Manitoba's Seasonal Influenza Immunization Program Plan 2022-23

August 2022

Manitoba Health
Population Health Division
Public Health Branch

* Subject to change; please go to www.manitoba.ca/health/flu/pro.html to access the most current version.

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Acronyms

ACIP	Advisory Committee on Immunization Practices
AEFI	Adverse event following immunization
CI	Confidence interval
DPIN	Drug Programs Information Network
GBS	Guillain-Barré syndrome
IIV	Inactivated influenza vaccine
ILI	Influenza-like illness
ISC	Indigenous Services Canada
LAIV	Live attenuated influenza vaccine
LTCF	Long-term care facility
MDV	Multi-dose vial
MH	Manitoba Health
MOH	Medical Officer of Health
NACI	National Advisory Committee on Immunization
ORS	Oculo-respiratory syndrome
PDW	Provincial Distribution Warehouse
PFS	Pre-filled syringe
PHIMS	Public Health Information Management System
PHIN	Personal health identification number
PVAC	Provincial Vaccine Advisory Committee
RCT	Randomized controlled trial
SDO	Service Delivery Organization
VE	Vaccine effectiveness
WHO	World Health Organization

Purpose

The purpose of this Program Plan is to provide all health care providers and Service Delivery Organizations (SDOs) , including Indigenous Services Canada, that participate in Manitoba's Seasonal Influenza Immunization Program, with the provincial program details for the upcoming 2021-22 influenza (flu) season.

2022-23 Program Dates

- **February 2022:** World Health Organization released the recommended strains for the 2022-23 northern hemisphere influenza vaccines in February. Manitoba is expecting egg-based flu vaccines with four recommended flu strains.
- **June 2022:** Manitoba Health received approvals to:
    - Expand eligibility criteria for the High-Dose Flu Vaccine to every individual aged 65+.
- **June 8:** Manitoba followed recommendations from the National Advisory Committee on Immunizations (NACI) to lower the age of co-administration for Flu and COVID-19 vaccines to individuals aged 5 years and older. NACI's "Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2022-23" can be accessed at: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2022-2023.html
- **August 15:** Health care providers and pharmacies are asked to place their first order for this year's flu vaccine. Orders will be collected and shipped once product arrives in Manitoba (late September). Shipment will follow a schedule based on priority locations and then based on client ID (more detail provided below under "Vaccine Distribution"). For more information on the provincial delivery of the flu vaccine, go to: www.manitoba.ca/health/flu/distribution.html.
- **August 25:** The updated provincial "seasonal flu" website, (www.manitoba.ca/health/flu/index.html) will go live. Updated print materials including promotional/educational resources (e.g. factsheet, poster, brochure, etc.) and order forms will be posted on the seasonal flu website when updated.
- **September 13** Deadline for health care providers, such as pharmacies, physicians, and SDOs, to submit their clinic dates, times and locations for inclusion on the Manitoba Health (MH) website and/or through Health Links–Info Santé. Please email information to: Vaccines@gov.mb.ca.
- **September 30 (tentative):** MH will mail the annual pneumococcal polysaccharide 23 (Pneu-P-23) reminder letter to people who have turned 65 years of age in the past year.
- **October 24:** Launch of the provincial 2022-23 Seasonal Influenza Immunization Program advertising campaign.

Provincial Eligibility Criteria and Recommendations for Use

For the 2022-23 influenza season, all Manitobans 6 months of age and older will be eligible to receive the seasonal influenza (flu) vaccine free of charge.

Note: This year, all Manitobans 65 years of age and older will be eligible to receive the high-dose influenza vaccine free of charge.

