

ALBERTA INFORMATION AND PRIVACY COMMISSIONER

Report on the Investigation into a Pharmacist's Collection of Individually Identifying Health Information for the Purpose of Selling Insulin

Ping Yu, Pharmacist, Wal-Mart Canada Corp.

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Investigation Report H2006-IR-001

(Investigation H0690)

I. Introduction

[para 1] An individual wrote the Commissioner with a concern that a pharmacist had attempted to collect information about the individual in contravention of the *Health Information Act* (HIA). Specifically, a pharmacist refused to sell him Insulin without the individual providing the pharmacist with his name and other personal information.

[para 2] The Commissioner determined he did not have jurisdiction to investigate the individual's complaint under section 73(2) of the HIA as this would require that the individual's health information had actually been collected by the pharmacist. However, the Commissioner determined the issue was an important one and decided to conduct an investigation under section 84(a) of the HIA. This provision allows the Commissioner to conduct investigations to ensure compliance with any provision of the HIA.

II. Background

[para 3] The incident occurred at a pharmacy ("the Pharmacy") located at a Wal-Mart store in Edmonton. The Pharmacy operates within the store's premises. Although the Pharmacy operates as "Wal-Mart Pharmacy", Wal-Mart does not hold the pharmacy license. Rather, pursuant to the provisions of the *Pharmaceutical Profession Act*, the license has been issued to Ping Yu, the Pharmacist Manager ("the Pharmacist"), who manages, controls and supervises the Pharmacy.

[para 4] An individual approached a counter attendant at the Pharmacy and stated that he wished to purchase one vial of Humulin N, a brand of Insulin. The

customer did not have a prescription for the Insulin; however, a prescription is not required as Insulin is listed as a "Schedule 2" drug under the *Pharmaceutical Profession Act*. Schedule 2 drugs must only be sold in a pharmacy under the direct supervision of a pharmacist but do not have to be dispensed for sale pursuant to a prescription.

[para 5] The attendant, who was a pharmacy student, asked the individual to provide some personal information. The individual refused and was referred to a senior pharmacist. The senior pharmacist advised the customer that, in accordance with normal store and professional practice, his name was required for the Pharmacy's records. The pharmacist attempted to explain why the Pharmacy required the information but the customer maintained his position. As a result, the pharmacist decided not to sell the Insulin to the customer.

[para 6] I was advised by the Pharmacist that the normal practice, in circumstances where a customer wishes to buy Insulin, is to collect the prospective purchaser's name, address, date of birth and phone number. Relevant information pertaining to any allergies or medical conditions is also collected. The Pharmacist further advised that the practice is based on the Standards of Practice as issued and enforced by the Alberta College of Pharmacists ("the College").

[para 7] The purpose of this investigation is to determine whether the Pharmacist's practice of collecting information from individuals, as described above, is authorized by the HIA.

III Application of HIA

[para 8] The HIA applies to 'health information' in the custody or under the control of a 'custodian'. To determine the Commissioner's jurisdiction in this matter, I must first find that the Pharmacist is a 'custodian' and that the information collected is 'health information'.

[para 9] The definition of custodian includes a pharmacist as defined in the *Pharmaceutical Profession Act*. The *Pharmaceutical Profession Act* says a pharmacist is an individual who is issued a certificate of registration and who holds an annual certificate entitling the individual to engage in the practice of pharmacy. I have confirmed that the Pharmacist meets the aforementioned criteria and is therefore a custodian and subject to the HIA.

[para 10] The definition of 'health information' includes diagnostic, treatment and care information, registration information and health service provider information. The information collected by the Pharmacist includes the prospective purchaser's name, address, date of birth and phone number, as well as relevant information pertaining to any allergies or medical conditions. The

definition of registration information includes demographic information, location information and residency information. Based on the definition of 'health information', I find the information collected by the Pharmacist is health information.

IV Analysis

[para 11] The relevant portion of the HIA concerning the collection of 'health information' and this investigation reads as follows:

20 A custodian may collect individually identifying health information
(a) if the collection of that information is expressly authorized by an enactment of Alberta or Canada, or
(b) if that information relates directly to and is necessary to enable the custodian to carry out a purpose that is authorized under section 27 of the HIA.

