

Administration of Drugs by Injection and Other Routes - Guidelines for Pharmacists

DEFINITIONS

In these standards:

“**Act**” means *The Pharmacy and Pharmacy Disciplines Act*;

“**Advanced method**” administration of drugs includes subcutaneous or intramuscular injection;

“Collaborative practice environment” means a relationship between the licensed pharmacist and other regulated health professionals involved in the care of the patient is such that the practitioners can reasonably rely upon the basic skills of the licensed pharmacist to administer drugs in the best interests of the patient;

“**Drug**” includes vaccines;

“**Pharmacist**” means licensed pharmacist;

“**Schedule I**” means Schedule I of the Administrative Bylaws of the Saskatchewan College of Pharmacy Professionals listing drugs that require a prescription for sale to the public;

“**Schedule II**” means Schedule II of the Administrative Bylaws of the Saskatchewan College of Pharmacy Professionals listing drugs that do not require a prescription for sale to the public, but must, amongst other things, be available from the area of the pharmacy (e.g. dispensary) where there is no opportunity for self-selection by the public.

GLOSSARY OF ACRONYMS

AED – Automated External Defibrillator

CCCEP – Canadian Council for Continuing Education in Pharmacy

CPDP – Continuing Professional Development for Pharmacists Unit, College of Pharmacy and Nutrition, University of Saskatchewan

CPR – Cardio-Pulmonary Resuscitation

NAPRA – National Association of Pharmacy Regulatory Authorities

PHAC – Public Health Agency of Canada

SCPP – Saskatchewan College of Pharmacy Professionals

AUTHORITY

A. The Pharmacy and Pharmacy Disciplines Act

The Act authorizes pharmacists to administer drugs by injection and other routes. In particular section 23(3) states:

“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 license, perform all or any of the following practices:

(a) Prescribe and administer drugs in accordance with the bylaws made pursuant to this Act and the regulations made pursuant to section 52...”

(Important: Section 52 of the Act authorizes regulations that establish prescription and non-prescription drug schedules I, II and III)

B. Regulatory Bylaws of the Saskatchewan College of Pharmacy Professionals

SCPP has created regulatory bylaws regulating the administration of drugs by pharmacists. In particular they establish the qualifications required of pharmacists to administer drugs and limit practice if those qualifications are not met. To summarize, the bylaws:

1. Require pharmacists to obtain Standard First Aid and CPR Level C with AED and other training as specified by Council;
2. Allow administration of drugs orally, including sublingual and buccal, topically, including ophthalmic, otic and intranasal, and via inhalation;
3. Allow “advanced method” administration of drugs, including vaccines, upon certification by the Registrar’s office. These methods include subcutaneous or intramuscular injection;
4. Specify the age limits for the administration of vaccines and other drugs;
5. “Advanced Method” certification must be renewed annually;
6. Expect pharmacists to meet provincial vaccination reporting requirements;
7. Expect pharmacists to report the administration of any Schedule II drug via advanced method to the patient’s primary care practitioner; and
8. Specify record keeping requirements:
 - a) the patient’s name and address;
 - b) the name of the drug and total dose administered;
 - c) for an advanced method or vaccination by any method, identification of the manufacturer, lot number and expiry date of the drug;
 - d) for an advanced method, the route of administration, dosage and the location on the body where the drug was administered;
 - e) the name of the licensed pharmacist administering the drug;
 - f) the date and the time of administration;
 - g) any adverse events; and,
 - h) the price, if there is a charge for administration.

C. Guidance

The following is intended to provide pharmacists with further guidance in the interpretation of the legislation and application of Council policy.

D. Collaboration

It is expected that these services be provided in a collaborative practice environment. The relationship within that environment means a relationship between two or more regulated health professionals that is developed to:

- a) facilitate communication,
- b) determine mutual goals of therapy that are acceptable to the patient,
- c) share relevant health information, and
- d) establish the expectations of each regulated health professional when working with a mutual patient.

For vaccinations, this also means collaborating with the public health system so that pharmacists' services are aligned with the direction given by public health authorities.