The flu vaccine is especially important for individuals at increased risk of serious illness from the flu, their caregivers and close contacts, including:

- people 65 years of age and older
- residents of personal care homes or long-term care facilities (LTCFs)
- children six to 59 months of age
- individuals with the following chronic health conditions:
  - an immune system weakened by disease or medical treatment (e.g. cancer)
  - cardiac or pulmonary disorders (e.g. cystic fibrosis, asthma)
  - long-term acetylsalicylic acid (Aspirin®) therapy (for those between six months and 18 years of age *only*)
  - neurologic or neurodevelopmental conditions including neuromuscular, neurovascular, neurodegenerative and seizure disorders (and, for children, including febrile seizures and isolated developmental delay), but excluding migraines and psychiatric conditions without neurological conditions
  - diabetes and other metabolic diseases
  - renal disease
  - anemia or hemoglobinopathy
  - obesity (body mass index ≥40)
- pregnant individuals
- health care workers and first responders
- those who provide services within closed or relatively closed settings to people at high risk (e.g., crew on a ship)
- people who provide essential community services
- regular caregivers of children up to five years of age
- household contacts of anyone at increased risk of serious illness from the flu including those with infants under six months of age and/or expecting a newborn
- Indigenous peoples

International students and out-of-province visitors continue to be eligible to receive the flu vaccine free-of-charge regardless of third-party insurance and/or Manitoba Health coverage.

All doses administered including to those without a Personal Health Identification Number (PHIN) from MH are to be reported to MH. See Documentation section below on the ways to report the administered doses.

The forms should be completed as thoroughly and accurately as possible (e.g. name, date of birth, province or location of residence, health number from place of residence). Completed forms are to be submitted to the location indicated on the forms.

Children younger than nine years of age who have NEVER received a flu vaccine need two doses, at least four weeks apart. As per NACI, children 6 months to less than 9 years of age who have been properly vaccinated with one or more doses of seasonal influenza vaccine in any previous season should receive 1 dose of influenza vaccine per season thereafter. Several studies have looked at whether these two initial doses need to be given in the same season. It appears that for children 6-23 months, similar immunogenicity was found whether the 2 doses were given in the same or separate season when there was no change or only minor vaccine strain change in the vaccine formulation between seasons. When there is a major B lineage change between seasons the seroprotection rates were considerably reduced. Because children 6-23 months of age are less likely to have had prior priming exposure to an influenza virus, special effort is warranted to ensure that a two-dose schedule is followed for previously unvaccinated children in this age group.

NACI recommends that all seasonal influenza vaccines, including live attenuated influenza vaccines (LAIV), may be given at the same time as, or at any time before or after administration of other vaccines, including COVID-19 vaccines for those aged 5 years and older. In general, NACI recommends that two live parenteral vaccines be administered either on the same day or at least 4 weeks apart. LAIV (such as Flumist) can be given together with or at any time before or after the administration of any other live attenuated or inactivated vaccine.

NACI recommends the inclusion of all pregnant individuals in the Flu Immunization program, at any stage of pregnancy. Pregnant individuals and newborn infants are considered at high risk of influenza-related complications including hospitalization. The risk of influenza-related hospitalization increases with length of gestation and therefore pregnant individuals are recommended to receive the flu vaccine at any stage of pregnancy. If not provided during pregnancy, the mother and other household contacts should be immunized as soon as

possible after birth of the child in order to protect the infant. Infants cannot be immunized against influenza until 6 months of age.

Influenza vaccination provides benefits to health care workers (HCWs) and to the patients to whom they provide care. Immunization of care providers decreases their own risk of illness, as well as the risk of death and other serious outcomes among the patients to whom they provide care. NACI considers the receipt of influenza vaccination to be an essential component of the standard of care for all HCWs and other care providers for their own protection and that of their patients, regardless of whether the high-risk individual has been vaccinated. For the purposes of influenza vaccination, health care workers include any person, paid or unpaid, who provides services, works, volunteers or trains in a health care setting. A health care setting is any location where heath care is provided, including emergency care, prehospital care, hospital, LTCF, home care, ambulatory care and facilities/locations in the community where care is provided (e.g. physician offices, immunization clinics, etc.). See page 8 of *Preventing the Transmission of Infection in Health Care*, www.manitoba.ca/health/publichealth/cdc/docs/ipc/rpap.pdf.

Overview of National/Provincial Recommendations

As per NACI, the national goal of the annual influenza immunization programs in Canada is to prevent serious illness caused by influenza and its complications, including death.

