



COVID-19 Immunizers FAQs

Note: This is an Emergency provision to implement the Saskatchewan COVID-19 Immunization Delivery Plan only as permitted through *The Disease Control (COVID-19) Amendment Regulations*. Therefore, the following information is time limited and applies only to those who are permitted to administer the COVID-19 vaccine.

This document focuses on who is permitted to do what in the pharmacy flow (screening, registration, vaccine preparation, immunization, documentation, post-immunization observation, and after-care information) and what is being done under their regular scope of practice, and what is being done under the Emergency provisions.

DEFINITIONS

"COVID-19 Immunizer" – in this document, refers to the "COVID Vaccination Providers" in the pharmacy disciplines listed in *The Disease Control (COVID-19) Amendment Regulations, 2021* who are authorized to inject the COVID-19 vaccines (or put "needles in the arms" of patients) as set out in the Saskatchewan COVID-19 Immunization Delivery Plan.

"Formerly Licensed Pharmacist" – as per the COVID-19 Immunization Delivery Plan, to be a COVID-19 Immunizer, a pharmacist who held a valid practising license with SCPP and was in good standing immediately before ceasing to be authorized to practice. Note: a formerly licensed pharmacist is NOT licensed to practice as a pharmacist or use the title "licensed pharmacist" unless they register with SCPP as a licensed pharmacist or temporary Emergency licensed pharmacist.

"Licensed Pharmacist" – a pharmacist registered with SCPP as a practicing pharmacist. When used in this document, this refers to pharmacists who have gone through one of 3 different pathways to licensure and therefore may have different terms and conditions attached to their practice. They include:

- **1. Fully licensed pharmacists** who can practice without supervision (Regulatory Bylaws Part E.1);
- 2. Conditional licensed pharmacists (category ends July 31, 2021) who have not met all of the entry-to-practice requirements and therefore must practice under supervision and other requirements set by SCPP (Regulatory Bylaws Part E.2). See <u>Conditional Licensure</u> <u>Guidelines</u>; and
- 3. **Temporary licensed pharmacists** enabled in extraordinary circumstances who had an active licence with SCPP within the last 3 years, however, must practice within the terms, limitations and supervision requirements specified by SCPP (Regulatory Bylaws Part E.11). See Emergency Registration and Licensure Policy.

- "Licensed Pharmacy Technician" a pharmacy technician registered with SCPP as a practicing pharmacy technician.
- "Pharmacist Extended Interns" (class of 2020 and class of 2021 beginning on June 3rd) pharmacy graduates from a pharmacy degree program but have not yet completed all of the licensure requirements, as outlined in SCPP Regulatory Bylaws Part B Section 5.
- "Pharmacist Student Interns (class of 2022, 4th year)" as defined in SCPP Regulatory Bylaws Part B, this includes pharmacy students who have completed their 3rd year in a university training program at an institution recognized by Council (i.e. written and passed exams in April) and will be starting their 4th year of study in the fall of 2021.
- "Pharmacist Student Interns (class of 2023, 3rd year)" as defined in SCPP Regulatory Bylaws Part B, this includes pharmacy students who have completed their 2nd year in a university training program at an institution recognized by Council (i.e. written and passed exams in April) and will be starting their 3rd year of study in the fall of 2021.

ACRONYMS

AESI – Adverse Events of Special Interest

AMC – Advanced Method Certification

AMSC - Advanced Method Student Certification

AMTC - Advanced Method Technician Certification

PIP - Pharmaceutical Information Program

SHA – Saskatchewan Health Authority

1) Who is permitted to inject the COVID-19 vaccine and under what conditions?

To implement the COVID-19 Immunization Delivery Plan, some COVID-19 Immunizers are enabled under status quo provisions as part of their regular scope of practice. Whereas other COVID-19 Immunizers have been enabled through Emergency provisions and as such, will have specific limitations and conditions attached. See "Who is Permitted to Inject the COVID-19 Vaccine and Under What Conditions" Table for details.

The COVID-19 Immunization Delivery Plan is constantly evolving due to progression of the disease, epidemiological factors, availability of the vaccine and the developing science. The Ministry of Health requires module specific training that is regularly being updated. To ensure that you are practicing with the most up-to-date brand-specific vaccine training monitor the SHA training page for more details as they become available.

WHO IS PERMITTED TO INJECT THE COVID-19 VACCINE AND UNDER WHAT CONDITIONS

			REGULAR LICENS	SED		
Title	What (Description)	Authority	Required Training	Supervision	Liability	Other Comments
Licensed Pharmacist	Administer Ministry approved COVID-19 vaccines, by injection as per product monograph in all settings: • Moderna • Pfizer • AstraZeneca • Covishield • Janssen (Johnson & Johnson) May supervise other COVID-19 Immunizers.	The Pharmacy and Pharmacy Disciplines Act and SCPP Regulatory Bylaws Part L Section 9(a).	 Valid AMC (incl. valid Standard First Aid and CPR Level C with AED) COVID-19 vaccine brand specific modules (See here)* Vaccine hesitancy training (See here) * Additional training as specified by the Ministry of Health. 	None required. Enabled to supervise entire injection administration process (must have AMC).	Covered under their own malpractice insurance providing no condition "A" on their licence. See also Question #7 below on liability risks.	* Employers must ensure COVID-19 Immunizers have completed the COVID specific training. SCPP records AMC but does not track completion of COVID specific training. See also Question #2, #3 and #4 below for standards of practice and role of employers.

