



Saskatchewan Influenza Immunization Policy 2018 – 2019

Revised July 2018

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The Saskatchewan Influenza Immunization Policy format is adapted, with permission, from Alberta Health's Influenza Immunization Policy.

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ACRONYMS

| | | | |
|-------|---|-------------|--|
| AHA | Athabasca Health Authority | PHB | Population Health Branch |
| AEFI | Adverse Events Following Immunization | PIP | Pharmaceutical Information Program |
| CCB | Cold Chain Break | PVD | Provincial Vaccine Depot |
| CMHO | Chief Medical Health Officer | PWD | Pharmacy Wholesale Distributor |
| DPEBB | Drug Plan and Extended Benefits Branch | PWGSC /PSPC | Public Works and Government Services Canada/Public Services and Procurement Canada (same entity) |
| FNJ | First Nations Jurisdiction | QIV | Quadrivalent inactivated influenza vaccine |
| GBS | Guillain Barré Syndrome | RRPL | Roy Romanow Provincial Laboratory |
| HSN | Health Services Number | SHA | Saskatchewan Health Authority |
| HCW | Healthcare Worker | SIIP | Saskatchewan Influenza Immunization Policy |
| LTC | Long-term Care | SIM | Saskatchewan Immunization Manual |
| MHO | Medical Health Officer | TIV | Trivalent inactivated influenza vaccine |
| NACI | National Advisory Committee on Immunization | VSWG | Vaccine Supply Working Group |
| ORS | Oculorespiratory Syndrome | | |

DEFINITIONS

(For the purposes of this document)

| | |
|--------------------------------------|--|
| Client | Individuals six months of age and older who present for publicly funded influenza vaccine. |
| Cold Chain Management | The process used to maintain optimal temperature and light conditions during the transport, storage, and handling of vaccines. This starts at the manufacturer and ends with the administration of the vaccine to the client. |
| Congregate Living Settings | For the purpose of publicly funded influenza vaccine administration, Congregate Living Settings are defined as for profit or not for profit public or privately owned buildings, which may or may not be licensed by the Government of Saskatchewan. These settings do not receive contracted or ongoing services from public health or other Athabasca Health Authority (AHA), Saskatchewan Health Authority (SHA), or First Nations Jurisdictions (FNJs) health practitioners and have no operational affiliation to the AHA, SHA, or FNJ (i.e. are not an AHA, SHA, FNJ or Affiliate facility). Examples of congregate living settings in Saskatchewan include private seniors' apartment buildings, personal care homes, Approved Private Service Homes (APSHs), assisted living facilities and group homes. |
| First Nations Jurisdictions | Includes the communities and organizations affiliated with First Nations and Inuit Health Branch (FNIHB) and the Northern Inter-Tribal Health Authority (NITHA). |
| Healthcare worker | Healthcare workers (HCWs) are those employed by the SHA, AHA, and FNJ facilities or affiliated facilities and does not include volunteers, students or physicians. |
| Health Services Number | The unique identifier assigned by Saskatchewan Health for identification within Saskatchewan's health system. A Health Services Number (HSN) is assigned to a person upon registration and presumes eligibility for basic health services as defined by Saskatchewan Health. |
| Panorama | The electronic integrated public health information system utilized by AHA and SHA public health providers and community nursing providers in some FNJs. |
| Panorama Immunization Module | A module within Panorama that provides a record of all immunizations administered by public health. It serves as the electronic registry for immunization in Saskatchewan. |
| Panorama Inventory Module | A module within Panorama that tracks publicly funded vaccine use and availability. It supports management of vaccine ordering, shipping, receiving and reconciliation. |
| Pharmacy Association of Saskatchewan | The association that represents pharmacists and pharmacies in Saskatchewan. |
| Pharmaceutical Information Program | The Pharmaceutical Information Program (PIP) is a secure computer application that provides health care providers information regarding prescriptions dispensed in Saskatchewan community pharmacies. |

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| Pharmacy Wholesale Distributors | A pharmacy wholesale distributor that has an agreement with the Saskatchewan Ministry of Health for the distribution of publicly funded influenza vaccine to pharmacists. |
| Privately Purchased Influenza Vaccine | Influenza vaccine purchased by pharmacies or prescribed by physicians or RN(NP)s and paid for by the client. |
| Provincial Vaccine Depot | The provincial vaccine depot is housed in the Roy Romanow Provincial Laboratory (RRPL). Publicly funded influenza vaccine is received through the RRPL Provincial Vaccine Depot for further distribution across Saskatchewan. |
| Saskatchewan College of Pharmacy Professionals | The self-governing body for the profession of pharmacy in Saskatchewan that regulates pharmacists, pharmacies, pharmacy technicians and drugs. |
| Saskatchewan Influenza Immunization Program | The publicly funded seasonal influenza program delivered via the SIIP. It typically begins in October and ends March 31. |
| Saskatchewan Immunization Manual | The primary immunization resource for public health personnel and other health care providers, health care students and post-secondary institutions in the province, the Saskatchewan Immunization Manual (SIM) provides evidence-based and standardized immunization-related information. |
| Vaccine Management | The processes used to maintain optimal temperature and light conditions during the transport, storage, and handling of vaccines. |
| Vaccine Provider | A licensed healthcare provider to whom provision of vaccine is permitted by legislation governing that provider, are in compliance with the SIIP; and meet one of the following criteria: <ul style="list-style-type: none"> • designated by the SHA, AHA and FNJs, and their affiliates, to provide influenza vaccine services; • physicians; • community pharmacists; and/or, • designated by the Facilities/Institutions that receive publicly funded influenza vaccine procured by the Ministry of Health. |

UPDATES FOR THE 2018-2019 INFLUENZA SEASON

Public Launch:

The Saskatchewan Influenza Immunization Program begins **October 22, 2018**. The administration of publicly funded influenza vaccine commences on this date.

Publicly Funded Vaccine Products:

- FLUZONE® and FluLaval Tetra® (quadrivalent) multidose vials for all immunizers.
- FLUZONE® (quadrivalent) thimerosal-free pre-filled syringes available to public health within the Saskatchewan Health Authority (SHA), Athabasca Health Authority (AHA) and First Nations Jurisdictions (FNJs).
- FLUZONE® High Dose (trivalent) for long-term care (LTC) facility residents 65 years and older.

Pharmacist Provision of Publicly Funded Influenza Vaccine:

The Pharmacy and Pharmacy Disciplines Act (Bill 151) proclaimed October 5, 2015, enables certified pharmacists to administer drugs by injection and other routes. A statement from Saskatchewan's Chief Medical Health Officer will permit pharmacists to administer publicly funded influenza vaccine to clients age five years and older, during home visits and in congregate living settings commencing in the 2018-19 influenza season.

Documentation Requirements:

All non-public health vaccine providers are required to report immunization details for children younger than nine years of age to public health for entry into Panorama; see [Section XIII. Reporting Requirements](#) for specific details.

Publicly funded influenza vaccines entered into Panorama must identify the provider "type" (e.g. public health, physician, registered nurse (RN), nurse practitioner (RN(NP)), pharmacist).

Vaccine Inventory for SHA, AHA and FNJs

- From October 22 to December 31, 2018, weekly vaccine counts for the previous Sunday to Saturday period are required to be reconciled in the Panorama Inventory Module by noon the following Tuesday . The first inventory count is due on Tuesday October 30, 2018.
- From January 1, 2019 to March 31, 2019, monthly vaccine counts are required.
- Timelines and frequency for vaccine inventory monitoring are subject to change by the Ministry of Health. More frequent inventory monitoring may be required.
- Inventory information must be accurate. The SHA, AHA and FNJs must ensure that staff members are appropriately trained and compliant with ensuring the Panorama Inventory Module is up-to-date as per timelines outlined above.
- It is strongly recommended that the 'pick/pack/ship' function of Panorama be utilized to move vaccines in/out of vaccine inventories so that vaccine counts remain accurate.

Vaccine Inventory for Pharmacists

- The inventory reporting process is coordinated by the Drug Plan and Extended Benefits Branch (DPEBB) using weekly reports from the Pharmacy Wholesale Distributor (PWD) for the quantity of vaccine ordered and shipped to pharmacies, and from the DPEBB claims database for the number of vaccine doses administered by pharmacists.

I. PURPOSE

Influenza is a vaccine-preventable disease. The elderly, the very young, pregnant women and those living with chronic or immune-compromising conditions are particularly vulnerable.

The Saskatchewan Influenza Immunization Program has two objectives:

1. Provide access to publicly funded influenza vaccine for Saskatchewan residents.
2. Reduce the incidence and impact of influenza disease in Saskatchewan.

