Manitoba's Influenza and COVID-19 Immunization Program Plan 2024/25 Season

*Updated September 2024

Manitoba Health, Seniors and Long-Term Care
Public Health Division
Population and 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
AESI	Adverse events of special interest
CI	Confidence interval
COVID-19	Coronavirus Disease of 2019
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
MHSLTC	Manitoba Health, Seniors and Long-Term Care
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
RHA	**Regional Health Authorities**
SH	**Shared Health**
VE	Vaccine effectiveness
WHO	World Health Organization

Purpose

The purpose of this Program Plan is to provide all health care providers, regional health authorities (RHAs), Shared Health (SH) and Indigenous partners, that participate in Manitoba's Seasonal Influenza and COVID-19 Immunization Program, with the provincial program details for the upcoming 2024/25 respiratory illness season.

2024-25 Program Dates

- **February 2024: The** World Health Organization released the recommended strains for the 2024-25 Northern Hemisphere influenza vaccines. Manitoba is expecting quadrivalent egg-based flu vaccines.
- **July 2024:** NACI released its statement on seasonal influenza vaccine for 2024-25, recommending the use of any age-appropriate quadrivalent or trivalent influenza vaccine for individuals 6 months of age and older who do not have contraindications or precautions.
- **August 2024:** All providers who want to participate in the influenza and COVID-19 immunization program must register **CLICK HERE TO REGISTER**. Providers are asked to complete the online registration form by August 16, 2023, to ensure receipt of all communications, allow for the creation of distribution groups, and allocation planning.
- **Early October 2024:** The annual senior reminder letter regarding pneumococcal, high-dose Influenza, and COVID-19 vaccines is scheduled to go out to people who have turned 65 years of age in the past year.
- **Early to mid-October:** Launch of the provincial 2024/25 Seasonal Influenza and COVID-19 Immunization Program advertising campaign.
- **October 15:** Regional public health immunization clinics can begin during this week. Regions should consider which group they are in when planning clinics (i.e. group 2 locations should not plan clinics to be held the first week). Offices within a region should work together to plan clinics over several weeks.
- **October 31:** Personal care homes should complete their influenza and COVID-19 immunization programs for their residents.

SEASONAL INFLUENZA

Eligibility Criteria

For the 2024/25 influenza season, all Manitobans 6 months of age and older will be eligible to receive the seasonal influenza (flu) vaccine free of charge.

An annual flu vaccine is especially important for those at increased risk of serious illness from the flu, their caregivers, and their close contacts. This includes:

People at high risk of influenza-related complications or hospitalization

- All children 6 to 59 months of age
- Adults and children with the following chronic health conditions
    - Cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis, and asthma);
    - Diabetes mellitus and other metabolic diseases;
    - Cancer, immune compromising conditions (due to underlying disease, therapy, or both, such as solid organ transplant or hematopoietic stem cell transplant recipients);
    - Renal disease;
    - Anemia or hemoglobinopathy;
    - Neurologic or neurodevelopmental conditions (includes neuromuscular, neurovascular, neurodegenerative, neurodevelopmental conditions, and seizure disorders [and, for children, includes febrile seizures and isolated developmental delay], but excludes migraines and psychiatric conditions without neurological conditions)
    - Morbid obesity (defined as BMI of 40 kg/m² and over); and
    - Children 6 months to 18 years of age undergoing treatment for long periods with acetylsalicylic acid, because of the potential increase of Reye's syndrome associated with influenza
- All individuals who are pregnant;
- All individuals of any age who are residents of nursing homes and other chronic care facilities;
- Adults 65 years of age and older; and
- Indigenous Peoples.

People capable of transmitting influenza to those at high risk

- Traditional healers, health care and other care providers in facilities and community settings who, through their activities, are capable of transmitting influenza to those at high risk
- Household contacts, both adults and children, of individuals at high risk, whether or not the individual at high risk has been vaccinated:
    - household contacts of individuals at high risk

    - household contacts of infants less than 6 months of age, as these infants are at high risk but cannot receive influenza vaccine
    - members of a household expecting a newborn during the influenza season;
- Those providing regular childcare to children 0 to 59 months of age, whether in or out of the home; and
- Those who provide services within closed or relatively closed settings to people at high risk (e.g., crew on a cruise ship).

Others

- People who provide essential community services; and
- People in direct contact with poultry potentially infected with avian influenza during culling operations.