COVID-19 Immunizers FAQs Page 3 of 27

Title	What (Description)	Authority	Required Training	Supervision	Liability	Other Comments
Conditionally Licensed Pharmacist	Administer Ministry approved COVID-19 vaccines by injection as per product monograph: Moderna Pfizer AstraZeneca Covishield Janssen (Johnson & Johnson)	The Pharmacy and Pharmacy Disciplines Act and SCPP Regulatory Bylaws Part L Section 9(a).	 Valid AMC (incl. valid Standard First Aid and CPR Level C with AED). COVID-19 vaccine brand specific modules (See here)* Vaccine hesitancy training (See here)* Additional training as specified by the Ministry of Health. 	Required (Part E.2 Section 5 and SCPP Conditional Licensure Policy) Not eligible to supervise interns or COVID-19 Immunizers.	Covered under their own malpractice insurance providing no condition "A" on their licence. See also Question #7 below on liability risks.	* Employers must ensure COVID-19 Immunizers have completed the COVID specific training. This category of membership will no longer exist as of July 31, 2021. These individuals will either move to the licensed pharmacist category (if meet licensure requirements) or to pharmacy assistant status. Those who do not meet licensure requirements and want to be a COVID-19 Immunizer, see Formerly Licensed category.

WHO IS PERMITTED TO INJECT THE COVID-19 VACCINE AND UNDER WHAT CONDITIONS

Title	What (Description)	Authority	Required Training	Supervision	Liability	Other Comments
Licensed Pharmacy Technician	Regular: Using aseptic technique: Reconstitute medications Draw up dose in syringe	Regular: The Pharmacy and Pharmacy Disciplines Act	Regular: COVID-19 vaccine brand specific modules (See here)* AMTC (includes required Vaccine hesitancy training. See here) Must practice within the limits of their personal competence (NAPRA MSOP)	Regular: Pharmacist oversight of pharmacy continues as per Part J of SCPP Regulatory bylaws.	Regular: Covered under their own malpractice insurance.	Pre-loading of syringes is not permitted. See <u>Chapter 8 SIM.</u> Preparation of the vaccine by anyone other than one who is administering the injection is not a good practice (<u>Travel Health FAQs Question #12</u>)
	Emerg. Enabled: Inject COVID-19 vaccines in a collaborative team environment as set out in the COVID-19 Immunization Delivery Plan.	Emerg. Enabled: The Disease Control (COVID-19) Amendment Regulations, 2021	 Emerg. Enabled: AMTC (includes required Vaccine hesitancy training. See here)* COVID-19 vaccine brand specific modules (See here)* Additional training as specified by the Ministry of Health. 	Emerg. Enabled: Must be supervised by a member of a regulated health profession who is already authorized to administer COVID-19 vaccine and has completed the required training (e.g., Licensed Pharmacist with AMC in a retail pharmacy, Physician in a SHA setting). Source: COVID-19 Immunization Plan).**	Emerg. Enabled: May be covered under own malpractice insurance and/or immunity clause under The Public Health Act See also Question #7 below on liability risks.	* Employers must ensure COVID-19 Immunizers have completed the COVID specific training. SCPP records AMTC but does not track completion of COVID specific training. See also Question #2, #3 and #4 below for standards of practice and role of employers. *** SCPP encourages pharmacy managers to apply the Supervision of Interns Policy to this category of COVID-19 Immunizer. Also see SCPP Training Table "Practice Considerations."

WHO IS PERMITTED TO INJECT THE COVID-19 VACCINE AND UNDER WHAT CONDITIONS

			EMERGENCY ENABLE	D ONLY		
Title	What (Description)	Authority	Required Training	Supervision	Liability	Other Comments
Pharmacist Interns (Extended Interns & Student Interns) (See definitions above)	Inject COVID-19 vaccines in a collaborative team environment as set out in the COVID-19 Immunization Delivery Plan.	The Disease Control (COVID-19) Amendment Regulations, 2021	 AMSC (includes required Vaccine hesitancy training. See here) * COVID-19 vaccine brand specific modules (See here)* Additional training as specified by the Ministry of Health. 	Must be supervised by a member of a regulated health profession who is already authorized to administer COVID-19 vaccine and has completed the required training. (e.g. Licensed Pharmacist with AMC in a retail pharmacy, Physician in a SHA setting). Source: COVID-19 Immunization Delivery Plan **	May be covered under the supervising regulated health professional's insurance and/or the immunity clause under <i>The Public Health Act</i> . See also Question #7 below on liability risks.	*Employers must ensure COVID-19 Immunizers have completed the COVID specific training. (See below Obligations of Community Pharmacy Employers textbox). Note: SCPP records AMSC but does not track completion of COVID specific training. ** SCPP expects Pharmacy managers to ensure the Supervision of Interns Policy is met. Also see SCPP Training Table "Practice Considerations"

COVID-19 Immunizers FAQs Page 6 of 27

Title	What (Description)	Authority	Required Training	Supervision	Liability	Other Comments
Formerly Licensed Pharmacist (see definitions above)	Inject COVID-19 vaccines in a collaborative team environment as set out in the COVID-19 Immunization Delivery Plan. Is NOT licensed to practice as a pharmacist and cannot provide clinical or therapeutic assessment and information.	The Disease Control (COVID-19) Amendment Regulations, 2021	 COVID-19 vaccine brand specific modules (See here)* Vaccine hesitancy training (See here)* SCPP specified training will be decided on a case-by-case basis (e.g. AMSC). Contact info@saskpharm.ca with details listed here. Additional training as specified by the Ministry of Health. 	Must be supervised by a member of a regulated health profession who is already authorized to administer COVID-19 vaccine and has completed the required training. (e.g. Licensed Pharmacist with AMC in a retail pharmacy, Physician in a SHA setting). Source: COVID-19 Immunization Delivery Plan **	Covered under the immunity clause of <i>The Public Health Act</i> and/or the supervising regulated health professional's insurance. See also Question #7 below on liability risks.	*Employers must ensure COVID-19 Immunizers have completed the COVID specific training. (See below Obligations of Community Pharmacy Employers textbox). Must inform employer you do not have a practicing license nor personal malpractice insurance but may be hired as a COVID-19 Immunizer only according to the COVID-19 Immunization Delivery Plan. ** SCPP encourages pharmacy managers to apply the Supervision of Interns Policy to this Immunizer category.