All vaccine providers must work together to implement the SIIP. Collaboration, coordination and communication amongst immunizers during all phases of the program (from vaccine distribution to front line administration) strengthen Saskatchewan's capacity to reduce the impact of influenza disease and contribute to the health and well-being of Saskatchewan residents.

II. LEGISLATIVE AUTHORITY

The SIIP is established under *The Public Health Act, 1994*.

III. NATIONAL RECOMMENDATIONS

The National Advisory on Immunization (NACI) produces an annual influenza statement that contains specific information and recommendations regarding the licensed vaccines for the forthcoming season <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html>. The Ministry of Health references the NACI recommendations to inform our annual planning and makes final policy recommendations with consideration to Saskatchewan's context.

IV. INFLUENZA PROGRAM DATES

- The provincial publicly funded influenza program is scheduled to begin on October 22, 2018 and end on March 31, 2019. Children younger than age nine requiring a second dose of vaccine can receive immunization until April 30, 2019.
- To ensure uniform access to publicly funded influenza vaccine in Saskatchewan, all vaccine providers are asked to comply with the provincial start date.
- Vaccine providers should schedule the administration of influenza vaccine as of October 22, 2018 onwards with the priority groups being those at high-risk of influenza-related complications.
- Consultation with the Chief Medical Health Officer (CMHO) is required if requests are received for earlier start dates. For example, during an outbreak in a licensed facility, immunization may be permitted to start earlier in that facility pending discussion with the CMHO.
- An extension to the influenza vaccine administration season may be established by the CMHO in the event of increased disease presence or severe morbidity with influenza disease.

V. CLIENT ELIGIBILITY

Saskatchewan's universal influenza immunization program began in September 2009. Individuals six months of age and older who do not have contraindications are eligible to receive publicly funded influenza vaccine (**see Table 1**). Particular groups are highly recommended to receive the vaccine to reduce the incidence and burden of influenza disease and related health complications. As the program aims to reach priority populations most at risk of complications from influenza, publicly funded influenza vaccine is provided to the SHA, AHA, FNJs, as well as physicians, community pharmacists and certain facilities/institutions providing health care services to these target populations. Publicly funded influenza vaccine is not provided to for-profit occupational health and safety companies. Exceptions may be considered in consultation with the Saskatchewan Ministry of Health and CMHO in the event of increased disease presence or severe morbidity related to influenza.

It is expected that vaccine providers confirm client eligibility to receive vaccine prior to administration. Confirmation may be obtained by reviewing the client's paper documentation and/or record within Panorama, the Pharmaceutical Information Program (PIP) and the eHR Viewer.

Table 1: Populations for Whom Influenza Vaccination is Particularly Recommended

Publicly funded influenza vaccines may be administered to people who are six months of age and older who do not have vaccine contraindications. In particular, the following people are highly recommended to receive the influenza vaccine to reduce the incidence and burden of influenza disease and related health complications:

- All HCWs, health care students, emergency response workers, visitors and volunteers who, through their activities, are capable of transmitting influenza to those at high-risk of influenza complications in independent practices, facilities, residences and community settings.
- Adults (including pregnant women) and children ≥ 6 months with a chronic health condition including but not limited to:
 - cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis & asthma);
 - diabetes mellitus and other metabolic diseases;
 - cancer and other immune-compromising conditions (due to underlying disease, therapy or both);
 - renal disease;
 - anemia or hemoglobinopathies;
 - neurologic or neurodevelopment conditions (includes neuromuscular, neurovascular, neurodegenerative, neurodevelopmental disorders and seizure disorders (and for children include febrile seizures and isolated developmental delay) but excludes migraine and psychiatric conditions without neurological conditions
 - morbid obesity (adult BMI ≥ 40 , child BMI assessed as $\geq 95^{\text{th}}$ percentile adjusted for sex and age)
- Children and adolescents with the following conditions:
 - Those undergoing treatment for long periods with acetylsalicylic acid, because of the potential increase of Reye syndrome associated with influenza.
- People of any age who are residents of nursing homes, long-term care facilities and other chronic care facilities.
- People ≥ 65 years of age.
- All children six to 59 months of age (younger than five years).
- Indigenous peoples.
- Visitors to health care facilities and other patient care locations.
- Household and close contacts of individuals at high-risk of influenza-related complications whether or not the individual at high-risk has been immunized.
- Household and close contacts of infants less than six months of age.
- Members of households who are expecting a newborn during the influenza season.
- Those providing regular child care to children ≤ 59 months of age, whether in or out of the home.
- Those who provide services within closed or relatively closed settings to persons at high-risk.
- People who provide essential community services (e.g., provincial corrections staff who have direct contact with inmates).
- People in direct contact during culling operations with poultry infected with avian influenza.
- People working with live or dead poultry or swine.
- Health sciences students (human and animal health).
- Travellers - Influenza occurs year-round in the tropics. In temperate northern and southern countries, influenza activity peaks generally during the winter season (November to March in the Northern Hemisphere and April to October in the Southern Hemisphere).

VI. EDUCATION/TRAINING

Vaccine Information

- **FLUZONE® Quadrivalent (QIV)** and **FluLaval® Tetra** (quadrivalent multidose vials for all immunizers) and **FLUZONE® Quadrivalent** thimerosal free pre-filled syringes (SHA, AHA and FNJ public health only) are publicly funded for those six months of age and older and contain the following viral strains:
 - an A/Michigan/45/2015 (H1N1)pdm09-like virus;
 - an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus;
 - a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage); and
 - a B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage).
- **FLUZONE® High-Dose** (trivalent thimerosal-free pre-filled syringes) is publicly funded for LTC facility residents 65 years and older and contains the following viral strains:
 - an A/Michigan/45/2015 (H1N1)pdm09-like virus;
 - an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus; and
 - a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage).
- These vaccines are safe for use in persons with latex allergy.
- Fluzone® Quadrivalent thimerosal free pre-filled syringes are prioritized for people who self-identify as having a diagnosed thimerosal allergy (documentation is not required). It may be administered to others who request it. It is only available to public health; other vaccine providers can refer clients requesting thimerosal free vaccine to public health for administration.
- These vaccines may be given concomitantly with, or at any time before or after, live attenuated vaccines or inactivated vaccines.
- The Ministry of Health does not reimburse the cost of privately-purchased influenza vaccines.
- See **Appendix 1: 2018-19 Publicly Funded Influenza Vaccines** for vaccine specific information.

All providers of publicly funded influenza vaccine are responsible for reviewing the SIIP and other influenza-related materials prior to the start of the influenza vaccine administration season. This may include completion of an employer-mandated education session.

With the support of the Ministry of Health, the Saskatchewan College of Pharmacy Professionals and the Continuing Professional Development for Pharmacy Professionals (CPDPP), the College of Pharmacy and Nutrition, University of Saskatchewan, developed the *Advanced Method Certification Requirements – Injection certification for pharmacists*. Pharmacists are required to complete the injection certification training prior to administering vaccine.

<https://www.usask.ca/cpdpp/continuing-education-/imtraining.php#ImmunizationandInjections>

Additional influenza vaccine resources include (but are not limited to):

- Saskatchewan Immunization Manual: <https://www.ehealthsask.ca/services/Manuals/Pages/SIM.aspx>
- Saskatchewan Influenza Fact Sheets: <http://www.saskatchewan.ca/residents/health/accessing-health-care-services/immunization-services#immunization-forms-and-fact-sheets>
- The NACI 2018-19 influenza vaccine statement available at <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html>

Precautions and Contraindications

- Previous anaphylaxis to an influenza vaccine is a contraindication to receiving influenza vaccine.
- Persons who had an anaphylactic reaction to a previous influenza vaccine dose or to any of components in a specific vaccine (with the exception of egg), or who developed Guillain-Barré Syndrome (GBS) within six weeks of a live or inactivated influenza vaccination, should not receive further doses of any influenza vaccines.

