

Administration of Drugs by Injection and Other Routes FAQs

Publicly Funded Vaccines (Roles of SCPP, Ministry of Health and PAS)

The *Pharmacy and Pharmacy Disciplines Act* and the SCPP Regulatory Bylaws define the authorized practices of pharmacists. This document outlines SCPP's terms, conditions, and standards that all pharmacists must follow when administering drugs, including vaccines, regardless of whether they are publicly or privately funded.

In recognition of the key role that Saskatchewan pharmacists play in delivering publicly-funded immunization programs (e.g., Seasonal Influenza Immunization Program, COVID-19 Immunization Delivery Plan), this document highlights areas where the <u>Saskatchewan Ministry of Health/Drug Plan and Extended Benefits Branch</u> may have set additional requirements. Common questions about the differences between Ministry and SCPP standards can be found in this FAQs document. However, it is important that pharmacies delivering publicly funded programs monitor the Ministry website to stay current on the comprehensive list of requirements.

When participating in a publicly funded immunization program, pharmacists and pharmacies agree to the Ministry's terms and conditions for the program (e.g., patient eligibility, informed consent, alternate locations, storage and handling, authorized immunizers, training, documentation, and reporting). However, if a term or condition is not specifically included in the Ministry's communications, then the SCPP requirements apply.

GLOSSARY OF ACRONYMS

AEFI – Adverse Events Following Immunization

AED - Automated External Defibrillator

AMC - Advanced Method Certification

DPEBB – Drug Plan and Extended Benefits Branch

CCCEP - Canadian Council for Continuing Education in Pharmacy

PHAC – Public Health Agency of Canada

SCPP – Saskatchewan College of Pharmacy Professionals

SIM - Saskatchewan Immunization Manual

SIIP - Saskatchewan Influenza Immunization Policy

USask CPE – USask Continuing Pharmacy Education, College of Pharmacy and Nutrition, University of Saskatchewan

TRAINING AND CERTIFICATION

1. What is needed to have the Advanced Method Certification (AMC)?

- a. A valid practising licence, with no condition "A" indicated on their licence.
- b. Valid Standard First Aid and CPR Level C with AED.
- c. Completion of training for Advanced Method Certification (see Question 2 below).
- d. Application for AMC certification with SCPP (see Question 3 below)

2. What training is required to attain the Advanced Method Certification (AMC)?

- a. CCCEP (two-staged) Competency-Mapped Accreditation training program, plus the Saskatchewan specific module provided through USask CPE.
- b. Prerequisites are current Standard First Aid and CPR Level C with AED. They can be taken at any time up to the live, practical skills training module. In other words, you must have current Standard First Aid and CPR Level C by the time you take the live session.
- c. Hepatitis B vaccination is strongly recommended for anyone who could be exposed to bodily fluids.
- d. For more information see SCPP Training Guide Table "Injection Administration"

3. How do I begin the process so I can legally administer injections?

The pharmacist must apply for AMC with SCPP. See Injections Training Requirements under the SCPP Registration website tab for more information.

A pharmacist who provides medication by injection and other routes while they have the condition "A" on their licence may not have adequate malpractice insurance.

4. When can I start injecting?

A pharmacist can start injecting when they receive confirmation of AMC from SCPP as described on the <u>SCPP Registration website</u> tab. AMC must be up to date to continue administering by injection.

5. How do I renew my AMC?

Pharmacists must renew AMC annually with SCPP in order to continue to provide injections. See <u>SCPP Registration website</u> tab for more information.

6. What happens if I let my certification lapse?

When a pharmacist does not meet all 3 requirements, the College will assign a "condition A" to their licence to indicate they are no longer certified. See SCPP Registration website tab for more information.

A pharmacist must take steps to remedy the cause that has resulted in their AMC lapsing if they wish to renew their certification.

See <u>Administration by Injection Section 2</u> and SCPP <u>Training Guide "Injection Administration"</u> for steps to ensure you are competent to inject if AMC is lapsed or you have not injected in the previous 24 months.

7. What is the annual certification fee?

Currently there is no advanced methods certification fee. This fee was waived in 2015/16 and is still under review by Council.

8. If I am currently certified in another province, am I able to be certified in Saskatchewan or do I have to take additional training?

