Laboratory Tests – Sale and Distribution of Medical Testing Devices and Other Diagnostic Products

Disclaimer - Medical Devices and Diagnostic Products in Pharmacy Practice

The term "diagnostic products/medical devices" will be used when speaking to those health care aids and devices referenced in *The Pharmacy and Pharmacy Disciplines Act* sections 23(2)(d) and 23(3)(b) and Part M of the SCPP's Regulatory Bylaws.

However, in doing so, the SCPP is **not** referring to the act of "diagnosing" or identifying a disease from its signs and symptoms. The act of "diagnosing" is **not** within a pharmacist's scope of practice and the use of the term in this document **does not** mean that the pharmacists' scope of practice has been expanded.

(See text box below – Regulatory Framework - "Selling and Distributing Medical Testing Devices and Other Diagnostic Products")

DEFINITIONS

"Diagnostic Products"- Products which may or may not be associated with a medical device that contain agents, drugs or chemicals **designed for patient use outside of conventional laboratory and health care facilities** for the purpose of testing, identifying, self-diagnosing, screening or monitoring a human condition or disease

"Medical Testing Devices" - Medical devices intended to be used outside the body for the examination of specimens. These are referred to as *in vitro* diagnostic devices by Health Canada, and have been categorized into 3 types of testing applications, laboratory-based, point-of-care tests and self-testing devices (referred to here as "patient-administered automated tests).

"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 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.

"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).

“Pharmacist” means licensed pharmacist.

“Pharmacy Technician” means a licensed pharmacy technician.

“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.)

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.

“Sale and/or Distribution” (adapted from the *Food and Drugs Act* and the *Controlled Drugs and Substances Act, and* Information on the definitions of "Sell") - includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made in exchange for money or other compensation. (Note: given that medical devices are regulated federally and provincially, these terms must be taken together as a whole with the definition of “sell” from *The Pharmacy and Pharmacy Disciplines Act*.)

“Sell” – (Source *The Pharmacy and Pharmacy Disciplines Act, S.2 cc):* includes advertising for sale; exposing or keeping for sale; selling or offering for sale, either directly or indirectly; or offering or attempting to sell or barter using any device or scheme.

“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.

Regulatory Framework - Selling and Distributing Medical Testing Devices and Other Diagnostic Products

Sections 23(2) and 23(3) of *The Pharmacy and Pharmacy Disciplines Act* (the Act) outline the involvement permitted for pharmacists, pharmacy technicians and interns practicing under the supervision of a pharmacist or pharmacy technician in the sale and distribution of health care aides and devices.

23*(2) A licensed pharmacist, licensed pharmacy technician or intern practising under the supervision of a licensed pharmacist or a licensed pharmacy technician may, subject to the terms, conditions and restrictions of that person's licence, perform all or any of the following practices:*

(a) advise patients and other health care providers by providing drug and non-drug therapy knowledge respecting drug and non-drug therapy selection and use;

(d) provide non-prescription drugs, parenteral nutrition and health care aids and devices;

23*(3) A licensed pharmacist who meets the qualifications set out in this Act and the bylaws, may, subject to the terms, conditions and restrictions on that licensed pharmacist's licence, perform all or any of the following practices:*

(b) prescribe treatments and health care aids and devices related to the practice of pharmacy in Saskatchewan;

The SCPP Regulatory Bylaws put further safeguards in place:

1 *A licensed pharmacist may:*

(e) prescribe treatments and devices approved by Council, which are related to the practice of pharmacy in Saskatchewan.

Also see the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) and Performing Tests for Drug Therapy Management for additional information that needs to be taken together as a whole.

