Laboratory Tests – Performing Tests for Drug Therapy Management

Understanding Part M of the SCPP Regulatory Bylaws (i.e. Performing Point-of-Care Tests (POCT) and Collecting Specimens to be Sent to a Laboratory)

Performing medical laboratory tests falls within the scope of practice of pharmacists only, as per Section 23(3)(d) of *The Pharmacy and Pharmacy Disciplines Act*. However, the governing legislation is not yet in place recognizing this role for pharmacists (i.e. *The Medical Laboratory Licensing Regulations*). As such, **a pharmacist is not authorized to perform testing unless:**

- The pharmacist is authorized under a laboratory licence AND they meet the SCPP terms and conditions for 1(c) of Part M of the SCPP Regulatory Bylaws; **OR**
- The pharmacist is performing a test that is permitted under *The Medical Laboratory Licensing Regulations* AND has been enabled to perform the test by the Registrar under Section 4 of Part M of the SCPP Regulatory Bylaws in extraordinary circumstances.

In extraordinary circumstances, should no other options exist to protect the health and well-being of the public, the Registrar may enact the emergency provisions outlined in Section 4 of Part M, if after consultation with health system stakeholders, the Registrar deems it to be in the best interest of the public. When enacted, any testing authorized by the Registrar would be time-limited and must be carried out within the terms and conditions specified by the Registrar.

When enabled, all pharmacist-administered tests or specimen collection, within or through a pharmacy must be done under the terms, conditions and standards in this policy, in addition to any other requirements specified by the Registrar if enacted in extraordinary circumstances.

These terms and conditions apply regardless of whether the test is being performed under a medical laboratory licence, or under an arrangement with a third party that is authorized under a medical laboratory licence. They must also be taken together as a whole with the terms and conditions found in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) and the Sale and Distribution of Medical Testing Devices and Other Diagnostic Products.

It is strongly recommended that pharmacists familiarize themselves with these requirements before participating in any testing activities to ensure that they are practicing within the scope and standards of practice as needed to maintain their licence and malpractice insurance.

DEFINITIONS

"Critical Test Results" – 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)

"**Drug therapy management**" – (also referred to as "pharmaceutical care") means patient-centered care to optimize safe, effective and appropriate drug therapy, and includes preventing, identifying and resolving drug related problems. Care is provided through collaboration with patients and their health care teams. (Also referred to as "pharmaceutical care.")

"Medical Laboratory Test" - Also referred to as "Test." See definition below.

"Patient-Administered Automated Tests" (PAATs) – refers to any test that is designed for patient self-use outside of a conventional laboratory or health care facility, without the assistance or supervision of a healthcare provider to yield a result (e.g. blood glucose testing, prothrombin time tests, blood pressure monitors, pregnancy tests). These testing devices must be approved by Health Canada for "self-testing" or for personal or home use by the general public, independent of the assistance or supervision of a health care worker. (See section 5 and "Appendix D - Pharmacies and Regulation of Medical Testing Devices in Canada" in Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) and the Sale and Distribution of Medical Testing Devices and Other Diagnostic Products.))

"Perform" – means the series of steps executed to obtain a test result (see definition of "test" below). The steps to performing a test include the collection, handling, transportation, documentation, and storage of specimens, as well as performing the analytical techniques on specimens to obtain the result. May also referred to as "conducting" or "administering" a test, or "testing."

"Pharmacist" – means licensed pharmacist.

"Pharmacy Professional" means licensed pharmacists, licensed pharmacy technicians and pharmacy interns (extended and student) who are practicing under the supervision of a licensed pharmacist or licensed pharmacy technician as required. (See . Supervision of Pharmacy Interns)

"Point-of-Care Testing" (POCT) – refers to analytical patient testing activities performed outside the physical facilities of a clinical laboratory, using a wide variety of test kits and medical devices (e.g. dipstick urinalysis, occult blood screening through robust hand-held kits to bench-mounted analyzers). POCT is typically performed by operators who are not laboratory-trained personnel, and may not require permanent dedicated space. Often referred to as near-patient testing, bedside testing or rapid tests. (See CPSS Laboratory Quality Assurance Policy and Section 5 in Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting))

Note: for the purposes of this document, "point-of-care testing" will be used when referring to the use of those devices approved by Health Canada as such, whereas "self-testing devices" will be used synonymously with PAATs.

"Other Licensed Health Care Professional" – For the purposes of implementing this policy related to Part M of the SCPP regulatory bylaws, this includes other licensed health care professionals whose scope of practice and liability coverage permits the specified practice within the terms and conditions set by their regulator. Note: pharmacy technicians, pharmacy interns (student and extended) are NOT included in this category of health care professionals.

"Specimen Collection" – refers to the process of obtaining specimens from the body (e.g. body fluids, secretions or excreta, including blood, urine, saliva, feces or drainage), for the purpose of administering laboratory or point-of-care test. It is one step in "performing" a test. Specimens may be collected using a variety of methods (e.g. nasal swab, throat swab, saliva sample, blood draw, nasopharyngeal). Receiving, storing and transporting specimens is part of the testing process, regardless of who collects it.

Note: Specimen handling, transportation and delivery for medical purposes, may be subject to the quality assurance requirements of the CPSS LQAP (see here for example). Transporting biological specimens is also subject to the *Transportation of Dangerous Goods Act, 1992*.

