

NEWFOUNDLAND AND LABRADOR PHARMACY BOARD

Standards of Pharmacy Practice



Privacy and Confidentiality of Personal Health Information

Approved by the Newfoundland and Labrador Pharmacy Board September 15, 2002

Introduction

In December of 2000 a background document entitled Principles for the Privacy Protection of Personal Health Information in Canada was developed by a working group, with Health Canada support, and including representatives from the Canadian Pharmacists Association, the Canadian Dental Association, the Canadian Healthcare Association, the Canadian Medical Association, the Canadian Nurses Association, and the Consumers' Association of Canada.

This background document pointed out that: "In recent years, the issue of privacy and health information has attained higher priority, given increased demand for health information. This increased demand is fuelled by the proliferation of information technology, as well as social and policy changes such as health system reform, movement to a population health framework, quality assurance initiatives, increased privatization of health care and efficiency and cost containment initiatives."

The document goes on to say: "Because of its nature, there is an expectation that health information will be used for the benefit of the individual who puts his or her trust in a health care provider or health care facility. Higher levels of privacy protection must therefore be afforded to health information than to other forms of personal information. This circumstance necessitates the development, adoption and implementation of specific principles for health information privacy protection that encompasses the rights and responsibilities of individuals as well as the legitimate societal concerns and obligations of the health system."

During the course of their practice, pharmacists receive personal information about their patients, including medication and other health information. Pharmacists have an ethical and legal obligation to protect the patient's right to privacy and confidentiality of personal health information. Provincial pharmacy regulatory authorities have developed documents or legislative instruments to guide and direct the pharmacist in meeting these obligations. Because of public concerns that individuals' privacy may be violated when technology, such as computer networks, is used to collect, store, use or transmit personal information, the Canadian federal and provincial governments are at various stages in implementing privacy legislation to protect personal information.

"Personal identifiable health information" is information about an identifiable individual that is recorded in any form, including information about:

- service history;
- provision of services to the individual;
- payment for service provided to the individual;
- any personal identification number or code, including address or telephone number;
- the results of tests or measurements on the patient; and
- the indication of any medical condition, including allergies.

Personal information also includes generic information about individuals who may not be explicitly identified, but whose identity could be implied from the individual or combination of data elements, including:

- name;
- identifying numbers assigned to the individual;
- address;
- telephone number;
- birth date;
- date of service, intervention or visit; and
- demographic information.

These Standards will not be applied to general, non-identifiable information that is not specific to an individual, including information on diseases, treatment and services. However pharmacists must pay strict attention to what qualifies as non-identifiable information.

Privacy is not an absolute. In certain situations it may not be desirable, practical or even possible to maintain confidentiality of a patient's information. Even when they cannot be adhered to rigorously, these standards must function as the guiding norm by pharmacists.

Consultation among professionals is a complex process, often based on informal communication conducted in good faith. However, the use of personal identifiable information must be guided at all times by professionalism and respect for the patient. Protection of privacy is enhanced when information is restricted to those who have a need-to-know that can be demonstrated and which is based on reasonable and rational justifications. All release of information must be governed by this fundamental concept.

In developing these Standards of Practice particular consideration was given to the *Model Code for the Protection of Personal Information* developed by the Canadian Standards Association (CSA), the *Draft Privacy, Confidentiality and Access Standards* developed by the Newfoundland and Labrador Centre for Health Information (NLCHI), the *Draft Model Guidelines to Comply with Provincial Privacy Legislation* developed by the National Association of Pharmacy Regulatory Associations (NAPRA), and have also incorporated some of the guidelines found in the *Confidentiality of Personal Health Information Guidelines* of the Nova Scotia Pharmaceutical Society.

While large organizations and individuals in private or small group practices share the same responsibilities for adhering to these Standards, there may be differences in the resources that each can bring to bear to fulfill these responsibilities. Where the demands of the Standards place an unreasonable administrative burden on individual or small group practices, there is a role for the Newfoundland and Labrador Pharmacy Board, in developing model policies, practices and procedures, to assist members of the profession in meeting the standards outlined in this document.