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. Administration fees may still apply.

Recommendations

Infants and Children

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 one (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.

Pregnant and Breastfeeding Women

NACI recommends the inclusion of all pregnant individuals in the influenza 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 as soon as it is available 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 to protect the infant. Infants cannot be immunized against influenza until 6 months of age. Annual influenza vaccination is recommended during breastfeeding if not given during pregnancy www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-3-vaccination-specific-populations/page-4-immunization-pregnancy-breastfeeding.html.

Health Care Workers

Influenza vaccination provides benefits to health care workers (HCWs) and to the patients to whom they provide care. Health care providers being immunized 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 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 health care is provided, including emergency care, prehospital care, hospital, LTCFs, home care, ambulatory care and facilities/locations in the community where care is provided (i.e. physician offices, immunization clinics, etc.).

All doses administered, including those to individuals without a Personal Health Identification Number (PHIN), are to be reported to ensure that they are captured in Manitoba's Immunization Registry. See the *Documentation section* below on the ways to report doses administered.

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 include achieving 80% coverage among:

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

Every year, NACI updates its recommendations regarding the use of the seasonal flu vaccine. MHSLTC and Manitoba's Provincial Vaccine Advisory Committee (PVAC) thoroughly review NACI's annual recommendations to inform provincial recommendations and program details.

NACI's Canadian Immunization Guide and Statement on Seasonal Influenza Vaccine for 2024-25 is available online at www.canada.ca/en/public-health/services/publications/vaccines-

immunization/national-advisory-committee-immunization-statement-seasonal-influenza-vaccine-2024-2025.html

NACI Seasonal Influenza Guidance in Context of H5N1:
Since 2022, there has been an ongoing global epizootic outbreak of highly pathogenic avian influenza (HPAI) A(H5N1). For the latest information on the avian influenza A(H5N1) outbreak in Canada and the United States, refer to PHAC's avian influenza A(H5N1) content and US CDC situation summary. NACI reiterates its recommendation that all individuals 6 months of age and older should receive an authorized, age-appropriate seasonal influenza vaccine. This includes those likely to have significant exposure to influenza A(H5N1) through interactions with birds or mammals (such as poultry, livestock, slaughterhouse and processing plant workers, wildlife officers/researchers, and veterinarians).

MHSLTC Seasonal Influenza Management Protocol is also available online at www.manitoba.ca/health/flu/pro.html.

Annual flu vaccination is recommended since the strains contained within the vaccine 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.

Vaccine Efficacy and Effectiveness

Influenza vaccine has been shown to be efficacious in clinical trials although real-world effectiveness can vary depending on several factors including how well the vaccine strain matches 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.

Contraindications and Precautions

Influenza vaccines are contraindicated in persons with a history of anaphylaxis after previous administration of the vaccine and in persons with proven immediate or anaphylactic hypersensitivity to any component, except egg, of the specific vaccine or its container.

NACI has reviewed the data on administering the 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. 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 at least 15 minutes is recommended.

Please refer to the most recent version of the Seasonal Influenza Vaccine Factsheet available online at www.manitoba.ca/health/flu/factsheets.html or the vaccine product monographs 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.

Adverse Events of Special Interest

With intramuscularly injected (needle) vaccines (Fluzone® Quadrivalent, Flulaval® 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 reactions post-injection compared to standard-dose IIV due to the higher antigen dose, 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.

There are a few Adverse Events of Special Interest (AESI)[1] that need to be watched out for when giving the flu vaccine, including but not limited to the following:

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 CAEFISS. 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.

[1] An AESI is defined as an adverse event (serious or non-serious) that is "of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor could be appropriate. Such an event might require further investigation in order to characterize and understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties (e.g., regulators) might also be warranted." (Council for International Organizations of Medical Sciences (CIOMS) VII

Individuals who have experienced ORS without lower respiratory tract symptoms may be safely re-vaccinated with the influenza vaccine. 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 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.

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) of IIV (Fluzone® Quadrivalent, 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 how to report an adverse event following immunization (AEFI), see the *Documentation section* below.

