

INFORMATION AND PRIVACY COMMISSIONER OF ALBERTA

Investigation into the collection of health information using standardized forms

October 4, 2012

Calgary Co-op Shawnessy Centre Pharmacy

Investigation Report H2012-IR-001

(OIPC File H4770)

Introduction

[1] On April 10, 2012, the Information and Privacy Commissioner received a complaint from an individual related to the collection of health information. Specifically, the individual stated he attended the Calgary Co-op Shawnessy Centre Pharmacy (the Pharmacy) for the purpose of receiving a Vitamin B12 injection which had been prescribed by his physician. The individual objected to the collection of information about immune system conditions on a form that he was told he needed to complete before the injection would be administered. The individual stated he had concerns about potential discrimination and stigmatization due to the specific condition he suffers from. The individual took the form with him when he left the Pharmacy and provided it to the Commissioner with his complaint.

[2] The Commissioner initiated an investigation of the general practice of collecting information about immune system conditions on a pharmacy intake form under section 84(1)(a) of the HIA. This provision of the HIA allows the Commissioner to conduct investigations to ensure compliance with any provision of the Act.

[3] This report outlines the findings and recommendations arising from this Investigation.

Application of the HIA

[4] The *Health Information Act* (HIA) applies to “health information” in the custody or under the control of a “custodian”.

[5] Health information is defined in section 1(1)(k) of the HIA as:

1(1)(k) “health information” means any or all of the following
(i) diagnostic, treatment and care information;
(ii) health service provider information;
(iii) registration information

[6] The term “diagnostic, treatment and care information” is defined in section 1(1)(i) to include:

1(1)(i) “Diagnostic, treatment and care information” means information about any of the following

(i) the physical and mental health of an individual;
(ii) a health service provided to an individual...;

...

(iv) a drug as defined in the Pharmacy and Drug Act provided to an individual;

...

And includes any other information about an individual that is collected when a health service is provided to the individual...

[7] The term “registration information” is defined in section 1(1)(u) of the HIA as:

1(1)(u) “registration information” means information relating to an individual that falls within the following general categories and is more specifically described in the regulations:

(i) demographic information, including the individual’s personal health number;

(ii) location information;

(iii) telecommunication information;

...

[8] I have reviewed the form the individual was asked to complete. The information the forms asks for is health information as it is information about the physical health of an individual and it is collected during the provision of a health service.

[9] The term “custodian” is defined in section 1(1)(f) of the HIA, which reads, in part:

1(1)(f) “custodian” means

...

(x) a licensed pharmacy under the Pharmacy and Drug Act;

...

[10] The Co-op Shawnessy Centre Pharmacy is a licensed pharmacy under the *Pharmacy and Drug Act*.

[11] As the information the form asks for is health information and the Pharmacy is a custodian, I find that the HIA applies to the collection of health information on the “Consent for Administration of Injection” form used by the Pharmacy.

Background

[12] The individual attended the Pharmacy for the purpose of obtaining a Vitamin B12 injection which had been prescribed by his physician. When he went to the Pharmacy, he was requested to complete a “Consent for Administration of Injection” form (the form). The form requested that the individual provide:

- Name
- Date
- Emergency contact information (name and phone number)

[13] The form also requested an individual respond to the following questions by answering “Yes/No” and “If Yes, describe”:

- Are you sick today?
- Do you have any allergies?
- Have you received any vaccinations in the last 6 weeks?
- Have you ever had a serious reaction to a vaccine?
- Do you have any condition that affects your immune system, such as cancer, aids, etc?
- If female, are you pregnant?

[14] The form also documents an individual's understanding that the drug indicated on the form would be administered via injection, the potential risks of such a procedure and the steps that would be taken in the event of an adverse reaction.

[15] In his letter to the Commissioner, the individual stated that he "objected to the question regarding any condition that affects your immune system such as "aids" etc because being forced to disclose [his] physical disability is an invasion of [his] privacy...". He went on to state that he believes the form to constitute "blatant screening" and excessive collection of information and that it "invites and attracts ignorance and discrimination". He cited previous instances of discrimination at another pharmacy on the basis of a condition that impacts his immune system.

[16] The Pharmacy states that it collects information on an individual's immune status using the form each time an individual seeks administration of a drug via injection and that the use of this form extends across the Calgary Co-op chain of pharmacies.

Issues

[17] The issues under consideration in this investigation are:

1. *Does the Pharmacy limit the collection of health information to what which is essential to perform the intended task as required by section 58(1) of the Health Information Act?*
2. *Does the Pharmacy take reasonable steps to inform an individual of the purpose for which information is collected, the legal authority for the collection and the title, business address and business telephone number of an affiliate of the custodian who can answer questions about the collection as required by section 22(3) of the Health Information Act?*

Analysis

Issue 1 - Does the Pharmacy limit the collection of health information to what which is essential to perform the intended task as required by section 58(1) of the Health Information Act?

