Acknowledgements

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Alberta College of Pharmacists
Nova Scotia College of Medical Laboratory Technologists
Pharmacy Association of Nova Scotia
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1 INTRODUCTION

The Pharmacy Act states that pharmacists are responsible for the provision of optimal patient care, monitoring drug therapy and ensuring the pharmaceutical and therapeutic appropriateness of drug therapy.

The Pharmacist Extended Practice Regulations enable pharmacists in the province to more fully apply their skills and competencies within the health care system as medication therapy experts in order to more effectively fulfill the intent and purpose of the Act.

In carrying out their responsibility to manage drug therapy, pharmacy practitioners must gather and evaluate appropriate information in order to respond to patients’ healthcare needs, and specifically to determine whether any actual or potential drug-related problems exist. Laboratory data and data from other tests are among the information that pharmacy practitioners may consider in determining the safety and effectiveness of patients’ drug therapy. As such, the Pharmacist Extended Practice Regulations enable pharmacists to order, conduct, receive and interpret tests for the purpose of drug therapy management.

Under the authority of the Regulations, the Standards of Practice: Testing establish the expectations of pharmacy practitioners with respect to conducting, ordering, receiving and interpreting tests. Pharmacy practitioners will undertake testing consistent with the scope of practice for their registrant category, and in accordance with these Standards of Practice, legislation, regulations, and the Code of Ethics.

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The Standards of Practice document includes the following:

- Definitions – glossary of terms referenced in the standards;
- Standards of Practice – requirements and expectations for pharmacy practitioners when ordering, conducting, receiving and interpreting tests; and
- Appendices – supporting tools and documents.

Approved: April 2015
Revised: June 2021
2 DEFINITIONS

Definitions for terms represented in the Standards of Practice: Testing are provided in the following table.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Critical test results</td>
<td>Any test results for which delays in reporting can result in serious adverse outcomes for patients and that may require intervention by a health care provider prior to a routine laboratory report review. Journal of Quality and Patient Safety, 31(2) Feb 2005</td>
</tr>
<tr>
<td>Council Directive</td>
<td>Directions from Council that sets out how the authority provided by the regulations to amend the conditions of practice during a public health emergency/state of emergency will be applied.</td>
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<tr>
<td>Drug Therapy Management</td>
<td>Drug therapy management is a healthcare service provided by pharmacists and other healthcare professionals to ensure the best therapeutic outcomes for patients.1 It encompasses a broad range of practice activities that a pharmacist undertakes in meeting their professional responsibilities to identify potential and actual drug-related problems; resolve actual drug-related problems (independently or in collaboration with other members of a patient’s care team when appropriate and in accordance with a pharmacist’s scope of practice); and prevent potential drug-related problems.2</td>
</tr>
<tr>
<td>Non-Invasive</td>
<td>Non-invasive tests do not break the skin or physically enter the body. Examples: urinalysis or pregnancy test.</td>
</tr>
<tr>
<td>Patient</td>
<td>For the purpose of these Standards, each reference to the patient means the patient or their agent as defined in the Pharmacy Act of 2011.</td>
</tr>
<tr>
<td>Pharmacy Practitioner</td>
<td>A pharmacist, pharmacy technician, intern, or student registered with the Nova Scotia College of Pharmacists</td>
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| Point of Care Testing (POCT)      | Medical diagnostic testing performed outside the conventional clinical laboratory, in the immediate vicinity of the patient to provide rapid results, where the result of the test is used for clinical decision making. For the purpose of these Standards, POCT typically:  
  ✓ is performed using kits and/or instruments that are portable, and 
  ✓ does not involve taking a sample and sending it away.  
Tests performed with POCT devices include but are not limited to: |
|                                   | • blood glucose                                                                                                                                     |
|                                   | • coagulation (INR)                                                                                                                                  |
|                                   | • urinalysis (basic)                                                                                                                                |
|                                   | • hemoglobin A1C                                                                                                                                 |
|                                   | • cholesterol                                                                                                                                 |
|                                   | • detection of microorganisms                                                                                                                      |
|                                   | • creatinine                                                                                                                                 |


