Manitoba's Influenza and COVID-19 Immunization Program Plan 2025/26 Season

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Manitoba Health, Seniors and Long-Term Care
Public Health Division
Population and Public Health Branch

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Acronyms

AEFI Adverse event following immunization

AESI Adverse events of special interest

CAEFISS Canadian Adverse Events Following Immunization Surveillance System

COVID-19 Coronavirus Disease of 2019

GBS Guillain-Barré syndrome

IIV Inactivated 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

PFS Pre-filled syringe

PHAC Public Health Agency of Canada

PHIMS Public Health Information Management System

PHIN Personal health identification number

PVAC Provincial Vaccine Advisory Committee

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, who participate in Manitoba's Seasonal Influenza and COVID-19 Immunization Program, with the provincial program details for the upcoming 2025/26 respiratory illness season.

Program Dates

- **February:** The World Health Organization released the recommended strains for the 2025-26 Northern Hemisphere influenza vaccines.
- April: NACI released its statement on seasonal influenza vaccine for the upcoming season, 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.
- July: Communication was sent out to all providers with directions on how to register if they
 want to participate in the influenza and COVID-19 immunization program <u>CLICK HERE TO</u>
 <u>REGISTER</u>. Providers are asked to complete the online registration form by August 15, 2025, to
 ensure receipt of all communications, allow for the creation of distribution groups, and
 allocation planning.
- Early October: The annual reminder letter for people aged 65 years and older regarding pneumococcal, enhanced 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 2025/26 Seasonal Influenza and COVID-19
 Immunization Program advertising campaign.
- October 13, 2025: 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, 2025: LTCFs should have completed their influenza and COVID-19 immunization programs for their residents.

SEASONAL INFLUENZA Eligibility Criteria

For the 2025/26 influenza season, all Manitobans 6 months of age and older will be eligible to receive the seasonal influenza (flu) vaccine free of charge.

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.

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);
 - o 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)
 - Class 3 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:
 - o 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
 - o 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 whose occupational and/or recreational activities increase their risk of exposure to avian influenza A(H5N1) viruses.

See more information on the Seasonal Influenza Vaccine Products here.

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.

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 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 thoroughly reviews NACI's annual recommendations to inform provincial recommendations and program details.

NACI's Canadian Immunization Guide and Statement on Seasonal Influenza Vaccine for 2025-26 is available online at National Advisory Committee on Immunization (NACI): Statements and publications - Canada.ca

NACI Seasonal Influenza Guidance in Context of H5N1:

Since 2020, 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 the <u>Public Health Agency of Canada's avian influenza A(H5N1)</u> content and <u>US CDC situation summary</u>. 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).

For more information, refer to the section <u>Groups for whom influenza vaccination is particularly important</u> and <u>List 1</u> of the updated <u>NACI statement</u>.

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

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.

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 flu vaccines 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 influenza vaccine are thimerosal-free.

Please refer to the vaccine product monographs at:

manitoba.ca/respiratoryviruses/resources-hcp.html#mono 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.

Seasonal Influenza Vaccine Products

As per the World Health Organization (WHO), standard-dose inactivated trivalent influenza vaccines authorized and available in Canada for the 2025-26 season are expected to contain the following strains:

- Influenza A(H1N1): The A/Victoria/4897/2022 (H1N1)pdm09-like virus.
- Influenza A(H3N2): The A/Croatia/10136RV/2023 (H3N2)-like virus (egg-based) and A/District of Columbia/27/2023 (H3N2)-like virus (cell-based).
- Influenza B (B/Victoria lineage): The B/Austria/1359417/2021 (B/Victoria lineage)-like virus.

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.

The products and in what volumes Manitoba receives varies based on national allotment and availability. For the 2025-26 season, please refer to the COVID-19/Influenza/Pneumococcal Vaccine

Quick Reference Guide and Comparison Chart, available at

www.gov.mb.ca/respiratoryviruses/resources-hcp.html#resources for details on the influenza

vaccines that are part of this year's Influenza Immunization Program.

Please refer to the product monographs for the most current and complete information at manitoba.ca/respiratoryviruses/resources-hcp.html#mono.