27(1) A custodian may use individually identifying health information in its custody or under its control for the following purposes:
(a) providing health services
(f) carrying out any purpose authorized by an enactment of Alberta or Canada
(g) for internal management purposes, including planning, resource allocation, policy development, quality improvement, monitoring, audit, evaluation, reporting, obtaining or processing payment for health services and human resource management.

[para 12] The Pharmacist says her practice of collecting health information, as applied to the sale of Insulin, is authorized by section 20(b) of the HIA. The Pharmacist cites sections 27(1)(a), 27(1)(f) and 27(1)(g) as the authorized purposes. This report will examine whether the Pharmacist has authority to collect health information for the purpose of providing health services, for a purpose authorized by an enactment of Alberta or Canada, and for internal management purposes.

1. Is the Pharmacist's practice of collecting health information authorized by section 20(b) and section 27(1)(a) of the HIA?

[para 13] Section 20(b), in conjunction with section 27(1)(a) of the HIA, authorizes a custodian to collect individually identifying health information for the purpose of providing health services.

[para 14] To find in favour of the Pharmacist, I must establish the following facts:

- the 'practice of pharmacy' is a health service,
- the sale of Insulin is included within the scope of the 'practice of pharmacy',
- the information is directly related to the sale of Insulin and
- the information is necessary to enable the Pharmacist to sell Insulin.

[para 15] The HIA says a 'health service' means a service that is provided to an individual, including a service provided by a pharmacist engaging in the 'practice of pharmacy' as defined in the *Pharmaceutical Profession Act*.

[para 16] I find that the 'practice of pharmacy' is a health service.

[para 17] Section 1(1)(u) of the *Pharmaceutical Profession Act*, defines 'practice of pharmacy' and includes *the preparation, compounding, dispensing, storing, controlling, handling and selling of drugs, non-prescription medications and health related products...*

[para 18] I find that the selling of drugs, including Insulin, is included within the scope of the practice of pharmacy.

[para 19] The following information was submitted by the Pharmacist as a description of how the information she collects relates to the practice of pharmacy and why the information is necessary to enable the Pharmacist to carry out the practice of pharmacy.

- *Recall and product withdrawal issues: Various drugs, including Insulin, Vioxx and Bextra, have been recalled by the manufacturer because of specific deficiencies or quality assurance issues. These include inappropriate amounts of active ingredients, preservative errors, wrong active ingredients being added, stability issues and errors concerning the information recorded on the label. In such circumstances, it is imperative for the pharmacy to contact the purchaser (or user) to inform them of the concern. The need to so communicate obviously requires that the purchaser's name, address and phone number have been recorded. The date of birth may be important in the event that two purchasers have the same name. For example, in the case of insulin, it may be determined following a purchase that the expiry date is more imminent than noted. A failure to contact the purchaser in a timely manner may result in the patient injecting expired insulin, with potentially devastating results to their health. Or, as has happened in the past, specific types of insulin have been withdrawn from the market i.e. beef and pork-based insulin. Customers were then contacted approximately one month ahead of the potential withdrawal in order to make necessary arrangements to obtain different insulin from other sources. Discontinuation of those kinds of insulin also necessitated dosage adjustments and consequential monitoring for some patients. Without appropriate contact information in the pharmacy's records, such timely*

notification would have been impossible.

- Monitoring and personal welfare of the patient: In the case of insulin, preferred practice dictates that, for the ongoing well-being and health of the diabetic patient, the pharmacy document certain information and create and maintain a patient profile. As again confirmed by the Standards of Practice, it is incumbent on the pharmacist to collect appropriate information concerning the patient in order to properly assess their medical state and condition, ensure that the insulin is truly necessary and monitor their ongoing care. Such a record also facilitates determination of potential drug interactions and disease interactions. Indeed, because most diabetics see their pharmacist more frequently than their physician, the pharmacist needs to have an informed dialogue with the patient in order to ensure optimal disease management.