As part of the National Immunization Strategy (NIS), the national influenza vaccination coverage goals by 2025 includes achieving 80% coverage among:

- Adults 65 years of age and older
- Adults 18-64 years with chronic medical conditions
- Health care professionals

For the 2022-23 influenza season, Manitoba aims to achieve influenza coverage uptake across the population as follows:

Age Group	Doses	Coverage %
0-4	23,886	22.7%
5-14	31,719	17.7%
15-49	115,878	17.9%
50-64	89,065	34%

65+	146,179	62.5%
All	**406,727**	**28.6%**

The immunization coverage rate for those with high-risk medical conditions is difficult to determine. Health care providers are encouraged to identify their high-risk clients and seek to increase their rate of influenza vaccine coverage.

Every year, NACI updates its recommendations regarding the use of the seasonal flu vaccine. MH and Manitoba's Provincial Vaccine Advisory Committee (PVAC) thoroughly review and examine NACI's annual recommendations to inform provincial recommendations and program details. **NACI's Canadian Immunization Guide and Statement on Seasonal Influenza Vaccine for 2022-23** is available online at https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2022-2023.html#a4.5 and the MH **Seasonal Influenza Management Protocol** is also available online at www.manitoba.ca/health/flu/pro.html.

Annual vaccination is recommended since the strains are changed every year to provide a better match against the viruses expected to circulate, and because the body's immune response to influenza vaccination is unlikely to persist beyond a year.

For more information about provincial immunization program standards, please access Manitoba's *Immunization Program Manual*, available online at: www.manitoba.ca/health/publichealth/cdc/div/manual/index.html.

Vaccine Efficacy and Effectiveness

Influenza vaccine has been shown to be efficacious in clinical trials although real-world effectiveness can vary depending on a number of factors including how well the vaccine strain match with circulating strains. Even when there is a less-than-ideal match or lower effectiveness against one strain, the possibility of lower VE should not preclude vaccination, particularly for people at high risk of influenza-related complications and hospitalization. Vaccinated individuals are still more likely to be protected compared to those who are unvaccinated. Immunization has been shown to reduce the number of physician visits, hospitalizations and deaths in high-risk adults.

Vaccine Safety

Influenza vaccines are safe and well tolerated. Data from post marketing surveillance of influenza vaccines in Canada) have shown seasonal influenza vaccines to have a safe and stable profile. In addition to routine passive surveillance, every year during the seasonal influenza vaccination

campaigns, PHAC and the Federal/Provincial/Territorial Vaccine Vigilance Working Group (VVWG) of the Canadian Immunization Committee conduct expedited reportingof adverse events following immunization (AEFI) with current influenza vaccines (usually weekly) during the flu season in order to identify vaccine safety signals in a more timely manner. Refer to the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) web page for more information on post-marketing surveillance and AEFIs in Canada.

Specifically in Manitoba, an enhanced vaccine safety signal detection methodology first implemented during the COVID-19 vaccination campaign, will be implemented as well during the flu campaign. This involves a systematic, near-realtime assessment of an identified risk associated with the use of the vaccine that may require urgent measures to protect the public, and uses dynamic data files and sequential analysis for early detection of adverse events.

In addition, the Canadian National Vaccine Safety (CANVAS) Network, a national network of sites across Canada for active vaccine safety surveillance, collects and analyzes information on AEFIs after influenza vaccination to provide influenza vaccine safety information to public health authorities during the core weeks of the annual influenza vaccination campaign.

All influenza vaccines currently authorized for use in Canada are considered safe for use in persons with latex allergies. The multi-dose vial (MDV) formulations of IIV contain minute quantities of thimerosal, which is a mercury-based preservative to keep the product sterile. Large cohort studies of health databases have found that there is no association between thimerosal-containing vaccines and neurodevelopmental outcomes, including autistic-spectrum disorders. All single dose formulations [i.e. pre-filled syringes (PFS) or nasal spray] of IIV or LAIV (Fluzone® Quadrivalent, FluMist® Quadrivalent, Afluria® Tetra, and Fluzone® High-Dose) are thimerosal-free.

For more information on the contents of influenza vaccine and others , please visit Contents of immunizing agents available for use in Canada: Canadian Immunization Guide - Canada.ca

For more information on their safety, please see: Canadian Immunization Guide: Part 2 - Vaccine Safety - Canada.ca

Note: For the 2022-23 influenza season, LAIV nasal spray will not be offered as part of Manitoba's Seasonal Influenza Program.