<table>
<thead>
<tr>
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| Practice of Pharmacy | For the purposes of this document, a pharmacy practitioner in the *Practice of Pharmacy* is responsible for:  
  a) the interpretation, evaluation and validation of prescriptions;  
  b) providing information and education respecting drug and non-drug therapy;  
  c) compounding, preparing and dispensing drugs and devices accurately;  
  d) taking all reasonable steps to ensure pharmaceutical and therapeutic appropriateness of drug therapy;  
  e) monitoring drug therapy;  
  f) identifying and assessing problems relating to drugs or devices and taking action to prevent or resolve these problems;  
  g) counselling patients respecting drug and non-drug therapy;  
  h) maintaining the security of and protecting the integrity of drugs and devices;  
  i) maintaining and preserving records for patients, drugs and devices;  
  j) preserving the confidentiality of patient information;  
  k) overseeing activities in the pharmacy;  
  l) ensuring the appropriate level of supervision and direction for employees of the pharmacy under the pharmacist’s authority;  
  m) overseeing the management, operation and control of pharmacies;  
  n) overseeing the sale of drugs and devices;  
  o) complying with, and requiring compliance with, the Pharmacy Act, the regulations and other enactments related to the practice of pharmacy; and  
  p) undertaking such other professional services as are authorized by law.  
A pharmacist who has any additional qualifications set out in the regulations may:  
  a) prescribe drugs and treatments;  
  b) order, receive, conduct and interpret tests and services needed to properly manage drug therapy;  
  c) directly administer drug therapy to patients; and  
  d) engage in collaborative or alternative practice. |
<p>| Primary Care | Primary care can be considered one of healthcare’s core services. The key features include: “the first point entry to a health care system; the provision of person-focused (not disease-oriented) care over time; the delivery of care for all but the most uncommon conditions; and the part of the system that integrates or co-ordinates care provided elsewhere or by others.” |
| Routine Practices | The foundation for preventing the transmission of germs during patient/client/resident care in all healthcare settings. They consist of a comprehensive set of infection prevention and control (IP&amp;C) measures developed for use in the routine care of all patients at all times in all healthcare settings. |</p>
<table>
<thead>
<tr>
<th>Term</th>
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<tr>
<td>Standard operating procedure</td>
<td>A universally accepted term that refers to detailed, written instructions to achieve uniformity of the performance of a specific function. It encompasses all of the procedures or techniques required to conduct a point of care test accurately, safely and effectively.</td>
</tr>
<tr>
<td>Testing</td>
<td>Ordering, receiving, conducting or interpreting a test to properly manage a patient’s drug therapy.</td>
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</table>
3 STANDARDS OF PRACTICE

The following Standards of Practice represent the overall requirements for the services associated with pharmacy practitioner testing to manage drug therapy of a patient.

3.1 FOCUS ON HEALTH CARE NEEDS OF PATIENT

3.1.1 A pharmacy practitioner may order or conduct a test where:
- the test is undertaken within the practice of pharmacy;
- the test is related to drug therapy management;
- the pharmacy practitioner has a professional relationship with the patient; and
- specifically for conducting a test, the patient is two years of age or older.

OR
- the test is undertaken in accordance with a Council Directive.

3.1.2 A pharmacy practitioner may conduct a Point of Care Test (POCT) (refer to Definitions for a description of Point of Care Testing) where:
- the test is compact, simple and low-risk, and is either non-invasive or involves a specimen such as capillary blood (from a finger prick), saliva or urine.

OR
- the test is undertaken in accordance with a Council Directive.

3.1.3 A pharmacist may delegate the technical activity of conducting a test to a pharmacy technician, intern, or registered student provided the pharmacist:
- is satisfied that the person to whom the task is being delegated has the necessary knowledge and training to ensure the test is conducted safely and appropriately.
- remains responsible for ensuring that the test is in the best interest of the patient and is in compliance with the Pharmacists’ Extended Practice Regulations.

3.1.4 A pharmacy technician, intern, or registered student may accept the delegation to conduct a test provided they:
- are satisfied that a pharmacist has determined that the test is in the best interest of the patient.
- have and maintain the knowledge and skills necessary to conduct the test safely and appropriately.
### 3.2 Understand and Take Accountability

3.2.1 A pharmacy practitioner is accountable for their decision to conduct, order, receive and/or interpret a test, including actions and omissions, and for the associated benefits and risks to the patient.

3.2.2 Once the pharmacy practitioner undertakes testing, they are responsible for following up on the results and taking necessary actions until they have confirmed that another appropriate health care provider has assumed responsibility for the results.

3.2.3 A pharmacy practitioner shall have a system in place to receive critical results for a test ordered, including but not limited to:
   - being available and accessible 24/7 or having an alternate plan in place to respond to and act upon any critical test results reported, such as participating in on-call groups with other pharmacy practitioners; and
   - making after hours and emergency contact information available to the facility processing the test to facilitate their ability to contact the pharmacy practitioner in the event of a critical test result.