These Standards of Practice were framed in the construct of 11 **Guiding Principles** that outline the legal and ethical obligations of the pharmacist with respect to privacy and confidentiality of personal health information, and corresponding **Operational Guidelines** to assist the pharmacist in meeting those legal and ethical obligations.

Guiding Principles

Principle 1 – Accountability

Principle 2 – Identifying Purpose

Principle 3 – Consent

Principle 4 – Collection

Principle 5 – Use, Disclosure, Access and Retention

Principle 6 – Accuracy and Integrity

Principle 7 – Security

Principle 8 – Openness of Policy Procedures and Process

Principle 9 – Individual Access

Principle 10 – Challenging Compliance

Principle 11 – Ownership of Information

Guiding Principles and Operational Guidelines

Principle 1: Accountability

Pharmacists are individually responsible for personal health information under their control and the pharmacist-in-charge of each pharmacy is accountable for that pharmacy's compliance with the Principles outlined below. Accountability for the pharmacy's compliance rests with the pharmacist-in-charge, even though other individuals within the pharmacy may be responsible for the day-to-day collection and processing of personal health information. This accountability includes ensuring that all staff, whether an authorized user or not, are educated on these principles.

Operational Guidelines

- 1.1 Policies and procedures set by the pharmacy to ensure compliance with this Standard must reflect the direct accountability of the individual pharmacist and pharmacy to the individual patient.
- 1.2 The pharmacist:
 - is accountable for the security of all personal identifiable information for which they have responsibility;
 - must ensure that only authorized staff have access to personal identifiable information and only as necessary to fulfill authorized purposes;
 - must inform anyone with access to personal identifiable information of their responsibility to protect personal identifiable information. They must agree to accept those responsibilities and recognize that appropriate sanctions for failing to protect confidentiality will be enforced;
- 1.3 The pharmacist-in-charge must have the autonomy, authority and resources necessary to ensure adherence to these Standards.
- 1.4 The pharmacist-in-charge shall develop and implement policies, procedures and practices that give effect to these Standards, including those that:
 - protect the security of personal identifiable information;
 - receive and respond to inquiries and complaints;
 - ensure that persons who collect, use or disclose personal identifiable information in that pharmacy are held accountable to the pharmacist-in-charge, and
 - ensure that individuals are adequately informed about the collection of their personal identifiable information, and that their informed consent is sought and obtained.

Principle 2: Identifying Purpose

Patients are entitled to know the purposes for which personal health information is being collected, at or before the time the information is collected. The patient is also entitled to know the potential uses of this information and who may be expected to have access to it. The pharmacist has a duty to inform the patient of the anticipated use (other than internal) or disclosure of personal health information collected.

Operational Guidelines

- 2.1 Personal identifiable information must only be used for the purposes identified to the individual at or before the time it is confided or collected.
- 2.2 The pharmacist must ensure individuals are provided information about the uses to which their personal data will be applied. This includes:
 - the information disclosed will become part of their electronic record;
 - the reasonably foreseeable purposes for secondary use;

- other individuals, groups or organizations who may have access to, collect, use or disclose information as it pertains to the primary purpose (for example provision of personal information as a condition of an agreement the patient may have made with a third party insurer).

2.3 In the field of health care, personal information is also collected for the prevention, treatment or management of symptoms of disease. Personal information may be collected for reasons other than direct individual care, including:

- public health;
- resource planning;
- quality assurance;
- research, and
- legal requirements

Principle 3: Consent

The pharmacist can only use or disclose personal health information with the consent of the patient, unless consent is exempted by law. Consent can be either explicit, or inferred if the pharmacist has fulfilled the duty to inform and has sufficient reason to believe that the patient would consent under the circumstances. Exceptions include preventing harm to the patient, or if it is in the patient's best interest (where lawful authority exists), or for any other purpose such as research or education when the identity of the patient is concealed.

