

OFF-SITE POLICY FOR COVID-19 VACCINE FOR GROUP ADMINISTRATION BY PHARMACIES

As Alberta continues to work towards achieving an immunization goal of at least 70% of all eligible Albertans being fully immunized as soon as possible, there has been an increasing number of requests from pharmacies and individual Albertans to facilitate the provision of COVID-19 vaccines off-site. This is particularly critical for rural communities where individuals may not be able to readily access Alberta Health Services Immunization Clinics or a community pharmacy.

The provision of COVID-19 vaccine off-site from a community pharmacy may be considered for any of the following scenarios;

1. Employer Groups seeking immunization services for their employees at a worksite or other location.
2. Community Groups seeking immunization services for their members in a community facility.
3. Pre-Filled Syringes (PFS) for single use for small groups (up to 5 individuals) as previously addressed in policy.

When considering provision of off-site immunization services, planning and operationalization should focus on the scope and quantity of expected individuals requesting immunization.

When operationalized, temporary off-site immunization clinics can maximize the capacity of all partners and increase immunization access to Albertans as they allow:

- The health care system to collaborate and connect with individuals that may be hard to reach, be hesitant to receiving the vaccine or have other barriers (e.g. lack of trust in government, transportation issues, language barriers.) that impede their ability to access immunization services.
- Access to groups of individuals over a short time-period in one location.
- Intervention at specific facilities or workplaces where outbreaks are occurring or where there may be regional or community hotspots.

Mandatory Requirements

The following guidelines **MUST** be adhered to for any off-site immunization. The safety of Albertans and the integrity of vaccine are of the utmost importance.

- This policy addresses the movement of **COVID-19 mRNA vaccine vials**.
- Any COVID-19 vaccine that has been constantly maintained in a **frozen state** and has never been thawed or in a thawing state **may be moved again as long as it remains in a frozen state**.
- Any COVID-19 vaccine that has been **thawed or in a thawing state** can only be moved **THREE times**, and total transportation time can be no longer than **10 hours** in total.
 - For example, in a thawing/thawed state, three moves would be;
 - 1 - transport from the pharmacy wholesale distributor to the pharmacy
 - 2 - pharmacy to the off-site clinic
 - 3 – off-site clinic back to pharmacy.
 - If the vaccine was removed from frozen and it took 6 hours to be shipped from the wholesale distributor to the pharmacy, then there are 4 hours available for transportation to an off-site clinic and return to the pharmacy.
- The transported vaccine must be labelled “transported thawing/thawed” and the total time in transportation must be tracked on the external container and in a temperature log.
- **Do not transport vials that have been diluted/reconstituted or punctured. Diluted/reconstituted or punctured vials leftover after the off-site clinic must be wasted.**
- Maintenance of cold chain with temperature monitoring devices (TMD) **MUST** be maintained at all times for any vaccine moved off-site. Documentation and maintenance of a temperature log is **mandatory** and these records must be kept for 3 years.
- ALL public health guidelines in effect at the time of the off-site immunization clinic (i.e. masking, social distancing, building capacity, etc.) **must** be adhered to at all times.
- **There must be one responsible individual assigned** who is the key contact for the off-site immunization and is responsible for ensuring all requirements are met before, during and after the off-site immunization. This includes daily AVI reconciliation and Alberta Blue Cross (ABC) claim submissions. **The responsible individual must be either a pharmacist or regulated pharmacy technician.**

It is critical that prior to conducting any immunization, including off-site immunizations, pharmacy partners review the requirements in the ACIP and ACPIP by reviewing the most current versions posted by Alberta Health.

[Alberta COVID-19 Immunization Policy \(ACIP\)](#)

[Alberta COVID-19 Pharmacy Immunization Program \(ACPIP\)](#)

COVID-19 Vaccine Reporting and Data Requirements

All requirements in the [Alberta Immunization Regulation](#) as well as the ACIP and ACPIP related to immunization reporting, adverse event reporting, cold chain breaks, AVI reconciliation and others **MUST** be adhered to for any off-site immunization.

- NETCARE/ImmARI reporting access is readily available to confirm immunization history and to pre-screen eligibility for individuals.
- Ensure individuals have valid Alberta Health Care, if not refer to AHS for immunization services.
- Ensure vaccine temperature monitoring is documented regularly throughout the duration of the clinic, and that cold chain temperature is maintained until administration of the vaccine.
- Ensure appropriate documentation and reporting if an [Adverse Event Following Immunization \(AEFI\)](#) occurs.
- Immunization claims to be submitted to ABC to meet same day submission requirements.
- Alberta Vaccine Inventory (AVI) reporting and reconciliation to be submitted to AVI to meet same day requirements for reporting.
- Documented informed consent was collected in either print or electronic records.
- Providing a record of immunization for proof of immunization.

Off-Site Administration Vaccine Compensation

- Claims for the Assessment and Administration of COVID-19 Vaccine may be submitted to ABC as per the ACPIP guidelines when an off-site immunization is conducted.