3.2.4 A pharmacy practitioner shall recognize and accept responsibility for the impact of conducting and ordering tests on the overall costs and sustainability of the health care system, which includes confirming, prior to ordering tests, that they have not already been ordered within a reasonable time frame, the results cannot be obtained from another source and that the test is needed for the management of drug therapy.

### 3.3 Use Knowledge and Understanding

3.3.1 A pharmacy practitioner shall only undertake a testing activity when they:
   - meet and maintain requirements for certification in First Aid and CPR (refer to Appendix B – First Aid and CPR Certification Requirements)
   - have reviewed the NSCP Standards of Practice: Testing.
3.3.2 When undertaking testing, a pharmacy practitioner shall comply with the Pharmacist Extended Practice Regulations, Standards of Practice: Testing as well as existing legislation, regulations, the Code of Ethics, other standards of practice and policy directives relevant to the practice of pharmacy in Nova Scotia (refer also to Appendix A- Reference Documents).

3.3.3 A pharmacy practitioner shall only undertake testing if they have have taken steps to ensure they have attained the competence to be able to:

- identify when the test is appropriate;
- determine which test to order;
- interpret the results in the context of other patient information; and
- take appropriate action based on the results, including:
  - initiating, adapting, or discontinuing current medication, where appropriate
  - collaborating with other members of the patient’s healthcare team, where appropriate, to initiate, adapt, or discontinue medication
  - communicating results to the patient and other appropriate members of their healthcare team
  - making appropriate referrals to other members of the patient’s healthcare team, where necessary
  - completing appropriate documentation
  - establishing and completing necessary follow-up

3.4 COLLABORATE WITH OTHER HEALTH CARE PROFESSIONALS

3.4.1 When a pharmacy practitioner undertakes testing, they shall collaborate and consult with other pharmacy practitioners or health care professionals in their pharmacy, the patient’s primary health care provider and other health care professionals if appropriate and in the best interest of the patient.

3.4.2 A pharmacy practitioner shall be aware of and consult, as appropriate, with medical laboratory services in their locality for specialist support and expertise, regarding the development, implementation and maintenance of a POCT service.
3.5 MAINTAIN PROFESSIONAL INDEPENDENCE

3.5.1 When involved in testing, a pharmacy practitioner shall avoid situations that present a conflict of interest that compromise their professional independence, judgment or integrity:

- accepting gifts, inducements or other benefits from a patient, other health care professional, manufacturer, supplier or other organization/person; or
- forming an association with a patient, other health care professional, manufacturer, supplier or other organization or person.

3.5.2 The decision by a pharmacy practitioner to conduct or order a test shall be based on clinical suitability, cost effectiveness and the patient’s best interest. Decisions to undertake testing based on bias-oriented information or on providing financial advantage to the pharmacy practitioner and/or pharmacy without providing benefit to the patient may be regarded as professional misconduct.

3.6 ENABLE INFORMED DECISIONS

3.6.1 A pharmacy practitioner shall provide the patient with information that is understandable and sufficient to allow them to make an informed decision to accept or decline the testing service. To support their decision, the pharmacy practitioner shall provide the opportunity for the patient to ask questions and obtain responses about the test. The information to be provided shall include the following:

- name of the test;
- objective of the test;
- benefits and risks;
- plan for follow-up, if appropriate, including timeline; and
- cost, where applicable.

3.6.2 A pharmacy practitioner shall obtain informed and voluntary consent from the patient in accordance with applicable legislative requirements when they order or conduct tests (refer to Appendix C - Patient Consent and Disclosure Requirements) and, where applicable, to disclose information regarding the test to other appropriate health care professionals. Consent can be written, oral, or implied. However, if relying on implied consent, pharmacy practitioners will be certain that the actions of the patient would be interpreted by others as having implied permission. Further, a pharmacy practitioner will not accept a signature on a consent form as a substitute for having a conversation with a patient such that it satisfies the requirements as described in Standard 3.6.1.
3.6.3 When a patient is represented by an agent, a pharmacy practitioner shall apply the standards for the relationship with the patient to the relationship with the agent, as appropriate.

3.7 ORDER AND INTERPRET TESTS

3.7.1 A pharmacy practitioner shall review any and all potential sources of current test data available to them before ordering a test for a patient.

3.7.2 When asked by the patient to interpret tests ordered by another health care provider, the pharmacy practitioner shall refer the patient to the health care provider who understands the context in which the test was ordered, unless it is pertinent to the care being provided by the pharmacy practitioner.