Title	What (Description)	Authority	Required Training	Supervision	Liability	Other Comments
Temporary Emergency Licensed Pharmacist (see definitions above)	Administer Ministry approved COVID-19 vaccines by injection as per product monograph in all settings: • Moderna • Pfizer • AstraZeneca • Covishield • Janssen (Johnson & Johnson) Perform other authorized pharmacy practices, including administration by injection (see here).	The Pharmacy and Pharmacy Disciplines Act and SCPP Regulatory Bylaws Part E.11 Emergency Memberships and Licences and Part L Section 9(a).	See Emergency Registration and Licensure Policy Section 3.3. and 4.1. Valid AMC (incl. valid Standard First Aid and CPR Level C with AED).** COVID-19 vaccine brand specific modules (See here)* Vaccine hesitancy training (See here) * Additional training as specified by the Ministry of Health.	Required (See Emergency Registration and Licensure Policy Section 4.2.) Not eligible to supervise interns or COVID-19 Immunizers.	Covered under their own malpractice insurance providing no condition "A" on their licence. See also Question #7 below on liability risks.	* Employers must ensure COVID-19 Immunizers have completed the COVID specific training **AMC is not mandatory for licensure in Saskatchewan. However, it is mandatory for all licensed pharmacists who choose to provide this service, which includes temporary licensed pharmacists. Note: Previously licensed pharmacists who wish to return to practice under normal provisions, see Part E.7 Migration From One Membership Category to Another and SCPP website.

Title	What (Description)	Authority	Required Training	Supervision	Liability	Other Comments
Non- Pharmacy Disciplines COVID-19 Immunizers	Inject COVID-19 vaccines in a collaborative team environment as set out in the COVID-19 Immunization Delivery Plan. Any other scope as determined by the regulatory body of the licensed professional.	The Disease Control (COVID-19) Amendment Regulations, 2021	 Any training as required by the regulatory body of the licensed professional. COVID-19 vaccine brand specific modules (See here)* Vaccine hesitancy training (See here)* Additional training as specified by the Ministry of Health. 	Any supervision requirements as set out by the regulatory body of the licensed professional.	Regulated health professionals may be covered under own malpractice insurance and/or the immunity clause of The Public Health Act. Non-regulated COVID-19 Immunizers covered under immunity clause of The Public Health Act. Employers & supervising pharmacists to confirm coverage with insurance provider re their own & the pharmacy's liability. See also Question #7 below on liability risks.	Employers and professionally licensed non-pharmacy discipline Immunizers are responsible to work with the regulatory body for that licensed professional to fulfill their obligations under the COVID-19 Immunization Plan and ensure that they are practicing within their scope of practice (e.g., licensed nurses require a medical directive) & Immunizer competence, while also adhering to The Pharmacy and Pharmacy Disciplines Act (i.e. clauses 26(a) and (b)). Formerly licensed professionals (from non-pharmacy disciplines) who are immunizing, yet no longer regulated, have a very narrow scope. See Question 3 below & Obligations of Community Pharmacy Employers textbox.

2) What do all of these Emergency overrides mean for the Standards of Practice?

When called upon, the safe delivery of the COVID-19 vaccine to the Saskatchewan public relies on pharmacy professionals (current, former and future) to uphold the standards of practice for their profession to the best of their ability in <u>all</u> practice settings, including community and publicly operated pharmacy practice (provincial and federal).

Pharmacy Professionals – Any <u>licensed pharmacist</u> or <u>pharmacy technician</u> performing
activities in support of the Saskatchewan COVID-19 Immunization Delivery Plan, must abide
by the terms and conditions of the Plan as communicated by the Ministry of Health while also
adhering to the NAPRA Model Standards of Practice for their respective professions and
promoting adherence to others working in the pharmacy flow.

3) What do these Emergency overrides mean for those practicing in a <u>retail community</u> pharmacy?

Pharmacy professionals rely on employers to ensure that the resources and processes are in place to uphold their standards of practice.

As per sections 26(a) and (b) of *The Pharmacy and Pharmacy Disciplines Act*, all of the services provided in community pharmacies must be provided safely, in the best interests of the public, members, and the standing of the profession. This includes the delivery of the COVID-19 Immunization Delivery Plan.

Obligations of Community Pharmacy Employers

COVID-19 Immunization Plan Requirements

The Saskatchewan COVID-19 Immunization Delivery Plan, as per *The Disease Control Regulations*, includes a list of COVID-19 Immunizers who are authorized to administer the vaccine, the training requirements and the authorized clinics or locations.

The individuals authorized under the COVID Immunization Delivery Plan are <u>only</u> permitted to provide the COVID-19 vaccination under the conditions set out by the Plan. These include:

- COVID-19 Immunizers must be competent to administer the vaccination and it must be safe and appropriate for the person to do so;
- In the case of an employee, hired by a community pharmacy authorized to deliver the COVID-19 vaccination, the employer must be satisfied that the COVID-19 Immunizer is competent to administer the vaccination and it is safe and appropriate for the employee to do so;
- The administration of the vaccination must only be for the purpose of the Plan or for training purposes;
- Only the persons authorized to administer the COVID-19 vaccination as per the Plan may do so; and

• The administration of a COVID-19 vaccine by an Emergency enabled COVID-19 Immunizer must be performed within a collaborative team environment that includes a member of a regulated health profession who is already authorized to administer COVID-19 vaccinations.

While the COVID-19 Immunization Delivery Plan activities are governed by an authority other than *The Pharmacy and Pharmacy Disciplines Act*, the SCPP is responsible to determine competencies for those in the pharmacy disciplines (see NAPRA approved competencies) The SCPP has created training to help employers (i.e. proprietors) ensure that the competency requirements are met.

Proprietors of community pharmacies are encouraged to monitor the <u>Ministry's COVID-19 Immunization Program website</u> for more information on employer requirements as it becomes available.