"**Test"** – (Also referred to as "Medical Laboratory Test unless specified, or the context indicates otherwise.) As per *The Medical Laboratory Licensing Act*, S2(i) means the **examination or analysis of a specimen taken or collected from a human body to obtain information** for screening, diagnosis, prophylaxis, treatment, **or any other health-related purpose.** This includes tests requiring the collection of a specimen to be analyzed at an accredited medical laboratory by a licensed medical laboratory technologist or through point-of-care testing, to obtain a result to inform a medical intervention.

1. POLICY STATEMENT

Advances in technology have resulted in the public being able to purchase self-testing products or access devices outside of conventional laboratory or healthcare settings for screening or monitoring disease states, chronic medical conditions and responses to drug therapies.

With the use of self-testing devices and products (or patient-administered automated tests), the public is able to monitor their medical conditions without the assistance or supervision of a health care provider to yield a result.

With the use of point-of-care testing devices, health care workers who are not laboratory-trained (e.g. pharmacists), may offer these as part of preventive and primary care activities such as patient education, screening or disease state risk assessment clinics held in pharmacies.

The Saskatchewan College of Pharmacy Professionals (SCPP) recognizes that there are risks and benefits of providing these services in the community pharmacy setting. When quality is sub-optimal, it may lead to public confusion over the role of the pharmacist compared with other health care professionals, over the validity of the results, or generate unjustifiable referrals to other health care resources.

However, when provided safely and the public is informed of the limitations, more access to these services, may increase the public's interest in wellness and personal responsibility for health.

Program/Service Maintains Collaborative Practice Environment

1.1. All pharmacists and pharmacies must ensure that their disease state monitoring, screening, testing and risk assessment activities aim to:

1.1.1. Achieve healthy outcomes;

1.1.2. Foster collaboration with other members of the health care system;

1.1.3. Contribute to the prudent use of health care resources; and

1.1.4. Minimize public confusion.

Program/Service Supports Drug Therapy Management

The Council policy is that the scope of practice of the licensed pharmacy professional is based on the concept of pharmaceutical care, which is defined as, "*the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (Hepler, D. and Strand, L: Am J Hosp Pharm 1990; 47:533-43)."*

The goals of pharmaceutical care are for the licensed pharmacy professional to establish a relationship with the patient to identify, solve and prevent the patient's drug-related problems.

1.2. All disease-state monitoring, screening, testing, risk assessment or educational products and activities offered in the community pharmacy as services must:

1.2.1. Be within the scope of practice of the pharmacy professional; and

1.2.2. Support drug therapy management, unless otherwise authorized by the Registrar in extraordinary circumstances,

Managing Risks of Testing without Laboratory Expertise

When testing and prescribing medical devices became an authorized practice for pharmacist's under *The Pharmacy and Pharmacy Disciplines Act,* it was acknowledged that:

- Pharmacists were not laboratory-trained personnel; and
- Pharmacies were not subject to the same quality assurance standards as required by licensed laboratories (i.e. CPSS' Laboratory Quality Assurance (QA) Program),

In recognition of these risks, this SCPP policy builds on the standards that apply to Saskatchewan Licensed Medical Laboratory Technologists who have extensive knowledge and understanding of the principles of laboratory testing and good laboratory practices.

It also builds on the CPSS Laboratory Quality Assurance – "Point-of-Care Testing Policy #1") which holds all point-of care testing to the same standard as clinical laboratory testing, so that all testing is safe, evidence-based, patient-centred, timely, efficient and equitable. The intent is to minimize the risks of unreliable test results so that patients can benefit from test results that are accurate, reproducible, and comparable to that of a licensed laboratory

And finally, the SCPP has also adapted the work of pharmacy regulators in other provinces to maintain the standards for the pharmacy profession, while also ensuring that:

- all point -of-care testing and other testing activities provided by pharmacists is held to the same standard as laboratory-trained personnel, and
- all point-of-care or other testing activities offered by or performed in pharmacies is held to the same standard as clinical/licensed laboratory testing.

(See SCOPe Special Edition "Laboratory Tests," November 2015 and Section 12 - Acknowledgments)

2. PHARMACY MANAGER REQUIREMENTS

In addition to the requirements outlined in section 5 of the SCPP's Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting), pharmacy managers must:

2.1. Provide active oversight of all testing programs and services provided by pharmacists, and offered within or through pharmacies, to ensure that they meet all SCPP terms and conditions, as well as the terms and conditions of the CPSS Laboratory QA program where applicable, including:

2.1.1. Ensuring that the quality assurance practices and standards for laboratories, as per section 4, are met.

2.2. Develop, implement and manage a POCT program/service in accordance with Sections 7, 8 and 9, if POCT is conducted within or through a licensed pharmacy; and

2.3. Develop, implement, and manage a specimen collection program/service in accordance with Sections 10 and 11; if pharmacists or other licensed health care professionals are collecting specimens other than for POCT;

(Also see the SCPP's Pharmacy Manager Responsibilities document.)