Additional training is needed.

To be certified, the following training must be completed:

- a. CCCEP-accredited Immunization and Injection Training SCPP will recognize training from other providers that are CCCEP-accredited; and
- b. The Saskatchewan-Specific Module: <u>Essential Competencies for Injection of Other Substances</u> available only from USask CPE.

Pharmacists providing vaccines in Saskatchewan should also be familiar with the <u>SIM</u>, when it is applicable and the SCPP <u>Disease Prevention and Travel Health Services Policy</u> and Framework.

Contact the USask CPE office at 306-966-6350 or cpe.admin@usask.ca to assess comparability with out-of-province training and to complete the Saskatchewan-specific module.

9. What should pharmacists know about the SIM?

- For the publicly funded influenza vaccine, pharmacists should reference the sections
 of the SIM as outlined in <u>SIIP</u>;
- SIM should be used to assess a patient's eligibility for a publicly funded vaccine (see Ch 10 SIM).
 - When a patient is eligible for a publicly funded vaccine, pharmacists must provide the patient with the option to access the vaccine free of charge from the proper health authority;

- SIM provides evidence-based and standardized immunization-related information for the provincial **publicly funded** immunization program.
 - o Pharmacists must understand that the SIM does not necessarily speak to NACI recommendations or eligibility as per product monograph. The intent of the SIM has been to guide public health immunization practice, therefore there are limitations to its use by non-public health providers. For example, AEFI and cold chain breaks are reported differently by non-public health providers for privately purchased vaccines.
- It is the responsibility of all immunizers to ensure they are using the most current version of the SIM posted on the Ministry of Health website at https://www.ehealthsask.ca/services/Manuals/Pages/SIM.aspx

10. Can a pharmacist who is taking a course for AMC, administer a drug by injection?

Yes, but only under direct supervision of a licensed pharmacist or another health care professional who is legally permitted and competent to administer a drug by injection. See SCPP Regulatory Bylaws, section 8 of Part L. The principles outlined in Supervision of Pharmacy Interns also apply to this situation.

11. Is Advanced Method Certification mandatory for pharmacist licensure?

No, AMC is only required for pharmacists who wish to administer drugs by injection and other methods. See <u>Administration of Drugs by Injection and Other Routes</u> for more details.

12. Can a pharmacist intern (i.e., pharmacist extended intern and pharmacist student intern) supervised by a licensed pharmacist with AMC administer a drug by advanced method?

No, under normal circumstances a pharmacist intern may not administer a drug by advanced method. However, exemptions during emergency circumstances may exist (e.g., Saskatchewan COVID-19 Immunization Delivery Plan). In these situations, SCPP in conjunction with provincial public health officials will notify pharmacy professionals when these exemptions are in effect and the conditions and limitations in place (e.g. training and supervision requirements).

Pharmacist interns do not have their own malpractice insurance and will typically function under the insurance of the licensed pharmacist who is supervising them and possibly the immunity clause under *the Public Health Act*. Insurance coverage depends on the situation, see text box below "Liability Risks and Insurance Coverage" for more information.

Liability Risks and Insurance Coverage

When practising in normal and extraordinary circumstances, liability risks may be impacted by many variables, such as:

- The authority under which the task is being performed (e.g., The Pharmacy and Pharmacy Disciplines Act and SCPP Regulatory Bylaws and/or The Disease Control Regulations);
- Whether the activity/ is a regular scope of practice or enabled through emergency provisions;
- · Category of licensure; and
- The setting in which the activity/task is being performed (i.e., retail community pharmacy, publicly operated facility (federal or provincial)).

Liability coverage may be dependent on the personal malpractice insurance and the employer's insurance (where applicable). Every insurance policy is different and liability coverage depends on the policy details. SCPP encourages all pharmacies and licenced members to speak with their insurance providers and employers to confirm coverage details, including the impact of such tools as the immunity clause within *The Public Health Act*.

Disclaimer: SCPP is <u>not</u> an insurance provider and therefore cannot confirm coverage details. This information is intended to provide background information that may assist in the conversation with the employer and insurance provider.