Relevant Adverse Events

With intramuscularly injected (needle) vaccines (Fluzone® Quadrivalent, Flulaval® Tetra, Afluria® Tetra, and Fluzone® High-Dose Quadrivalent), injection site reactions are common but are generally classified as mild and transient. Fluzone® High-Dose Quadrivalent tends to induce higher rates of systemic reactions post-injection compared to standard-dose IIV due to the increased antigen volumes, but most of these reactions are mild and short-lived. Please refer to the most recent version of the Seasonal Influenza Vaccine Factsheet available online at: www.manitoba.ca/health/flu/factsheets.html for more information on vaccine safety for each of the flu vaccines that are offered as part of Manitoba's Seasonal Influenza Immunization Program.

Guillain-Barré syndrome (GBS): Studies suggest that the absolute risk of GBS in the period following seasonal and influenza A(H1N1)pdm09 influenza vaccination is about one excess case per one million vaccinations. In comparison, the risk of GBS associated with influenza illness is larger with about 17 cases per million influenza-coded health care encounters, which are a proxy for influenza illness. Avoiding subsequent influenza vaccination of persons known to have had GBS within six weeks of a previous influenza vaccination appears prudent at this time. However, the potential risk of GBS recurrence associated with influenza vaccination must be balanced against the risk of GBS associated with influenza infection itself.

Oculo-respiratory syndrome (ORS): ORS was identified during the 2000/01 flu season. Since then, there have been far fewer cases reported per year according to the Canadian Adverse Events Following Immunization Surveillance System. ORS is not considered to be an allergic response. Persons who have an occurrence or recurrence of ORS upon revaccination do not necessarily experience further episodes with future vaccinations.

Individuals who have experienced ORS without lower respiratory tract symptoms may be safely re-vaccinated with influenza vaccine. Persons who experienced ORS with lower respiratory tract symptoms should have an expert review. Health care providers and who are unsure whether an individual previously experienced ORS versus an immunoglobulin E (IgE) mediated hypersensitivity immune response should seek advice. 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.

Vaccine Contraindications and Precautions

NACI has reviewed the data on administering flu vaccine to egg allergic persons and has concluded that egg allergic individuals may be vaccinated using a full dose of any of the seasonal influenza vaccines available, including egg-based vaccines and LAIV. This is

irrespective of a past severe reaction to egg and does not require a prior influenza vaccine skin test. However, immunizers must be prepared with the necessary equipment, knowledge and skills to respond to a vaccine emergency. The observation period post-vaccination of 15 minutes is recommended.

Please refer to the most recent version of the Seasonal Influenza Vaccine Factsheet available online (www.manitoba.ca/health/flu/factsheets.html) for a complete list of contraindications and precautions for each of the flu vaccines that are offered as part of Manitoba's Seasonal Influenza Immunization Program.

Vaccine Products

As per the World Health Organization (WHO), all quadrivalent influenza vaccines that have egg-based or recombinant manufacturing processes for the 2022-23 season in the northern hemisphere contains:

- A/Victoria/2570/2019 (H1N1)pdm09-like virus;
- A/Darwin/9/2021 (H3N2)-like virus;
- B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
- B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

For the 2022-23 season, the following table provides details on the different flu vaccines that are part of this years Seasonal Influenza Immunization Program. The volume of each product will vary based on national allotment and availability.

Vaccine	Ingredients/ Potential Allergens	Supplied/Storage	Dosage/Route/Schedule
Fluzone® Quadrivalent Sanofi Pasteur Limited Product Monograph Use in 6 months of age and older	• Thimerosal (multidose vial only) • Formaldehyde • Egg protein • Triton® X-100 **Latex free**	**Supplied:** 0.5 mL single dose prefilled syringes (package of 10) or 5.0 mL multidose vial (10 doses). **Multidose vial:** shake well to uniformly distribute the suspension before withdrawing each dose. **Prefilled syringe:** shake well to uniformly distribute the suspension before administering each dose. After shaking well, solution is clear to slightly opalescent in colour. There should NOT be any particulate matter and/or	**6 months to 8 years** **Dosage:** 0.5 mL 1 or 2 doses - children 6 months to less than 9 years of age who have NOT previously been vaccinated against influenza should receive a second dose of 0.5 mL after an interval of at least 4 weeks. IM in the deltoid for adults and children greater than 1 year of age.