See <u>DPEBB Bulletin No. 761</u> regarding **no incentives shall be provided** by the Proprietor, or an agent on behalf of the Proprietor, to any other person in relation to the provision of publicly funded COVID-19 immunization. "Incentives" means any money, gifts, donations to a charity, rebates, refunds, customer loyalty programs, points, coupons, discounts, goods and/or rewards which can be redeemed for a gift or other benefit.

SCPP Requirements

The expectations of employers in the COVID-19 Immunization Delivery Plan are further reinforced by *The Pharmacy and Pharmacy Disciplines Act*. This act recognizes that the proprietor is the person who controls the operation of the retail community pharmacy. Clauses 26(a) and (b), hold them responsible to ensure that the services provided in community pharmacies are provided in the best interests of the public or the members, and maintain the standing of the profession.

In addition to its expectations that retail community pharmacy proprietors (i.e. employers), uphold the laws governing the activities occurring within a permitted pharmacy (including the COVID-19 immunization), the SCPP also expects pharmacy owners to work closely with pharmacy managers to ensure that a staffing plan is established that meets the patient care needs of that pharmacy, taking into consideration the anticipated increase in workload arising from the pharmacy's involvement in providing COVID-19 immunizations

It should also be noted that in normal and extraordinary circumstances the Pharmacy Manager is responsible for ensuring that all certification and supervision requirements for the pharmacy disciplines are met.

(See SCPP COVID-19 Immunizer Training and Pharmacy Manager Responsibilities.)

4) What do these Emergency overrides mean for those practicing in a <u>publicly operated</u> setting (Provincial or Federal)?

- Under the authority of *The Pharmacy and Pharmacy Disciplines Act*, the SCPP regulates pharmacists, pharmacy technicians, retail pharmacies and drugs to ensure the public receives safe and quality pharmacy care.
- While publicly operated settings have authority over, and are responsible for, the care in publicly operated settings, the SCPP regulates how pharmacy professionals practice in any care setting. This means, unless explicitly stated in the SCPP bylaws or policies, when performing any activity in a publicly operated setting (e.g. Indigenous Services Canada, Saskatchewan Health Authority, Saskatchewan Cancer Agency), members must continue to practice in accordance with the SCPP legislation, standards of practice and code of ethics as expected of all pharmacy professionals, and any applicable policy of the publicly operated setting.
- For example, those in the pharmacy disciplines who are administering the COVID-19 vaccine within a publicly operated setting must meet the training, competency and supervision requirements as determined by the policy of the publicly operated setting, in addition to those already established by SCPP.
- 5) What are the other roles (besides injecting the COVID-19 vaccine) that COVID-19 Immunizers may perform in the community pharmacy setting?

See "Staff Roles in the Community Pharmacy Setting" Table. Also see Related Resource CPDPP "The Injection Process: Whose Role is it Anyways."

COVID-19 Immunization Delivery Plan: Staff Roles in Community Pharmacies

Note: This chart does not include the activities permitted by other COVID-19 Vaccination Providers (non-pharmacy disciplines) listed in the COVID Immunization Delivery Plan if hired by the community pharmacy employer. In these situations, the onus is on the pharmacy manager, the proprietor, and the person hired to determine what is in scope, competence and liability insurance coverage (i.e., business and malpractice insurance). Please monitor the Ministry's COVID-19 Immunization Program website for any further developments.

* "All COVID-19 Immunizers" includes those in the pharmacy disciplines who are enabled through <u>Emergency provisions</u> to participate in the COVID-19 Immunization Delivery Plan. It also reflects authorized activities as part of the regular scope of practice for licensed pharmacists and pharmacy technicians enabled through normal provisions.

Note: COVID-19 immunization activities performed within Ministry of Health approved locations (e.g. Saskatchewan Health Authority, Indigenous Services Canada) must be done in accordance with their respective policies.

** In normal circumstances non-regulated staff (e.g., pharmacy assistants) perform tasks in the pharmacy under supervision of licensed professionals. In extraordinary circumstances these staff may continue to perform these tasks if it is permissible within the Saskatchewan COVID-19 Immunization Delivery Plan requirements.

In this chart, "COVID Immunization Plan" means the Saskatchewan COVID-19 Immunization Delivery Plan

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Provide information materials to patient	All COVID-19 Immunizers Other pharmacy staff**	Distribute Ministry vaccine info sheet for the specific vaccine, and other info as required, to patients. Also see DPEBB Bulletin No. 758	Pharmacy Manager or licensed pharmacist (with AMC) responsible for overseeing COVID-19 Immunizers, are ensuring appropriate info materials are provided to patients.	Pharmacy manager to put processes in place to ensure staff is aware of and following requirements set out in the Saskatchewan COVID-19 Immunization Delivery Plan.
				See <u>DPEBB Bulletin No. 758</u> for how my assistant can help out with the immunization process (e.g. booking appointments, submitting claims) and what vaccine specific patient education resources will be available.

COVID-19 Immunizers FAQs Page 13 of 27

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Pre-Screening	All COVID-19 Immunizers Other pharmacy staff**	Collect or help patients fill in screening form(s).	COVID-19 Vaccine Information: Adhere to COVID Immunization Plan requirements. Access to Personal Health Info: All provincial and SCPP privacy requirements remain in place, therefore: If needed, PIP access occurs under the authorization of a licensed pharmacist or pharmacy technician, in accordance with eHealth PIP requirements (e.g. Accessing PIP Policy, signed confidentiality agreement, users are registered with the PIP Administration Office). Pharmacists may access the results of tests or immunization information from the electronic Health Record (eHR) Viewer or other technology as administered by eHealth Saskatchewan (eHS), or from local sources under appropriate arrangements and must abide by all eHS requirements.	Pharmacy manager has processes in place to follow the COVID Immunization Plan, meet PIP Guidelines, eHS requirements and other privacy requirements as applicable. Pharmacy proprietor is the trustee for all PIP data accessed by the pharmacy and is responsible for ensuring that all pharmacists, pharmacy technicians or other persons with access to patient and PIP data within the pharmacy comply with these Guidelines. Other Resources: medSask COVID-19 Vaccine Screening and Consent Form.