3.7.3 A pharmacy practitioner shall have a tracking process to ensure that they receive results from tests ordered.

3.7.4 When ordering a test, the pharmacy practitioner shall advise the patient when to expect the test results. If the results are not received within the expected time frame, the pharmacy practitioner shall follow-up with the patient and the facility conducting the test regarding its status.

3.7.5 A pharmacy practitioner shall consider patient and test specific circumstances when interpreting the test results such as the following:

- medical history
- timing of test
- drug therapy
- ethnicity
- disease
- drug side effects
- therapeutic effects
- organ function
- diet
- fluid status and
- test quality

3.7.6 A pharmacy practitioner who makes a drug therapy decision or recommendation as a result of interpreting test data shall:

- ensure the results have been generated by a test or instrument that had been approved under the Medical Devices Regulations to the Food and Drugs Act.
- explain their interpretation of the results and rationale for the decision to the patient or their agent; and
document their decision and its rationale in the patient record.

### 3.8 CONDUCT TESTS

3.8.1 All point of care tests and related materials (e.g. device, software, reagents, strips, etc.) used by the pharmacy practitioner shall be classified and licensed, if appropriate, under the *Medical Devices Regulations* to the *Food and Drugs Act*.

3.8.2 A pharmacy manager shall determine each type of point of care test that will be available to be conducted in the pharmacy, including the specific device to be used for each type of test and the pharmacy practitioners who can perform the test, through consideration of the following:

- purpose of the test;
- accuracy, precision and reliability of the test;
- quality control procedures for the test;
- degree of difficulty in using the test device;
- training required to conduct the test;
- whether the pharmacy’s level of staffing enables and supports safe and effective testing without compromising the quality of other pharmacy services; and
- agreements that are required with testing device and material suppliers regarding education, support, adverse event reporting, etc.

3.8.3 The pharmacy manager shall establish, implement and maintain a manual containing a standard operating procedure for each POCT it performs, which includes:

- title and purpose of the standard operating procedure;
- date created, along with the time interval and name of individual responsible for reviewing the standard operating procedure;
- purpose and limitations of the test;
- performance specifications (e.g., precision, sensitivity, specificity);
- required equipment and reagents;
- definition of sample and appropriate collection/handling techniques to support safe and effective immediate use of the sample in a POCT;
- procedural steps on how to accurately complete the test;
- device calibration and quality control processes to monitor the integrity of the test devices by comparing results with expected values, and appropriate record keeping of device testing;
• information on interpretation of results, including defining what constitutes a ‘critical’ test value;
• processes to address an incomplete test, an inoperable device, results outside of defined acceptable limits, and a failed test;
• instructions on the proper use, maintenance and storage of the testing device and/or instruments;
• information on device limitations, potential interferences, cross reactions and potential sources of variability or error;
• instructions on safe working practices and specimen collection (refer to 3.8.7);
• requirements for training, ongoing competency assessment of individuals performing the tests and documentation of such training/assessments; and
• applicable literature references.

The manual shall be kept in an area where it can be easily accessed by those providing POCT services.

3.8.4 The pharmacy manager is responsible for the pharmacy’s quality assurance process for POCT, which includes:

• ensuring standard operating procedures are established, maintained and their activities carried out as required by the standard operating procedure for each test performed;
• processes for error reporting;
• ensuring only trained and fully competent pharmacy practitioners conduct tests;
• monitoring the competence of pharmacy practitioners who conduct POCTs to ensure:
  • adequate and appropriate initial and ongoing training, on standard operating procedures and safe work practices;
  • ongoing demonstration of:
    • an understanding of the appropriate use of the device, its clinical utility and limitations and appropriate action when results fall outside predefined limits;
    • an understanding of the technical limitations of the device, the stability and proper use of reagents, and recognition of error;
    • the ability to consistently obtain a proper sample from the patient; and
    • the skills required to follow quality procedures of a test and to assess and verify the validity of test results prior to reporting.
• processes for communicating test results;
• test documentation and follow-up requirements;
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- adherence to approved policies, procedures, and standards;
- ensuring that the manufacturer’s instructions for procedure and quality control are followed; and
- reporting any POCT adverse events as quality related events in accordance with the NSCP *Standards of Practice for Continuous Quality Assurance Programs in Community Pharmacies*.

3.8.5 The pharmacy practitioner shall conduct each test in a manner that complies with the pharmacy’s standard operating procedure for that test.

3.8.6 The pharmacy manager shall ensure that the pharmacy environment is clean and safe for sample collection, conducting the test, and device and supply storage. The environment shall comply with any conditions defined by the manufacturer of the test. Generally, tests shall be conducted in a separate room to provide privacy for the patient.