1. PURPOSE

The Saskatchewan College of Pharmacy Professionals (SCPP) acknowledges that there are benefits and risks when medical testing devices and other diagnostic products are used. When used properly, these medical testing devices/products permit earlier detection of health problems and monitoring of existing conditions and encourage increased patient involvement in personal health. However, when used improperly, they are of limited value and may even be detrimental to the patient's health. As such, the SCPP recognizes the following foundational principles:

1.1. The role of the pharmacy professional in distributing medical testing devices/products and assisting the patient to understand their proper use;

1.2. The diagnostic role of the physician and other practitioners, as well as, the role of the Saskatchewan Health Authority and other health-care personnel in conducting laboratory and diagnostic testing; and

1.3. That given their code of ethics and the requirement that pharmacy professionals work in a collaborative practice environment with the health care system, the role of the pharmacy professional should complement, rather than interfere with or infringe upon the statutory role of other health-care personnel.

This document is intended to describe the roles and requirements of the pharmacy professional in the sale and distribution of PAATs (i.e. medical testing devices/products intended for patient use outside of conventional laboratory and health care facilities recognizing the role of the pharmacy professional, their legal liability, and the public interest.)

While "selling and distributing" medical testing devices/diagnostic products does not fall under *The Medical Laboratory Licensing Act,* some actions carried out by the pharmacy team when selling a medical device may be subject to this additional regulatory framework. Therefore, **any involvement in pharmacy-sponsored disease state screening and risk assessment programs requires a clear understanding of the role of the pharmacy professionals in both the sale and distribution of medical testing devices/products and in laboratory testing as defined in *The Medical Laboratory Licensing Act*.**

2. STANDARDS AND GUIDELINES

In addition to the Standards of Practice outlined in the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting), the following standards and guidelines apply to the sale and distribution of medical testing devices/products intended for patient use outside of conventional laboratory and health care facilities:

2.1. All medical testing devices/products sold within the permitted pharmacy area must be for medical or other purposes consistent and in keeping with the foundational principles noted in section 1.

2.2. Only PAATs (i.e., medical testing devices/diagnostic products) approved by Health Canada for "self-testing" or "self-use by a patient") may be sold in a pharmacy.

2.3. To ensure that pharmacies are complying with on-label use as approved by Health Canada, any POCT distributed by a pharmacy must be done in conjunction with a third party (e.g., privately licensed laboratory or a government) that is authorized to do so under applicable legislation when needed.

(See section 2.13 below for circumstances where a pharmacy may distribute point-of-care testing devices and section 3 below where a pharmacy may be involved in the sale or distribution of testing devices through private third party arrangements.

2.4. All medical testing devices/products sold or distributed must contain the official package insert to provide adequate written instructions for the patient.

2.5. All pharmacy professionals and non-regulated pharmacy staff may receive, store and manage expired or recalled medical devices in compliance with manufacturer's specifications.

2.6. Where possible, all activities and information around the sale and distribution of a medical testing device/product **must** be documented in the patient's pharmacy profile, in order to support the rationale and quality of these activities (e.g. brand/model/Health Canada device identifier/lot/expiry date of device for which indication, instructions provided to the patient).

2.6.1. Regardless of the role they are fulfilling, pharmacists and pharmacy technicians must ensure that this documentation has occurred.

2.7. All pharmacy professionals and non-regulated pharmacy staff who sell or provide medical testing devices/products **should**:

2.7.1. Be familiar with the contents of the device/product, the test procedures and protocols established and documented on the official package insert by the manufacturer.

2.7.2. Be sufficiently trained in order to train the patient on the proper use and maintenance of the device/product.

2.8. Pharmacy professionals and non-regulated pharmacy staff may only perform the roles as listed in sections 2.8 and 2.9 consistent with their knowledge, training, scope of practice and other statutory limitations:

2.8.1. Pharmacy interns are supervised in accordance with the SCPP's Supervision of Pharmacy Interns policy;

2.8.2. Pharmacy technicians recognize when it is beyond the limits of their competence and the clinical expertise of the pharmacist is required;

2.8.3. Non-regulated staff are supervised by a pharmacist or pharmacy technician who recognizes when the clinical expertise of a pharmacist is required or it is beyond limits of their competence.