Seasonal Influenza Vaccine Products

As per the World Health Organization (WHO), standard-dose inactivated quadrivalent influenza vaccines authorized and available in Canada for the 2024–25 season are expected to contain the following strains:

- A/Victoria/4897/2022 (H1N1)pdm09-like virus
- A/Thailand/8/2022 (H3N2)-like virus;
- B/Austria/1359417/2021 (B/Victoria lineage)-like virus
- B/Phuket/3073/2013 (B/Yamagata lineage)-like virus

For the 2024-25 season, please refer to the table available at www.gov.mb.ca/health/flu/docs/influenza_product_quick_reference_guide.pdf to find details on the different flu vaccines that are part of this year's Seasonal Influenza Immunization Program. Which products and in what volumes Manitoba will receive will vary based on national allotment and availability.

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. Please, refer to the Publicly Funded Provincial Immunization Program Standards available at www.manitoba.ca/health/publichealth/cdc/div/manual/docs/standards.pdf

Fluzone® High-Dose Quadrivalent

Fluzone® High-Dose Quadrivalent contains four influenza strains (2A + 2B) and four times the amount of influenza virus antigen per strain (60 µg vs. 15 µg) compared to the standard-dose IIV. These are the same strains that are part of the standard-dose IIV. It is the recommended flu vaccine product for all individuals aged 65 years of age and older.

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.

COVID-19 (SARS-CoV-2)

Eligibility Criteria

All people in Manitoba aged 6 months and older are eligible for COVID-19 vaccination. The 2024-2025 COVID-19 vaccines are the most updated formulations that are anticipated to protect against the KP.2 strain of the COVID-19 virus. Please, refer to www.manitoba.ca/covid19/vaccine.html for more information.

International students and out-of-province visitors continue to be eligible to receive the COVID-19 vaccine free-of-charge regardless of third-party insurance and/or Manitoba Health coverage. Administration fees may still apply.

Recommendations

All providers are required to review a client's immunization history to determine the last dose of COVID-19 vaccine. Since COVID-19 vaccines have not been broadly available since May 1, 2024, the majority of Manitobans will be eligible to receive the 2024-2025 COVID-19 vaccine as soon as it becomes available, with the recommended interval of at least 6 months between doses. Those most at risk of severe disease who received a dose of the COVID-19 vaccine in the spring or later will require a minimum interval of 3 months between the previous dose and the updated 2024-2025 COVID-19 vaccine. Please note there may be a decreased immune response to the vaccine when provided sooner than the recommended interval of at least 6 months.

Beginning in the fall of 2024, NACI recommends the following for the use of the most recently updated COVID-19 vaccines:

- COVID-19 vaccination is strongly recommended for previously vaccinated and unvaccinated individuals at increased risk of SARS-CoV-2 infection or severe COVID-19 disease as follows:
    - All adults 65 years of age or older
    - Those 6 months of age and older who are:
        - Residents of long-term care homes and other congregate living settings
        - Individuals with underlying medical conditions that place them at higher risk of severe COVID-19, including children with complex health needs
        - Individuals who are pregnant
        - Individuals in or from First Nations, Métis and Inuit communities
        - Members of racialized and other equity-deserving communities
        - People who provide essential community services
- All other previously vaccinated and unvaccinated individuals (6 months of age and older) who are not at increased risk for SARS-CoV-2 infection or severe COVID-19 disease (i.e., not on the list above) may receive the most recently updated vaccine in the fall of 2024.

For more information on the National Advisory Committee on Immunization (NACI) recommendations, please refer to Guidance on the use of COVID-19 vaccines during the fall of 2024 - Canada.ca.

Vaccine Schedule

For previously vaccinated individuals

For those previously vaccinated against COVID-19, all individuals aged 6 months and older are eligible to receive **one dose** of the updated formulation of the COVID-19 vaccine.

Schedule for unvaccinated individuals

Individuals 6 months to 4 years of age:

Children 6 months to 4 years of age who have never been vaccinated against COVID-19 infection are eligible to receive **two doses** with a minimum interval of 4 weeks between doses. Children must be at least six months of age at the time of their immunization appointment.

Individuals 5 years of age and older:

Individuals 5 years of age and older who have never been vaccinated against COVID-19 are eligible to receive **one dose** of the updated COVID-19 vaccine.

Immunocompromised Individuals:

Immunocompromised individuals six months of age and older who are moderately to severely immunocompromised and have never been vaccinated against COVID-19 infection are eligible to receive **three doses** of the COVID-19 vaccine. The recommended interval between doses is four to eight weeks. Health-care providers may recommend a different immunization schedule based on a review of medical history and individual circumstances.