Operational Guidelines

- 3.1 Informed consent of the individual is required for the collection, use, or disclosure of personal identifiable information, except where required by law.
- 3.2 Consent or choice as to who has access to one's personal identifiable information is a fundamental component of privacy. To be meaningful, consent must be informed, voluntary, and not obtained through misrepresentation or fraud. The individual must be competent to understand what their consent entails. A statement in clear and simple language about how the information will be used or disclosed is required to obtain informed consent.
- 3.3 Other than for primary or previously identified secondary use, written consent from the patient should be obtained for the disclosure of personal identifiable information. At a minimum, the pharmacist should be satisfied that the patient has expressly permitted the disclosure.
- 3.4 In emergency care situations consent for the collection, use or disclosure of personal identifiable information may be implied. The implied consent must be consistent with legislation governing emergency care.
- 3.5 There may be other situations where an individual may be unable to give informed consent, and these situations are governed by law.
- 3.6 Implied consent does not deprive the individual of the right to refuse consent or subsequently challenge the pharmacist's assumption of implied consent.
- 3.7 The patient may revoke consent at any time, but such revocation cannot be retroactive.
- 3.8 Consent or revocation can be given verbally or in writing. When consent or revocation is given verbally, the pharmacist must document that direction, especially when it relates to sensitive or potentially controversial information.

Principle 4: Collection

The pharmacist may collect personal health information only for the purposes of providing pharmacy services, or as required by law. Information shall be collected by fair and lawful means.

Operational Guidelines

- 4.1 The primary purpose of the collection of personal identifiable information is to benefit the patient who permits information to be collected. Collection for legitimate secondary use shall be restricted to what is necessary and shall not impede the giving or collection of information for the primary purpose.
- 4.2 Collection of personal identifiable information for the primary purpose may be as extensive as necessary.
- 4.3 Collection of personal identifiable information for secondary purposes shall be as minimal as necessary, in recognition of the need to protect the individual's right to privacy.
- 4.4 Collection of personal identifiable information without individual consent shall only occur in circumstances where required by law, or when ordered by a court of law.
- 4.5 Personal identifiable information shall not be collected by means that are unlawful, unfair or exploit the patient's vulnerability. Nor shall any of the patient's beliefs or potentially false expectations about subsequent collection, use, disclosure or access be exploited.
- 4.6 If a fax machine, or other electronic equipment, is used by the pharmacist to receive any type of personal identifiable information, the fax machine, or other electronic equipment, should be physically located within the dispensary and access to the information received must be restricted to authorized persons only.

Principle 5: Use, Disclosure, Access and Retention

The pharmacist shall not use or disclose personal health information for purposes other than those for which it was collected, except with the consent of the individual or as required by law. The pharmacist may disclose personal health information only to those who have a legitimate need for that information. Where others such as pharmacy employees or information managers have access to personal health information collected and stored by the pharmacist, the pharmacist shall ensure that policies or formal agreements exist to ensure that all pharmacy staff respect the patient's right to confidentiality. All pharmacy personnel should be required to sign a confidentiality declaration. Personal health information shall be retained for as long as necessary for the fulfillment of the purposes for which it was collected, or as required by law. In any case, personal health information collected by the pharmacist must be retained for a minimum of two years.

Operational Guidelines

- 5.1 The primary purpose for the use, disclosure, access and retention of personal identifiable information is to benefit the individual patient who permits information to be collected. Use, disclosure or access for legitimate purposes shall be restricted to what is necessary and shall not impede the giving or collection of information for the primary purpose.
- 5.2 Examples of situations in which a pharmacist may be required by law to disclose personal identifiable information include but are not limited to:
 - the pharmacist is presented with a warrant by a police officer;
 - the pharmacist is served with a subpoena which requires delivery of documents containing patient records;
 - release of information is required by rules of court that relate to production of information in a lawsuit;
 - an inspector or investigator authorized under the Pharmacy Act to have access to the records makes a request to access the records; or