Vaccine	Ingredients/ Potential Allergens	Supplied/Storage	Dosage/Route/Schedule
		discolouration – if these exist – do not administer. **Storage:** 2 to 8 degrees C. Do not freeze. Discard product if exposed to freezing. Protect from light. Do not use vaccine after expiration date. Once punctured, vaccine can be used to the expiry date. **A maximum of 10 doses total can be withdrawn from a multidose vial.**	IM in the anterolateral aspect of the mid-thigh (vastus lateralis) for children less than 1 year of age. **≥ 9 years of age** **Dosage:** 0.5 mL 1 dose IM in the deltoid for adults and children greater than 1 year of age.
FluLaval® Tetra GlazoSmithKline Inc. Product Monograph Use in 6 months of age and older	• Egg proteins • Sodium deoxycholate • Ethanol • Formaldehyde • Sucrose • α-tocopheryl hydrogen succinate • Polysorbate 80 • Phosphate buffered saline • Thimersosal - in the multidose vial presentation only. **Latex free**	**Supplied:** 5.0 mL multidose vial (10-doses). **Multidose vial:** shake prior to each administration and inspect visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the vaccine. Opalescent translucent to off-white suspension that may sediment slightly. **Storage:** 2 to 8 degrees C. **Do not freeze.** Discard product if exposed to freezing. Protect from light. Once punctured, the multi-dose vail should be discarded within 28 days. Unpunctured vial is stable until expiry date on package.	**6 months to 8 years** Dosage: 0.5 mL 1 or 2 doses - children 6 months to less than 9 years of age who have NOT previously been vaccinated against influenza should receive a second dose of 0.5 mL after an interval of at least 4 weeks. IM in the deltoid for adults and children greater than 1 year of age IM in the anterolateral aspect of the mid-thigh (vastus lateralis) for children less than 1 year of age **≥ 9 years of age** Dosage: 0.5 mL 1 dose IM in the deltoid for adults and children greater than 1 year of age

Vaccine	Ingredients/ Potential Allergens	Supplied/Storage	Dosage/Route/Schedule
Alfuria® Tetra Seqirus Product Monograph Adults and children 5 years or older	• Calcium chloride • Dibasic sodium phosphate (anhydrous) • Monobasic potassium phosphate • Monobasic sodium phosphate • Potassium chloride • Sodium chloride • Thimerosal (multidose vial only) • Water for injection • sodium taurodeozycholate • ovalbumin (egg proteins) • beta-propiolactone • neomycin sulfate • polymyxin B sulfate • hydrocortisone • sucrose **Latex free**	**Supplied:** 0.5 mL single dose prefilled syringes (package of 10) or 5.0 mL multidose vial (10 doses). **Multidose vial:** Should be thoroughly shaken and inspected prior to withdrawing each dose. **Prefilled syringe:** shake to uniformly distribute the sediment and inspect visually. Slightly opaque liquid with some white particulate sediment that resuspends upon shaking to form a homogenous suspension. Do not use if extraneous particulate matter and/or discolouration is observed. **Storage:** 2 to 8 degrees C. **Do not freeze.** Discard product if exposed to freezing. Protect from light. Multidose vial must be used within 28 days from removal of the first dose. **The number of needles punctures should not exceed 10 per multi-dose vial.** Unpunctured vial is stable until expiry date on package.	**5 to 8 years of age** 0.5 mL 1 or 2 doses – children 5 to < 9 years of age who have NOT previously been vaccinated against influenza should receive a second dose of 0.5 mL after an interval of 4 weeks IM in the deltoid for adults and children greater than 5 year of age **≥ 9 years of age** 0.5 mL 1 dose IM in the deltoid for adults and children greater than 5 year of age
Fluzone® High-Dose Quadrivalent Sanofi Pasteur Product Monograph	• Octylphenol ethoxylate (Triton® X-100) • Sodium phosphate buffered isotonic sodium chloride solution	**Supplied:** 0.7 mL single dose prefilled syringe **Prefilled syringe:** shake well to uniformly distribute the suspension before administering the dose. If extraneous particulate matter and/or discolouration exist, the product should not be	**65 years and older** 0.7 mL 1 dose IM in the deltoid for adults 65 year of age and older

Vaccine	Ingredients/ Potential Allergens	Supplied/Storage	Dosage/Route/Schedule
Indicated in adults 65 years and older	• Traces of formaldehyde and ovalbumin **Latex free and thimerosal free**	administered. After shaking the syringe well, clear and slightly opalescent in colour. **Storage:** 2 to 8 degrees C. **Do not freeze.** Discard product if exposed to freezing. Do not use after the expiration date shown on the label.	