2.8.4. Pharmacists are upholding the standards and requirements as per the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting).

2.9. Pharmacy technicians, pharmacy interns (student and extended) and non-regulated pharmacy staff:

2.9.1. **May** perform the following roles in the sale and distribution of medical testing devices/**products intended for patient self-use (i.e., PAATs)** including:

2.9.1.1. Providing information that does not require application of therapeutic knowledge to patients requiring assistance in selecting devices/products (e.g., devices indicated for the patient's disease condition as per the manufacturer's package insert); and

2.9.1.2. Instructing patients about the operation and maintenance of the device/ product as per the manufacturer's package insert (e.g., how to turn on the device, explain procedures for conducting the test).

2.9.2. **Must** refer patients to the pharmacist for any question or issue that potentially requires patient assessment, clinical analysis, or application of therapeutic knowledge (e.g., how to adjust drug therapy or seek medical attention in response to a test result).

Scope of Practice – Distributing Point of Care Testing Devices in the Pharmacy

Point-of-care testing devices are approved by Health Canada for use with the involvement of health care professionals.

In Saskatchewan, only pharmacists may be authorized to be involved in point-of-care testing.

Although "distribution" is not an authorized practice, any questions about the point-of-care testing device (e.g. medical relevance or implications) or the proper follow up would need to be answered by the pharmacist.

Also see the Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting) and Performing Tests for Drug Therapy Management for additional information that needs to be taken together as a whole.

2.10. In addition to the actions listed in 2.9, using their clinical knowledge respecting the selection of medical testing devise/products (i.e., health care aids and devices), as per section 23(2)(a) of the Act, pharmacists:

2.10.1. **Must** be available to counsel the patient on the proper use of the device/product. This includes physical characteristics and limitations of each test, and how the test result can be used to monitor a disease state;

2.10.2. **May** supervise the performance and interpretation by the patient of a self-use medical testing device/product performed in the pharmacy, if requested by the patient;

2.10.3. **Must** advise the patient to consult a physician/health practitioner if the results suggest possible risk for the patient; and

(See text box below “Cautions when Demonstrating Self-Testing Devices and Products in the Pharmacy.”)

2.10.4. **May** explain the meaning of, and how to interpret or use the results provided by the device/product.

2.11. Other licensed health care professionals may conduct the activities identified in 2.9 and 2.10, so long as:

2.11.1. It is permitted within their scope of practice and that they are meeting the standards of practice required by their regulatory body;

2.11.2. They are meeting the SCPP’s standards of practice for these activities in a pharmacy; and

2.11.3. It is permitted by *The Medical Laboratory Licensing Act,* where applicable.

2.12. Pharmacy managers are responsible for providing active oversight of all practices within the pharmacy for the sale and distribution of medical testing devices/products and ensuring that the standards of practice of the SCPP and other regulators, as necessary, are upheld.

Cautions when Demonstrating Self-Testing Devices and Products in the Pharmacy

As per *The Medical Laboratory Licensing Act,* unless the pharmacy is licensed as a medical laboratory and the pharmacist, or other licensed health care professional, is authorized by that license, a specimen **must not be**:

- collected from, or by a patient, in a pharmacy **for medical purposes**, or
- applied to a medical testing device/product in the pharmacy **for medical purposes**.

This includes situations where they are “demonstrating” how to use a testing device/product. (See text box “Demonstration of Testing Devices and Performing Point-of-Care Tests” in Section 5 of Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting).)

However, the SCPP also recognizes that Health Canada has approved self-testing devices/products (or PAATs) for the general public to perform the test independently from sample collection to reading the results. Self-testing is a completely independent process that may be safely done at home without the supervision or assistance of a healthcare professional.

Therefore, if needed pharmacists and other licensed health care professionals may demonstrate how to use devices as long as no specimen is collected or used (e.g. using reagents, control solutions, videos) on occasions specified in sections 2.10.2 and 2.11.