- Vaccine administration should usually be postponed in persons with serious acute illnesses until their symptoms have abated. Immunization should not be delayed because of minor acute illness, with or without fever.
- As with all vaccine administration, immunizers must have the necessary equipment and medications to be prepared to respond to a vaccine emergency at all times.
- Egg-allergic individuals can receive a full dose of an injectable influenza vaccine without prior influenza vaccine skin testing, including those who have experienced anaphylaxis due to egg ingestion, as a routine practice that is supported by NACI.
- The Ministry of Health recommends that when a decision is made to re-immunize those who have suffered a past severe allergic immunization reaction (**not anaphylaxis, as it is a contraindication**) related to an influenza vaccine or its components, these individuals should be vaccinated in a setting where appropriate expertise, equipment and medications to manage respiratory or cardiovascular compromise is available (as discussed with the Medical Health Officer [MHO]) and that they are observed post-immunization (e.g., minimum of 30 minutes).
- Oculorespiratory syndrome (ORS) is defined as the presence of bilateral red eyes **plus** one or more respiratory symptoms (cough, wheeze, chest tightness, difficulty breathing, difficulty swallowing, hoarseness or sore throat) that start within 24 hours of vaccination, with or without facial edema. ORS is **not** considered to be an allergic response. Persons who experienced ORS with lower respiratory tract symptoms should have an expert review. Health care providers who are unsure whether an individual previously experienced ORS versus an IgE-mediated hypersensitivity immune response should seek advice. Although the pathophysiologic mechanism underlying ORS remains unknown, it is considered distinct from an IgE-mediated allergic response.
- Persons who have a recurrence of ORS upon revaccination do not necessarily experience further episodes with future vaccinations. Data on clinically significant adverse events do not support the preference of one vaccine product over another when revaccinating those who have previously experienced ORS.

Table 2: Influenza Vaccine by Age and Dosage

| Age | Vaccine | Dosage (mL) | Number of doses required per season |
|--|--|-------------|-------------------------------------|
| 6 months to 8 years | QIV | 0.5 mL IM | 1 or 2 * |
| ≥9 years (excluding LTC residents ≥65 years) | QIV | 0.5 mL IM | 1 |
| LTC residents ≥65 years | TIV (FLUZONE® High-Dose) or (QIV if TIV unavailable) | 0.5 mL IM | 1 |

* Children six months to eight years of age (<9 years old) who have never received influenza vaccine require two doses, with a minimum interval of four weeks between doses.

- QIVs are considered interchangeable for children requiring two doses.
- The first time that a child younger than nine years old receives seasonal multivalent influenza vaccine, a two-dose schedule is required. This recommendation applies whether or not the child received monovalent pH1N1 vaccine in 2009-2010.
- QIV influenza vaccines will be available until April 30, 2019 to allow children who received their first dose on or prior to the March 31, 2019 program end date to receive their second dose.

Consent for Immunization

- All immunizations in Saskatchewan are voluntary and the appropriate Ministry of Health vaccine fact sheets must be provided to all clients. Fact sheets are posted at: <http://www.saskatchewan.ca/residents/health/accessing-health-care-services/immunization-services#immunization-forms-and-fact-sheets>. French versions are also available at this link.
- Post-immunization, all providers must provide clients with a *Ministry of Health Record of Influenza Immunization Wallet Card* bearing the name and date of immunization. (See **Picture 1: Ministry of Health Record of Influenza Immunization Wallet Car**)

Picture 1: Ministry of Health Record of Influenza Immunization Wallet Card

| | |
|--|---|
|   <p>RECORD OF INFLUENZA IMMUNIZATION</p> <p>Name: _____</p> <p>Immunization Date: _____</p> <p>Vaccine type: TIV QIV LAIV</p> <p>Date of 2nd Dose for Child:* _____</p> <p>HCW: Yes No Provider initials: _____</p> | <p>*NOTE: 2 doses are required for children younger than 9 years old who are getting immunized with influenza vaccine for the first time.</p> <p>Dose #2 appointment date: _____ YY/MM/DD</p> <ul style="list-style-type: none"> • Immunization Record App available at www.immunize.ca/en/app.aspx • For more information about Saskatchewan's immunization programs, go to: www.saskatchewan.ca/immunize • Pneumococcal 23 immunization date: _____ YY/MM/DD |
|--|---|

- *Record of Influenza Immunization* Wallet Cards will be provided by the SHA, AHA and FNJ public health to other vaccine providers who obtain their vaccine supply from public health. Community pharmacies can order these wallets cards free of charge through the Ministry of Health's Publication Centre website at <http://publications.gov.sk.ca/deplist.cfm?d=13&c=1073>.
- All individuals must be screened for contraindications prior to immunization.
- Influenza vaccine is safe and well-tolerated. Immunization providers should discuss with clients:
 - The risks and benefits of influenza vaccine, as well as the risks of not getting immunized.
 - Vaccination is the most effective way to prevent influenza and the spread of influenza viruses.
 - Each year there are new vaccine formulations to protect against the influenza virus strains that are expected in the coming influenza season. Even if the strains have not changed, getting influenza vaccine every year is necessary to maximize protection.

VII. VACCINE SUPPLY, DISTRIBUTION AND INVENTORY

The Ministry of Health purchases influenza vaccine through a national procurement process. The majority of influenza vaccine is received by the Provincial Vaccine Depot (PVD), located at the RRPL, from vaccine manufacturers over several months. The PVD distributes vaccine throughout the influenza season, balancing immunization provider demand for vaccine with vaccine supply and availability. Access to influenza vaccines supply is closely monitored.

The PVD ships influenza vaccine to:

1. The SHA, FNJ and AHA vaccine depots for further distribution to all public program vaccine providers, excluding community pharmacists. Vaccine orders are placed using the Panorama Inventory Module.
2. The Pharmacy Wholesale Distributors (PWDs) (e.g. McKesson Canada, Kohl & Frisch Ltd.) for distribution to community pharmacies.

Allocation for vaccine providers

The Ministry of Health has allocated vaccine quantity for the SHA, AHA, FNJs and community pharmacies based on the previous year's covered population and doses administered.

The provincial allocation plan supports vaccine providers in planning for influenza season with a focus on early uptake in the season. The Ministry of Health will have an unallocated reserve to provide additional support to areas where significant uptake and/or need occurs. The Ministry may also reallocate vaccine from the original provincial allocation as of December 1, 2018, depending on immunization provider supply needs throughout the influenza season.

Ordering threshold per order per day of QIV by community pharmacies is shown in **Table 3**. Requests for exemptions to the ordering thresholds may be considered by the Saskatchewan Ministry of Health DPEBB.

Table 3: Community Pharmacy Daily Ordering Thresholds

| Minimum order | Maximum order |
|---------------|---------------|
| 10 doses | 200 doses |

VIII. ADMINISTRATION OF VACCINE

- A. Occasionally, there may be an issue during vaccine administration to a client (e.g. vaccine leaks out during injection) resulting in less than a full 0.5 mL IM dose being administered. When this happens:
- With the client's consent, re-immunize them with a full dose in another limb, **or** in the same limb at least 2.5 cm from the last injection site.
 - Report the first dose on the wastage report, so that the dose is accounted for.

Note that pharmacists can only claim one Influenza Immunization Fee in this situation.

- B. Community pharmacists may administer publicly funded influenza vaccine only to clients five years of age and older. It is expected that PIP and the client's immunization record in the eHR Viewer be reviewed prior to vaccinating all clients but particularly children five to eight years of age.

Off-site delivery of influenza immunization must be coordinated with local public health offices in the SHA, AHA and FNJs by August 31st. Should local public health confirm that public health (or home care) services will be delivered in the site under consideration, community pharmacists are not permitted to proceed with delivery of influenza vaccine in that site unless the transfer of responsibility is agreed to by public health. Delivery to congregate living settings must further be coordinated by the community pharmacy with the facility.

For further information regarding off-site influenza immunization service delivery, including contact information for local public health offices; see **Appendix 2: Community Pharmacists Delivery of Publicly Funded Influenza Vaccine**.

IX. COLD CHAIN BREAK (CCB) Management

Appropriate storage and handling of vaccine is essential to provide safe and effective product to the public. Detailed requirements are outlined in the SIM, Chapter 9 – Management of Biological Products <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf>. All known exposures of influenza vaccine to temperatures outside of +2.0 – 8.0 degrees Celsius must be reported as soon as possible and within one business day of the occurrence. See **Appendix 3: Cold Chain Break Report form**.

Report all CCBs as follows:

Community Pharmacies:

- The individual discovering the CCB must complete the *Cold Chain Break Report form* <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf> 9 (see **Appendix 3**) and fax directly to the Ministry of Health at 306-787-3237. More information regarding completion of the form can be found in **Appendix 4: How to Complete the Cold Chain Break Report form** and at <http://formulary.drugplan.ehealthsask.ca/InfluenzaProgram.aspx>.

All other vaccine providers:

- The individual discovering the CCB must complete the *Cold Chain Break Report* form. <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf> 9 (see **Appendix 3**) and submit to the SHA, AHA or FNJ local area Immunization Coordinator or designate for review. Following review, and if deemed a CCB, the Form will then be faxed to the Ministry of Health at 306-787-3237. More information regarding completion of the Form can be found in **Appendix 4** and in the SIM Chapter 9. <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf> 9

Following review of the reported CCB, the Ministry will provide confirmation of whether the vaccine remains viable or should be wasted by the vaccine provider as outlined below.