- an inspector authorized under the Controlled Drugs and Substances Act and/or the Food and Drugs Act to have access to the records makes a request to access the records.
- 5.3 Release of personal identifiable information to legal counsel may be required for providing legal services to the Newfoundland and Labrador Pharmacy Board and/or a registered pharmacist.
- 5.4 Pharmacists must use caution and professional discretion when:
- police or other law enforcement agencies or officials request the information, pursuant to regulation, and the pharmacist deems it to be in the best interest of the patient or public to provide such information;
 - other pharmacists, or other health care professionals actively treating the patient request the information and the pharmacist deems it to be in the best interest of the patient or public to provide such information;
 - information is requested by third party payors. Generally, third party payors rights to personal health information are governed by the agreements they have with the patient and with the pharmacy. Pharmacists should refer to those agreements when in doubt. Steps should be taken to ensure that the person requesting the information legitimately represents the third party payor and only the information authorized by the patient agreement should be disclosed;
 - information is requested by family members or other agents(e.g. a spouse requesting duplicate receipts for income tax purposes). The pharmacist must be satisfied that the patient consents to the release of personal health information to that family member or other agent;
 - information is requested concerning a deceased patient. The executor of the estate is entitled to ask for personal health information. A family member should have legal authority to handle the deceased patient's affairs before personal health information can be released;
 - information is requested by the parent of a minor. Confidentiality is owed to all patients, regardless of age. In the case of a mature minor, the consent of the child should be obtained prior to the release of personal health information.
- 5.5 Trustees of information systems that link several databases must implement systems of control over appropriate access or disclosure.
- 5.6 The pharmacist must take appropriate measures to ensure that personal identifiable information is not seen or overheard by other customers, trades-people, service crews, pharmaceutical representatives, etc., who may be in or about the dispensary.
- 5.7 Pharmacist/patient communication should take place in an area where discussion cannot be overheard by others. An appropriate area should be established for consultation purposes which provides either a private consulting room, or a semi-private area with suitable traffic/noise barriers.
- 5.8 The pharmacist-in-charge must develop a system to ensure patient confidentiality when delivering prescriptions. Only the information necessary for proper delivery should be visible on the package and all items should be packaged to prevent tampering.
- 5.9 The pharmacist must ensure patient confidentiality when disposing of prescription files, computer records, labels or receipts, and old vials or packaging that contain personal identifiable information.
- 5.10 Pharmacists may disclose to a third party, such as a commercial data compiler, prescription information which may include the identity of the prescriber, the pharmacist and the pharmacy; but which must not, and may not reasonably be expected to, identify the patient. This information may be provided only on the basis that the third party will not disclose information with respect to the prescriber, pharmacist or pharmacy, except in an aggregate format (i.e. which does not disclose specific individual prescribing or dispensing information) without signed consent from the prescriber, pharmacist and pharmacy. The onus to obtain this consent lies with the third party requesting such information.

Principle 6: Accuracy and Integrity

Before using or disclosing personal health information, the pharmacist must take reasonable steps to ensure that the information is accurate, complete and not misleading. Personal health information shall be as accurate as possible, and up to date as is necessary for the purposes for which it is to be used. The information held by the pharmacy needs to be sufficiently accurate, complete and up-to-date to minimize the possibility that inappropriate information is used to make a decision about the individual.

Operational Guidelines

- 6.1 The accuracy and integrity of personal identifiable information are necessary to support the individual's right to privacy and to meet the requirements for its collection, use, or disclosure.
- 6.2 The pharmacist is responsible for the accurate recording of information.
- 6.3 Where an individual believes there is an error or omission in his or her personal record, an amendment may be made. The requested amendment shall be made by adding it to the record in such a manner that it will be read with and form a part of the record, or be adequately cross-referenced.
- 6.4 When the accuracy of information is in dispute, it shall be clearly marked in the original record.
- 6.5 The pharmacist must protect the integrity of the personal health information in their custody and have assurance that the integrity of information received from, or passed onto, other pharmacists or organizations has been, and will continue to be, similarly safeguarded.

Principle 7: Security

The pharmacist shall protect personal health information from accidental or malicious disclosure, interruption, modification, removal or destruction. The pharmacist shall establish policies governing the retention, security and destruction of personal health information to maintain patient privacy and confidentiality.