Standard Dose Influenza Vaccines

Standard dose flu vaccines contain standardized amounts of the HA protein from representative seed strains of the 2 human influenza A subtypes (H3N2 and H1N1) and 1 influenza B lineage (Victoria). All flu vaccines currently available in Manitoba are produced in eggs, except for Flucelvax®, which is a mammalian cell culture-based inactivated, subunit influenza vaccine that is prepared from viruses propagated in mammalian cell lines. Flucelvax® is a standard dose flu

vaccine newly available in Manitoba this year. Standard dose vaccines are offered to everyone aged six months 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 flu vaccine.

Enhanced Influenza Vaccines for individuals 65 years of Age and Older

Individuals aged 65 years and older are recommended to receive an enhanced influenza vaccine rather than the standard-dose flu vaccine.

Enhanced flu vaccines are specifically formulated to produce a stronger immune response in older adults, who are at higher risk of severe complications from influenza. They contain the same three strains that are part of the standard-dose flu vaccines (2A + 1B).

In Manitoba, two enhanced flu vaccines are available:

- Fluad® (adjuvanted)
- Fluzone® High-Dose

If an individual has already received a standard-dose influenza vaccine when eligible for an enhanced vaccine (such as Fluzone® High-Dose or Fluad® adjuvanted), it is not recommended to administer an additional dose of the enhanced vaccine during the same influenza season.

Any reported adverse events following administration of Fluzone® High-Dose or Fluad® Adjuvanted Trivalent are reviewed based on provincial procedures.

Fluzone High-Dose contains four times the amount of influenza virus antigen per strain (60 μg vs. 15 μg) compared to the standard-dose flu vaccine. The higher antigen concentrations contained within Fluzone High-Dose may result in higher rates of post-injection local adverse events compared to standard-dose flu vaccines, 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, but serious adverse events were similar in frequency between the high- and standard-dose flu vaccines.

Fluad® is an adjuvanted trivalent influenza vaccine specifically designed for adults 65 years of age and older. It contains an adjuvant, MF59, which enhances the immune response. The most

frequently reported solicited local adverse events within 4 days of vaccination were injection site pain, followed by temperature at the injection site ("warm" or "hot") and erythema. Local injection-site reactions (pain and temperature at the injection site) were more frequent in subjects who received the MF59 adjuvanted vaccine than in those who received nonadjuvanted vaccine. The most frequently reported solicited systemic adverse events were headache, fatigue, malaise and myalgia.

Based on supply provided to Manitoba of the enhanced influenza vaccines, the following outlines the eligibility for these vaccines:

Fluzone® High-Dose

- Adults aged 65 years and older at highest risk of severe outcomes from influenza:
 - o residents of long-term care facilities (LTCF), including new and unimmunized residents admitted to an LTCF during flu season;
 - o residents of supported and assisted living facilities;
 - o clients in interim/transitional care beds;
 - o clients receiving homecare services while on a waiting list for admission into a LTCF;
 - Indigenous Manitobans regardless of residence;
 - o people living in a remote/isolated community or north of the 53rd parallel of latitude;
 - individuals in provincial correctional facilities, including those who are newly
 incarcerated or transferred from other federal or out-of-province correctional facilities.
 - o Community dwelling individuals aged 80 years and older

Fluad® Adjuvanted Trivalent

• Community dwelling individuals aged 65-79 years and older

Adverse Events

With intramuscularly injected (needle) vaccines, injection site reactions are common but are generally classified as mild and transient.

Enhanced flu vaccines for adults 65 years of age and older create a stronger immune
response and induce higher rates of reactions post-injection compared to standard-dose
flu vaccines due to the higher antigen dose in the Fluzone® High-Dose vaccine and the
adjuvant in the Fluad® adjuvanted vaccine, but most of these reactions are mild and shortlived.

Please refer to the most recent version of the Seasonal Influenza Vaccine Factsheet available online at manitoba.ca/respiratoryviruses/resources-public.html and the product monographs at https://manitoba.ca/respiratoryviruses/resources-hcp.html#mono 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 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 revaccinated 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

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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

the preference of one vaccine product over another when revaccinating those who have previously experienced ORS.