REQUIREMENTS FOR ALL TESTING ACTIVITIES

3. OVERARCHING TERMS AND CONDTIONS

3.1. Regardless of whether the pharmacist or pharmacy is acting under the authorization of a laboratory licence, or providing the service in affiliation with a third party that is authorized under a laboratory licence, all testing activities performed by pharmacists or provided within or through pharmacies must:

3.1.1. Meet the applicable SCPP policies, terms and conditions in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) document.:

3.1.2. Where applicable, comply with:

3.1.2.1. *The Medical Laboratory Licensing Act* and when needed:

3.1.2.1.1. Seek the advice of the CPSS Laboratory Quality Assurance Program to determine whether testing products or services meet acceptable standards for competency of personnel, and instrument, equipment and testing proficiency.

3.1.2.2. *The Radiation Health and Safety Regulations* and when needed:

3.1.2.2.1. Seek advice on radiation-emitting devices from the Radiation Safety Unit in the Saskatchewan Ministry of Labour Relations and Workplace Safety

(For context see Saskatchewan Pharmaceutical Association Newsletter, October 2001.)

4. PHARMACY PREREQUISITES

4.1. In addition to any other requirements specified by the Registrar if enacted in extraordinary circumstances, all pharmacies involved in any of the steps required to perform a point-of-care test or other testing activity, must have:

4.1.1. An environment that is clean, safe, private, and appropriate for collecting the sample, conducting the test, storing the device and supplies, and managing hazardous waste disposal, with consideration to such things as

4.1.1.1. Physical layout and design of the space (e.g. HEPA air filtration systems, dedicated space, physical barriers) to minimize exposure of employees and patients to biohazards introduced from the testing program or service (e.g. airborne or bloodborne diseases);

4.1.1.2. Management of patient flow through the pharmacy (e.g. separate waiting and testing areas, separate entrances, dedicated times of service for testing patients with highly contagious diseases);

4.1.2. Written policies and procedures in place for routine and advanced infection control precautions, and that staff are trained to carry them out with diligence (See SCPP's Infection Control Guidelines, the Hand Hygiene Guidelines and Standards, the Respiratory Hygiene and Cough Etiquette Standards and Guidelines and the Needlestick Injury Guidelines).

Standard Operating Procedures

4.1.3. Clear and comprehensive written standard operating procedures and processes in place to ensure that pharmacists are performing these activities in accordance with the best practices and standards for

laboratory medicine and the manufacturer's instructions on the package insert as approved by Health Canada. The standard operating procedures must cover the following:

4.1.3.1. Purpose of the test;

4.1.3.2. Limitations of the test and device, potential interferences, cross reactions and potential sources of variability or error;

4.1.3.3. Proper patient identification policy that is consistent with the spirit and intent of the standards, policies and procedures in the SCPP's Patient Identification Verification policy;

4.1.3.4. Criteria for referral of patient to a primary care practitioner for further follow up in a timely manner;

4.1.3.5. Training requirements and procedures;

4.1.3.6. Quality control procedures including ensuring reagents, materials, and equipment are stable and not expired;

4.1.3.7. Maintenance and storage of reagents, test units, and materials and how to address when not done properly;

4.1.3.8. Calibration of equipment (instrument/reagent) as required by the manufacturer;

4.1.3.9. Validation/verification of device/equipment;

4.1.3.10. Actions to address an incomplete test, and inoperable device, and a failed test;

4.1.3.11. When to call the manufacturer if the POCT appears to be malfunctioning, or if help is required for calibrating the device due to instrumentation errors (if not stored properly);

4.1.3.12. Establishment of acceptable target or reference ranges for quality control materials;

4.1.3.13. Cleaning of contaminated surfaces and equipment;

4.1.3.14. Personal protective equipment,

4.1.3.15. Stepwise instructions for use;

4.1.3.16. Preparation of reagents and other materials;

4.1.3.17. Specimen collection, identification, and handling;

4.1.3.18. Disposal of waste;

4.1.3.19. Reference interval (“normal values”) for populations being treated;

4.1.3.20. Special alerts and processes to address “critical test result” values and those falling outside of defined acceptable limits (also see section 7 of the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting));

4.1.3.21. Remedial action for out-of-control readings;

4.1.3.22. Adverse event protocols related to all phases of testing; and

4.1.3.23. Reporting and documentation of results.

Quality Assurance Process

4.1.4. Quality assurance process in place which includes:

4.1.4.1. Monitoring and evaluation of testing process for compliance with the standard operating procedures and opportunities for improvement;

4.1.4.2. Regular quality control testing of equipment and consumables;

4.1.4.3. Regular maintenance of equipment;

4.1.4.4. Centralized coordination of training, certification and assessment of ongoing competence for all personnel that perform the test;

4.1.4.5. Proficiency testing for test and for personnel performing the test;

4.1.4.6. A system for documentation and regular review of errors and incidents, and

4.1.4.7. A system for regular review of quality control records and documents

5. PERSONNEL REQUIREMENTS

In addition to any other personnel requirements specified by the Registrar if enacted in extraordinary circumstances, the following requirements apply to personnel who are involved in a testing activity (e.g., performing a point-of-care test, collecting the specimen to be sent to a clinical laboratory, or supervising the self-collection of a specimen by a patient).

5.1. The personnel operating the equipment or device, interpreting the results, and educating the patient, or collecting the specimen, or supervising the self-collection of a specimen by a patient, must be competent to do so. This may mean engaging other health care professionals who are competent in these areas.