Operational Guidelines

- 7.1 Personal identifiable information shall be protected by security safeguards appropriate to the information, and against unintended or unauthorized access, use or intrusion, or such dangers as accidental loss or destruction.
- 7.2 The pharmacist-in-charge shall establish policies and procedures to protect data integrity:
 - physically, (e.g. locked doors and locked cabinets);
 - technically, (e.g. passwords and security codes); and
 - organizationally, (e.g. education and policies on access).
- 7.3 Security safeguards shall be established to protect all personal identifiable information that will not unreasonably impede the collection, use, or disclosure of information by authorized persons.
- 7.4 Persons authorized to access information must be informed of the authority, parameters, purposes and responsibilities of their access, and the consequences of failing to fulfill their responsibilities.
- 7.5 Access to information shall be limited to only that information which is required for the authorized purpose.

Principle 8: Openness of Policy Procedures and Process

The pharmacist-in-charge shall make readily available to individuals specific information about the policies, procedures and practices relating to the management of personal health information. Individuals must be able to clearly understand the extent and circumstances of the collection, use and disclosure of their personal health information.

Operational Guidelines

- 8.1 A pharmacist must make information on its policies and practices relating to the management of personal identifiable information available upon request. Methods may include, but are not limited to, brochures, mail, electronic and print media, online access or a telephone number.
- 8.2 Individuals shall be able to discuss the pharmacy's policies, procedures and practices concerning their personal identifiable information with a knowledgeable person.

Principle 9: Individual Access

Individuals have a right of access to their personal health information. Upon request, an individual shall be informed of the existence, use, and disclosure of his or her personal health information and shall be given access to that information. In rare and limited circumstances, withholding personal health information from an individual is permissible if disclosure may have a significant likelihood of substantial adverse effect on the physical, mental or emotional health of the individual or a third party. The onus lies on the pharmacist to justify to the individual a denial of access. An individual shall be able to challenge the accuracy and completeness of the information and have it amended as appropriate.

Operational Guidelines

- 9.1 Individuals have a right to access their personal identifiable information and to obtain a copy of that information.
- 9.2 If an individual is denied access, that individual has a right to complain under the provisions of the Pharmacy Act.
- 9.3 Lawful agents (such as a legal guardian, or the executor of an individual's estate) can exercise the rights of the individual.

Principle 10: Challenging Compliance

Individuals, upon request, must be informed and understand that the pharmacy's policies, procedures and practices are open to scrutiny and challenge. An individual shall be able to address a challenge concerning compliance with the above standards to the designated individual or individuals accountable for that pharmacy's compliance.

Operational Guidelines

- 10.1 The pharmacist and pharmacy shall respond to all complaints about their compliance with these Standards, and when necessary take appropriate measures, including amending its policies and procedures to improve compliance.
- 10.2 Complaints about compliance with these Standards which have not been handled to the satisfaction of the patient by the pharmacist-in-charge at the pharmacy level may be made to the Newfoundland and Labrador Pharmacy Board in accordance with the Pharmacy Act.

Principle 11: Ownership of Information

Individuals are the owners of any and all personal identifiable information pertaining to them regardless of where it is held.

Operational Guidelines

- 11.1 Health related information about an individual (personal health information) belongs to the patient, but the electronic and paper records that carry this information are the property of the pharmacy. Such records include, but are not limited to, prescriptions, patient profiles and reports, which contain certain information that identifies an individual with a pharmacy service.
- 11.2 Responsibility for the accuracy and primary maintenance of the record rests with the pharmacist or pharmacy that recorded the original information.
- 11.3 Conclusions reached by a pharmacist may constitute intellectual property of the pharmacist or pharmacy. Where they are recorded the possibility of shared ownership of data may exist.
- 11.4 Where a pharmacist uses personal identifiable information to publish a professional study or article, the anonymity of patients involved must be protected. Copyright shall rest with the author because the basis of the study or article is the pharmacist's professional interpretation or assessment of a series of personal identifiable information and data of various individuals.