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Therapeutic or Clinical Assessment	Licensed Pharmacist with AMC (as per definitions above includes Fully, Conditional and Temporary)	Must obtain appropriate information before administering a drug (vaccine) by injection to ensure patient safety (e.g. medical conditions, allergies, reviewing PIP profile and eHR viewer). Assess therapeutic appropriateness (e.g. contraindications, precautions, history of vaccine reactions, vaccine brand and time interval for second dose). Note: Community pharmacies are NOT authorized to provide second doses to patients until communicated by the Ministry.	Pharmacists are expected to comply with the standards described in the training and SCPP requirements for Advanced Method Certification and with NAPRA Model Standards of Practice. Pharmacist must perform a therapeutic assessment for every patient at every visit. Pharmacist must check immunization history on eHR Viewer for every patient at every visit before a COVID-19 vaccine is administered to confirm whether the patient has previously received a publicly funded COVID-19 vaccine. See DPEBB Bulletin No. 761	Pharmacy manager develops written process around who to contact with the following questions such as: • Clinical therapeutic questions for special patient populations (e.g. cancer patients, immunocompromised, pregnant): medSask • Billing and Pharmacy Registration for Covid-19 Immunization Program: DPEBB • Communication with the local hospital where needed. E.g. contact and phone number (see Practice Tip below). Practice Tip: Information regarding drug treatment for COVID-19 received in hospital will not be recorded in PIP and may not be in eHR Viewer. A phone call to the hospital may be required to obtain this information. Other Resources: • medSask COVID-19 Vaccine Screening and Consent Form and Guide. • DPEBB Bulletin No. 761 "Who to Contact".

COVID-19 Immunizers FAQs Page 15 of 27

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Informed Consent	Licensed Pharmacist with AMC (as per definitions above includes Fully, Conditional and Temporary)	Patient Education and Assessment Step: Provides standard information to patient and discusses the risks and benefits as per therapeutic or clinical assessment. Saskatchewan's immunization programs are voluntary, and it is the professional and legal responsibility of the immunization provider to obtain valid informed consent prior to immunization. (SIM Ch. 3 Informed Consent).	 COVID Immunization Plan: Informed consent required; Verbal consent is permitted, however documentation MUST clearly indicate that the consent was obtained verbally. See here for any updates; Record retention for COVID Immunization Plan is a minimum of 7 years. SCPP requires that informed consent be given prior to administering the vaccine. It must be specific, given voluntarily, confirms that patient understands, and is documented. (See Informed Consent for complete requirements. Also see #35 & #36 Administration by Injection FAQs, and Summary of Record Keeping Requirements). Note: a signature on a consent form is NOT a substitute for having a conversation with a patient. 	Pharmacy Manager ensures that the process of informed consent consists of: A description of the drug and administration procedure Confirms information provided is understood Provides opportunity for questions and answers; and Meets additional requirements of the COVID Immunization Plan. Aware of resources and consent tools available and that pharmacists contact medSask re: clinical questions. See Other Resources below. Other Resources: medSask COVID-19 Vaccine Screening and Consent Form and Guide. SHA consent form to use when a substitute decision maker or physician is providing consent. Informed Consent Quick Reference (medSask/CPDPP).
	All COVID-19 Immunizers	Technical Step: Outlines the technical process of administration to the patient and explains positioning procedures. Note: As per NAPRA Standards of Practice, Pharmacy Technicians, regardless of the role they are fulfilling, must exercise their professional judgment at all times, including recognizing when the clinical expertise of the pharmacist is required.	If administering the vaccine, they must: Ensure that the patient/patient's representative understands the COVID-19 Vaccine information as explained by the pharmacist; Obtain and document consent for the technical step of the injection. Ensures that a therapeutic assessment by the pharmacist has occurred for every patient at every visit.	Pharmacy Manager puts process in place to ensure that informed consent occurs, and does not permit a signature to be used as a substitute for having a conversation with the patient.

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Infection Prevention and (Routine and Advanced Precautions)	All COVID-19 Immunizers	Incorporate routine, and advanced infection control practices, into all immunization procedures.	Follow infection control practices and procedures established by the pharmacy. See SCPP requirements: Infection Control Standards and Guidelines Hand Hygiene Standards and Guidelines Respiratory Hygiene and Cough Etiquette Standards and Guidelines	Pharmacy Manager establishes infection control policies and procedures to be followed by pharmacy staff, and provides necessary personal protective equipment (PPE). Other Resources: SHA: PPE/Infection Prevention and Control documents, posters and videos. CPhA - PPE: Suggested Best Practices for Pharmacies during COVID19Pandemic document and tools.
Vaccine Preparation (without supervision)	Fully Licensed Pharmacist with AMC (as per definition above) Licensed Pharmacy Technician with AMTC	Using aseptic technique: Reconstitute the vaccine Draw up dose in syringe	As per the directions required by the COVID Immunization Plan, any special instructions for drawing up syringes must be followed: • Pooling residual COVID-19 Vaccine to obtain full dose; • Pre-filling syringes is not permitted. Refer to Chapter 8 SIM.	Note: Reconstituting medications is in the scope of practice of a licensed pharmacist and a licensed pharmacy technician, therefore, either licensed professional may perform independently (i.e. without supervision). Preparation of the vaccine by anyone other than one who is administering the injection is not a good practice (Travel Health FAQs Question #12)
Vaccine Preparation (under supervision)	Conditional and Temporary Licensed Pharmacist with AMC (as per definition above) COVID-19 Immunizers	Using aseptic technique: Reconstitute the vaccine Draw up dose in syringe	As above plus supervised according to their category: Pharmacist Interns, Conditional License Pharmacists, Temporary Licensed Pharmacists. Formerly licensed pharmacists should be supervised according to the Supervision of Interns policy.	Pharmacy manager ensures that the SCPP supervision requirements are being followed.