3.8.7 The pharmacy practitioner shall apply safe work practices when conducting tests, including:

- routine hand washing / sanitizing (refer to to Appendix A - Hand Hygiene Practices in Healthcare Settings);
- use of personal protective equipment;
- adherence to Routine Practices (refer to Definitions and Appendix A - Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care Settings) including;
  - specimen handling consistent with standard precautions;
  - routine cleaning and decontamination procedures;
  - safe disposal of sharps/biohazardous waste;
  - follow-up in the event of accidental exposure to blood or body fluids;
- maintenance of their personal immunizations in accordance with Nova Scotia *Immunization Schedule for Adults*;
- test device maintenance and service in accordance with manufacturer’s recommendations; and
- maintenance of POCT device and supply inventory.

3.9 COMPLETE FOLLOW-UP

3.9.1 A pharmacy practitioner shall ensure that there is appropriate follow-up on tests conducted, ordered, received and interpreted.
3.9.2 When test results are outside of the normal range, a pharmacy practitioner shall undertake appropriate follow-up actions including, but not limited to:

- developing a plan for ongoing monitoring;
- modifying the patient’s drug therapy either by undertaking prescribing (see margin note) or recommending a change in drug therapy to an applicable member of the patient’s health care team;
- repeating the POCT if it is anticipated that it may provide different results;
- recommending that the patient seek the care of another health care professional as appropriate to the situation; and
- communicating and documenting, as set out in Standards 3.10 and 3.11 respectively, details regarding follow-up communication and documentation.

3.9.3 A pharmacy practitioner shall ensure follow-up of abnormal, inappropriate and/or critical test results, in consultation with health care professionals as appropriate, including promptly forwarding the results to the patient’s primary healthcare provider.

3.9.4 If a patient does not have a primary health care provider, a pharmacy practitioner shall, as appropriate for the situation:

- counsel the patient to obtain emergency or other medical care; and
- advise the patient about available health care resources.

3.10 COMMUNICATE EFFECTIVELY

3.10.1 A pharmacy practitioner shall communicate directly with the patient regarding tests to be ordered or conducted, including any related follow-up plan regarding test results or communication to other health care professionals.

3.10.2 A pharmacy practitioner who provides testing shall interpret and advise the patient of the results of the test.

3.10.3 A pharmacy practitioner shall conduct communications with a patient or other health care professionals in a manner that respects the patient’s wishes and confidentiality. This includes:

- when communicating with a patient in person, using a separate counseling room providing visual and sound barriers for privacy and a comfortable environment for the patient to share information;
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- when communicating with a patient via telephone, mail, fax, etc., ensuring that the information cannot be overheard or accessed by others;
- adhering to any applicable privacy legislation with respect to the collection, use and disclosure of any patient information related to testing; and
- notifying the patient as soon as possible if the confidentiality of any information related to the test is compromised.

3.10.4 A pharmacy practitioner shall communicate with and promptly forward the test results to the patient’s primary health care provider in any of the following circumstances:

- the results of a test they order fall outside the normal or expected range;
- the test results reveal an issue that is outside the pharmacy practitioner’s knowledge, skills and competencies;
- the pharmacy practitioner considers it to be in the best interest of the patient to involve another health care provider; or
- changes in the patient’s drug therapy have been made by the pharmacy practitioner as a result of the test.

The communication shall include, but not be limited to, details regarding the test results and any associated treatment, and any follow-up plan.

The communication to the patient’s primary health care provider shall be in writing when appropriate (refer to Appendix D – Test Results Notification Form).

With respect to critical test results, a pharmacy practitioner shall take the necessary steps to immediately ensure that the patient’s primary health care provider or other appropriate healthcare provider is aware of these results.

3.10.5 A pharmacy practitioner shall communicate with the patient’s primary health care provider from time to time regarding the general state of health of patients for whom the pharmacy is monitoring through ongoing tests.

3.10.6 A pharmacy practitioner shall communicate the results of tests to, and collaborate with, the patient’s other health care providers as appropriate.