13. Can a pharmacist administer a drug by advanced method to a family member or themselves?

No. A pharmacist must not administer a drug, including a vaccine, to a family member or themselves unless it is a drug commonly intended for self-administration, or there exists an extenuating circumstance and there is no other alternative. The circumstance and rationale must be documented.

STORAGE & COLD CHAIN MANAGEMENT

14. What type of refrigerator is recommended for the storage of vaccines?

A purpose-built refrigerator is recommended but a food storage refrigerator can be used if it meets the standards for maintaining the cold chain. A bar fridge is not permitted. See Refrigerator and Temperature Monitoring Equipment Requirements.

Note: The Ministry of Heath may have additional refrigerator and temperature monitoring recommendations or requirements for storage of publicly funded vaccines. Pharmacies providing publicly funded vaccines are responsible for meeting the Ministry of Health requirements.

15. How do we know our refrigerator meets SCPP's vaccine storage requirements?

Review SCPP's <u>Vaccine Storage</u>, <u>Handling and Transport Guidelines</u> and <u>Refrigerator and Temperature Monitoring Equipment Requirements</u> to ensure your refrigerator, thermometer and cold-chain management is up to the SCPP's standards. It is important for every pharmacy to have a designated vaccine coordinator who will ensure that vaccine storage and handling protocols are met.

The Ministry of Health also has specific requirements for refrigeration of publicly funded vaccines that are communicated directly to participating pharmacies. Also review Section 2.0 of the SIM Chapter 9. The Ministry of Health strongly encourages the use of data loggers, to help with continuous temperature monitoring (see section 2.5.1 of SIM Chapter 9).

Temperature logs may be audited by the Ministry of Health or SCPP Field Operations and must show proof of at least twice daily minimum and maximum temperature readings.

16. Can I use a bar fridge to store vaccines?

No, bar fridges are not permitted because they are incapable of consistently maintaining temperatures within the cold-chain storage requirements (i.e. 2°C to 8°C range). Also, temperature-control sensors do not react appropriately resulting in varying temperatures.

See PHAC's <u>National Vaccine Storage and Handling Guidelines for Immunization Providers 2015, Section 3.4.4</u> for further details.

As we are collaborating with the public health system, it is important to review and follow Chapter 9 of the SIM.

17. Do we need to store vaccines such as the flu vaccine in a separate refrigerator?

The Ministry of Health strongly recommends that vaccines are not to be stored in the same refrigerator as other drugs due to the fragility of the vaccine and requirements to maintain constant storage temperature. Please refer to Chapter 9 of the SIM for further recommendations.

The College requires that all pharmacies adhere to the <u>SCPP Vaccine Storage</u>, <u>Handling and Transport Guidelines</u> to ensure that the cold-chain is maintained for all products (e.g. biologics, drugs, vaccines).

18. The refrigerator we have is monitored by a security system – do we still need to keep a paper log?

Yes, even for continuous temperature monitors with alarms, all pharmacies must record the current, minimum, and maximum temperatures at least twice a day along with time and initials of the person recording. The use of data loggers is **strongly encouraged** to help with continuous temperature monitoring (see section 2.5.1 of SIM Chapter 9).

Documentation is important to track recurring problems, contribute to quality assurance assessments, and for auditing and legal purposes.

Temperature logs are recommended to be retained for at least two years. See SCPP <u>Summary of Record Keeping Requirements</u> for more details.

19. Who do I report to in the event of a cold-chain break?

For all publicly-funded and private drugs and vaccines, SCPP **requires** that a written emergency plan has been developed to manage cold chain breaks in the event of power outages and other unforeseen incidents (see Section 3 of <u>Vaccine Storage</u>, <u>Handling and Transport Guidelines</u>). By default, this role lands with the pharmacy manager.

For publicly-funded flu vaccines, report cold-chain breaks by filling out <u>Appendix 3</u> of the SIIP and fax directly to the Ministry of Health at 306-787-3237. Please refer to the <u>SIM</u> and <u>SIIP</u> for further details.

For all other cold chain breaks please refer to SCPP <u>Vaccine Storage</u>, <u>Handling and Transport</u> Guideline.

ADMINISTRATION

20. Are there any requirements on the space in which a pharmacist can provide injections?

Yes, the pharmacist must ensure the pharmacy creates and maintains a clean, safe, appropriately private, and comfortable environment within which the injection is to be administered (e.g., a private care area).