E. Advanced Method Certification Requirements - Injection

1. CCCEP (two-staged) Competency-Mapped Accreditation training program, plus the Saskatchewan specific module;
 - a) CCCEP maps the training program against the NAPRA approved competencies (14 PHAC competencies for administering vaccines plus the 15th supplementary NAPRA competency for administering other drugs). This provides assurance that the training program addresses all of the competencies relating to the administration by injection of vaccines and other drugs. These competencies can be found at http://napra.ca/sites/default/files/2017-09/Supplemental_Competerencies_on_Injecton_for_Canadian_Pharmacists2012.pdf.
 - b) While we will recognize training from other providers that is CCCEP (two-staged) Competency-Mapped Accredited, we recommend taking the training offered by CPDP as it meets all of our requirements. In addition, everyone must take the Saskatchewan-specific module available only from CPDP at this time. As we are aligning access to vaccinations from pharmacies with the Saskatchewan Immunization Program, including publicly funded vaccines, it is important for pharmacists to know all of the elements of this program, especially those that are unique to Saskatchewan. This module covers issues such as target populations, protocols, limitations, vaccine supplies, record keeping and reporting.
2. Standard First Aid and CPR Level C with AED are requirements for injection certification. They can be taken at any time according to the policy of the injection training provider. However members are strongly encouraged to meet these requirements as soon as possible to maximize the benefits of both the on-line and live, practical skills modules of the injection training.
 - a) We have engaged CPDP at the U of S to provide injection training for members. CPDP advises that, with some exceptions, they prefer that First Aid and CPR be taken before the live, practical skills sessions;
3. Immunization (up-to-date Hepatitis B) is not mandatory but is strongly recommended;
4. Application for certification to the SSCP office (procedures to be determined);

5. Payment of the certification fee (waived for 2015-2016 membership year. Council will review) and,
6. Annual renewal will no longer require that members self-declare that they have given at least one injection during the past year, however the member is responsible to self-assess their competence and to take advantage of “refresher” education should it be warranted.

Members must continue to self-declare that they have current or up-to-date Standard First Aid and CPR Level C with AED training. If this Certification has elapsed the member will not be authorized to provide injections until such time as re-certification has been completed.

F. Other Training Requirements

For routes of administration other than by injection, SCPP Council policy is to rely upon pharmacists' ethical obligations to be competent before offering any service. This means using self-directed learning strategies to assure competency in the relevant route of administration. Pharmacists who are not confident in their abilities are expected to use their learning portfolios to identify and meet their learning needs.

G. General

Pharmacists are expected to comply with the standards described in the training for Advanced Method certification, including but not limited to:

1. A pharmacist administering a drug, using an advanced method, or a vaccine regardless of the route of administration, must:
 - a) Collaborate with the patient and receive consent;
 - b) Be satisfied there has been compliance with the Standards of Practice;
 - c) Take appropriate steps to ensure the patient is given the right drug including a vaccine, for the right reason, in the right dose, at the right time and using the right route;
 - d) Review relevant and applicable immunization guidelines, such as those set out by Saskatchewan Health (Saskatchewan Immunization Manual at <https://www.ehealthsask.ca/services/Manuals/Pages/SIM.aspx> and the Public Health Agency of Canada (Canadian Immunization Guide at <https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html>) when administering a vaccine;
 - e) Possess current certification in Standard First Aid and CPR Level C with AED;
 - f) Be properly certified;
 - g) Comply with the Saskatchewan Immunization Manual and the Ministry of Health's Seasonal Influenza Immunization Program when administering an immunizing agent;
 - h) Ensure the pharmacy creates and maintains a policy and procedures manual that includes administration of drugs, including vaccines, and emergency response protocols; and
 - i) Ensure the pharmacy maintains a readily accessible supply of epinephrine for emergency parenteral administration (e.g. “pens”), diphenhydramine, cold compresses and non-latex gloves.
2. Before administration, the pharmacist must:

- a) Perform basic assessment of the patient proportional to the complexity of administration, that includes:
 - i. History,
 - ii. Overall condition, e.g., vital statistics,
 - iii. Appropriate information if administering a drug by injection, including appropriate immunization information when administering a vaccine, e.g. reviewing immunization records, and
 - iv. Condition of the administration site.
- b) Assess the appropriateness of the drug, including a vaccine, for the specific patient, including but not limited to:
 - i. Indication
 - ii. For a publicly funded vaccine, the patient's eligibility for that program, as set out by Saskatchewan Health
 - iii. Dose
 - iv. Allergy status
 - v. Risk factors and contraindication
 - vi. Route of administration including
 - 1. Appropriateness for the patient
 - 2. Appropriateness of the drug, including a vaccine
 - 3. Drug and route follows established protocols, if applicable
- c) Obtain consent from the patient or from the person authorized to consent on the patient's behalf to administer the drug, including consent for administration of a vaccine;
- d) Follow appropriate hand hygiene protocols.
- e) In addition to the above, and before administering a drug:
 - i. Provide the patient the following information:
 - 1. Name of the drug, including a vaccine, to be administered,
 - 2. Indication for the drug, including a vaccine,
 - 3. Expected benefits and material risks of the administration and the drug,
 - 4. Expected reaction,
 - 5. Usual and rare side effects,
 - 6. Rationale for the 15-30 minute wait following the administration,
 - 7. Importance of immediately consulting with the pharmacist if a reportable event occurs,
 - 8. Contacts for follow-up or emergency, and

9. Any other information that a reasonable person in the same circumstances would require in order to make a decision about the drugs to be administered.
 - ii. ensure the pharmacy creates and maintains a clean, safe, appropriately private and comfortable environment within which the injection is to be administered.
 - iii. be satisfied the drug, including a vaccine, to be injected is stable, has been prepared for administration using aseptic technique, has been stored properly and is clearly labeled. This includes adhering to cold chain requirements if applicable, including as described in the SCPP “Guidelines Regarding Vaccine Storage, Handling, and Transport” (<https://scp.in1touch.org/uploaded/58/web/refmanual/Vaccine-Storage-Handling-and-Transport-GuidelinesFor-09-10.pdf>).
 - iv. ensure the route of administration and the site has been appropriately prepared for the administration.
3. After Administration, the pharmacist must:
 - a) Ensure the patient is appropriately monitored;
 - b) Respond to complications of therapy, if they arise;
 - c) Ensure devices, equipment and any remaining drug, including a vaccine, is disposed of safely and appropriately;
 - d) Document the administration of the drug, including a vaccine, as required;
 - i. In the case of an immunizing agent, record the immunization information, or take steps to ensure that the immunization information is recorded, in the electronic provincial immunization registry database maintained for that purpose
 - e) Report any reportable events to the Regional Health Authority Medical Health Officer, other applicable agency or organization as appropriate, and to the patient;
 - i. In the case of an immunizing agent, as soon as possible after becoming aware of a reportable event, report it in accordance with the Disease Control Regulations under The Public Health Act, 1994;
 - ii. Provide relevant information to other regulated health professionals and provincial health agencies as appropriate, including reporting patient names and vaccine doses to the provincial vaccine registry

From the Saskatchewan specific training module:

“Reporting Problems after Administration...”

All health professionals in Saskatchewan are obligated to report serious adverse events following drug administration. If any of your patients experience a serious adverse event it is important that you fill out the necessary adverse reaction forms.

The Canada Vigilance Adverse Reaction Reporting Form for medication adverse reaction reporting can be accessed through the Compendium of Pharmaceuticals and Specialties or the Public Health Agency of Canada (http://caddac.ca/cms/CADDAC_pdf/HCAverseReactionForm.pdf).

The Report of Adverse Events Following Immunization (AEFI) must be completed for any vaccine. The form is accessible electronically through the Compendium of

Pharmaceuticals and Specialties or the Public Health Agency of Canada
(<http://www.phac-aspc.gc.ca/im/aeffi-essi-form-eng.php>).