3.11 Complete Documentation

3.11.1 The pharmacy practitioner shall record the test details in the patient record including:
- type of test conducted, ordered, received, and/or interpreted;
- date of test;
- test results;
- relevant medical or medication history, if applicable;
- name of pharmacy practitioner who conducted or ordered/ received/interpreted the test;
- date and method of referral or notification to another health care professional(s), if applicable;
- follow-up action(s) completed, if applicable, for abnormal test results (refer to Section 3.9 for further details on follow-up); and
- any other information related to the test that is relevant to the patient’s care.
APPENDIX A - REFERENCE DOCUMENTS

A pharmacy practitioner shall conduct, order, receive and interpret tests related to drug therapy management in accordance with the Pharmacist Extended Practice Regulations, Standards of Practice: Testing as well as existing legislation, regulations, the Code of Ethics, other standards of practice and policy directives relevant to pharmacy practice in Nova Scotia (refer to www.nspharmacists.ca) and the following references as appropriate:

- Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care, Health Canada
- Hand Hygiene Practices in Healthcare Settings, Public Health Agency of Canada
- Infection Prevention and Control Best Practices for Long Term Care, Home and Community Care including Health Care Offices and Ambulatory Clinics June, 2007
- Guidelines for Safe and Effective Management and Use of Point of Care Testing in Primary and Community Care, Dublin
- Ordering, Monitoring and Interpreting Laboratory Tests to Optimize Medication Management, Canadian Pharmacists Association
- Guidelines for Pharmacists Ordering Laboratory Tests and Using Laboratory Data, Alberta College of Pharmacists, 2011
- Point-of-Care Testing Standards, Accreditation Canada, 2014
- Point of Care Testing Position Statement, NS College of Medical Laboratory Technologists, Oct. 12, 2012
- Choosing Wisely Canada
APPENDIX B - FIRST AID AND CPR CERTIFICATION REQUIREMENTS

A pharmacy practitioner shall maintain current certification in First Aid and Cardiopulmonary Resuscitation (CPR) as required qualifications for testing as specified in Standard 3.3.1 in the Standards of Practice: Testing.

The specific requirements established by Council for First Aid and CPR certification are outlined below. Certifications are to be obtained through an organization approved by Council as follows:

Canadian Red Cross
St. John Ambulance Canada
Lifesaving Society
Canadian Ski Patrol
Heart and Stroke Foundation of Canada

FIRST AID

Certification in Emergency First Aid (Minimum)

CARDIOPULMONARY RESUSCITATION (CPR) CERTIFICATION

CPR certification (Minimum CPR Level C or equivalent)
APPENDIX C - PATIENT CONSENT AND DISCLOSURE REQUIREMENTS

A pharmacy practitioner shall obtain informed and voluntary consent for extended practice services, including testing, being provided to the patient. The pharmacy practitioner shall also disclose information related to the service provided in accordance with applicable legislative and regulatory requirements.

For reference, the following overview provides a general understanding of who can provide consent (i.e., Consent Authorities) as well as documentation and information disclosure requirements. For further details and specifics beyond those provided in this appendix, refer directly to the applicable legislation / regulations.

CONSENT AUTHORITIES

Adult Patients

A pharmacy practitioner shall obtain informed and voluntary consent from an adult patient, provided that the patient has the capacity to consent.

A pharmacy practitioner can assume that an adult patient has the capacity to consent and make their own treatment decisions, unless the pharmacy practitioner has reason to doubt the patient's capacity. Through communicating with the patient and obtaining required information to support the testing (communication conducted in person if practicable), a pharmacy practitioner can confirm a patient’s capacity to consent by determining that the patient has the ability to:

- understand information that is relevant to making a treatment decision, and
- appreciate the reasonably foreseeable consequences of a decision.

Mature Minors

A pharmacy practitioner can obtain informed and voluntary consent from a mature minor. A mature minor is one who is capable of understanding the nature and consequences of the treatment and has, therefore, legal capacity to consent to their treatment.

A pharmacy practitioner shall rely on their own judgment to ascertain whether a minor is sufficiently mature to make treatment decisions. The following factors can assist the pharmacy practitioner in assessing the maturity of a minor:

- What is the nature, purpose and utility of the recommended medical treatment? What are the risks and benefits?
- Does the minor demonstrate the intellectual capacity and sophistication to understand the information relevant to making the decision and to appreciate the potential consequences?
- Is there reason to believe that the minor’s views are stable and a true reflection of their core values and beliefs?
- What is the potential impact of the minor’s lifestyle, family relationships and broader social affiliations on their ability to exercise independent judgment?
- Are there any existing emotional or psychiatric vulnerabilities?
Does the minor’s illness or condition have an impact on their decision-making ability?

Is there any relevant information from adults who know the minor (e.g., physicians)?

In situations where a pharmacy practitioner determines that a minor has the necessary maturity to make their own treatment decisions, all rights in relation to giving or withholding consent will belong to the minor. The parent or guardian will no longer have any overriding right to give or withhold consent.