5.2. Where a laboratory licence is required, the pharmacists or other health care professionals involved, must be:

5.2.1. Permitted under *The Medical Laboratory Licensing Act;* and

5.2.2. Practicing in accordance with any proficiency levels and standards set by the Laboratory Quality Assurance Program (LQAP) administered by the College of Physicians and Surgeons of Saskatchewan.

(Also see text box “Understanding Part M of the SCPP Regulatory Bylaws (Testing Devices in the Pharmacy)” and Section 5 in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting).)

5.3. Other licensed health care professionals performing testing activities in the pharmacy must:

5.3.1. Be permitted within their scope of practice, recognized as competent to do so, and practicing within the standards required by their regulatory body; and

5.3.2. Meet the SCPP’s standards of practice for performing these activities in a pharmacy.

6. CONFLICTS OF INTEREST

As per the Code of Ethics, pharmacy professionals and proprietors shall hold the health and safety of the public to be of first consideration and shall not engage in any practice which may compromise acceptable standards of the profession. Therefore, before testing programs or services are performed by pharmacists or provided within or through a pharmacy:

6.1. Pharmacy managers and proprietors must assess the suitability of the premises, availability of personnel and other essential resources (e.g., personal protective

equipment, cleaning supplies), the patient population they serve, and the extent to which they meet the pharmacy prerequisites, when considering whether to offer testing programs or services.

6.2. Testing programs/services must only be offered when the pharmacy has the capacity (e.g., health human resources, space) to provide pharmacy services in accordance with the SCPP terms, conditions, and standards.

6.2.1. If permitted by the Registrar in extraordinary circumstances as per Section 4 of Part M, the choice to engage in testing activities that are not related to drug therapy management must not impede or limit the public's access to, or the safe delivery of, core pharmacy services that are medically necessary for patients and primarily provided by pharmacists in the community pharmacy (i.e. drug therapy management, and dispensing drugs to the general public).

(See Appendix A - "What is Core Pharmacy Services? What is Considered Medically Necessary?)

6.3. Pharmacy managers and proprietors must not enter arrangements with third parties, to perform or offer testing activities, where the conditions of such practice would compromise the standards of the profession or pharmacy practice.

6.4. Disease state screening programs may only be offered or promoted to the public in a professional manner, which includes but is not limited to:

6.4.1. Uses pharmacy resources appropriately enabling member to follow up properly with the patient;

6.4.2. Must be properly resourced so that it does not reduce resources required to maintain regular pharmacy workflow and patient safety (e.g. the pharmacist performing the test must not be running back and forth to perform testing and dispensing duties);

6.4.3. Referring patients to other health services providers when appropriate;

6.4.4. Taking reasonable steps to ensure that those who need the service receive it; and

6.4.5. Avoiding conflicts of interest that arise when such activities result in the purchase of goods and services that limit the patient's right of choice, or that may not be needed.

6.5. Pharmacists shall avoid situations that present a conflict of interest that compromise their professional independence, judgment, or integrity, such as:

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.

6.6. Decisions to perform the testing program or service shall be based on clinical suitability, cost effectiveness and the patient's best interest.

6.7. Decisions to perform the testing program or service based on bias-oriented information

or on providing financial advantage to the pharmacist and/or pharmacy without providing benefit to the patient may be regarded as professional or proprietary misconduct (as per sections 25 and 26 of *The Pharmacy and Pharmacy Disciplines Act)*.

6.8. Patients must be advised when a publicly-funded testing program/service option is available, the eligibility requirements and where they can receive it at no additional cost.

6.9. Patients must be informed when the testing program or service may not be acceptable for their intended purpose. (Also see sections 9.12 to 9.16)

POINT-OF-CARE TESTING PROGRAM/SERVICE REQUIREMENTS

In addition to any other terms and conditions specified by the Registrar if enacted in extraordinary circumstances, the following requirements apply to all pharmacists and all point-of-care testing programs/services offered within or through pharmacies, regardless of whether the pharmacy is authorized under a laboratory licence, or affiliated with a third party that is operating under the authority of a laboratory licence.

7. POINT-OF-CARE TESTING DEVICES

7.1. Any test that is conducted must:

7.1.1. Be indicated to assist with drug therapy management for the patient, unless otherwise authorized by the Registrar in extraordinary circumstances;

7.1.2. Use a device that is approved by Health Canada as a point-of-care test and used as indicated on the official package insert (i.e. on-label usage only for approved indications, intended users, intended settings and intended conditions for use, including whether device is intended for single use or certified for multi-patient use);

7.1.3. Meet Council criteria outlined in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) reference document;

7.1.4. Sufficient evidence exists from credible sources that the device is reliable and medically relevant for the indication, and accepted by the Roy Romanow Provincial Laboratory or other health authorities, where applicable; and

7.1.5. Be authorized under a medical laboratory licence issued under *The Medical Laboratory Licensing Act*, where applicable.

7.2. Considerations when selecting point-of-care testing devices for pharmacy programs/services must include:

7.2.1. Purpose of the test;

7.2.2. Accuracy, precision and reliability of the test;

7.2.3. Quality control procedures for the test;

7.2.4. Degree of difficulty in using the test device;

7.2.5. Training required to conduct the test;

7.2.6. Whether the level of staffing enables and supports safe and effective testing without compromising the quality of other pharmacy services;

7.2.7. Agreements that are required with testing device and material suppliers regarding education, support, and adverse event reporting;

7.2.8. Whether the test has been approved by Health Canada for point-of-care testing by a health care worker; and

7.2.9. Whether pharmacists are authorized to use the device as per the SCPP's terms and conditions and *The Medical Laboratory Licensing Act*, where applicable.

