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Guideline: Informed Consent

1.0 Purpose

Under the code of ethics pharmacists must respect the autonomy, values, and dignity of each patient. Patients have the right to make informed decisions about their care and pharmacists have a professional obligation to obtain a patient's informed consent when providing healthcare or collecting and using personal health information.

The purpose of this document is to provide guidance on the requirements of the Informed Consent Practice Direction and describe the key components of obtaining meaningful informed consent.

For consent requirements around the collection and use of personal health information pharmacists should refer to *The Personal Health Information Act*. These guidelines apply when providing immunizations, however additional requirements for immunization providers can be found in the Manitoba Health Informed Consent Guidelines for Immunization.

2.0 What is informed consent?

When this guideline uses the term "consent" it is referring to informed consent. Informed consent is a patient's authorization to receive healthcare after they are provided with enough information needed to make an informed decision on whether to receive care. The process of consent involves the patient in their healthcare and is an ongoing process that requires communication between the pharmacist and patient.

Valid consent must:

- be specific and relate to the healthcare being provided,
- be given voluntarily,
- not be obtained through misrepresentation or fraud, and
- be informed, with patient the given enough information to make an informed decision.

The process of collecting consent must be open and honest. Pharmacists cannot influence, persuade or pressure a patient into providing consent. In certain situations an agent my be authorized by the patient or by law to provide consent on their behalf.

3.0 Types of consent

There are two types of consent, express consent and implied consent. Express and implied describe the way consent is communicated from the patient to the pharmacist, in both instances the consent must still be informed to be valid.

Express consent is when a patient directly and explicitly provides consent verbally or in writing such as a patient saying, “Yes, I want to receive a flu shot today”.

Implied consent is when a patient provides their consent indirectly. Implied consent is inferred from a patient’s action or inaction in response to the current situation, such as a patient handing over a prescription to be filled.

4.0 Determining the appropriate type of consent

When choosing the type of consent to obtain (implied or express) the pharmacy professional must consider

- the nature of the care the consent is being obtained for, and
- any applicable laws or practice directions.

If a practice direction or the Pharmaceutical Regulation (Regulation) requires the collection of consent this should be understood to mean express consent unless otherwise stated. When collecting express consent, it is acceptable to obtain it verbally or in writing unless otherwise stated.

If either express or implied consent is permittable the pharmacist should use their professional judgement to determine the most appropriate type of consent to collect. This should be done in the context of the current circumstances and the care that is to be provided. Pharmacists are encouraged to collect express written consent in situations where there is a higher degree of risk to the patient.

If it determined that implied consent is appropriate, but it is unclear to the pharmacist as to whether a patient is providing implied consent, the pharmacy professional should obtain explicit consent.

5.0 Collecting consent

A signature on a consent form alone does not constitute informed consent. The pharmacist obtaining consent must have a meaningful discussion with the patient and provide them sufficient and balanced information to make an informed decision. This may include but is not limited to:

- the nature of the healthcare,

- expected benefits,
- potential risks and/or side effects,
- alternative courses of action, and
- likely consequences of not having the pharmaceutical care.

The information provided must be clear, accurate and presented in a manner that the patient can understand.

Assumptions should not be made towards the patient's level of knowledge and professional judgement should be used to determine the extent of information provided based on what information a reasonable person in the same circumstance would need to make the decision.

Following the discussion, the patient must be given an opportunity to ask questions, and have their questions addressed.

For a patient to be able to provide informed consent they must:

- understand what they are consenting to and why,
- understand relevant information, and
- appreciate the reasonably possible consequences of a decision or its alternative.

6.0 Documentation of consent

Informed consent must be documented when it is required to do so by law or a practice direction.

When consent is not required to be documented pharmacist must use their professional judgement when choosing whether to do so. In general documentation is recommended as it establishes accountability and supports your professional judgement.

How consent is documented may differ on the circumstances and the pharmacy's policy and procedure, but documentation should always be clear, auditable and accessible to regulatory review.

When documentation is required, it must be retained for at least 5 years in a physical or electronic format. Documentation must include

- who provided the consent,
- the date the consent is given,
- the purpose for the consent, and
- the date consent is revoked (if applicable).

7.0 Withdrawal of consent

Consent is an ongoing process. A patient may refuse to give, or withdraw, their consent at any time. A pharmacist must respect the patient's decision to refuse or withdraw consent and modify or discontinue care as appropriate.