Note: This year, all Manitobans 65 years of age and older will be eligible to receive the high-dose influenza vaccine free of charge.

Please note, **ALL** flu vaccines **MUST** be administered by a health care professional who is registered or licensed to provide health care under an Act of the Legislature and authorized under that act to administer vaccines.

Fluzone® High-Dose Quadrivalent

Starting in the 2022-23 influenza season, Fluzone® High-Dose will be offered to any individuals aged 65+.

In an effort to provide stronger protection to older Manitobans, Manitoba Health will expand the eligibility of high-dose inactivated influenza vaccine (Fluzone® High-Dose Quadrivalent) to everyone 65 years of age and older.

Fluzone® High-Dose Quadrivalent contains four times the amount of influenza virus antigen per strain (60 µg vs. 15 µg) compared to the standard-dose IIV. It also contains the four influenza strains (2A + 2B) predicted to be circulating in North America during the 2022-23 season. These are the same strains that are part of the standard-dose IIV.

NACI conducted an updated literature review in 2018, which showed that Fluzone® High-Dose has higher relative efficacy against severe outcomes, including hospitalizations and deaths, compared to a standard-dose IIV in adults 65 years of age and older. Given the evidence of better efficacy in this age group, it is expected that Fluzone® High-Dose Quadrivalent will provide superior protection compared with standard-dose IIV.

Staff and residents of LTCFs, assisted living, and supportive housing who are less than 65 years of age should be immunized with standard-dose IIV. In the event that someone has

been immunized with the standard dose when they were eligible for the high dose Influenza product, it is recommended to not administer the Fluzone® High-Dose Quadrivalent.

The higher antigen concentrations contained within Fluzone® High-Dose Quadrivalent may result in higher rates of post-injection local adverse events compared to standard-dose IIV, but they are expected to last only two to three days and rarely interfere with normal activities. Studies reported higher rates of malaise, myalgia, and moderate to severe fever. Various studies noted a higher rate of systemic reactions with Fluzone® High-Dose Quadrivalent, but serious adverse events were similar in frequency between the high- and standard-dose IIV.

Any reported adverse events following administration of Fluzone® High-Dose Quadrivalent are reviewed based on provincial procedures.

Vaccine Ordering and Distribution Process

Manitoba uses a mixed provider delivery model for Manitoba's Immunization Program, with nurses, nurse practitioners, midwives, physicians, physician assistants, and pharmacists administering vaccines in private and public health settings.

For the 2022/23 influenza season, Manitoba Health is introducing a new, enhanced order and delivery model. Similar to the way physicians and pharmacists currently order their COVID-19 vaccine, the new distribution model is anticipated to increase access to influenza vaccine to all health care providers earlier and also reduce wastage by allowing for increased order frequency throughout the season.

In lieu of ordering either via fax or email, providers will be sent a link to an online survey to order every other week depending on which of the two groups a provider has been assigned to. Orders placed should be based on anticipated usage for the next 2-3 week period, as opposed to the entire influenza season, as in previous years. This way, providers can place orders and receive vaccine shipments on a regular schedule (subject to vaccine manufacturer supply).

Providers are required to register for the flu program to receive the online survey. If your location is not already signed up to order publicly funded vaccines of any kind, please complete the New Immunization Provider Application Form that can be found at the following link prior to registering to be a part of the influenza program: https://www.gov.mb.ca/health/publichealth/cdc/protocol/npaf.pdf.

For information on the new distribution model as well as how to register for the program, please go to www.manitoba.ca/fludistribution.

Orders will be reviewed and may be adjusted based on vaccine availability, historical doses administered, as well as any shortages or delays that may occur. A confirmation email will include a list of all the products to be shipped, the approved quantities, as well as an approximate timeline for when deliveries should be expected.