For the purposes of COVID-19 vaccine recommendations, the following individuals are considered moderately to severely immunocompromised due to a medical condition and/or treatment:

- are receiving active chemotherapy (or immunotherapy) for cancer;
- have received a solid organ transplant and are currently receiving chemotherapy or other immunosuppressive therapy;
- were born with moderate or severe dysfunction of their immune system;
- are living with untreated or advanced HIV-AIDS; or
- are taking certain medications that severely affect the immune system.
- The following people should talk to their doctor to see whether they are considered to be immunocompromised:
    - receiving hemodialysis or peritoneal dialysis;
    - are on the list to receive a solid organ transplant; or
    - have a ventricular assist device (VAD).

For more information on the National Advisory Committee on Immunization (NACI) recommendations, please go to the Canadian Immunization Guide at canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html

Immunization after a COVID-19 infection

Advice for immunization after a COVID-19 infection:

- For individuals who have recently had a positive COVID-19 test result, the risk of getting COVID-19 is low in the months after infection. It is recommended to wait 3 to 6 months between infection and immunization with the COVID-19 vaccine. The immune response is better when there is more time between infection and vaccination.
- For individuals who have or had a mild illness and did not get a COVID-19 test, it is recommended to get immunized rather than waiting 3 to 6 months to receive the vaccine. Anyone with a high fever should postpone getting the vaccine until recovered.
- Recommendations may be different for those who are moderately to severely immunocompromised and should speak to their health care provider to get the best advice on when to get the vaccine after a COVID-19 infection.

Adverse Events of Special Interest

Adverse events most commonly associated with COVID-19 vaccination are mild and go away on their own with minimal to no intervention. These include local reactions like redness, soreness and swelling as well as systemic reactions like chills, fatigue, joint pain, headache, low-grade fever and muscle aches.

Less commonly, more concerning adverse events have been reported. Below is a listing of AESI[2] that have been reported following COVID-19 vaccination in Manitoba in the two-year period from 2021 to 2022:

AESI	Count*	Rate (per 100k doses)
mRNA		
Anaphylaxis	54	1.65
Myocarditis/Pericarditis	45	1.38
Bell's Palsy	31	0.95
Seizure	24	0.74
Venous Thromboembolism	19	0.58
Arrythmia	14	0.43
Stroke	11	0.34

[2] An AESI is defined as an adverse event (serious or non-serious) that is "of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor could be appropriate. Such an event might require further investigation in order to characterize and understand it. Depending on the nature of the event, rapid communication by the trial sponsor to other parties (e.g., regulators) might also be warranted." (Council for International Organizations of Medical Sciences (CIOMS) VII

Coronary Artery Disease	6	0.18
Guillain-Barré syndrome	3	0.09
Thrombocytopenia	3	0.09
Viral vector†		
Venous Thromboembolism‡	15	15.69
Bell's Palsy	5	5.23
Thrombocytopenia‡	5	5.23
Anaphylaxis	4	4.18
Stroke	4	4.18
Seizure	3	3.14

*Only lists AESIs with count of 3 or more

†All associated specifically with the AstraZeneca product, which the province no longer carries

‡Including but not limited to the Thrombosis with Thrombocytopenia Syndrome/Vaccine-Induced Thrombosis with Thrombocytopenia

For more information on how to report an adverse event following immunization (AEFI), see the *Documentation section* below.

Learn more about:

- Reported side effects following COVID-19 vaccination
- Vaccine safety and possible side effects: Allergic reactions

Contraindications and Precautions

People who had a severe and immediate (4 hours or less following vaccination) allergic reaction after receiving an mRNA COVID-19 vaccine or have a suspected or known allergy to a component of the vaccine (e.g., tromethamine, PEG in COVID-19 mRNA vaccines) should be referred to an allergist for further assessment.

Individuals with a history of an allergic reaction to contrast dye can still receive an mRNA COVID-19 vaccine and should be observed for 30 minutes after vaccine administration.

As a precautionary measure, further doses of mRNA COVID-19 vaccines should be deferred among individuals who have experienced myocarditis and/or pericarditis within 6 weeks following a previous dose of an mRNA COVID-19 vaccine.

Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations can receive the next dose once they are symptom-free and at least 90 days have elapsed since vaccination.