Insulin, by its very nature, can be a problematic drug if not used properly. For example, it can be harmful if injected by a person not properly trained (e.g. overdose). Further, maintaining a patient file record containing pertinent information can assist in monitoring the patient's use of insulin and may facilitate an appropriate change to the medication regime itself (e.g. adding a longer acting insulin). In such circumstances, the pharmacist can intervene to ensure that a diabetic patient is receiving optimal care/treatment of their chronic disease, but this is obviously only possible where the patient can be contacted.

Further, it is not uncommon for diabetic patients to have to attend at a hospital for emergency treatment. Appropriate file data may assist the hospital when contacting the pharmacy to gather or verify the requisite information necessary for proper care of the patient.

The pharmacist also needs to ensure that the proper insulin product is being purchased in each case, especially in the absence of a physician's prescription. For example, on occasion there is confusion over whether the purchaser is seeking "human insulin" or "Humulin N" insulin. (Human insulin refers generically to insulin synthetically made versus being produced from an animal. "Humulin N" is a specific brand of human insulin, but there are others such as "Novolin").

It should be noted that the pharmacy profession, beyond the enforcement of the Standards of Practice, encourages the creation and maintaining of an appropriate patient file. Indeed, the University of Alberta pharmacy school recommends and teaches this procedure to its students, training them to document appropriately. Moreover, the profession's Code of Ethics mandates the swearing of an oath to the effect that the pharmacist will look out for the best interests of the patient and attempt to achieve the best possible health outcome. This objective, in turn, necessitates the gathering of relevant data and information from the patient, especially with risk-sensitive drugs like insulin.

- Determining appropriate need for insulin: More recently, the profession

has observed a growing and disturbing trend, particularly noticeable among non-diabetic young males, for insulin to be injected for bodybuilding purposes i.e. as a substitute for steroids. This development reinforces the requirement for pharmacists to ensure that the purchaser has a legitimate need for the drug and is aware of the serious side effects and risk factors associated with its use. For example, taking the wrong amount of insulin can cause a hypoglycemic reaction, with potentially fatal consequences. In short, it would be considered unethical for a pharmacist to sell non-prescribed insulin to a customer for the wrong reasons, especially where the person has not been educated on possible adverse reactions and cannot be contacted in the future.

[para 20] I accept the information provided by the Pharmacist as a description of the relationship between the information and the practice of pharmacy. I find the collection of the information relates directly to and is necessary to enable the Pharmacist to sell Insulin.

[para 21] As the selling of Insulin is a health service, and as the information collected is directly related to and necessary to enable the Pharmacist to sell Insulin, I conclude that the Pharmacist's practice of collecting health information is authorized by section 20(b) of the HIA.

[para 22] Although I have found that the Pharmacist's practice of collecting health information is authorized by section 20(b) in conjunction with section 27(1)(a), I have decided to also consider the additional authorities put forward by the Pharmacist.

[para 23] The Pharmacist says her practice of collecting health information is also authorized by section 20(b) and section 27(1)(f) of the HIA. She maintains that her practice of collecting health information is based on the Standards of Practice as developed and enforced by the Alberta College of Pharmacists ("the College") under the authority of the *Pharmaceutical Profession Act*.

2. Is the Pharmacist's practice of collecting health information authorized by section 20(b) in conjunction with section 27(1)(f) of the HIA?

[para 24] Section 20(b), in conjunction with section 27(1)(f) of the HIA, authorizes a custodian to collect individually identifying health information for a purpose that is authorized by an enactment of Alberta or Canada.

[para 25] To find in favour of the Pharmacist, I must establish the following facts:

- the selling of Insulin is authorized by the *Pharmaceutical Profession Act*,
- the information is for the purpose of selling Insulin and
- the *Pharmaceutical Profession Act* is an enactment of Alberta.

[para 26] Earlier in this report I found that the selling of drugs, including Insulin, to be included within the scope of the 'practice of pharmacy' as described by the *Pharmaceutical Profession Act*.

[para 27] Section 90(1) of the *Pharmaceutical Profession Act* authorizes the College to develop standards for the practice of pharmacy respecting "competency, ethical conduct and the application of pharmaceutical knowledge and skills".

[para 28] Section 27(3)(b) of the *Pharmaceutical Profession Act* says the holder of a pharmacy license shall comply with the standards for the practice of pharmacy developed by the College.