7.3. A pharmacy is not permitted to perform tests using PAATs as part of its point-of-care testing program, service or activity, as this would be considered off-label use, it creates a potential conflict of interest, and would require a laboratory licence. (Also see section 6 Conflict of Interest).

8. POINT-OF-CARE TESTING PROGRAM/SERVICE OBLIGATIONS

8.1. In addition to any other terms and conditions specified by the Registrar if enacted in extraordinary circumstances, each point-of-care testing program or service provided by the pharmacy must:

8.1.1. Identify each type of POCT that will be available to be conducted, including the specific device to be used for each type of test; and the pharmacists who are permitted to conduct the test;

8.1.2. Include a clear and comprehensive written standard operating procedure for each POCT performed;

8.1.3. Ensure that there is an appropriate practice environment and facilities for testing;

8.1.4. Ensure that pharmacists, or other health care professionals, who conduct tests are trained, competent, and follow standard operating procedures and manufacturer standards;

8.1.5. Ensure that pharmacists, or other health care professionals, who conduct tests are verifying the patient identification;

8.1.6. Establish expectations of pharmacists receiving, using, interpreting or conducting tests;

8.1.7. Ensure that POCT equipment is properly managed, including proper calibration at manufacturer recommended intervals, and ensure that there are adequate and safe supplies for the POCT program;

8.1.8. Ensure that pharmacists responsible for conducting the POCT, consult and collaborate with laboratory POCT experts when required; and

8.1.9. Include a quality assurance process for POCT.

9. STANDARDS OF PRACTICE – PERFORMING POINT-OF-CARE TESTS

In addition to the standards of practice listed in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) document, and any other standards specified by the Registrar if enacted in extraordinary circumstances, all pharmacists performing point-of-care tests must adhere to the following standards of practice:

9.1. Before a pharmacist conducts a POCT, a pharmacist must consider whether a laboratory test would be more appropriate, and if so, then to make the appropriate referral to the patient's primary practitioner.

9.2. If a pharmacist practices in a pharmacy that offers or provides POCT, either within the pharmacy or through the pharmacy, the pharmacist must:

9.2.1. Satisfy themselves that the pharmacy manager has developed, implemented, and manages the POCT program as required under sections 7 and 8 of this policy; and

9.2.2. adhere to the POCT program.

9.3. A pharmacist who is not practicing in or through a pharmacy, and conducts a POCT, must ensure that there is a program in place or must implement a program that meets the minimum standards fora POCT program under section 7 and 8 of this policy,

9.4. If there is no POCT program that complies with the requirements of section 7 and 8 of this policy, then a pharmacist must not conduct a POCT.

9.5. A pharmacist must only conduct a POCT if

9.5.1. The test is undertaken for a purpose within the practice of pharmacists;

9.5.2. The test is indicated to assist with drug therapy management for the patient, unless otherwise authorized by the Registrar in extraordinary circumstances;

9.5.3. The test is being used in accordance with the official product label or package insert as approved by Health Canada (i.e., on-label usage only for approved indications, intended users, intended settings and intended conditions for use, including whether device is intended for single use or certified for multi-patient use).

9.5.4. The test is required for the pharmacist to manage a disease state or chronic condition for a patient, unless otherwise authorized by the Registrar in extraordinary circumstances (see section 2 of the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting));

9.5.5. The pharmacist has verified the identify of the patient;

9.5.6. The pharmacist has a professional relationship with the patient, unless otherwise authorized by the Registrar in extraordinary circumstances;

9.5.7. The laboratory test data is not otherwise available (e.g. in the electronic health record);

9.5.8. The pharmacist has obtained the informed consent of the patient (see sections 9.12 to 9.16);

9.5.9. The pharmacist has conducted a patient specific assessment and is satisfied that the POCT is appropriate after considering clinical suitability, cost

effectiveness, and the patient's best interests; (See section 2 in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) for Council requirements and criteria for assessing clinical suitability.)

9.5.10. The device is intended for single use or certified for multi-patient use and it is being used as indicated; and

9.5.11. The pharmacist has adequate knowledge of:

9.5.11.1. The specific POCT including the physical and diagnostic characteristics and limitations of the POCT,

9.5.11.2. When the testing is appropriate for a patient given their disease state or chronic condition,

9.5.11.3. Which POCT to select in the specific situation,

9.5.11.4. How the results should be interpreted in the context of other patient information, and

9.5.11.5. What action should be taken based on the results.

9.6. A pharmacist must only conduct a POCT in accordance with their scopes of practice, personal knowledge, skills, and competencies.

9.7. A pharmacist must only use POCTs and related materials (e.g. device, software, reagents, strips) that are classified and licensed by Health Canada (where required by the *Medical Devices Regulations* to the *Food and Drugs Act*, (See Appendix D in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting)).

9.8. A pharmacist must only conduct a POCT in accordance with a written standard operating procedure that meets any conditions or requirements of the manufacturer.