[18] The HIA gives custodians considerable authority to collect, use and disclose health information without consent for the purposes of providing health services. This broad authority is balanced through a number of provisions in the Act, including section 58(1), which reads:

58(1) When collecting, using or disclosing health information, a custodian must, in addition to complying with section 57¹, collect, use or disclose only the amount of health information that is essential to enable the custodian or the recipient of the information, as the case may be, to carry out the intended purpose.

[19] The Pharmacy's position is that the collection of all of the information on the form is "necessary and directly related to providing health services to a patient in a safe and effective manner."

[20] I asked the Pharmacy a number of questions related to their use of the form and the clinical relevance of the information collected on it. I was advised that:

¹ Section 57 is a general duty to collect, use and disclose health information at the highest degree of anonymity possible. Section 57(5) indicates that this duty does not apply when the collection, use or disclosure of health information is for the purpose of providing a health service.

- Pharmacists must be certified to administer drugs via injection.
- The certification program advises pharmacists to check the medication record of the patient, determine the reason for administering the injection, assess the compatibility of the injected substance with any other drugs the patient is taking, consider the potential for adverse event/contraindication, assess the patient for allergies and obtain informed consent before administering any injection.
- The Pharmacy has patients fill in the form each time they present for an injection as their health may have changed since their last injection.
- The Pharmacy needs to know if a patient is sick and, if so, what their symptoms are so that it can monitor the patient post-injection for an adverse reaction.
- The Pharmacy must know if a patient has allergies to any of the active or inactive ingredients involved in the injection as it may not be appropriate to administer the injection. An allergic reaction in response to an injection could have life threatening consequences.
- The Pharmacy must know if a patient has received a vaccination in the last six weeks as some injections cannot be administered simultaneously to or within a certain period after vaccination. In other cases, the efficacy of an injected drug is reduced if it is administered too quickly after the last injection.
- The Pharmacy enquires after previous serious reactions as a previous adverse reaction to a vaccine may preclude the patient from receiving future vaccinations. The Pharmacy cited a specific example where the administration of the flu vaccine is contraindicated for patients who developed Guillain Barre within eight weeks of a receiving a previous flu shot or who had an allergic reaction to a component of another vaccine.
- The Pharmacy asks about immune system conditions as immunocompromised individuals cannot receive live vaccines or may be on medications that render some injections ineffective. It also states that the timing of some immunosuppressant therapies (such as chemotherapy) can impact whether or not an injection is advisable.
- The Pharmacy asks after pregnancy as some injections are contraindicated for pregnant women and may not be safe or appropriate to administer.

[21] The Pharmacy told me that there are situations where an immunocompromised patient should not receive a drug or vaccine by injection. In cases where knowledge and awareness of a patient's immune system function is essential to the provision of a health service, a custodian is clearly authorized to collect this information.

[22] In the case currently before me, the Pharmacy told me that the administration of a Vitamin B12 injection is not contraindicated for a patient who is immunocompromised. Barring any other allergies or risk factors, an immunocompromised patient would not be refused a vitamin B12 injection by the Pharmacy. In other words, information as to whether or not a patient's immune system is compromised is not clinically relevant to the decision to administer a vitamin B12 injection.

[23] Health services providers are generally granted considerable latitude in determining what information they require to support the provision of care. That being said, the collection of health information is contextual – what is reasonable to collect is predicated on the nature of the health service being sought by the individual. Given that certain vaccines are contraindicated for immunocompromised individuals, it would have been entirely appropriate for the Pharmacy to ask for immune system information if the patient had presented to receive one of those vaccines. That is not the case, though, and the individual presented for the provision of a health service where the Pharmacy itself stated that immune system status is clinically irrelevant.

[24] The HIA requires a custodian to limit their collection of health information to that which is essential to carry out the intended purpose. Where health information is not required to support and inform treatment and care decisions, it cannot be collected.

[25] The Pharmacy's practice of collecting immune system function information on every patient seeking injection contravenes the requirements of section 58(1) of the HIA as it is not sufficiently limited. I recommend that the Pharmacy immediately implement practices to limit the collection of health information to that which is essential to perform the intended task. I specifically recommend that any form used to collect health information be amended to only collect information relevant to the specific health service being provided, or if such amendment is not reasonable, that the use of the form to elicit a patient history be suspended.

Issue 2 - Did the Pharmacy take reasonable steps to inform the individual of the purpose for which information is collected, the legal authority for the collection and the title, business address and business telephone number of an affiliate of the custodian who can answer questions about the collection as required by section 22(3) of the Health Information Act?

