing of information with ISMP Canada. It is important to note that, although QCIPA does not prevent disclosure of this information, PHIPA restrictions will still apply to any information that is personal health information.

The one category of information requested by ISMP Canada that may be restricted under QCIPA is "recommendations as to how the institution intends to prevent similar incidents in the future". If recommendations are arrived at during a quality of care review process, they are protected as quality of care information. However, the Act allows for disclosure of the actual follow-up actions taken by an organization following a QCIPA review as long as the conclusions or opinions of the quality of care committee that led to the follow-up action being taken are not shared. ISMP Canada would therefore request that any recommendations shared with regard to how the institution intends to prevent similar incidents in the future, be limited to recommendations arrived at outside a QCIPA review process or to ones that have actually been implemented.

October 2011 Update—*Freedom of Information and Protection of Privacy Act (FIPPA)*

On January 1, 2012, Ontario hospitals will become "institutions" under Ontario's *Freedom of Information and Protection of Privacy Act* (FIPPA.) Like PHIPA, FIPPA provides privacy protections via rules that apply to the collection, use and disclosure of "personal information." Like personal health information, "personal information" is identifying information about an individual, such as a name, address and other information about a person. "Personal health information" continues to be governed under PHIPA and the rules in FIPPA for "personal information" do not apply to "personal health information".¹

In addition, FIPPA is an access-to-information statute: FIPPA provides "every person" with a right of access to general records in the custody or control of the institution, as well as to their own "personal information." The FIPPA definition of "record" includes "any record of information", "whether in printed form, on film, by electronic means or otherwise." FIPPA provides a broad right to make access requests, although certain kinds of records are excluded or exempt.

What is important to note is that the rules in place regarding "personal health information" under PHIPA and "quality of care information" under QCIPA as they apply to flows of medication incident information to ISMP Canada will not change. In our view, the flows and procedures that facilitate reporting of incident information to ISMP Canada—limited to non-identifying facts about the incident, not about the patient—are not impacted by FIPPA. While FIPPA will establish new obligations for hospitals with regard to receiving access requests, there is nothing in the statute that would impinge upon the ability of health practitioners and hospitals to voluntarily share non-identifying facts about medication incidents.

¹ Note that where "personal information" is included in a record of "personal health information", all of the information in the record is considered to be "personal health information" and governed under PHIPA.

Conclusion

ISMP Canada embraces the protections of information mandated in Ontario by PHIPA, QCIPA and now FIPPA, and its commitment to the safe use of medications works within these statutes. This position paper is meant to explain how ISMP Canada works in accordance with the legislative structures of PHIPA, QCIPA and FIPPA. It is also our hope that we have provided comfort to health care practitioners and institutions who share important information with us in the wake of an adverse event involving a medication error. The confidentiality of quality of care committee deliberations are of utmost importance to ISMP Canada, as are the privacy interests of those patients involved in these types of events, which we respect throughout the implementation of our mandate.

The original May 2006 position paper was prepared by ISMP Canada in consultation with Borden Ladner Gervais LLP. Contributors included Sylvia Hyland (Vice President, ISMP Canada), Kristin L. Taylor (Borden Ladner Gervais LLP) and Karen Weisbaum (Privacy Consultant and Policy Advisor to ISMP Canada.)

The October 2011 updates regarding FIPPA were prepared in consultation with Borden Ladner Gervais LLP. Contributors included Sylvia Hyland (Vice President, ISMP Canada), Patrick J. Hawkins (Borden Ladner Gervais LLP) and Karen Weisbaum (Privacy Consultant and Policy Advisor to ISMP Canada.)