21. Do we need to inject in a private room?

Standards expect that all professional services must be provided where privacy is assured which, depending on your environment, may or may not be a private room in the pharmacy.

22. Can a pharmacist provide injections outside the pharmacy?

Pharmacists may provide injections off-site with the intention to address barriers to access (e.g., immobile persons, frail seniors). Pharmacists must act in the best interests of the patient and ensure administration standards and standards of practice are adhered to.

The <u>federal government</u> requires Transportation of Dangerous Goods (TDG) training and certification when transporting dangerous goods to promote public safety. It is the employer's responsibility to ensure that employees are trained with respect to TDG should the services they provide fall under the <u>Transportation of Dangerous Goods Act</u> and <u>Regulations</u> (e.g. transporting biohazards and/or cytotoxic medications including used

sharps following their injection). SCPP does not mandate which TDG training program should be taken to meet requirements.

For more information see <u>SGI Transporting dangerous goods</u> and <u>Saskatchewan Safety</u> Council for in class training or Saskatchewan TDG Training for online training as options.

The Ministry of Health has specific requirements regarding populations and off-site locations for community pharmacists injecting the publicly-funded influenza vaccine, please see <u>SIIP</u> for more details. For the **seasonal influenza program**, TDG is not required however the Ministry of Health is encouraging TDG training for pharmacists providing off site seasonal flu immunizations where biohazard products such as used sharps will be transported via motorized vehicles.

23. Can a pharmacist inject Botox® or other dermal filler products for cosmetic purposes?

No. Pharmacist's authority to administer drugs by injection and other routes is intended for the purposes of pharmaceutical care and drug therapy management of the patient. Administration is not intended for other purposes, such as cosmetic.

(Source: SCOPe Newsletter, November 2016, Page 9, Injectable Cosmetic Treatments)

Note: pharmacists are also <u>not</u> permitted to administer Botox® for therapeutic purposes (e.g. treatment of hyperhidrosis, chronic migraine). See <u>Administration by Injection</u> section 2.5.

DOCUMENTATION

24. What documentation must I obtain and retain?

- a. Informed patient consent, patient history, patient immunization record, notification form to primary care provider and serious adverse events following drug administration, if applicable.
 - See <u>Administration of Drugs by Injections and Other Routes</u> and Publicly Funded Seasonal Influenza Immunization Program section below for additional requirements for informed consent.
- b. Information as per record keeping requirements listed in <u>section 7 of Part L of the SCPP Regulatory Bylaws</u>.
- c. When prescribing for vaccine preventable diseases and travel health, forms created by <u>medSask</u> must be used. These forms are frequently reviewed and updated so it is recommended not to download or pre-print these forms, but to access them live to ensure most up-to-date forms are utilized.
- 25. Does a digitally scanned copy of the documentation, such as consent, meet SCPP requirements?

Yes. Once all the appropriate forms are completed, they can be digitally scanned and attached to the patient profile in a similar manner as attaching scanned prescriptions to the patient profile. See SCPP <u>Summary of Record Keeping Documents</u> for more information.

26. How long do records need to be kept?

Patient records must be kept for 10 years or longer from the last date of recorded pharmacy service provided to the patient. See SCPP <u>Summary of Record Keeping Documents</u> for more information.

27. Why is the AEFI reporting procedure for publicly funded vaccines different from non-publicly funded vaccines?

The system is designed to meet obligations under federal and provincial legislation and needs unique to our program. This is subject to agreement between federal and provincial jurisdiction. See section 5.3 of the <u>Administration of Drugs by Injection and Other Routes</u> for reporting details.

28. Does AEFI reporting represent a breach of patient privacy?

No. While pharmacists are likely to have patient consent for such disclosure, SCPP considers it to be a without-consent authorized secondary purpose under the Health Information Protection Act, as long as proper procedures presented in the medSask guidelines and USask CPE training are followed.