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Administer the vaccine by injection (without supervision)	Fully Licensed Pharmacist with AMC (as per definition above)	Inject COVID-19 vaccine (or put "needle in the arms" of patients)	Ensure consideration has been given to the appropriate site, route and method of administration (including landmarking and injection technique) and the appropriate length and gauge of needle.	Pharmacy manager ensures that processes are in place to manage exposures to blood or body fluids and other safety risks, including proper follow up if an exposure has occurred. Other Resources: Administration of Drugs by Injection and Other Routes, Needlestick Injury Guidelines
Administer the vaccine by injection (under supervision)	Conditional and Temporary Licensed Pharmacist with AMC (as per definitions above) COVID-19 Immunizers	Inject COVID-19 vaccine (or put "needle in the arms" of patients)	As above plus supervised according to their category: Pharmacist Interns, Conditional License Pharmacists, Temporary Licensed Pharmacists. As per the COVID Immunization Plan, this step must occur in a collaborative team environment that includes a licensed pharmacist with AMC.	As above plus Pharmacy manager ensures that the SCPP supervision requirements are being followed.

COVID-19 Immunizers FAQs Page 18 of 27

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Documentation, Notification and Reporting	All COVID-19 Immunizers	Document the details of the vaccine administration and other reporting as required (See DPEBB COVID-19 Immunization Program website.)	 Info to the Patient: Patient Immunization Record Wallet Card Info to the Primary Care Provider: Provider may access COVID-19 vaccine administered in pharmacy via eHR viewer. Info to Ministry: In timeframe & platform specified by Ministry, report: Vaccine inventory (e.g. doses received, administered, wasted) Health Care Worker immunizations and other populations specified. Record retention for COVID Immunization Plan is a minimum of 7 years. Info to SHA: AEFI and AESI reports to local public health office (see Anaphylaxis section below). Info for Pharmacy Records: Record Keeping list in Part L Section 7 and Admin by Injection Section 5 and FAQs (e.g. informed consent, patient history and immunization record). Retain as per SCPP requirements. 	Pharmacy manager ensures staff are aware of and following all federal, provincial and COVID Immunization Plan documentation and record keeping requirements. Related Resources: • medSask COVID-19 Vaccine Screening and Consent Form and Guide. • DPEBB Bulletin No. 761 Also see Question 6 below for complete details.

COVID-19 Immunizers FAQs Page 19 of 27

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Post- Administration Observation	All COVID-19 Immunizers	Immediate or within 30 minute observation window: Observe patients in the designated waiting area for at least 15 mins after (30 mins if specific concern about vaccine reaction) for post-administration adverse reactions (e.g. feeling faint, anaphylactic reaction) and inform the licensed pharmacist with AMC immediately if assistance is needed. Ensure the patient understands the rationale for remaining under observation post-administration and to immediately consult with the pharmacist if an adverse event occurs. Clinical patient questions must be directed to the licensed pharmacist with AMC. Delayed onset (e.g., outside 30-minute observations must be directed to the licensed pharmacist with AMC.	COVID Immunization Plan: Licensed pharmacist with AMC must be on site as COVID-19 vaccinations must be administered in a collaborative health care team environment, which includes a regulated health care professional trained to manage anaphylaxis. SCPP: If an adverse event occurs, no COVID-19 Immunizer (other than a licensed pharmacist with AMC or a temporary licensed pharmacist with AMC as per Supervision Policy) is permitted to administer any other medications which may be required in the event of anaphylaxis, such as epinephrine or diphenhydramine.	 Pharmacy manager has process in place to support all COVID-19 Immunizers to: Explain the rationale and instructions for the post-administration monitoring; Recognize adverse reactions in patients; To seek help from the licensed pharmacist with AMC when required; and Practice within their permitted tasks. Other Resources: Public Health Agency of Canada Guidance on the post-immunization waiting period for COVID-19 immunization clinics (includes observing people outside the clinic or in their vehicles providing they meet certain criteria).

COVID-19 Immunizers FAQs Page 20 of 27

Step	Who *	What	Terms and Conditions	Other Resources or Comments
Manage anaphylaxis or other post- administration reactions	Licensed Pharmacist with AMC (as per definitions above includes Fully, Conditional and Temporary)	Anticipate, identify, manage and report adverse effects following COVID-19 vaccine injection. (See Reporting of COVID-19 Vaccine Adverse Events of Special Interest) Respond to anaphylactic reactions with appropriate use of Emergency kits and following established step-by-step protocols.	COVID Immunization Plan (AEFI & AESI Reporting): AEFI reporting forms must be available at all pharmacies providing COVID-19 immunization (including off-site and alternate locations). For the publicly funded COVID-19 vaccine, the AEFI form should be submitted to the local public health office within 24 hours of the adverse event, so that the Saskatchewan Health Authority (SHA) Medical Health Officer can provide recommendations. The AEFI form is to be used for both AEFI & AESI reporting. SCPP Requirement: Administration by Injection Section 5.3.	Pharmacy manager to ensure the pharmacy creates and maintains a policy and procedures manual that includes administration of drugs and Emergency response protocols as well as maintains an anaphylaxis management kit that is not past its expiry date. Other Resources: Canadian Immunization Guide: Management of Anaphylaxis Protocols and Anaphylaxis Management Kits: Recommended Items. Saskatchewan Immunization Manual: Ch. 12 – Management of Anaphylaxis
Provide Patient with After-Care Information	All COVID-19 Immunizers	Provide appropriate after-care information materials to patient as specified by the pharmacist (e.g. Pfizer BioNTech or Moderna After Care Sheet)	As directed by public health officials as it becomes available. SCPP: The licensed pharmacist with AMC must ensure the patient understands after-care instructions (e.g., importance of receiving a second dose, when and how to receive it).	Due to the evolving nature of the health system response to the COVID-19 pandemic, pharmacy managers must monitor communications from the SCPP and public health officials to ensure that the pharmacy is providing the after-care as required by the COVID Immunization Plan.