[para 29] The College has developed and issued the Standards of Practice which includes expectations regarding the sale of Insulin.

[para 30] Insulin is listed as a Schedule 2 drug under the *Pharmaceutical Profession Act*. The professional expectation of pharmacists, relating to Schedule 2 drugs, is recognized by the following Standards of Practice:

- Section 4.7(c): *The pharmacist shall interact with the patient regarding the selection and proper use of the Schedule 2 drug or nonprescription medication listed in Appendix A and, when appropriate, shall document the interaction.*

[para 31] The College also provides an Interpretation of Standards to give pharmacists additional information for the application of standards.

- Section 4.7.4: *The pharmacist should document the patient/pharmacist interaction in a clear , concise and easy to read format (i.e. patient profiles, consultation sheets or requisition form) that includes but is not limited to:*
 - i) *patient's name;*
 - ii) *name, strength and quantity of Schedule 2 drug or non-prescription medication listed in Appendix A;*
 - iii) *the date of sale or interaction;*
 - iv) *the recommendations made;*
 - v) *a follow-up, where possible, to determine patient outcome;*
 - vi) *a notation containing the reason counseling did not take place, if applicable; and*
 - vii) *the pharmacist's initials.*

[para 32] The Standards of Practice and accompanying Interpretation of Standards requires the pharmacist to collect and document information regarding the interaction with the patient.

[para 33] Based on the requirements of the Standards of Practice, I find that the collection of individually identifying health information is for the purpose of selling Insulin.

[para 34] I accept the fact that the *Pharmaceutical Profession Act* is an enactment of Alberta.

[para 35] As the selling of Insulin is authorized by an enactment of Alberta, and as the information collected by the Pharmacist is for the purpose of selling Insulin, I conclude that the Pharmacist's practice of collecting health information is authorized by section 20(b) of the HIA.

[para 36] The Pharmacist says her practice of collecting health information is also authorized by section 20(b) and section 27(1)(g) of the HIA. The Pharmacist suggests the information collected during the selling of Insulin is for internal management purposes.

3. Is the Pharmacy's collection practice authorized by section 20(b) in conjunction with section 27(1)(g) of the HIA?

[para 37] Section 20(b), in conjunction with section 27(1)(g) of the HIA, authorizes a custodian to collect individually identifying health information for a variety of internal management purposes.

[para 38] To find in favour of the Pharmacist, I must establish the following facts:

- the information collected is used for internal management purposes.

[para 39] The HIA does not define 'internal management'. However, section 27(1)(g) says that internal management includes '*planning, resource allocation, policy development, quality improvement, monitoring, audit, evaluation, reporting, obtaining or processing payment for health services and human resource management*'.

[para 40] The following information was also submitted by the Pharmacist. While the Pharmacist did not make specific reference to internal management purposes, the examples relate to what I consider to be internal management purposes:

- *Miscellaneous purposes: Other, less obvious purposes for recording basic demographic information in connection with the purchase of insulin include facilitating future refills and transferability to other stores and provinces as*

well as generating a valid receipt for income tax purposes.

- *Professional discipline and civil lawsuits: Finally, pharmacists who proceed to sell insulin without first requesting and obtaining basic health information run the risk of a subsequent complaint to the Alberta College of Pharmacists or exposing the pharmacy to a civil lawsuit. Either action is a distinct possibility in a variety of circumstances. For example, if appropriate contact information is not obtained from the purchaser and the insulin in question is subsequently recalled, the person may very well continue to use the deficient product to the potential detriment of their health and well-being.*

[para 41] I find that the information collected may be for internal management purposes.

[para 42] I conclude that the Pharmacist's practice of collecting health information is authorized by section 20(b) of the HIA.

V. Conclusion

[para 43] The Pharmacist's practice of collecting the prospective purchaser's name, address, date of birth and phone number and relevant information pertaining to any allergies or medical conditions for the sale of Insulin is authorized by section 20(b) of the *Health Information Act*.

[para 44] This investigation was initiated based on a complaint regarding an individual's attempt to purchase Insulin. The outcome may not be the same for the sale of other drugs listed in Schedule 2 of the *Pharmaceutical Profession Act*.

Submitted by

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