Key Considerations

When considering the design and operationalization of an off-site immunization clinic for groups, it is important to address the following:

- **Client Eligibility:** Ensure that all individuals attending an off-site immunization clinic for groups have valid Alberta Health Care coverage and are eligible for immunization (i.e. temporary foreign workers, out of province, other)
- **Administration of Vaccine:** Vaccine may only be administered by practitioners who are authorized/enabled to do so.
- **Immunization Logistics:** Processes need to be in place for checking immunization records prior to booking appointments and immunizing off-site and all public health measures in place at that time must be adhered to (i.e. masking, social distancing, etc.).
- **Immunization Supplies/Materials:** Ensure that a complete and up-to-date anaphylaxis kit is on-hand at all times during the off-site immunization. Ensure there is appropriate ancillary supplies (i.e. PPE, diluent, syringes/needles, alcohol swabs, etc.) and information materials to support vaccine administration and education.

- **Vaccine Supply and Distribution:** Determine the quantity of vaccine required for the off-site clinic, where/when the vaccine is coming from, and how the vaccine will be transported to the off-site clinic location.
 - Ensure all vaccine doses are planned to be administered within 30 days once vaccine is removed from freezer for vials that have not been punctured.
- **Vaccine Storage and Handling:** Adhere to the policies and protocols for COVID-19 vaccine off-site for groups as well as the [Alberta Health Vaccine Storage and Handling for COVID-19 Vaccine](#) policy, determine how the vaccine is to be stored in cold-chain to remain viable off-site, and what temperature monitoring system will be utilized.
- **Vaccine Wastage Mitigation Strategies:** Ensure that only the required number of doses are transported to the off-site location. Extra vaccine should not be transported, only the minimum needed to immunize confirmed individuals. Establish a plan if there are fewer than expected individuals who come for immunization, so that excess vaccine is managed given that it cannot be moved again.
- **Special Considerations for Group/Employer Specific Clinics:**
 - Determine if the group or employer successfully sponsored previous immunization clinics.
 - Determine if the organization implemented other strategies to enhance worker or population uptake of vaccine (i.e., arranged block booking, provided time off, transportation, worked with local immunizer).
- **Establish a plan for the off-site immunization to be repeated to support second dose administration (if required).**

Physical Environment

Establishing an off-site immunization clinic away from the pharmacy requires consideration of the physical set-up and surrounding areas.

- Queue management ensuring social distancing pre and post immunization.
- Security.
- Waste Management for personal protective equipment (PPE), injection supplies (i.e. needles/syringes), other waste generated and the proper disposal thereof.
- A private space to accommodate the set-up and administration of the vaccines, including:
 - Internet access;
 - Access to power outlet(s);
 - Printer access;
 - Registration table and chairs;
 - Appropriate area to allocate for individuals waiting to be vaccinated;
 - Required furniture for immunization station(s), including tables and chairs;
 - Appropriate area and adequate spacing for individuals waiting 15-minutes following immunization;
 - Appropriate space for storing vaccine and handling equipment
 - Appropriate temperature monitoring devices.

COVID-19 Vaccine for Off-Site Group Immunization– Policy and Protocols

Packaging and Transport of Vials of COVID-19 Vaccine

To ensure vaccine viability, you must select a suitable storage option for off-site immunizations. Vaccine carriers, portable storage units, hard-sided insulated or Styrofoam container(s) are all options. A soft-sided container can also be considered if it is a qualified container or packout.

A thick barrier (at least 1 inch) of bubble wrap or corrugated cardboard box may be utilized as a barrier between the transport container cooling agent (frozen gel pack, ice packs, etc.), and the container with COVID-19 vaccine vials. This is to prevent direct contact vials of vaccine and the cooling agent that may cause the vaccine to freeze or deviate from appropriate cold chain.

Wrap the vials of vaccine in preconditioned bubble wrap, cardboard or other material in a manner that would minimize any vibration or shock to the vaccine. The temperature monitoring device probe must be placed with the vaccine and not by the cooling agent.

Transport vaccine at a temperature between 2°C to 8°C, with constant temperature monitoring by a digital TMD that can be read without opening the transport container.

The temperature in the transport container will be recorded every time the transport container is opened and/or at least three times a day.

The immunizer/transporter must be aware of their role in maintaining the cold chain.

- The temperature within the vehicle should not be outside room temperature 15°C to 20°C and minimizes movement of the vaccine.
- Implement special precautions to prevent excessive movement/“jostling” of the vaccine including conducting ground transport on paved or smooth gravel/dirt roads.
- The vaccine will be handled with care to avoid shocks, drops and vibration as much as possible.
- The vaccine will not be exposed to extreme heat or cold during transport.
- Vaccine in insulated transport containers should be placed in the area of the vehicle that maintains room temperature, i.e. not the trunk of the car.
- The vaccine can be transported from the pharmacy to the immunization site and should not be left unattended at any time.

Discard any remaining vaccine in open vials at the end of the workday as they cannot be transported back to the pharmacy.

Never transfer prefilled or reconstituted vaccine back into a vial for storage.



Examples of approved barrier boxes, wrapping/cushioning for vials of vaccine, and temperature monitoring device to be packed directly with vials of vaccine. The packed barrier box containing the temperature monitoring device and vials of vaccine would then be placed in the larger transport box with the cooling agent.