Providers will also be expected to communicate any special hours of operation (e.g. Closed for lunch between 12-1, closed on Fridays, etc.) and whether or not they are open for Saturday deliveries. This information is extremely important and will ensure an efficient and timely delivery schedule.

To expedite the order process and reduce the number of individual orders that are being shipped to one single location, health care providers at the same facility should submit one order for influenza and pneumococcal vaccine (that covers all providers in the facility).

As in previous years, health care providers are encouraged to start offering influenza and pneumococcal vaccines to their patients as soon as they receive the product.

All future updates pertaining to influenza vaccine distribution/supply including shortages, and/or delays will be posted online at www.manitoba.ca/fludistribution and will also be emailed to providers at the email address provided at the time of registration.

Please note that vaccine wastage should be less than 5% at the end of the influenza season. Any unused vaccine from the previous influenza season should also be returned to the Provincial Distribution Warehouse. Please, follow *Manitoba Health's Return Policy and Procedure* available at: https://www.gov.mb.ca/health/publichealth/cdc/div/docs/vbrp.

Documentation

Adverse events following immunization (AEFI), doses administered, consent obtained and incidents of adverse storage conditions must be recorded and reported to MH.

a. Adverse Events Following Immunization (AEFI)

In accordance with The Public Health Act, health care providers and pharmacies are to report to the regional Medical Officer of Health (MOH) a reportable AEFI within seven days of becoming aware of the AEFI (as per section 59 of The Act). Health care providers should report a serious AEFI (see below) within one business day, which can be by telephone, followed by the complete report thereafter.

A reportable AEFI is an event that:

1. is temporally associated with a vaccine
2. has no other clear cause at the time of reporting
3. is either serious or unexpected

An AEFI is considered “serious” if any of the following criteria are met:

- results in death
- is life-threatening, that is, where the patient was at real, rather than hypothetical, risk of death at the time of the event/reaction
- requires in-patient hospitalization, defined as any of the following:
    - hospital stay lasting ≥ 24 hours based on known date/time of admission and discharge or,
    - hospital stay involving all or part of two consecutive days (i.e. admission and discharge date are at least one day apart but specific time of admission is not specified)
- results in prolongation of existing hospitalization
- results in persistent or significant disability/incapacity (if known at the time of reporting)
- is a congenital anomaly/birth defect
- is medically important, defined as:
    - an event or reaction that might not be immediately life-threatening, or result in death or hospitalisation, but might jeopardise the patient or might require intervention to prevent one of the other seriousness criteria

An AEFI is considered “unexpected” if either of the following criteria is met:

- is not listed in the most current Health Canada-approved product monograph for vaccines marketed in Canada
- listed in the product monograph but is different in nature, severity, frequency, specificity or outcome

The AEFI module of PHIMS allows public health providers with access to PHIMS to report AEFIs directly into PHIMS. Health care providers without access to PHIMS should complete a **Reporting Form for Adverse Events Following Immunization** online at: www.manitoba.ca/health/publichealth/cdc/docs/aefi_form.pdf and submit to your regional MOH (see bottom of form for link to list of MOH contact information). All forms received will also be entered into PHIMS for vaccine safety surveillance in Manitoba, and will be included as part of the client immunization record in the provincial immunization registry within PHIMS. All MOH recommendations of an individual’s AEFI should be recorded in the client’s personal health record.

Manitoba Health reviews all submitted AEFI reports. If a link is found between a possible adverse event and a vaccine, public health officials take appropriate actions to ensure the safety of patients.

For more information on AEFI, visit: www.manitoba.ca/health/publichealth/cdc/div/aefi.html.

b. Data Entry

Every health care provider and facility in Manitoba **MUST ACCOUNT FOR EVERY DOSE OF VACCINE ORDERED AND ADMINISTERED, INCLUDING FLU VACCINE.** Immunizations must be documented in a timely manner in the client's electronic public health record via the Manitoba Immunization Registry (PHIMS) to ensure accurate and up to date information is available. This can be completed in one of three ways:

- Electronically uploaded from the Drug Program Information Network (DPIN) when non-COVID immunizations including the influenza vaccine are administered by pharmacists. **Pharmacies are to only enter COVID-19 immunizations directly into PHIMS.**
- Electronically uploaded from the Claims Processing System (Physician Billing) when publicly funded immunizations are administered by fee-for-service physicians and other health care providers, that shadow bill (e.g. regional nurse practitioners).
- Direct entry into the Public Health Information Management System (PHIMS): health care providers (excluding pharmacists) that have access to PHIMS can enter flu vaccine doses administered directly into Manitoba's Immunization Registry (assuming their permissions allow for data entry).