X. Influenza Vaccine Wastage

In order to mitigate wastage at the end of the influenza season, a judicious approach to influenza vaccine ordering is required.

Ongoing Wastage Reporting for the SHA, AHA, FNJs, and Community Pharmacists:

All influenza vaccine that is wasted must be recorded on the *Product Wastage Report* form <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf> 9 (see **Appendix 5**) on a monthly basis and faxed by the 5th day of the following month to the Ministry of Health at 306-798-0071. Wasted influenza vaccines must be disposed of locally according to regional bio-medical waste policy and procedures.

Ongoing Wastage Reporting for all other Vaccine Providers:

All influenza vaccine that is wasted by other providers (e.g. physicians, nurse practitioners, other nursing offices) must be recorded on the *Product Wastage Report* form <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf> 9 (see **Appendix 5**) on a monthly basis and provided to your local public health office as per their direction and within their required timeframe.

Vaccine Problem Reporting for all Vaccine Providers:

If the vaccine wastage is due to a defective product, a *Vaccine Supply Problem Report* (<http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf>; see **Appendix 6: Vaccine Supply Problem Report**) must also accompany the *Product Wastage Report* form as outlined above.

End of Season Wastage Reporting for the SHA, AHA, FNJs, and Community Pharmacists:

The Ministry of Health will send direction to the SHA, AHA, FNJs, community pharmacies and pharmacy wholesale distributors as to management of any remaining influenza vaccine stock at the end of the influenza season. If vaccine providers are directed to return vaccine to the PVD at the RRPL, they are responsible to ship the returned vaccine following PVD instructions.

Further information regarding vaccine wastage, including vaccine problem reporting (See **Appendix 6: Vaccine Supply Problem Report**) and vaccine returns, can be found in the SIM, Chapter 9 – Management of Biological Products <http://www.ehealthsask.ca/services/manuals/Documents/sim-chapter9.pdf>)

XI. ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI)

Monitoring the health and safety of those people to whom influenza vaccine is administered is paramount. Immunizers must have protocols in place for the management and reporting of anaphylaxis and other serious adverse events.

The reporting of all adverse events following immunization (AEFIs) is mandatory under the *Saskatchewan Public Health Act* (1994).

To ensure patient safety, all immunizers shall immediately report any unusual, severe, serious or unexpected adverse event assessed to be temporally related to publicly funded influenza immunization utilizing the Public Health Agency of Canada (PHAC) *Report of Adverse Event Following Immunization* form. Non-public health vaccine providers must fax this Form to their SHA, AHA or FNJ local public health office as noted in **Appendix 7: Adverse Events Following Immunization (AEFI) for Publicly Funded Influenza Vaccine**. All publicly funded influenza AEFI reports will be reviewed by a SHA, AHA or FNJ MHO. Only a MHO is qualified to make recommendations following a reported client AEFI.

MHO recommendations will guide future recommendation regarding immunization for the client. These recommendations will be communicated to the patient by the reporter or other designate (e.g. the vaccine provider). See **Appendix 7: Adverse Events Following Immunization (AEFI) for Publicly Funded Influenza Vaccine**.

Vaccine providers must report, using the above process, all AEFIs temporally related to influenza vaccine administered in a previous season but only communicated by the client upon presentation for vaccine this season. Administration of influenza vaccine in the 2018-19 season should be delayed until receipt of the MHO recommendation.

Public health offices must immediately notify the Ministry of Health by fax at 306-787-9576 regarding any unusual, severe, serious or unexpected AEFIs in addition to submitting an AEFI report for the client.

An unexpected AEFI is an event that is not listed in the product monograph yet may be due to the immunization, or a change in the frequency of a known AEFI. GBS within six weeks following immunization and ORS within 24 hours of immunization are of particular interest for influenza vaccines.

Publicly funded influenza vaccine AEFI reports that meet **reporting criteria** as outlined in the *PHAC's User Guide: Report of Adverse Events Following Immunization (AEFI)* available at http://www.phac-aspc.gc.ca/im/aeffi-essi_guide/page1-eng.php will be recorded in the client's electronic immunization record in Panorama by the SHA, AHA and FNJ as applicable (the client record may need to be created to enable historical immunization information to be documented and indicate the AEFI); refer to the Panorama User Guide Immunization: Add Historical Immunization <https://www.ehealthsask.ca/services/panorama/Pages/Access-Training-Resources.aspx>).

As well, the SHA, AHA and FNJ will document complete AEFI reports for publicly funded influenza vaccines into the Panorama client record (if they have access) as a client warning (refer to Panorama bulletin 0024 *Where Do I Document in Panorama?* <https://www.ehealthsask.ca/services/panorama/Pages/Bulletins.aspx>).

NOTE: AEFI reports for all privately purchased vaccines, including influenza, must be submitted directly to Health Canada by the immunizer: <http://www.phac-aspc.gc.ca/im/pdf/raefi-dmcisi-eng.pdf>. They are not to be submitted to public health offices in the SHA, AHA and FNJs or the Saskatchewan Ministry of Health.

XII. RECORDING REQUIREMENTS (CLIENT RECORD DOCUMENTATION)

Community Pharmacies:

It is expected that influenza vaccine administration to all clients, regardless of age, be entered into the PIP. The client must also receive a *Record of Influenza Immunization* Wallet Card to serve as the client's record of vaccine administration.

In addition, it is required that influenza immunization administered to children five to eight years of age be entered into their client record within the Panorama Immunization Module. The *Notification of Administration of Influenza Vaccine* form must be completed, by the vaccine provider, and forwarded, within 3 business days of administering vaccine, to the local public health office. See **Appendix 8: Notification of Administration of Influenza Vaccine** and **Appendix 9: SHA, AHA, and FNJ Public Health Office Contact Information for Notification and AEFI Report Submission**.

All Other Non-Public Health Vaccine Providers

It is expected that influenza vaccine administration to all clients, regardless of age, be entered into the client service record maintained by the provider. In addition, the client must receive a *Record of Influenza Immunization* Wallet Card to serve as the client's record of vaccine administration.

It is required that influenza immunization administered to children six months to under nine years of age be entered into their client record within the Panorama Immunization Module. The *Notification of Administration of Influenza Vaccine* form (See **Appendix 8**) must be completed, by the provider, and forwarded, within 3 business days of administering vaccine, to the local public health office (See **Appendix 9: List of Public Health Offices**).

Local public health will provide non-public health vaccine providers (excluding community pharmacies) with consent forms and/or line lists for use in documenting vaccine administration to clients 18 years and older. These consent forms/ lists are to then be submitted to public health for data collection.

SHA, AHA and FNJ Public Health:

Influenza immunization administered by providers other than community pharmacists to any person younger than nine years of age must be entered into the client's record within the Panorama Immunization Module. The client must also receive a *Record of Influenza Immunization* Wallet Card to serve as the client's record of vaccine administration.

In addition to the entry of influenza vaccine provided by public health to children under the age of nine, the SHA, AHA and FNJs will be responsible for back-entry into Panorama influenza vaccine provided to children age five to eight years of age by community pharmacists, and all children six months to under nine years of age by all other non-public health providers.

The SHA, AHA and FNJS are responsible for submitting administration statistics to the Ministry of Health to support statistical reporting. Children six months up to and including 17 years of age whose immunizations are recorded into the provincial immunization registry (Panorama) will be extracted by the Ministry of Health.

Persons 18 years of age or older who received immunization at a mass immunization clinic will be counted manually and do not need to be entered into Panorama. These clients will have, at minimum, their name and date of birth collected for documentation purposes. See **Table 4** below for summary.