[26] The individual told me that he tried to question the collection of immune status information with the Pharmacy and was told that completion of the form was mandatory. The individual was not able to speak with someone about his concerns.

[27] It is not reasonable for a custodian to assume that all patients, even those well-educated with respect to their conditions and treatment plans, will understand the clinical relevance of all health information that they are asked to provide during the provision of a health service. The HIA requires custodians to demonstrate a measure of openness and transparency to patients. Specifically, the HIA requires that patients be told of the purposes for which their health information is collected and provided with an opportunity to ask questions. This requirement is laid out in section 22(3) of the HIA, which reads:

22(3) When collecting individually identifying health information about an individual directly from the individual, the custodian must take reasonable steps to inform the individual
(a) of the purpose for which the information is collected,
(b) of the specific legal authority for the collection, and
(c) of the title, business address and business telephone number of an affiliate of the custodian who can answer the individual's questions about the collection.

[28] The Pharmacy told me that it collects information on a patient's immune system to determine if it is safe to administer a particular injection to a particular patient. While I found that the collection of information related to immune system function is not authorized in all cases, it is certainly reasonable that a custodian would ask for the information in those cases when a patient presents for an injection where immune system function is clinically relevant. What is regrettable in this case is that the information provided to me as to the clinical relevance of the immune system information was never explained to the individual. He states that when he attempted to question the collection of this information he was told the form was mandatory and that he would not receive the service without completing the form. He told me that he was never offered the opportunity to question the Pharmacy's collection of the information and that the lack of this option was a direct contributing factor to his complaint to the Information and Privacy Commissioner.

[29] I asked the Pharmacy what steps it generally takes to meet the notification requirements of section 22(3) of the HIA. I was advised that the Pharmacy directs all pharmacists to verbally advise patients seeking injection that the information on the form is collected to ensure the

patient's health and safety and to allow the pharmacist to deliver safe and effective health services. The Pharmacy concluded, however, that verbal notification of the purpose of collection was not sufficient to meet the requirements of section 22(3) of the HIA. The Pharmacy acknowledged that it does not notify individuals of the legal authority for the collection of information, nor does it provide information on how individuals can contact an affiliate who can answer questions about the collection of information. The Pharmacy immediately undertook remediation of this compliance issue and, on August 17, 2012 provided me with a draft patient notification poster for my review and comment. I have been advised that the Pharmacy will post the notification immediately after the content has been reviewed and accepted by our Office.

[30] I appreciate the Pharmacy's proactive approach to this issue and have no additional recommendations to make to the Pharmacy with respect to patient notification.

Summary of Recommendations

[31] I recommend that the Pharmacy:

1. Limit the collection of health information to that which is essential to perform the specific health service requested by an individual. In particular, I recommend that the Pharmacy not collect information on immune conditions where such information is not clinically relevant to the service being provided.
2. Evaluate whether or not the form can be modified or amended in such a way as to limit the collection of health information to that which is essential to provide the requested service and report back to the Commissioner within 30 days. At this time, the Pharmacy must advise the Commissioner of the steps it has taken to develop information collection practices that reflect the limitation principle in the HIA, including any amendments or modifications to the form.

[32] The Pharmacy accepted these recommendations on September 27, 2012 and has begun the process of amending the consent form and the associated policies, practices and procedures.

Conclusion

[33] In concluding my investigation, I reflect upon the experiences of the individual who brought this complaint forward. It is clear to me that the individual is very concerned about the collection of information related to his immune condition. He believes that the specific condition he suffers from is stigmatized and that he will likely suffer from discrimination if health services providers learn of his condition. Until I had an opportunity to explain the Pharmacy's position on the potential clinical relevance of his immune system status, he firmly believed that he was being screened by the Pharmacy and would be denied health services on the basis of his condition and a perceived potential risk he posed to staff. He also told me that he would likely lie about his health condition if forced to provide the information to health services providers without a clear understanding the reason that they need the information. This illustrates to me the importance of communicating with patients openly when presented with questions or concerns over the collection of health information.

[34] In its submission, the Pharmacy states that it takes the health and safety of its patients seriously and is committed to offering the highest level of professional care. A component of professional care is limiting the collection of personal information to that which is essential to provide the requested service. A second component of professional care is not only notifying

patients of purposes for which their health information is collected but being prepared to engage in dialogue when patients have questions.

[35] Custodians must be attuned to the fine line that exists between the collection of information that is essential for the provision of services and the collection of extraneous information. This line is never more important than when the collection involves information which is considered highly sensitive and personal by the patient.

[36] I extend my sincere appreciation to the Calgary Co-op Shawnessy Centre Pharmacy for their full participation in this investigation and their willingness to undertake immediate action on my recommendations.

Submitted by

Leahann McElveen
Portfolio Officer, Health Information Act