**Patient Agents**

When providing a service to an adult or mature minor patient who is not available to provide consent and another individual indicates by direction or implication that they are the patient’s agent, the pharmacy practitioner shall take reasonable steps to confirm the identity of the individual who is acting as the patient’s agent and to confirm that the individual has the patient’s authorization to act on their behalf. The pharmacy practitioner shall consider the nature, purpose and process of the activity requiring consent, including the associated benefits and risks, when using professional judgment to accept consent from the patient’s agent in this situation.

**Non-Mature Minors**

For non-mature minors, a pharmacy practitioner shall obtain informed and voluntary consent from the patient’s agent. The patient’s agent shall be determined in accordance with the considerations and ranked order outlined in the Patients Lacking Capacity to Consent section.

**Patients Lacking Capacity to Consent**

For patients who lack the capacity to consent, a pharmacy practitioner shall obtain informed and voluntary consent from the patient’s agent. The pharmacy practitioner shall deal with the patient’s agent as represented by a substitute decision maker appointed by the patient through the Personal Directives Act or the Medical Consent Act (where completed prior to April 1, 2010) to make personal care decisions (including health care decisions) should the patient become incapable of making decisions.

In situations where a personal directive or medical consent appointment exists, the pharmacy practitioner shall request a copy of it, follow the instructions and general principles regarding personal care decisions set out in the directive and file it in the pharmacy records for the patient.

In situations where a personal directive or medical consent appointment does not exist (and for non-mature minors as referenced above), the pharmacy practitioner shall deal with the patient’s agent as represented by a substitute decision maker in the following ranked order:

- Legal guardian (appointed by the court)
- Nearest relative (as applicable), in this order:
  - Spouse – includes married, common-law (partners living together for one year or more) and registered domestic partners
  - Child
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Appendix C – Patient Consent and Disclosure Requirements

- Parent
- Person standing in the place of a parent
- Sibling
- Grandparent
- Grandchild
- Aunt or uncle
- Niece or nephew
- Other relative
- Public trustee

There is a limitation on the determination of the nearest relative by the ranked order. In order to be a substitute decision maker, the patient’s nearest relative shall meet the following criteria:

- has been in personal contact with the patient over the preceding 12 months or has been granted a court order to waive the 12-month period (note that spouses are exempt from this 12-month personal contact requirement);
- is willing to assume decision-making responsibility;
- knows of no person of a higher rank in priority who is able and willing to assume decision-making responsibility; and
- makes a statement in writing to certify the relationship with the patient, that they are willing to act as the substitute decision maker and know of no person ranked higher in priority.

In addition, the pharmacy practitioner shall be satisfied through direct or telephone discussions with the individual and using their professional judgment that the nearest relative can act as the patient’s agent given the nature and purpose of the treatment, the intellectual capacity of the individual and the impact on the patient.

Documentation Requirements

Documentation of Informed Consent

When appropriate, a pharmacy practitioner shall include documentation in the pharmacy records for the patient that informed and voluntary consent was obtained and from whom. Written consent from the patient or patient’s agent is not required. Documentation of consent in the pharmacy records for the patient shall include:

- the name of the person who provided consent,
- confirmation of consent (can be satisfied by checking a “consent obtained” box) for the pharmacy practitioner testing and for disclosure of any subsequent treatment details and information to the patient’s primary health care provider and/or other appropriate health care professionals, and
- where applicable, confirmation of consent directly on the patient’s record for the pharmacy practitioner to undertake the testing.
Documentation for Patients Lacking Capacity to Consent

For a patient who lacks the capacity to consent, and a personal directive or medical consent appointment exists, a pharmacy practitioner shall obtain a copy of the Personal Directive or Medical Consent (where completed prior to April 1, 2010) and file it in the pharmacy records for the patient.

For a patient who lacks the capacity to consent / non-mature minors where the patient’s agent is the “nearest relative”, a pharmacy practitioner shall obtain and file written confirmation from the agent that they are the nearest relative (supported by a birth certificate or other identification), that they have been in personal contact with the patient over the preceding 12 months, is willing to assume decision-making responsibility with respect to the service being provided by the pharmacy practitioner, and knows of no one who ranks higher in the hierarchy of relatives who is able and willing to assume decision-making responsibility.

For a patient who lacks the capacity to consent / non-mature minors where the patient’s agent is a legal guardian or public trustee, a pharmacy practitioner shall review the court issued order to confirm applicability and retain a copy of the documentation.

Information Disclosure Requirements

In accordance with the Pharmacist Extended Practice Regulations and section 3.10 of these Standards, when appropriate, a pharmacy practitioner shall communicate with the patient’s primary health care provider and/or other appropriate health care professionals.