Table 4: Summary of Documentation Requirement by Client Age and Vaccine Provider

| Age of client | SHA/AHA/FNJ Public Health | Community Pharmacist | All other Public Health providers |
|------------------------------|---|--|--|
| 6 months to 59 months | <ul style="list-style-type: none"> • Entered into Panorama • <i>Record of Influenza Immunization</i> Wallet Card provided to client | <ul style="list-style-type: none"> • n/a | <ul style="list-style-type: none"> • Client record maintained by provider • Back entered by public health into Panorama • <i>Record of Influenza Immunization</i> Wallet Card |
| 5 to 8 years | <ul style="list-style-type: none"> • Entered into Panorama • <i>Record of Influenza Immunization</i> Wallet Card provided to client | <ul style="list-style-type: none"> • Recorded in PIP • Complete form and fax to public health • <i>Record of Influenza Immunization</i> Wallet Card provided to client • Back entered by public health into Panorama | <ul style="list-style-type: none"> • Client record maintained by provider. • <i>Record of Influenza Immunization</i> Wallet Card provided to client • Back entered by public health into Panorama |
| 9 years to 17 years | <ul style="list-style-type: none"> • Entered into Panorama • <i>Record of Influenza Immunization</i> Wallet Card provided to client | <ul style="list-style-type: none"> • Recorded in PIP • <i>Record of Influenza Immunization</i> Wallet Card provided to client | <ul style="list-style-type: none"> • Client record maintained by provider. • <i>Record of Influenza Immunization</i> Wallet Card provided to client |
| 18 to 64 years | <ul style="list-style-type: none"> • Consent form/lists • <i>Record of Influenza Immunization</i> Wallet Card provided to client | <ul style="list-style-type: none"> • Recorded in PIP • <i>Record of Influenza Immunization</i> Wallet Card provided to client | <ul style="list-style-type: none"> • Client record maintained by provider and/or Consent form/lists • <i>Record of Influenza Immunization</i> Wallet Card provided to client |
| 65 years and older | <ul style="list-style-type: none"> • Consent form/ lists • <i>Record of Influenza Immunization</i> Wallet Card provided to client | <ul style="list-style-type: none"> • Recorded in PIP • <i>Record of Influenza Immunization</i> Wallet Card provided to client | <ul style="list-style-type: none"> • Client record maintained by provider and/or Consent form /lists • <i>Record of Influenza Immunization</i> Wallet Card provided to client |

XIII. REPORTING REQUIREMENTS (ADMINISTRATION STATISTICS)

- The following statistical information is required by the Ministry of Health and provided to the Population Health Branch (PHB) (refer to **Appendix 10: Data Collection and Submission Processes for SHA, AHA and FNJs 2018-19**):
 - Number of doses provided to residents in LTC facilities (include number of residents as of November 30, 2018);
 - Number of doses provided by Public Health, non-Public Health Providers and Community Pharmacists to individuals five to eight years (entered into Panorama);
 - Number of doses provided by Public Health to individuals nine to 17 years (as they are entered into Panorama);
 - Number of doses provided by non-Public Health Providers and Community Pharmacists to individuals nine to 17 years;
 - Number of doses provided to individuals 18 years to 64 years of age (provided by all providers);
 - Number of doses provided to individuals ≥ 65 years of age (provided by all providers); and,
 - Number of doses provided to HCWs (by March 31, 2019) as well as the number of HCWs in the organization (as of March 31, 2019).

The SHA, AHA and FNJs will be required to submit General Public Immunization stats **for the previous Sunday to Saturday period by noon the following Tuesday** using the section of the SHA, AHA and FNJ Influenza Immunization Statistical Collection Excel spreadsheet 2018-19. The completed spreadsheet will be included as an email attachment when distributed to SHA, AHA and FNJs. Following December 31, 2018, monthly stats are collected for January through April. Immunization stats for each month are to be submitted as indicated in **Appendix 10: Data Collection and Submission Processes for AHA/SHA AND FNJs 2018-19**.

- Submit the General Public Immunization stats the following email address: PopHealth@health.gov.sk.ca with the subject line: **(your SHA, AHA or FNJ name) Influenza vaccine administered report as of week (see week submission chart in Appendix 10: Table 2). Immunization stats not submitted on time will be recorded as data not submitted.**
- FNJs are required to submit manually the number of children six months up to and including 17 years of age who were immunized according to age breakdown (refer to **Appendix 10**).
- The age of a client at presentation for immunization is to be noted, and recorded appropriately. For example, a 64 year-old who presents in November 2018 for immunization must be recorded in the 18 to 64 years category, even if the person is turning 65 in January of 2019.
- Numbers immunized should only be recorded one time in one place. For example, if immunizations are entered into the provincial immunization registry for those under nine years of age, the numbers should not be counted manually as these numbers will be extracted from the provincial immunization registry.
- The SHA, AHA and FNJs are responsible for the retrieval of administration stats from practitioners and facilities **who have received** publicly funded influenza vaccines from them. **Frequent retrieval** is preferred and the SHA, AHA and FNJs are strongly encouraged to obtain stats before releasing further vaccines to the requesting practitioners/facilities.
- The Ministry of Health will be collecting vaccine administration data from community pharmacists via the DPEBB claims system as well as by the PHB, via Panorama, for those individuals five to eight years of age.
- **SHA, AHA and FNJs must submit their final statistics to the Ministry by April 15, 2019 to PopHealth@health.gov.sk.ca.**
- For organizations not using Panorama, a second dose of influenza vaccine administered April 1 – 30, 2019 will be reported by May 7, 2019.

XIV. CHARGES/BILLING

In order to administer influenza vaccines as part of the SIIP, any immunizer or their employer:

- Must not charge a client who has a valid HSN for the administration of the publicly funded influenza vaccine, or for the influenza vaccine itself; and
- Persons without a valid HSN, are from out of province, or from out of country, should be directed to a public health office for publicly funded influenza vaccine. See **Appendix 9: SHA, AHA, and FNJ Public Health Office Contact Information for Notification and AEFI Report Submission** for support in locating a public health office.

XV. COMMUNICATIONS

- The Saskatchewan Ministry of Health's Communications Branch will coordinate with AHA/SHA communications staff regarding public messaging. The DPEBB is responsible to issue communication to provincial pharmacists.
- The Saskatchewan Ministry of Health, in cooperation with AHA/SHA/FNJ, develops consistent public messaging to communicate eligibility criteria, including risk groups, to the public.
- For provincial media interviews, Saskatchewan's Chief Medical Health Officer/Deputy Chief Medical Health Officer and the SHA, AHA and FNJs' MHOs are the main spokespersons.
- HealthLine 811 will link to the AHA/SHA clinic locations.
- AHA/SHA/FNJs will ensure clinic details are posted on local websites.
- The Influenza Vaccine English and French fact sheets and related documents will be posted on the Ministry website by September of each year at <http://www.saskatchewan.ca/residents/health/accessing-health-care-services/immunization-services#immunization-forms-and-fact-sheets>

APPENDIX 1: 2018-19 Publicly Funded Influenza Vaccines

| | FluLaval® Tetra (GSK) QIV split virion | FLUZONE® Quadrivalent (SP) QIV split virion | FLUZONE® High Dose (SP) TIV split virion |
|---|--|---|---|
| Population | Everyone ≥ 6 months | Everyone ≥ 6 months | LTC residents ≥ 65 years |
| Dose | 0.5 mL IM | 0.5 mL IM | 0.5 mL IM |
| Components | Latex and antibiotic free and contains both influenza A strains and B viral strains, sodium chloride, potassium chloride, disodium hydrogen phosphate heptahydrate, potassium dihydrogen phosphate, α-tocopheryl hydrogen succinate, and polysorbate 80, and may contain traces of egg proteins (ovalbumin), sodium deoxycholate, ethanol, formaldehyde and sucrose. | Latex, antibiotic and gelatin free and contains all surface antigens of this year's influenza A and B viral strains, formaldehyde, sodium phosphate-buffered, isotonic sodium chloride solution, and Triton® X-100, and may contain traces of egg protein and sucrose. | Latex, antibiotic, thimerosal and gelatin free and contains all surface antigens of this year's influenza A strains and one B viral strain, formaldehyde, sodium phosphate-buffered, isotonic sodium chloride solution, and Triton® X-100, and may contain traces of egg protein. |
| Preservative | <ul style="list-style-type: none"> Thimerosal in multidose vials. | <ul style="list-style-type: none"> Thimerosal in multidose vials. | No preservatives |
| Normal and Expected Reactions Mild to moderate reactions generally last 1-4 days. | <ul style="list-style-type: none"> Soreness, warmth, redness, and swelling at the injection site. Temporary limited movement of the immunized arm or leg. Headache, fever, tiredness, muscle aches, and chills. Loss of appetite. | <ul style="list-style-type: none"> The most common reactions occurring after vaccine administration are injection site pain (11%-57%), erythema (7%-30%) and edema (6%-21%). The most common systemic reactions observed after vaccine administration are asthenia (2%-18%), headache (2%-10%) and myalgia (2%-9%). | <ul style="list-style-type: none"> The most common reactions occurring after vaccine administration are injection site pain (36%), erythema (15%) and edema (9%). The most common systemic reactions observed after vaccine administration are myalgia (21%), malaise (18%) and (2%-18%), headache (17%). |
| Presentation | 5 mL multidose vial containing 10 doses of 0.5 mL | <ul style="list-style-type: none"> 5 mL multidose vial containing 10 doses of 0.5 mL 0.5 mL prefilled syringes (thimerosal free) | <ul style="list-style-type: none"> 0.5 mL prefilled syringes (thimerosal free) |
| Contra-indications | <ul style="list-style-type: none"> Persons with a history of a severe allergic or anaphylactic reaction to a previous influenza vaccine dose or any component of an influenza vaccine should discuss their situation with a public health nurse or their physician. Persons who developed GBS within 6 weeks of a previous influenza vaccine. | | |
| Instructions for Administration | <ul style="list-style-type: none"> Do not administer vaccine from a vial that has been opened for ≥28 days or has expired. To get 10 doses out of a vial, GSK recommends that each 0.5 mL dose is withdrawn into a 1 mL syringe equipped with a needle gauge not larger than 23G. | <ul style="list-style-type: none"> Vaccine may be administered from a MDV that has been opened up to the expiry date indicated on the vial. | <ul style="list-style-type: none"> Nothing specific for this vaccine. |
| Special Instructions – | <ul style="list-style-type: none"> Gently shake pre-filled syringe or vial before administration Do not freeze or use if vaccine has been frozen. The Ministry recommends that vaccines be administered directly from the fridge or cooler and not warmed to room temperature prior to administration. Date vials when opened. Protect from light. Pre-drawing is not recommended. Store 2°C-8°C. | | |