Note: As reported in SCOPe Volume 8/Issue 5 November 2016, "Reference manual Update: Addition to the Pharmacy Technician Scope of Practice Chart," pharmacy technicians are permitted to demonstrate the use of monitoring devices and health aids to the patient while instructing on operation. However, this demonstration must not involve the collection of a specimen.

2.13. Point-of-care testing devices/products that are approved by Health Canada for use "by a health care worker", may be distributed from a pharmacy on the condition that the pharmacy and all pharmacists involved comply with:

2.13.1. Terms and conditions set for the publicly-funded (federal/provincial) programs or initiatives, where applicable;

2.13.2. Terms and conditions of *The Medical Laboratory Licensing Act*, where applicable;

2.13.3. Terms and conditions of the *Food and Drugs Act,* including interim exemptions, where applicable (see Medical Devices Compliance Program Bulletins for current list); and

2.13.4. Any additional terms and conditions set by the SCPP if required by Part M of the SCPP Regulatory Bylaws.

Medical Device Establishment Licence when Selling/Distributing Medical Devices for Purposes Other than Personal Use

To ensure that medical devices sold or imported into Canada meet the safety requirements set out under the *Medical Devices Regulations,* and that procedures are in place to protect the public should a problem with a device be identified, a Medical Device Establishment Licence (MDEL) is generally required for any person who imports or sells a medical device for human use in Canada.

However, retailers, such as community pharmacies, that **sell medical devices to the end-user for their own personal use are exempt from this requirement**.

When selling or distributing medical devices to those other than the end-user (e.g. businesses for workplace occupational health and safety screening), pharmacy managers /proprietors are responsible for understanding when a MDEL is required and confirming whether any Health Canada exemptions are in place.

Also see "Interim enforcement approach for federal, provincial and territorial COVID-19 testing initiatives – December 13, 2021. which permits distribution of COVID rapid antigen tests as part of the "Test to Protect" federal/provincial occupational health and safety testing initiative.

Note: The EpiPen is a drug product (i.e., epinephrine) delivered through a medical device (i.e. auto-injector) that may be sold or distributed for non-personal use (e.g. to have on-hand in case of emergency at a business or camp).

It is a drug listed in the Health Canada Drug Product Database. **It is not** a diagnostic product/medical testing device listed in Health Canada's Medical Devices Active Licence Listing. Therefore, it is the SCPP's interpretation that it does not require a MDEL when selling Epipen to anyone but the end-user. Instead see the *Food and Drug Regulations* for dispensing.

Sources: Guidance on Medical Device Establishment Licensing (GUI-0016), and Policy on Drug/Medical Device Combination Products - Decisions

3. 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:

3.1. 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), and the patient population they serve when considering the sale or distribution of a medical testing device/product.

3.2. Medical testing devices/products 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 including the foundational principles identified in section 1, including:

3.2.1. The sale and distribution of medical testing devices/products does 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?" in the Performing Tests for Drug Therapy Management.)

3.3. Pharmacy managers and proprietors must not enter arrangements with third parties, to distribute **point of care testing devices**, where the conditions of such practice would compromise the standards of the profession or pharmacy practice.

3.4. Decisions to sell or distribute tests shall be based on clinical suitability, cost effectiveness and the patient's best interest.

3.5. Decisions to sell or distribute tests 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 Act).

3.6. Patients must be advised when a publicly-funded medical testing device or option is available, the eligibility requirements and where they can receive it at no additional cost.

3.7. Patients must be informed that the medical testing device/product may not be acceptable for non-medical purposes, where applicable.

4. AUTHORITY

4.1. Section 23(3)(c) of *The Pharmacy and Pharmacy Disciplines Act*

4.2. Section 1(d) of Part M of the Saskatchewan College of Pharmacy Professionals Regulatory Bylaws

5. ACKNOWLEDGEMENTS

5.1. Alberta College of Pharmacy

5.2. Nova Scotia College of Pharmacists

5.3. Ontario College of Pharmacists