9.9. The pharmacist must cooperate with the patient's practitioner. This includes disclosing relevant information to the practitioner with the patient's consent, and providing the practitioner with an appropriate recommendation. (Also see sections 2 and 9 in Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting).)

Choice of Point-of-Care Test

9.10. In addition to the clinical suitability and other Council criteria, pharmacists make informed choices among tests based on an understanding and evaluation of test characteristics. These characteristics must include:

9.10.1. Intended purpose of the test (e.g., disease state management, screening);

9.10.2. Type of test (quantitative or qualitative);

9.10.3. Specimen or sample that is required and the related testing considerations (e.g., environment, regulatory and other considerations if sample is blood, urine, or saliva);

9.10.4. Test performance characteristics (e.g., sensitivity, specificity, accuracy, repeatability, reproducibility, measurement/reference range, and interferences);

9.10.5. Patient population (e.g., pediatric population vs adults, as predictive value varies in different populations);

9.10.6. Test system (e.g., simplicity, length of time to obtain result, level of technical support provided by manufacturer, special training required, and patient information required);

9.10.7. Specimen or sample collection protocols and equipment, sample stability;

9.10.8. Method to discard specimens/samples and other testing material;

9.10.9. Cost to patients (i.e., when to refer to central lab for testing);

9.10.10. Cost to the health system (i.e., cost stewardship);

9.10.11. Comparability of the POCT data with the laboratory test data; and

9.10.12. Whether they are authorized to use the testing device. (See Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting));

9.11. The test performed by the pharmacist must be approved by Health Canada for point-of-care testing, and not indicated for personal use or self-testing at home (ie. PAAT) as this would be considered off-label usage and may be a conflict of interest. (See section 6, Conflict of Interest.)

Informed Consent

9.12. Pharmacists must obtain informed consent from the patient prior to performing a POCT. (Note: also applicable to collecting a specimen or supervising the self-collection of a specimen by a patient to be sent to a laboratory.)

Also see Powers of Attorney, Health Care Directives and Substitute Decision Makers Guidelines for Pharmacists and Pharmacy Technicians

9.13. Consent must be informed, specific, given voluntarily and documented (e.g., patient signature). **Note: A signature on a consent form is NOT a substitute for having a conversation with a patient.**

9.14. The pharmacist should provide the patient with information that is understandable and sufficient, in order to allow the patient to make an informed decision to accept or to decline the testing service, and also provide the opportunity for the patient to ask questions and obtain responses about the test. The information should include:

9.14.1. Name of the test;

9.14.2. Objective of the test;

9.14.3. How it will be performed;

9.14.4. Benefits, risks and limitations;

9.14.5. Plan for follow-up, if appropriate, including timeline;

9.14.6. Whom the test results may be shared with (e.g., primary health care provider, public health authority), where applicable; and

9.14.7. Cost, where applicable.

9.15. Where an activity has limitations in quality, such as limitations in the reliability of test results, the pharmacist must disclose these limitations in writing to the patient to ensure that informed consent has occurred.

9.16. Any information that may impact the patient's decision to use the testing program or service offered within or through the pharmacy must also be addressed (e.g., publicly funded option available at no extra charge, test result may not satisfy non-medical purposes such as proof of negative test result for work, school, travel or recreational). (Also see section 6 Conflict of Interest.)

Testing Environment

9.17. POCTs must only be conducted in an environment that is clean, safe, private, and appropriate for collecting the sample, conducting the test, storing the device and supplies, and managing hazardous waste disposal:

9.17.1. Sample collection and testing must comply with any conditions defined by the manufacturer of the test and the standard operating procedure; and

9.17.2. Environment supports routine and advanced infection control precautions specific to the testing activity being performed.

Precautions for Infection Control

9.18. A pharmacist must apply routine and advanced infection control practices, when necessary, to prevent transmission of infection while conducting tests. This includes but is not limited to:

9.18.1. Hand hygiene;

9.18.2. Use of personal protective equipment;

9.18.3. Specimen handling consistent with standard precautions;

9.18.4. Routine cleaning and decontamination procedures;

9.18.5. Safe disposal of sharps/biohazardous waste; and

9.18.6. Follow-up in the event of accidental exposure to blood or body fluids.

(Also see section 4.1.2 of this policy.)

Interpreting Test Results

9.19. A pharmacist must interpret the results of any POCT the pharmacist performs. In addition to the considerations in section 6 of Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting), the pharmacist must also consider and interpret the data in the context of:

9.19.1. Patient-specific factors;

9.19.2. The physical characteristics and limitations of each test; and

9.19.3. The purpose of the test and how the results will be applied.

Providing Test Results

9.20. A pharmacist who conducts a POCT must:

9.20.1. Advise the patient of the purpose of the test and how the results will be applied; and

9.20.2. Advise the patient of the results.

(Also see text boxes around privacy and scope of practice in Section 8 of the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting).