APPENDIX 2: Community Pharmacists Delivery of Publicly Funded Influenza Vaccine

| Population or Location | Eligible to Bill DPEBB | Requires Coordination with Public Health | How to Proceed with Coordination (if required) |
|--|------------------------|--|--|
| Individuals five years and older | yes | no | n/a |
| Home Visits | yes | yes | Contact public health representative (See Appendix 9: SHA, AHA, and FNJ Public Health Office contact information for Notification and AEFI Report Submission). If public health (or home care) not providing service in home, Pharmacy permitted to contact client. |
| Congregate Living Settings where public health or other health practitioners are not providing ongoing service | yes | yes | Contact public health representative (See Appendix 9: SHA, AHA, and FNJ Public Health Office contact information for Notification and AEFI Report Submission). If public health not providing service in Facility, Pharmacy permitted to contact Facility to inquire into providing service. |

Off-site delivery of influenza immunization by pharmacists must be coordinated with local public health offices in the SHA, AHA and FNJs by August 31st.

APPENDIX 3: Cold Chain Break Report

Complete for all Saskatchewan Health publicly funded products. Do not assume that products must be wasted.

Section 1

Date of Break: (yyyy-mm-dd) _____ Date of Report: (yyyy-mm-dd) _____ Reporter Name: _____

Telephone Number: _____ Fax Number: _____ Reporter Email Address: (optional) _____

Location of Break (SHA, AHA or FNJ/ City / Town) _____ Facility Name: _____

Facility type:
 Public Health Pharmacy Physician office Long-Term Care Acute Care Employee Health Other _____

Are products: Quarantined, Labeled: DO NOT USE, and stored on cold chain? Yes No (attach explanation)

Section 2

Check box for type of break and fill out corresponding category:

Vaccine left out of fridge:
 in cooler with cold packs in cooler with no cold packs in package on counter not in package on counter
 Vaccine returned to storage between 2°C and 8°C on date _____ at (time) _____
 Length of time outside recommended temperature range of 2 - 8°C _____
 Room temperature at time of break _____°C on date _____ at (time) _____

Fridge temperature excursion
 Fridge temperature when break identified: _____°C on date _____ at (time) _____
 Max. temp recorded during break interval _____°C Min. temp recorded during break interval _____°C
 Length of time outside recommended temperature range of 2 - 8°C _____
 Last fridge temperature record before the break _____°C on date _____ at (time) _____
 Room temperature before the break _____°C on date _____ at (time) _____
 Is temperature log being submitted? Yes No If No, indicate why: _____
 Refrigerator type: _____ Thermometer/Monitor Type (Not Brand Name): _____
 Lab or Biological Fridge(any size) Domestic Fridge Digital Min/Max Chart / Wheel Recorder
 Bar Fridge Other _____ Warm/Cold Mark No Monitor Other _____
 Date last serviced: _____

Break during transportation
 Vehicle type (e.g. car/courier) _____ Time delivery received: _____
 Specify: Provincial Depot to RHA/FNJ/ wholesaler Public Health to community Intraregional
 Was there a data logger included in the cooler? Yes No If yes, is it being sent back to SDCL? Yes No
 Was there a warm/cold marker in cooler? Yes No If yes, was it activated? Yes No Reading: _____

Other situation: provide description _____

Section 3

Description of break: _____

Cause of cold chain break: Human error Power outage Other _____ **Corrective action details and additional comments:** _____

Thermometer malfunction Refrigerator malfunction
 Transportation Backup generator failed

Have any affected products been administered to clients? Yes No

- If yes, indicate the date the Medical Health Officer was notified: _____
- If yes, identify these products using a separate page if necessary.

APPENDIX 4: How to Complete the Cold Chain Break Report

How to Complete the Cold Chain Break Report Form

Section 1

Complete all components of this section. The Reporter is the person who discovered the cold chain break or is responsible for reporting the cold chain break. Their contact information is important to facilitate follow up.

Section 2

There are four categories in this section. The Reporter **only** needs to **fill out the one category** that is most applicable to the cold chain break:

1. **Vaccine left out of fridge** – in cooler, box, on counter, etc.
2. **Fridge temperature excursion** – when fridge thermometer indicates temperatures outside of cold chain maintenance (2 to 8°C).
3. **Break during transportation** – Temperature indicator card and/or data logger indicates break in cold chain during transport from one facility to another (includes vaccine from Roy Romanow Provincial Laboratory [RRPL] and intra-regional transport) **
4. **Other situation** – any situation not covered in the three scenarios above. Include as much information about the situation including time, temperature and cause.

All products must be immediately quarantined when involved in a cold chain break.

****Data loggers** that are in the coolers of vaccine found to be in a cold chain break should be sent into RRPL and marked with the name of the former Regional Health Authority (RHA), Athabasca Health Authority (AHA) or First Nations Jurisdiction (FNJ); facility; date of cold chain break and contact person. The data logger should then be put in an envelope and placed back in the cooler to be sent to **Roy Romanow Provincial Laboratory at 5 Research Drive, Regina SK. S4S 0A4** NOTE: This does not apply to vaccines sent from wholesalers to community pharmacies.

Section 3

- **Description of Break:** Provide as much detail as possible regarding the cold chain break including how and why the break occurred.
- **Cause of cold chain break:** Please check off the cause that is most applicable. Provide details of the corrective action or plan.
- **Have any affected products been administered to clients?** Please check off yes or no, and answer subsequent questions as appropriate.

Section 4 (Page 2)

- Print all vaccine information clearly using one line per lot number. List open vial vaccines on separate lines even if lot number is the same. Use appropriate vaccine and manufacturer abbreviations.
- Circle the applicable answer for “open multidose vial” and “previous cold chain break.”
- Page 2 will be faxed back to the SHA, AHA or FNJ Immunization Supervisor/ Designate or Community Pharmacist indicating whether the vaccine is:
 - Viable – usable – maintain in cold chain and use as soon as possible; **OR**
 - Discard – not to be used. Discard as per organizational policy.

NOTE: The Ministry of Health will fax recommendations to Immunization Supervisor/Designate or reporting Community Pharmacy as appropriate.

APPENDIX 5: Product Wastage Report

DO NOT REPORT COLD CHAIN WASTAGE ON THIS FORM.

- **USE FOR:** all vaccines, Tubersol™, Tlg, Ig, Rablg, azithromycin, amoxicillin, benzathine penicillin (bicillin), cefixime, ceftriaxone, ciprofloxacin, doxycycline, erythromycin, rifampin, epinephrine and lidocaine. Diluents for MMR, Var and MMRV do not need to be reported.