If you do not have access to PHIMS, are unable to enter information directly into PHIMS (i.e. Private Flu Clinic), or need to submit doses administered to persons without a PHIN you can report those doses by completing and submitting the appropriate fillable form available at https://www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf. All doses administered and reported will be recorded into Manitoba's Public Health Information Management System (PHIMS).

Surveillance of influenza immunization uptake is included in the weekly and end of season influenza surveillance reports. Reports for 2022-23 as well as for previous seasons can be accessed online at: https://www.gov.mb.ca/health/publichealth/surveillance/influenza/index.html

c. Consent

As per Manitoba Health *Informed Consent Guidelines for Immunization* (www.manitoba.ca/health/publichealth/cdc/protocol/consentguidelines.pdf), verbal and/or written consent must be obtained prior to immunization and must be documented via a consent form, medical chart or electronic health record. To assist with obtaining consent for influenza and Pneu-P-23 immunizations, a *Seasonal Influenza and Pneumococcal Vaccine Consent Form* is available online at: www.manitoba.ca/health/flu/docs/flupneumo_consentform.pdf

d. Storage and Handling Requirements

As with all vaccines and biologics, please refer to the online *Cold Chain Protocol – Immunizing Vaccines and Biologics* and corresponding resources for all storage and handling requirements (www.manitoba.ca/health/publichealth/cdc/coldchain.html).

Vaccines must be stored in a temperature monitored refrigerator between 2º to 8º Celsius. In the event that vaccines have been exposed to temperatures outside of 2º to 8º Celsius, health care providers and pharmacists MUST report the adverse storage condition incident to MH by completing/submitting the online form (www.manitoba.ca/health/publichealth/cdc/docs/ccf.pdf) or submit the required information directly through PHIMS.

Manitoba Health does not allow the use of bar fridges to store vaccines and regular mercury thermometers are not to be used to monitor the fridge temperature.

Fridges should only contain vaccines. No food or other biologics should be kept in the vaccine fridge. Health care providers and pharmacists who are holding clinics outside of their main facility, where a fridge may not be present, should review the **Packing, Storage and Handling for Off-Site Immunization Clinics** section of the *Cold Chain Protocol* to ensure that vaccines are stored and transported properly and temperature of the vaccines are maintained and recorded throughout the time they are out of the fridge.

Communications

All promotional/educational resources (e.g. factsheets, posters, brochures) will be available to order, free of charge, from the Materials Distribution Agency, and will also be posted on MH's Seasonal Flu website (www.manitoba.ca/health/flu/index.html). The flu promotional/educational resources may be updated for the 2022-23 season. Confirmation of such a change will be made once any final decisions are made and a communiqué will be sent advising of when the updated resources are available.

As with previous years, Manitoba Health will communicate with health care providers including SDOs, pharmacists, and Indigenous Services Canada (ISC) frequently throughout the summer to support planning of mass clinics. Generally, mass letters are faxed to all health care providers in June, or as soon as possible, advising of the general parameters of the Program (e.g. eligibility criteria) and then again in September (or as needed), with any updated details of the program (resources, vaccine products and ordering, high-risk groups, etc.).

All provincial advertising and official program launch will commence October (estimated start date: October 24).

In order to provide more information to the public, MH will continue to post any clinics that are being held where the public is able to attend. MH has also expanded the visibility of the influenza vaccines for the public through GIS mapping where they can geographically see any locations that have indicated that they have influenza vaccine supply available and are accepting walk-ins/appointments from the public. This information is posted on the *Where Can I Get My Flu Vaccine* website (www.gov.mb.ca/health/flu/where.html). Health care providers and pharmacies that are planning on hosting public clinics are to ensure that the information is provided via email to vaccines@gov.mb.ca at least three week in advance.