

Practice Direction: Informed Consent

Scope and Objective

1.0 Expected Outcome

- 1.1 This document is a practice direction by Council concerning informed consent. This practice direction ensures patient safety by providing direction to pharmacists about the requirements and methods for collecting meaningful informed consent.

2.0 Document Jurisdiction

- 2.1 All pharmacists are expected to adhere to this practice direction.

3.0 Regulatory Authority Reference

- 3.1 Section 6(3)(c) of *The Pharmaceutical Act* allows Council to create this practice direction.

4.0 Definitions

- 4.1 “Informed Consent” is authorization to carry out a medical intervention or service after the patient or their agent is provided the information needed to make an informed decision.

Practice Direction

5.0 Collecting Informed Consent

- 5.1 Informed consent must be obtained from the patient or, where authorized, their agent.
- 5.2 Prior to collecting informed consent, the patient or their agent must be provided with enough information to make an informed decision and ensure they understand the information presented. The extent of information provided is a matter of professional judgement, based on what a “reasonable person in the same circumstances would require in order to make a decision about the treatment.” The pharmacy professional should confirm the patient’s, or their agent’s, understanding and respond to any requests for additional information.
- 5.3 Informed consent can only be collected when it is voluntary, related to the care being offered, and does not involve misrepresentation or fraud.

- 5.4 When a practice direction requires the collection of consent, the consent must be collected explicitly through verbal conversation or in writing, unless otherwise stated.
- 5.5 A patient or their agent's decision to withhold or withdraw consent must be respected and complied with immediately.

6.0 Documentation

- 6.1 Informed consent must be documented when it is required to do so by law or another practice direction.
- 6.2 All express consent must be documented.
- 6.3 When documentation of informed consent is required, it must be retained for 5 years in either physical or electronic format.
- 6.4 Documentation of informed consent must include:
- 6.4.1 who provided the consent,
 - 6.4.2 the date the consent is given,
 - 6.4.3 the purpose for the consent, and
 - 6.4.4 the date the consent is revoked (if applicable).

7.0 Compliance Adjudication

- 7.1 All documentation must be readily accessible and open to regulatory review.

8.0 Appendices

8.1 Guideline: Informed Consent

A Practice Direction is a written statement made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations. Compliance with practice directions is required under the Pharmaceutical Act.

The process for development, consultation, implementation, appeal and review is published on the College website.

Development Source:	Standards of Practice Committee
Regulatory Reference:	Section 6(3)C, <i>The Pharmaceutical Act</i>
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