Ensuring Appropriate Action and Follow Up

9.21. A pharmacist who conducts a POCT must take appropriate action based on the results of the test. (See examples in section 7 of the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting)

9.22. Once the pharmacist 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.

Documentation, Record Keeping and Communication

In addition to the requirements outlined in section 9 of the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) the following standards apply to pharmacists who have conducted POCTs:

9.23. A pharmacist must record each POCT conducted and the results of the test in the patient record immediately after the activity is performed and take responsibility for its completeness and accuracy, including:

9.23.1. Patient identifiers (Health Services Number, date of birth, first and last name, sex, address);

9.23.2. Date and time of the assessment;

9.23.3. POCT device used, Health Canada device identifier, lot number, the result, and any follow-up action taken;

9.23.4. Name of the patient's primary health practitioner;

9.23.5. Patient assessment, including any recommendations; and

9.23.6. The name of the pharmacist providing the service.

9.24. A pharmacist who has conducted a POCT must ensure that documentation regarding the tests conducted, and the results are communicated as soon as is reasonably possible to other health professionals caring for the patient, as appropriate. (Note: POCT data is not uploaded into the electronic health record (i.e., eHR viewer) and could result in duplication of tests by other healthcare providers.)

9.25. A pharmacist who makes a decision based on the interpretation of POCT data must:

9.25.1. Document the decision and the rationale for it in the patient record;

9.25.2. Discuss the decision and the rationale with the patient;

9.25.3. Include any reference to testing data in any communication about the decision with members of the patient's health care team; and

9.25.4. In the case of reportable communicable diseases, promptly report the results of positive tests to the medical officer of health.

9.26. The documentation and in communication of the data to others, must specify that it is the result of a POCT and include details of the POCT technology and the purpose of the test and how the results will be applied; and

9.27. Any other documentation, reporting and communication as required by the Registrar if enabled to address extraordinary circumstances.

SPECIMEN COLLECTION PROGRAM/SERVICE REQUIREMENTS

10. SPECIMEN COLLECTION PROGRAM/SERVICE OBLIGATIONS

10.1. In addition to any other terms and conditions specified by the Registrar if enacted in extraordinary circumstances, the specimen collection program must:

10.1.1. Ensure that the laboratory to which collected specimens are sent to, is licensed in Saskatchewan;

10.1.2. Ensure that patient identity is verified before collecting specimen.

10.1.3. Ensure that the pharmacist has obtained the informed consent of the patient (as per sections 9.12 to 9.16);

10.1.4. Ensure that the pharmacist only collects specimens of body fluids that have been approved by the Registrar (e.g. saliva, nasal, blood, feces, or urine) through methods approved by the Registrar (e.g. gargle, throat swab, nasal swab, nasal pharyngeal);).

10.1.5. Identify each type of specimen collection that will occur, and the pharmacists if any, who can collect the specimen;

10.1.6. Include a clear and comprehensive written standard operating procedure for each type of specimen collected, written in accordance with the policies and procedures of the laboratory for which they are collecting the specimen, that describes how the pharmacist is to collect, label, store, and transport specimens;

10.1.7. Ensure that there is an appropriate practice environment and facilities for collecting the specimen;

10.1.8. Ensure that pharmacists who collect the specimen are trained, competent, and follow standard operating procedures;

10.1.9. Ensure that pharmacists understand the etiology and treatment protocols for the disease state or chronic condition for which the specimen is being collected; and

10.1.10. Outline the nature of the collaborative relationship among the pharmacist, the laboratory and other involved health professionals with respect to:

10.1.10.1. Responsibilities and protocols for acting on the test results; and

10.1.10.2. Communicating the test results and subsequent actions taken.

11. STANDARD OF PRACTICE – COLLECTING SPECIMENS FOR LABORATORY TESTING

In addition to the standards of practice listed in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) document, and any other standards specified by the Registrar if enacted in extraordinary circumstances, all pharmacists involved in specimen collection that is sent to a laboratory for analysis (e.g. pharmacist performing the specimen collection, pharmacist supervising patients who are self-collecting the specimen) must adhere to the following standards of practice.

These standards apply regardless of whether the pharmacy is authorized under a laboratory licence or working under an arrangement with a third party that is authorized under a laboratory licence, for which the CPSS Laboratory Quality Assurance Program standards also may apply.

11.1. If a pharmacist practices in a pharmacy that collects specimens, or supervises a patient self-collecting a specimen, within the pharmacy, or through the pharmacy, the pharmacist must:

11.1.1. Satisfy themselves that the pharmacy manager has developed, implemented, and manages the specimen collection program as required under section 10; and,

11.1.2. Adhere to the specimen collection program.

11.2. If there is no specimen collection program that complies with the requirements of Section 10, then a pharmacist must not collect a specimen.

11.3. A pharmacist who is not practising in or through a pharmacy, and collects a specimen, must ensure that there is a program in place or must implement a program that meets the minimum standards for a specimen collection program under Section 10 .

Documentation, Record Keeping and Communication

11.4. A pharmacist must record each specimen collected in the patient record, in addition to other pertinent information as identified in section 9 of the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting).

11.5. When collecting specimens for medical laboratory testing, pharmacists are expected to practice to similar standards expected of laboratory-trained and licensed personnel (e.g. SSMLT). Therefore, unless specified by the medical laboratory, pharmacists must:

11.5.1. Must not pre-label the tubes;

11.5.2. Label all specimens in the immediate presence of the patient at the time of collection;

11.5.3. Ensure tubes must be labeled with the patient's first and last name, and Health Services Number;

11.5.4. Record the date and time of collection, and the initials of the person collecting the specimen in the patient profile when the collection has been completed; and

11.5.5. Complete any other documentation, record keeping or communication as required by the medical laboratory.

(Adapted from the Saskatchewan Health Authority (Regina Qu'Appelle Health Region) Laboratory Services Manual).