COVID-19 Immunizers FAQs Page 21 of 27

DOCUMENTATION, NOTIFICATION, REPORTING

Information Management/Flow Critical for Continued Patient Care

Accurate and up-to-date documentation, reporting and notification is critical to ensuring that pharmacists, primary care practitioners and public health officials are making decisions based on the most up-to-date information for individual patients and the Saskatchewan public.

Information requirements come from the SCPP to implement the regulatory bylaws, and from the federal and provincial ministries of health and or the SHA as part of the Saskatchewan COVID-19 Immunization Delivery Plan. They include:

- 1. Information for the Patient (Patient Immunization Record);
- 2. Information for the Patient's Primary Care Provider;
- 3. Information for the Ministries of Health (Federal and Provincial)/SHA; and
- 4. Information for the Pharmacy Team and Records.

The following section is intended to help pharmacy managers ensure that processes are in place to support the pharmacists and other pharmacy discipline COVID-19 Immunizers to meet the critical information requirements for regular operations as well as those of the COVID-19 Immunization Delivery Plan.

6) What documentation, notification and reporting is required?

COVID-19 immunizations, given at a community pharmacy, will be captured during the adjudication process and sent automatically to Panorama. This will make the record of COVID-19 vaccination available to patients, primary care providers, the SHA and the Ministry of Health. For this reason, it is critical that this information be accurate and submitted daily.

(Please check DPEBB COVID-19 Immunization Program <u>website</u> frequently for the most current information and updates).

a) Information for the Patient (Patient Immunization Record)

A pharmacist who administers a vaccine must provide the patient with a Record of Immunization Card. (Administration by Injection 5.2.1. and 5.2.3.)

 As with other publicly funded vaccines, the Ministry will specify the form which must be used for the COVID-19 vaccine (e.g. <u>Record of COVID-19 Immunization Wallet Card</u>).
 Please monitor the DPEBB COVID-19 Immunization Program <u>website</u> for most current information.

b) Information for the Patient's Primary Care Provider

- A pharmacist who administers a drug must report all drug administration details to the
 patient's primary care provider. This can occur via documentation provided directly to the
 prescriber or through a provincial electronic database intended for this purpose (<u>SCPP</u>
 <u>Bylaws Part L</u>)
- The record of COVID-19 vaccinations will be available to primary care providers through the eHR Viewer. Therefore, a fax or manual notification to the primary care provider is not needed. Primary care providers may contact the pharmacy if they require more administration details (e.g. Lot #, etc.) than what is contained in eHR Viewer.

c) Information for the Ministries of Health (Federal and Provincial)/SHA

As with other publicly funded vaccines, the Ministry will specify information required from community pharmacies. For the COVID-19 vaccine this includes:

- Tracking and reporting vaccine inventory (e.g. doses received, administered, wasted)
 in timeframe and platform specified by the Ministry.
 - See <u>DPEBB Bulletin No. 760 Recording Vaccine Inventory in the Vaccine Distribution Tracking System (VDTS)</u>.
- Track and enter immunizations provided to health care workers and other populations specified by the Ministry. Note: this must be done before the claim is billed to DPEBB.
 - See <u>DPEBB Bulletin No. 761 COVID-19 Vaccine and COVID-19 Immunization Fee Claims Procedure</u> for more information. Also review the DPEBB's COVID-19 Immunization Program Policy document and the Vaccine Risk Factor Portal-User Guide at https://formulary.drugplan.ehealthsask.ca/COVIDImmunizationProgram.
- Any other information that may be identified as the <u>vaccine delivery phases</u> roll out.
- Report serious adverse events following immunization (AEFI and AESI) to public health and provide follow up communication to the patient as specified in the <u>DPEBB</u> COVID-19 Immunization Policy.
- Also note that the COVID-19 Vaccine requires additional reporting Adverse Events of Special Interest. (See <u>Memo from Chief Medical Health Officer</u>).
 - (Note: See <u>Administration by Injection Section 5.3.</u> for federal AEFI reporting requirements for publicly-funded, non-publicly funded vaccines or other drugs).
- Record retention for COVID-19 Immunization Delivery Plan is a minimum of 7 years.

d) Information for the Pharmacy Team and Records

- Emergency enabled COVID-19 Immunizers must document their name, designation and certification and the name of the licensed pharmacist with AMC supervising the injection. (See medSask COVID Vaccine Screening and Consent Form as a resource).
- Regular requirements see <u>Part L Section 7</u> SCPP Bylaws and the textbox below.

SCPP Status Quo Record Keeping for Administration of a Drug (Vaccine)

SCPP Regulatory Bylaws Part L Section 7 excerpt:

Record Keeping

- 7 A licensed pharmacist who administers a drug to a patient must make and retain a record in the pharmacy of the following:
- (a) patient's name and address;
- (b) 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) name of the licensed pharmacist administering the drug;
- (f) date and time of administration;
- (g) any adverse events; and
- (h) price, if there is a charge for administration.

See <u>Administration by Injection Documentation FAQs</u> for additional information to be obtained and retained (e.g. informed consent, patient history and immunization record, notification to primary care provider, serious adverse events) and see <u>Summary of Record Keeping Requirements</u>.

7) What are the liability risks for COVID-19 Immunizers in the pharmacy disciplines?

Disclaimer

The following is intended to provide you with background information and questions to ask your employer and insurance provider to confirm coverage details.

Every insurance policy is different and liability coverage depends on the policy details. SCPP encourages you to speak to your insurance provider and employer regarding the interplay between:

- Your own personal malpractice insurance (if applicable);
- The immunity clause within The Public Health Act; and
- Your employer or workplace liability insurance.