**Submit to: Roy Romanow Provincial Laboratory
 Provincial Vaccine Depot
 5 Research Drive
 Regina, SK, S4S 0A4
 Fax: 306-798-0071
 Phone: 306-787-7638**

SHA, AHA or FNJ site/Pharmacy/Wholesaler submitting report:

Reporter name: _____ Date: _____

Phone #: _____ Fax #: _____

| | | | | | Indicate only 1 reason for wastage | | | |
|--------------|--------------|------------|-------------|------------|---|------------------|------------------|--|
| Product Name | Manufacturer | Lot Number | Expiry date | # of Doses | EXPIRED OPENED | EXPIRED UNOPENED | Not administered | Defective or damaged (Note: Vaccine Problem Report must also be submitted) |
| | | | | | | | | |
| | | | | | | | | |
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Rev. May 2018

APPENDIX 6: Vaccine Supply Problem Report

Vaccine Supply Problem Report (SPR-001)

Vaccine Supply Problem Report
Mail completed report and defective product to:
Ministry of Health
Public Health Nursing Consultant
3475 Albert Street, Regina, SK S4S 6X6

- ❖ **Reported by:** [name, title, region/jurisdiction]
-
- ❖ **Date of report:** [year/month/day]
-
- ❖ **Vaccine:** [type, brand name, manufacturer, format]
-
- ❖ **Lot number:**
-
- ❖ **Supplier:**
-
- ❖ **Contract number:** (Ministry of Health to complete).....
-
- ❖ **PWGSC contract or direct with supplier?** (Ministry of Health to complete).....
-
- ❖ **Nature of the problem experienced:** [Attach additional page if necessary.]
-
-
-
-

❖ **Administration / Packaging:**

| | |
|--|--|
| | Dull needle |
| | Needle separates from syringe |
| | Contents cloudy or contains particles |
| | Label concerns (e.g. can't read Lot #) |
| | Other: |

❖ **Details:** [Please provide details of the problem experienced; including when experienced and frequency / extent of problem. Attach additional page if necessary.]

.....

.....

.....

.....

❖ **Additional comments?** [Attach additional page if necessary.]

.....

.....

.....

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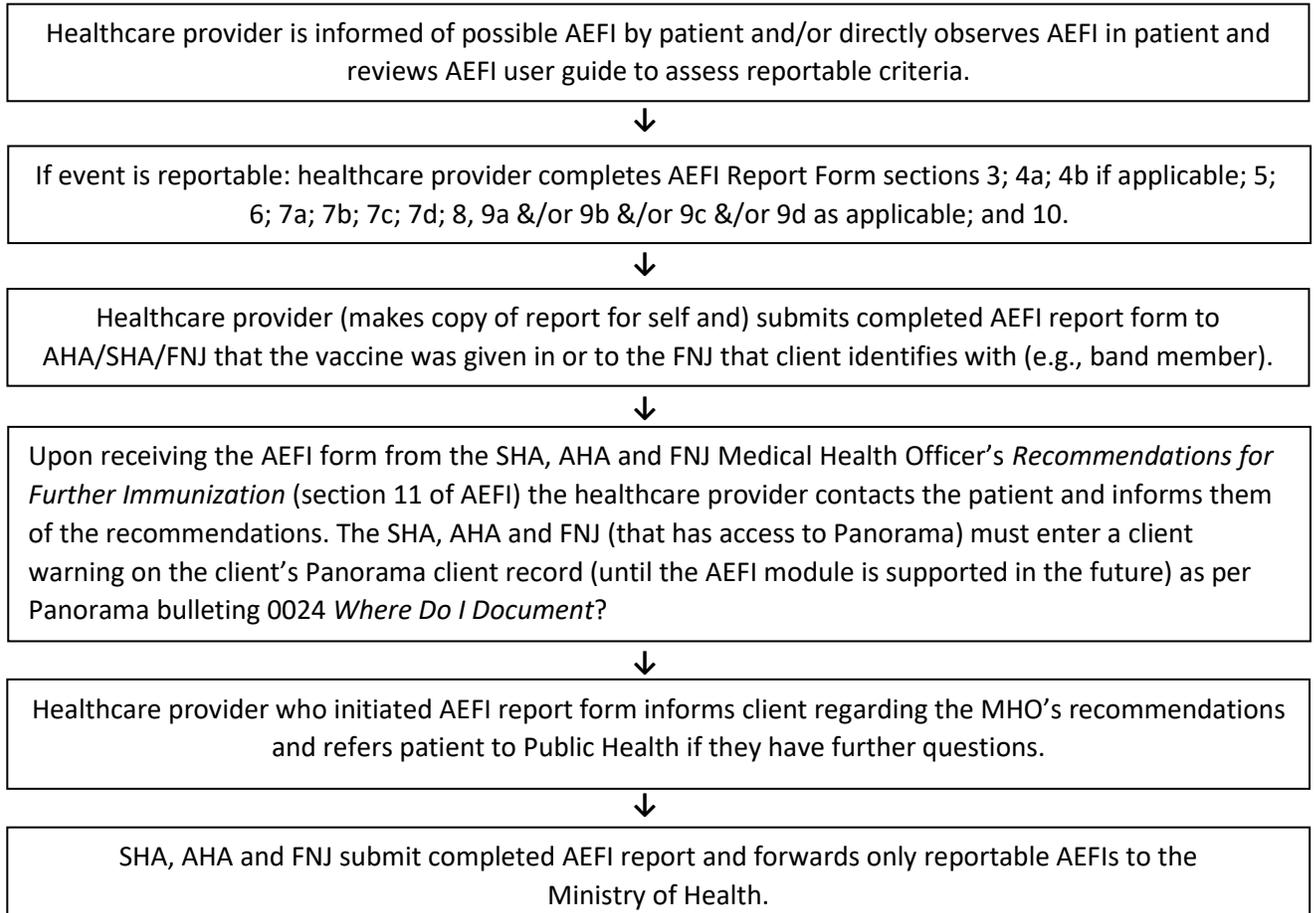
FOR YOUR INFORMATION: PURPOSE OF THE VACCINE SUPPLY PROBLEM REPORT

The Vaccine Supply Problem Report is intended to allow for the central collection of information on problems experienced in the procurement and/or use of vaccines, even if the problem has been satisfactorily resolved by the supplier. Saskatchewan Ministry of Health will collect the problem reports from Saskatchewan and forward to the Vaccine Supply Working Group (VSWG). A summary of problem reports will be shared with all jurisdictions. Where necessary, the problems identified will be formally reported to Public Services and Procurement Canada (PSPC) or to Health Canada.

If appropriate, and if agreed to by the VSWG, the information collected may be considered in the evaluation of bids and the awarding of future contracts.

Problem reports will be collected and collated and a summary distributed once a month to the VSWG. A brief discussion of problem reports will be added as a standing item on each VSWG monthly teleconference.

APPENDIX 7: Adverse Events Following Immunization (AEFI) for Publicly Funded Influenza Vaccines



APPENDIX 8: Notification of Administration of Influenza Vaccine



Notification of Vaccine Administration

Please fax completed form to public health in your area

A. Provider Information:

Select one:

Physician Nurse Practitioner Pharmacist Registered Nurse Other (specify) _____

Provider Name: _____

Clinic/Address: _____

Phone Number: _____

B. Client Information:

Client Name: _____
First Name Last Name

Birth Date: _____ HSN#: (indicate province) _____
MM/DD/YYYY

Client Address: _____

City/Town : _____ Postal Code: _____

Phone number: (h) _____ (w) _____ (c) _____

Parent/Guardian providing consent: _____

C. Vaccine Information:

| Administration Date | Vaccine Brand Name | Dosage, route, site (e.g., 0.5 ml IM left arm) | Lot Number | Location of Service (i.e.: Emerg. Dept.; Name of Dr. office; pharmacy) |
|---------------------|--------------------|---|------------|---|
| MM/DD/YYYY | | | | |
| MM/DD/YYYY | | | | |
| MM/DD/YYYY | | | | |

PLEASE FAX THIS COMPLETED FORM TO:

If you have questions please contact your local public health office.