AEFI reports must be submitted to the main Public Health office in your Regional Health Authority for review by a Regional Medical Health Officer (MHO). They will make recommendations in which you are obligated to inform the patient and follow through as required by the MHO.”

4. Age Limits and other Restrictions:

- a) Except for vaccines, a pharmacist who has completed the CPR, First Aid, and other requirements established by Council may administer a drug to patients over the age of 5 by the following means:
 - i. orally, including sublingual and buccal;
 - ii. topically, including ophthalmic, otic and intranasal;
 - iii. via inhalation
 - iv. advanced method, except b. below
- b) Despite subsection (a) a publicly funded vaccination may only be administered to a patient who is 9 years of age and over or as otherwise specified by the Chief Medical Health Officer for the Province of Saskatchewan. Non-publicly funded vaccinations may only be administered in accordance with the Canadian Immunization Guide and the vaccine's official product monograph.
- c) A pharmacist must not administer a drug, including a vaccine, to a family member unless there is no other alternative.

5. Infection Control:

- a) The pharmacist must use precautions for infection control, which includes:
 - i. Handling all body fluids and tissues as if they were infectious, regardless of the patient's diagnosis,
 - ii. Washing hands before and after caring for the patient, and after removing gloves; and wearing gloves to prevent contact with body fluids, excretions or contaminated surfaces or objects;
 - iii. Proper disposal of waste materials
 - iv. Maintaining a setting for administration that is clean, safe, comfortable and appropriately private and furnished for the patient
 - v. Management of needle stick injuries.

6. Prescriptions:

- a) The pharmacist requires a prescription to dispense Schedule I drugs. These include:
 - i. Drugs intended for parenteral nutrition,
 - ii. vaccines except for those which are part of the Saskatchewan routine immunization program (e.g. Diphtheria toxoid, Tetanus toxoid, Pertussis, Poliomyelitis, Haemophilus influenza type B, Measles, Mumps, Pneumococcus, Rubella, Hepatitis B Pediatric, Influenza, cholera vaccine (oral, inactivated) when used for prophylaxis

against traveller's diarrhea & due to enterotoxigenic Escherichia coli (ETEC); and those requiring special enhanced public access due to disease outbreaks: Meningococcus);

- b) The pharmacist does not require a prescription to dispense a Schedule II drug. Many of the drugs are listed in that Schedule because of their injectable dosage form;
- c) The pharmacist does not require a prescription to administer a drug. The decision to administer the drug is subject to the professional discretion of the pharmacist.
- d) Where the pharmacist receives a prescription to dispense a drug and is, or is not, requested by the prescriber to administer the drug and after assessment determines that administering the drug is appropriate, the pharmacist shall advise the prescriber that the drug has been administered. Advising the prescriber can occur via documentation provided directly to the prescriber or through a provincial electronic database intended for this purpose.
- e) Where the pharmacist receives a request from a patient to provide a Schedule II drug and after assessment to determine that administering the drug is appropriate, the pharmacist shall advise the patient's primary care practitioner [e.g. physician, Registered Nurse (Nurse Practitioner)] in the same manner as in paragraph d. above.

7. Implementation:

- a) Upon certification, the pharmacist may administer drugs by advanced method as follows:
 - i. Influenza vaccines – as soon as the provincial seasonal influenza program is in place
 - ii. Other publicly funded vaccines – where the pharmacist has been approved by the Ministry of Health to administer the vaccine
 - iii. Non-publicly funded vaccines – in accordance with the Saskatchewan Immunization Manual (<http://www.ehealthsask.ca/services/manuals/Pages/SIM.aspx>) or the Canadian Immunization Guide (<http://www.phac-aspc.gc.ca/publicat/cig-gci/index-eng.php>), and the vaccine's official product monograph, where applicable.
 - iv. For drugs other than vaccines, as patient needs determine and according to the drug's official product monograph.

The pharmacist may administer drugs by other routes as patient needs determine and as they are competent, or become competent through identifying and meeting their learning needs.