There can be other circumstances that require or justify a pharmacy practitioner to disclose information regarding actions taken without the patient’s informed and voluntary consent, including:

- reporting suspected abuse related to the administration of medication in accordance with the Protection for Persons in Care Act (note that such reporting is not a mandatory duty for a pharmacy practitioner),
- reporting an adult in need of protection in accordance with the Adult Protection Act,
- reporting child abuse in accordance with the Children and Family Services Act, and
- reporting notifiable diseases in accordance with the Reporting of Notifiable Diseases and Conditions Regulations.

Refer to the cited legislation for additional information regarding the disclosure of information in the above circumstances.
APPENDIX D - TEST RESULTS NOTIFICATION FORMS

When appropriate, the pharmacy practitioner shall communicate in writing, as set out in Standard 3.10 - *Communicate Effectively*, the required information to the patient’s primary health care provider and/or other relevant health care professionals as soon as reasonably possible after results are available and immediately in the event of a critical test result.

<table>
<thead>
<tr>
<th>Test Results Notification</th>
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<tbody>
<tr>
<td><strong>To Physician / Health Care Provider:</strong> You are receiving this form to facilitate you maintaining an accurate and complete patient record and to avoid duplication of interventions.</td>
</tr>
</tbody>
</table>

**Notification Information**
- Health Care Professional Notified:
- **Notification Date:**
- **Method:** □ Fax □ Phone □ Other __________

**Patient Information**
- **Name:**
- **Health Card #:**
- **Age:**
- **Informed Consent provided by:** □ Patient □ Patient’s Agent (specify agent name) __________

**Information on Test Ordered**
- **Test Name:**
- **Test Date:**
- **Rationale for Test:**
- **Test Result:**
- **Other Details (if applicable):**

**Follow-up Plan (if applicable)**
- **Therapeutic Goal**
- **Follow-up Action(s) to be Undertaken**
- **Date for Follow-up**
- **Individual Responsible for Follow-up**

**Notes:**

**Pharmacist Information**
- **Name:**
- **Phone:**
- **Fax:**
- **Pharmacy:**

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When prescribing is undertaken as a result of test information, both the prescribing and testing results shall be reported on the *Test & Prescribing Results Notification* form.

<table>
<thead>
<tr>
<th><strong>Test &amp; Prescribing Results Notification</strong></th>
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<tbody>
<tr>
<td><em>To Physician / Health Care Provider:</em> You are receiving this form to facilitate you maintaining an accurate and complete patient record and to avoid duplication of interventions.</td>
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<td><strong>Notification Information</strong></td>
</tr>
<tr>
<td>Health Care Professional Notified:</td>
</tr>
<tr>
<td>Notification Date:</td>
</tr>
<tr>
<td>Method: ☐ Fax ☐ Phone ☐ Other __________</td>
</tr>
<tr>
<td><strong>Patient Information</strong></td>
</tr>
<tr>
<td>Name: ______________________ Health Card #: ______________________ Age: ______________________</td>
</tr>
<tr>
<td>Informed Consent provided by: ☐ Patient ☐ Patient’s Agent (specify agent name) ______________________</td>
</tr>
<tr>
<td><strong>Information on Test Ordered</strong></td>
</tr>
<tr>
<td>Test Name: ______________________ Test Date: ______________________</td>
</tr>
<tr>
<td>Rationale for Test: ______________________ Test Result: ______________________</td>
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<tr>
<td>Other Details (if applicable): ______________________</td>
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<tr>
<td><strong>Follow-up Plan (if applicable)</strong></td>
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<td>Therapeutic Goal</td>
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<td>______________________</td>
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<tr>
<td>______________________</td>
</tr>
<tr>
<td><strong>Prescription Information (if applicable)</strong></td>
</tr>
<tr>
<td>Prescription Date: ______________________</td>
</tr>
<tr>
<td>Prescription Details (include prescribing category): ______________________</td>
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<tr>
<td>Prescribing Rationale: ______________________</td>
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<tr>
<td>Patient Communication / Instructions: ______________________</td>
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<tr>
<td>Prescribing follow-up (if appropriate) ______________________</td>
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<td><strong>Notes:</strong> ______________________</td>
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<tr>
<td><strong>Pharmacist Information</strong></td>
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<td>Name: ______________________ Phone: ______________________ Fax: ______________________</td>
</tr>
<tr>
<td>Pharmacy: ______________________</td>
</tr>
</tbody>
</table>

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