Current data do not show a product-specific difference in the risks of myocarditis and/or pericarditis after a dose of an updated formulation of mRNA COVID-19 vaccine.

COVID-19 Vaccine Products

For the 2024/25 COVID-19 Immunization Program the following products will be available:

- Moderna (Spikevax) – 6 months of age and older
- Pfizer (Comirnaty) – 12 years of age and older

Note: The Government of Canada is NOT procuring Pfizer infant or pediatric vaccines, or the non-mRNA Novavax vaccine for those 12 years of age and older.

To see the details of the various COVID-19 products available please see the influenza, COVID-19, and pneumococcal Vaccine Comparison Chart located at www.gov.mb.ca/health/flu/docs/covid-and-flu-vaccine-comparison-chart.pdf.
Please refer to the product monographs for more specific details about each product www.manitoba.ca/covid19/health-care-providers.html#product-monographs.

PNEUMOCOCCAL IMMUNIZATION PROGRAM

Manitoba offers one dose of pneumococcal conjugate (Pneu-C-20) vaccine to all those 65 years of age and older if they have not yet received Pneu-P-23 since turning 65 years old.
The Pneu-C-20 vaccine can be offered year-round although it can be co-administered with the flu and COVID-19 vaccines if the client is eligible.
Some people under the age of 65 years of age could also be eligible for a Pneu-C-20 vaccine or the pneumococcal conjugate (Pneu-C-15) vaccine. Please, see the full eligibility criteria at www.manitoba.ca/health/publichealth/cdc/vaccineeligibility.html.

For additional information and resources, please visit the Manitoba Health Invasive Pneumococcal Disease webpage: www.manitoba.ca/health/publichealth/diseases/pneumococcal.html.

Flu and COVID-19 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.

Providers are required to register for the flu and COVID-19 immunization program.

Those who register will be sent order surveys throughout the season. Responses to those surveys will be required by the indicated deadlines in order to receive products for that time period. Deliveries will be scheduled every other week alternating between two (2) distribution groups.

Note: This year, priority locations (hospitals, FN, LTC) will be able to receive deliveries weekly.

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 be sent to each location that placed an order that will include a list of all the products to be shipped, the approved quantities, as well as an approximate timeline for when deliveries are expected to arrive.

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 weekend 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, COVID-19, and pneumococcal vaccines (that covers all providers in the facility).

Health care providers are encouraged to start offering influenza, COVID-19 and pneumococcal vaccines to their patients as soon as they receive the product.

For information on the distribution model as well as how to register for the program, please go to www.manitoba.ca/fludistribution. All future updates pertaining to influenza and COVID-19 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.

Any unused vaccine from the previous influenza season is to be returned to the Provincial Distribution Warehouse. Please, follow *Manitoba Health's Return Policy and Procedure* available at: www.manitoba.ca/health/publichealth/cdc/div/docs/vbrp.

Monitoring the Safety of Vaccines

Vaccines are safe and well tolerated. Notwithstanding data from pre-marketing trials showing vaccines to have a safe and stable profile, steps are undertaken by national and provincial vaccine programs to monitor their use in post-marketing for any new safety issue that might emerge. 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 reporting of AEFIs with current influenza vaccines (usually weekly) 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 was first implemented during the COVID-19 vaccination campaign and has since been employed as well for other vaccine products and will continue to be implemented during the flu and COVID-19 immunization campaign. This involves a systematic, near-real-time assessment of an identified risk associated with the use of the vaccine that uses dynamic data files and sequential analysis for early detection of adverse events. Urgent measures to protect the public are then immediately undertaken, where appropriate.

Documentation

An immunizer is a health care provider who is registered or licensed to provide health care under current legislation and who is authorized under that legislation to administer vaccines to a client/patient.

Immunizers MUST record and maintain doses administered, informed consent, adverse events following immunization (AEFI), and incidents of adverse storage conditions as outlined in the provincial immunization program standards. Audits will be conducted periodically and documentation may be required to be submitted to MHSLTC, as requested.

Pharmacies that contract nurses to conduct flu and COVID-19 immunizations must ensure that they meet those standards and keep records of doses administered, informed consent, AEFI, and any other incidents.

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 and the Provincial Immunization Competency Guideline at www.manitoba.ca/health/publichealth/cdc/div/manual/docs/immcomp.pdf.

a. Reporting an AEFI

In accordance with section 59 of 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. Health care providers should report a serious AEFI (see below) within one business day, which can be by telephone, followed by the complete written report within 72 hours.