11.6. Any other documentation, reporting and communication as required by the Registrar if enabled to address extraordinary circumstances.

12. ACKNOWLEDGMENTS

12.1. Alberta College of Pharmacy - Standards of Practice – Laboratory and Point of Care Testing

12.2. Alberta College of Pharmacy – Guidance for Pharmacists and Pharmacy Technicians, Laboratory and Point of Care Testing (POCT)

12.3. College of Physicians and Surgeons of Saskatchewan - Laboratory Quality Assurance Program - Policy Manual

12.4. Nova Scotia College of Pharmacists - Standards of Practice: Testing

12.5. Ontario College of Pharmacists - COVID-19 Testing of Asymptomatic Persons in Community Pharmacies

12.6. Saskatchewan Health Authority – Regina Qu'Appelle Health Region – "Laboratory Services Manual," February 2020

12.7. Saskatchewan Health Authority - Regina Qu'Appelle Health Region Regional Point of Care Testing Program Policy, December 2016 Saskatchewan Society of Medical Laboratory Technologists (SSMLT) – National Standards of Practice for Medical Laboratory Technologists

Appendix A: What are Core Pharmacy Services? What is Considered "Medically Necessary"?

What are Core Pharmacy Services? What is Considered "Medically Necessary"?

To avoid a conflict of interest, the following are some considerations for the pharmacy manager and proprietor as they assess whether an expanded service will impede safe access to medically necessary core pharmacy services, that are primarily offered in the pharmacy.

Core Pharmacy Services

Section 23 of *The Pharmacy and Pharmacy Disciplines Act* outlines the authorized practices (or scope of practice) for licensed pharmacists and pharmacy technicians. Together these form the core services typically offered in or through a pharmacy.

Some of these services are provided primarily by pharmacy professionals through a community pharmacy and are not available elsewhere, including:

- Preparing, compounding, dispensing or selling drugs, and
- Monitoring, counselling, supervision and management of drug distribution systems to maintain public safety and drug security);

Other authorized practices may be carried out by other health providers, but are often carried out by pharmacy professionals to support health care delivery in the province. This includes:

- Prescribing and administering drugs (e.g. continuing existing prescriptions, minor ailments, travel health and other vaccines),
- Administering drugs (e.g. publicly-funded vaccines),
- Prescribing treatments, health care aids and devices related to pharmacy practice, and
- Accessing, using and interpreting medical laboratory tests for drug therapy management.

<u>Application in the Pharmacy:</u>

- Dispensing based on a prescription by an authorized practitioner; and collaboration with the practitioner (e.g. via telephone) to ensure that critical communication occurs in a prompt manner (i.e. maintain collaborative practice environment) are core pharmacy services.
- Additional services that are **not an authorized practice for pharmacy professionals** are not considered core pharmacy services. These services may be provided by other vendors or health care professionals.

If these services impede access to any core pharmacy services, then the pharmacy risks breaching the SCPP's conflict of interest policy.

Medically Necessary Services

The interpretation of "medically necessary" has evolved over time and may vary depending on the stakeholders and the health care policy challenges being addressed (e.g. federal and provincial governments, sustainability versus comprehensive coverage).

Canada Health Act

For the purposes of protecting the public, the SCPP's conflict of interest policy observes the terms, conditions and standards used by the Government of Canada as it administers the *Canada Health Act* with the thirteen provincial and territorial health insurance plans.

Medically necessary services are not explicitly defined in the *Canada Health Act*. However, in order to receive federal funding for health care as part of Canada's national health insurance program, the provinces/territories must pay for all hospital services that are:

- medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness, or disability; and
- provided or ordered by a physician as a "medically required service.

While provinces/territories may offer "additional benefits" under their respective health insurance plans, funded and delivered under their own terms and conditions (e.g. prescription drugs targeted to specific population groups at partial or full coverage), a number of services provided by hospitals and physicians are not considered medically necessary, and are not insured by provincial and territorial health insurance plans. This includes the provision of medical certificates required for work, school, insurance purposes and fitness clubs; and cosmetic services.

Supreme Court of British Columbia

The findings of Canadian courts also provide useful guidance. For example, the Supreme Court of BC has defined "medically necessary" to mean a "medical service that is essential to the health and medical treatment of an individual."

<u>Application in the Pharmacy</u>

- Pharmacies may deliver additional services that are within the pharmacist's scope of practice, however, they may not be medically necessary (e.g. services for work, school or recreation). Should additional services impede access to medically necessary core services, the pharmacy may be in breach of the SCPP's conflict of interest policy.

Closing

Licensed pharmacy professionals are an integral part of the provincial health system and provide a variety of health services within or through the pharmacy. Pharmacy managers and proprietors must carefully assess the impact of expanding services to areas that are not solely within the domain of pharmacy professionals or pharmacies. They risk breaching the SCPP's conflict of interest policy when they prioritize services that are available elsewhere over those that are only obtainable through a pharmacy.

Proprietors also risk proprietary misconduct. As per section 26(a) of *The Pharmacy and Pharmacy Disciplines Act,* it is considered proprietary misconduct if a proprietor's conduct is harmful to the best interests of the public. As such, proprietors are responsible to put the safety of their patients first.

Sources:

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