VACCINE PREVENTABLE DISEASES AND TRAVEL HEALTH

29. Do I now need a prescription for vaccines?

Yes. With the full implementation of the <u>Disease Prevention and Travel Health Services</u> <u>Policy and Framework</u>, vaccines, except publicly funded vaccines (e.g. influenza) are now Schedule 1. This includes common vaccines previously dispensed without a prescription such as <u>Dukoral®</u> or <u>Gardasil®</u>.

PUBLICLY FUNDED SEASONAL INFLUENZA IMMUNIZATION PROGRAM

30. When can fully trained pharmacists begin administering the publicly funded influenza vaccine?

Advanced Method Certification (AMC) is required for any pharmacist who wants to administer the publicly funded influenza vaccine. Once the pharmacist has received confirmation of AMC from SCPP, they can begin administering drugs by injection. See SCPP Registration website tab for more information.

A pharmacist may administer the influenza vaccine on the prescribed date for the flu season as described by the <u>Seasonal Influenza Immunization Program</u>.

31. Can the influenza vaccine be drawn up ahead of time to prepare for a clinic?

No. It is recommended that no vaccine be drawn up unless using immediately, as sterility and cold chain cannot be assured with pre-drawn syringes. Refer to Chapter 8 of the SIM for more details.

32. Can I share my influenza vaccine with another pharmacy if they request it?

- a. No, public influenza vaccine stock should not be shared with another pharmacy as the DPEBB is tracking the ordering, administration, and billing of the publicly funded influenza vaccine. Discrepancies in stock ordered and used may cause the DPEBB to withhold delivery of any additional stock.
- b. It is important that the DPEBB has current and accurate numbers as they routinely report the number of vaccines administered by pharmacists to the Population Health Branch of the Saskatchewan Ministry of Health. The ability for the provincial influenza program to be regularly reassessed or to respond to current conditions depends on the accuracy of the information submitted by all providers of the vaccine.

33. Are there additional forms I must use?

You can use any form to document the requirements listed in <u>Administration of Drugs by</u> Injections and Other Routes.

In addition to those requirements, the DPEBB requires the provision of:

- a. Immunization fact sheets for informed consent;
- Wallet cards post-immunization, if requested by the patient (patients must be informed they will be able to view their immunization record in MySaskHealthRecord).

34. Can we store the influenza vaccine in a cooler if we have a clinic in our pharmacy?

Yes, if the cold chain can be maintained for the necessary duration. A cold chain break must be prevented by observing precautions according to SCPP <u>guidelines</u> and <u>Chapter 9</u> of the SIM.

35. Can a pharmacist obtain verbal informed consent for administering an influenza vaccine or does consent have to be provided by the patient in written form?

In Saskatchewan, immunizations are voluntary and obtaining a valid, informed consent from every client is a professional and legal responsibility before providing immunization services. Generally speaking, and depending on the circumstances, consent may be obtained in different forms (including verbally), provided that the consent meets the requirements for informed consent and is appropriately documented.

The key requirements for informed consent for all pharmacists are set out in the SCPP's Regulatory Bylaws and Reference Manual (e.g., must be informed, specific, given

voluntarily and documented). It does not specify the form in which it must be obtained (i.e., written or verbal).

However, additional requirements for those participating in the seasonal flu program will be found in the SIM, the SIIP and the Saskatchewan Drug Plan Influenza Immunization Program (IIP) Policy and Procedures. Typically, the SIIP and IIP require that written, express consent be obtained by pharmacists in order to be compensated by the Saskatchewan Drug Plan and that community pharmacists use consent forms for any clients older than 59 months. Pharmacists are responsible to ensure they are aware of the most current requirements should there be changes. See Pandemic for exemptions to the written express consent for 2022-2023 flu season.

36. If patient consent must be provided by a written patient signature, does that signature have to be "wet" or can it be provided via digital means?

Where written signatures are required, those signatures may be provided electronically, provided that the signature and related documents satisfy certain requirements pursuant to *The Electronic Information and Documents Act* (Saskatchewan):

- The documents must be retained in a way and format that allows for their future use;
- It must be possible to establish the integrity of the document (i.e., it has remained complete and unaltered while stored); and
- The electronic signature must be both reliable for the purpose of identifying the relevant individual and the association of the signature with the relevant document must be reliable for the purpose for which the document was made (i.e., it must be possible to show that a specific individual signed a specific document).