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 report AEFIs directly into PHIMS. Health care providers without access to PHIMS should complete a **Reporting Form for Adverse Events Following Immunization** available online at: www.manitoba.ca/health/publichealth/cdc/docs/aefi_form.pdf and submit it to their regional MOH. A listing of regional MOH contact information is found here: www.gov.mb.ca/health/publichealth/contactlist.html.

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.

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

For more information on AEFI, visit www.gov.mb.ca/health/publichealth/cdc/protocol/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 AND COVID-19 VACCINES.** Immunizations must be reported 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 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).
    - The updated tariff codes to be used for Manitoba's Publicly Funded Immunization Program can be located at www.gov.mb.ca/health/publichealth/surveillance/immunization/docs/mims_tariff_codes.pdf
- Direct entry into the Public Health Information Management System (PHIMS): health care providers that have access to PHIMS can enter flu and COVID-19 vaccine doses administered directly into Manitoba's Immunization Registry (assuming their permissions allow for data entry).
    - Pharmacists are required to enter flu and COVID-19 vaccines that they administer directly into PHIMS.
- If you do not have access to PHIMS or are unable to enter information directly into PHIMS (i.e. Private Flu Clinic), complete and submit for the doses administered using www.manitoba.ca/health/publichealth/cdc/div/docs/iifhcp.pdf.
    - For doses administered to persons without a PHIN complete and submit www.manitoba.ca/health/publichealth/cdc/div/manual/docs/vaccine-admin-reporting-no- phin.pdf and fax to Manitoba PHIMS Quality Assurance at 204-945-6482.
    - All doses administered and reported will be recorded into PHIMS.

Documentation and record storage should also comply with the respective health care providers' regulatory body.

Surveillance of influenza and COVID-19 immunization uptake is included in the weekly and end-of-season respiratory surveillance reports. Reports for 2024-25 as well as for previous seasons can be accessed online at: 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, a combined influenza, COVID-19, and Pneu-C-20 Vaccine Consent Form is available online at: www.gov.mb.ca/health/publichealth/cdc/div/manual/index.html

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.

Flu and COVID-19 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, the location MUST report the adverse storage condition incident to MHSLTC by completing/submitting the online form www.manitoba.ca/health/publichealth/cdc/docs/ccf.pdf or submit the required information directly through PHIMS.

For information on the storage and handling of COVID-19 vaccines, please refer directly to the product monographs. Storage and Handling information is also included in the COVID-19, Influenza and Pneumococcal Vaccine Quick Reference Guide 2024-2025 available online: www.gov.mb.ca/health/flu/pro.html and www.gov.mb.ca/covid19/health-care-providers.html.

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.* This will ensure that vaccines are stored and transported properly and temperature of the vaccines is maintained and recorded throughout the time they are out of the fridge.

Communications

Promotional/educational resources (i.e. factsheets, posters, brochures) will be available to order, free of charge, from the Materials Distribution Agency, and will also be posted on MHSLTC's

Seasonal Flu website at www.manitoba.ca/health/flu/pro.html and COVID-19 website at www.manitoba.ca/covid19/vaccine.html where they can be downloaded electronically.
The flu and COVID-19 promotional/educational resources were updated for the 2024-25 season. Confirmation of such a change will be made once any final decisions are made and will be broadly communicated once the updated resources are available. The Order Form to order promotional and educational resources is available here: www.gov.mb.ca/health/flu/docs/resources-order-form.xlsx. As with previous years, MHSLTC will communicate with health care providers including RHAs, SH, pharmacists, and Indigenous partners frequently to support the planning of mass clinics.

In order to provide more information to the public, MHSLTC will continue to identify on the Flu and COVID-19 Vaccine Provider Map, any locations that have registered to participate in the flu and COVID-19 immunization program as well as regional clinics for the public. Flu and COVID-19 Vaccine Provider Map can be found at www.gov.mb.ca/covid19/vaccine.html#finder.

Health care providers and pharmacies that are planning on hosting public clinics are to ensure that information about the clinic (i.e. date, times, location, accessibility, appointment or walk-in) is provided via email to vaccines@gov.mb.ca at least three weeks in advance. MHSLTC will make every effort to include these in the Flu and COVID-19 Vaccine Provider Map.