May 2018

APPENDIX 9: SHA, AHA, and FNJ Public Health Office Contact Information for Notification and AEFI Report Submission

ATHABASCA HEALTH AUTHORITY

Box 124
BLACK LAKE SK S0J 0H0
Tel: 306-439-2200
Fax: 306-439-2212

CYPRESS HEALTH REGION

#400 - 350 Cheadle Street West
SWIFT CURRENT SK S9H 4G3
Tel: 306-778-5253
Fax: 306-778-5282

FIRST NATIONS & INUIT HEALTH BRANCH

Indigenous Services Division
6th floor, 1783 Hamilton Street
REGINA SK S4P 2B6
Tel: 306-780-3499
Fax: 306-780-8826

FIVE HILLS HEALTH REGION

107-110 Ominica Street West
MOOSE JAW SK S6H 6V2
Tel: 306-691-1509
Fax: 306-691-1539

HEARTLAND HEALTH REGION

Box 1300
ROSETOWN SK S0L 2V0
Tel: 306-882-2672 Extension 2293
Fax: 306-882-4683

KEEWATIN YATTHÉ HEALTH REGION

Box 40
BUFFALO NARROWS SK S0M 0J0
Tel: 306-235-2220
Fax: 306-235-4604

KELSEY TRAIL HEALTH REGION

Box 6500
MELFORT SK S0E 1A0
Tel: 306-752-6310
Fax: 306-752-6353

MAMAWETAN CHURCHILL RIVER HEALTH REGION

La Ronge Health Centre
227 Backlund Street
P.O. Box 6000
LA RONGE SK S0J 3G0
Phone: 306-425-2422
Confidential Fax: 306-425-8530

NORTHERN INTERTRIBAL HEALTH AUTHORITY

Box 787
PRINCE ALBERT SK S6V 5S4
Tel: 306-953-5000
Fax: 306-922-5020

PRAIRIE NORTH HEALTH REGION

11427 Railway Ave., Suite 101
NORTH BATTLEFORD SK S9A 1E9
Tel: 306-446-6403
Fax: 306-446-7378

PRINCE ALBERT PARKLAND HEALTH REGION

Public Health Nursing
Danielle Sande – Immunization/Communicable Disease Lead
2nd Fl. LF McIntosh Mall
800 Central Avenue
Box 3003
PRINCE ALBERT SK S6V 6G1
Tel: 306-765-6521
Fax: 306-765-6536

REGINA QU'APPELLE HEALTH REGION

Population and Public Health Services
2110 Hamilton Street
REGINA SK S4P 2E3
Tel: 306-766-7902 Notification forms
Fax: 306-766-7906 Notification forms
Tel: 306-766-7770 AEFI questions
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June 2018

APPENDIX 10: Data Collection and Submission Processes for SHA, AHA, AND FNJs 2018-19

Public health in the SHA, AHA and FNJs are responsible for the provision of approximately half of the seasonal Influenza immunization program. Public health further distributes influenza vaccine to non-public health providers such as physicians, nurse practitioners, and other nursing offices (e.g. post-secondary institutions) in order to increase client accessibility to the influenza vaccine.

Public health is responsible for submitting influenza vaccine administration data to the Ministry of Health for both public health and the non-public health providers that public health has provided vaccine to.

Community pharmacists providing influenza vaccine will have their statistical information collected by the DPEBB of the Ministry of Health. Data for children five to eight years will be back entered in Panorama and data will be extracted by the Ministry of Health.

Table 1: Data collection expectations by provider, age and reporting frequency

| Provider | Collection, for | Submission, by age | | Reporting Frequency ^{2,5} |
|--|-----------------|--|---|---|
| | | SHA, AHA | FNJ ¹ | |
| Public Health ¹ | General Public | <u>2 age groups:</u> <ul style="list-style-type: none"> • 18 to 64 years • 65 years and older | <u>6 age groups:</u> <ul style="list-style-type: none"> • 6 to 23 months • 2 to <5years • 5 to <9 years • 9 to 17 years • 18 to 64 years • 65 years and older | Weekly (up to Dec. 31,2018) & Monthly (Jan-Feb-Mar-2019) |
| Physicians, RN(NP) and Post-secondary Institutions ¹ (Excludes community pharmacists) | General Public | <u>3 age groups:</u> <ul style="list-style-type: none"> • 9 to 17 years • 18 to 64 years • 65 years and older | Not applicable | Weekly (up to Dec. 31,2018) & Monthly (Jan-Feb-Mar-2019) |
| LTC | Residents | <u>2 age groups:</u> <ul style="list-style-type: none"> • Up to 64 years • 65 years and older | <u>2 age groups:</u> <ul style="list-style-type: none"> • Up to 64 years • 65 years and older | <u>2 submissions³</u> <ul style="list-style-type: none"> • #s (residents and immunized) as of Nov. 30, 2018 and • #s for Dec. 1, 2018 to Mar. 31, 2018 (residents) |
| SHA OH&S/ Employee Health | HCW | <u>1 age group:</u> <ul style="list-style-type: none"> • All HCWs regardless of age | <u>1 age group:</u> <ul style="list-style-type: none"> • All HCWs regardless of age | <u>1 submission⁴</u> <ul style="list-style-type: none"> • #s immunized as of March 31, 2019 • Total number of HCWs as of March 31, 2019 |

¹ SHA/AHA and FNJs recording in Panorama are recommended to enter immunization records in Panorama for clients, born since 2000 who received influenza vaccine from public health. For those 18 years and older attending mass clinics, entry into Panorama is not required.

² April 15, 2019 by 5:00 pm for all administered doses (season-end submission).

³ The total number of residents living in LTC facilities is to be determined as of November 30, 2018. This will serve as the denominator to determine their influenza vaccine coverage. Numbers after November 30th will consist of total numbers of residents vaccinated. Submission of the number of LTC residents after November 30, 2018 is not required because percentage coverage will not be calculated for this period.

⁴ HCWs are those employed by SHA, AHA AND FNJ facilities or affiliated facilities and do not include volunteers, health science students or physicians. Total number of HCWs for the SHA, AHA AND FNJ will be the denominator to calculate coverage.

⁵ Reporting frequency is subject to change at the Ministry of Health's discretion.

Frequency of reporting:

The SHA, AHA and FNJs will report the number of influenza vaccine doses administered, in the above categories (except for LTC and HCWs), on a weekly basis between October 22 and December 31 of 2018. Following December 31, 2018, influenza administered doses will be reported on a monthly basis. See reporting schedule below in Tables 2 and 3.

Weekly administered dose numbers are **required to be reported by noon on the Tuesday** following the previous Sunday through end of day Saturday. The statistical collection week is from Sunday to 5:00 pm Saturday. Monthly administered dose numbers are required by noon on the Tuesday within the first ten days of the following month. See Tables 2 and 3 for specific dates. Any missing or delayed reporting numbers should be rolled into the following week. Example: if numbers are delayed being tallied by a region (for public health and non-public health administered) and submission time is not met, the SHA and AHA will be reported as previously reported administered for that week for those 18 years and older (however, numbers pulled from Panorama by the Ministry will be reported). The missing/delayed numbers should be included in the following week's/month's submission but DO NOT report adjusted numbers to the Ministry.

Timely submission is important because it allows the Ministry to report promptly to Ministry officials and the SHA, AHA and FNJs, as well as support PHB planning for the season. **Please email the administered dose reports, weekly, monthly, and end of season to: PopHealth@health.gov.sk.ca** with the subject line: **(your SHA, AHA or FNJ name) Flu vaccine administered report as of week (see submission chart below).**

Table 2: Due dates for report submission are as follows: (These are subject to change)

| Calendar Week | Submission time period | Date of submission |
|-------------------------------------|--------------------------------|--------------------|
| Week 43 | Oct 22– 28, 2018 | Oct 30, 2018 |
| Week 44 | Oct 28 – Nov 3, 2018 | Nov 6, 2018 |
| Week 45 | Nov 4- 10, 2018 | Nov 13, 2018 |
| Week 46 | Nov 11 - 17, 2018 | Nov 20, 2018 |
| Week 47 | Nov 18 - 24, 2018 | Nov 27, 2018 |
| Week 48 | Nov 25 – Dec 1, 2018 | Dec 4, 2018 |
| Week 49 | Dec 2 – 8, 2018 | Dec 11, 2018 |
| Week 50 | Dec 9 - 15, 2018 | Dec 18, 2018 |
| Week 51 | Dec 16 - 22, 2018 | Dec 25, 2018 |
| Week 52 | Dec 23 – 31, 2018 | Jan 8, 2019 |
| January 2019 | Jan 1 – 31, 2019 | Feb 5, 2019 |
| February 2019 | Feb 1-28, 2019 | Mar 5, 2019 |
| March 2019 | Mar 1-31, 2019 | Apr 9, 2019 |
| Final submission (year-end summary) | Oct 22, 2018 to March 31, 2019 | April 15, 2019 |

***For those FNJs providing a second dose and not recording in Panorama, the deadline for data submission will be May 7, 2019.

Second doses provided by community pharmacists will need to be submitted to Public Health for back entry by May 7, 2019. A Notification of Administration of Influenza Vaccine form for each child five to eight years of age must be completed and sent to the local public health office within three business days of vaccine administration. See Appendix 9: Notification of Administration of Influenza Vaccine form.

Table 3: Due dates for LTC report submission is as follows:

| Submission time period | Date of submission |
|-----------------------------|--------------------|
| As of November 30, 2018 | December 15, 2018 |
| December 2018 to March 2019 | April 15, 2019 |

Submission of Numbers:

The Ministry of Health is providing an Excel spreadsheet to assist in the collection and reporting of vaccine administered doses to the Ministry of Health. The SHA, AHA and FNJ should submit their updated Excel file as their report.