SCPP is not an insurance provider and therefore cannot confirm coverage details.

Your liability risks may be impacted by your personal malpractice insurance, your employer's insurance, and other variables such as:

- The authority under which you are performing the task (i.e. *The Pharmacy and Pharmacy Disciplines Act* and *SCPP Regulatory Bylaws* and/or *The Disease Control Regulations*);
- Whether the activity or task is part of your regular scope of practice or whether it has been enabled through Emergency provisions (e.g. formerly licensed member, temporary licensed pharmacists, pharmacy technicians injecting);
- · Your category of licensure; and
- The setting where you are performing the activity or task and whether it is a retail pharmacy setting or publicly-operated (federal or provincial), such as Indigenous Services Canada or the SHA.

Every insurance policy is different and the SCPP encourages you to consult with your insurance provider to confirm coverage details in light of the variables listed above. The SCPP also encourages you to speak with your employer to confirm how the workplace liability coverage may apply to you and the role you are performing (e.g., supervising those performing activities under Emergency-enabled provisions, or performing activities outside of your regular scope enabled under Emergency provisions).

Licensed pharmacists and pharmacy technicians carrying out activities under the authority of *The Pharmacy and Pharmacy Disciplines Act and the* SCPP Regulatory Bylaws, are covered under their professional malpractice insurance providing that they are performing within their scope of practice and competencies, under the conditions and standards of practice established by SCPP.

Anyone participating as an Immunizer in the Saskatchewan COVID-19 Immunization Delivery Plan, under the authority of *The Disease Control Regulations*, are covered under the immunity provisions in *The Public Health Act, 1994* when acting in good faith while carrying out their duties within the terms and conditions specified in the COVID-19 Immunization Delivery Plan.

Even though the COVID-19 Immunization Delivery Plan holds employers responsible to ensure that the competency requirements are met for COVID-19 Immunizers, the SCPP has taken steps to help former, current and future pharmacy professionals minimize the liability risks. The SCPP has approved training programs based on its competency requirements for administration by injection (See COVID-19 Immunizer Requirements and NAPRA approved competencies), and has clarified scope of practice and other expectations in this document.

Following are some additional suggestions from the SCPP:

Licensed pharmacists:

• Fully Licensed Pharmacists - who are practicing within their regular scope of practice under the terms and conditions specified by the SCPP (e.g. no condition A on license) and in accordance with the Saskatchewan COVID-19 Immunization Delivery Plan are covered through their malpractice insurance.

However, it is recommended that they confirm with their insurance provider how their insurance and the immunity clause in *The Public Health Act*, would cover them in their roles as **a pharmacist supervising Emergency enabled Immunizers** under the COVID-19 Immunization Delivery Plan.

It is also recommended that they check with their employer to confirm how the workplace liability coverage would apply to them as supervisors whether it be carried out in the SHA or the community pharmacy setting.

• Conditionally Licensed Pharmacists – are covered by their personal malpractice insurance and are covered if practicing within their regular scope of practice under the terms and conditions specified by the SCPP (e.g. no A on license and with supervision).

The SCPP recommends that the supervising pharmacist and employer also confirm coverage details for the workplace setting.

Temporary Licensed Pharmacists – as a condition of licensure these pharmacists must
carry their own professional liability insurance and it would cover them so long as they were
practicing within their scope of practice and other terms and conditions specified by the
SCPP and the COVID-19 Immunization Delivery Plan. However, the SCPP recommends
that they confirm this with their insurance provider, and also check with their supervisor and
employer should they have questions about coverage details for the workplace setting.

Licensed pharmacy technicians - Pharmacy technicians would be covered by their own malpractice insurance, when carrying out their regular scope of practice.

However, the SCPP encourages them to confirm coverage details with their insurance provider, when they are performing tasks authorized under Emergency provisions and in accordance with the terms and conditions specified by the SCPP and the Saskatchewan COVID-19 Immunization Delivery Plan. For example, what is the impact of immunity clause in *The Public Health Act* vs their malpractice insurance vs obligations of the employer to deem them competent and provide a collaborative team environment.

Pharmacist Interns - Pharmacist interns (extended interns and students) are not authorized under *The Pharmacy and Pharmacy Disciplines Act* to administer by injection under supervision or delegation in normal circumstances.

Given that pharmacist interns are participating in the COVID-19 Immunization Delivery Plan and enabled through Emergency provisions, it is expected that they would be practicing under the supervisor's malpractice insurance and the immunity clause under *The Public Health Act*. The

SCPP encourages all pharmacist interns to speak with their supervisor and their employer to confirm coverage details, if they are hired on as a COVID-19 Immunizer.

Student interns who are immunizing within the experiential learning placement may want to contact their program at the University of Saskatchewan with any questions or concerns.

The SCPP also expects supervising pharmacists and employers to speak with their respective insurance providers to confirm how their existing liability coverage (i.e. malpractice and workplace insurance) would be extended to pharmacist interns in light of the immunity clause under *The Public Health Act* and the obligations of the employer under the COVID-19 Immunization Delivery Plan.

Formerly Licensed Pharmacist – covered under the immunity clause of *The Public Health Act* and/or the malpractice insurance of the supervising regulated health professional. The SCPP strongly recommends that they speak with their supervising pharmacists to confirm coverage details, and with their employer to confirm coverage that may be in place under the workplace liability insurance.

Non-Pharmacy Disciplines COVID-19 Immunizers – Regulated health professionals may be covered under own malpractice insurance and/or the immunity clause of *The Public Health Act*, subject to confirmation with their insurance provider. Non-regulated COVID-19 Immunizers may be covered under immunity clause of *The Public Health Act*.

The SCPP recommends that supervising pharmacists and employers confirm coverage details with their respective insurance providers.

Employers – employers should contact their own liability insurance provider and/or legal counsel to discuss possible liability and other legal implications.