For more information on the contents of influenza and COVID-19 vaccines, please visit 'Contents of immunizing agents authorised for use in Canada: <u>Canadian Immunization Guide</u> – Canada.ca'

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

COVID-19 (SARS-CoV-2) Eligibility Criteria

All people in Manitoba aged 6 months and older are eligible for COVID-19 vaccination. The fall COVID-19 vaccines are the most updated formulations that are anticipated to protect against the current 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

Since COVID-19 vaccines have not been broadly available since June 30, 2025, the majority of Manitobans will be eligible to receive the 2025-2026 COVID-19 vaccine as soon as it becomes available. Those most at risk of severe disease who received a dose of the COVID-19 vaccine in the summer will require a minimum interval of 3 months between the previous dose and the updated 2025-2026 COVID-19 vaccine.

In January 2025, NACI updated its recommendations up to the summer of 2026:

- COVID-19 vaccination is strongly recommended for individuals at increased risk of SARS-CoV-2 exposure or severe COVID-19 disease, which includes the following individuals:
 - All adults 65 years of age or older
 - o Those 6 months of age and older who are:

- Residents of long-term care homes and other congregate living settings
- Individuals with <u>underlying medical conditions</u> that place them at higher risk of severe COVID-19, including children with complex health needs
- Pregnant women and individuals who are pregnant
- Individuals in or from First Nations, Métis and Inuit communities
- Members of racialized and other equity-denied communities
- Health care workers and other care providers in facilities and community settings
- All other individuals (6 months of age and older) who are not at increased risk for SARS-CoV-2 exposure or severe COVID-19 disease (i.e., not on the list above) may receive a COVID-19 vaccine.

For more information on the National Advisory Committee on Immunization (NACI) recommendations, please refer to <u>Guidance on the use of COVID-19 vaccines for 2025 to summer 2026</u>.

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.

Some high-risk individuals are recommended to also receive a second dose to mitigate the waning protection from COVID-19 vaccines.

Schedule for unvaccinated individuals

Unvaccinated individuals should receive COVID-19 vaccine according to the recommended schedule based on age, with one or two additional doses for those who are moderately to severely immunocompromised, see the COVID-19 chapter of the CIG for vaccine schedules for unvaccinated individuals.

Contraindications and Precautions

In individuals with a confirmed severe, immediate (≤4 hours following exposure) allergy (e.g., anaphylaxis) to a component of a specific COVID-19 vaccine (e.g., PEG), or its container,

consultation with an allergist is recommended before receiving the specific COVID-19 vaccine. Individuals with a known or suspected serious allergy to a component of a COVID-19 vaccine for whom the vaccine is felt to be appropriate should be observed for at least 30 minutes after vaccination, if they receive a vaccine containing that component or have a proven serious allergic reaction to any injectable therapy.

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 2025-26 season, updated COVID-19 vaccines will target the Omicron LP.8.1 variant of COVID-19.

For details on the different COVID-19 vaccines that are part of this year's COVID-19 Immunization Program, please refer to the COVID-19/Influenza/Pneumococcal Vaccine Quick Reference Guide and Comparison Chart, available at www.gov.mb.ca/respiratoryviruses/resources-hcp.html#resources.

Note: Only mRNA COVID-19 vaccines will be available for the 2025-26 season as part of publicly funded COVID-19 immunization programs across Canada, including Manitoba. The Pfizer infant vaccine and the non-mRNA COVID-19 vaccine previously supplied by Novavax will not be procured for public programs by provinces and territories.

Please refer to the product monographs for the most current and complete information at https://manitoba.ca/respiratoryviruses/resources-hcp.html#mono.

Adverse Events

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.

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

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 to participate in 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 to receive products for that time period.

- Priority locations (i.e. Hospitals, First Nations Communities and Long-Term Care facilities)
 will receive vaccine first and will have access to weekly ordering and deliveries.
- All other registered providers will be placed into one of two distribution groups and will
 have access to biweekly vaccine deliveries for the start of the campaign, contingent on
 available stock at the provincial warehouse.

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, which 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 they are open for weekend deliveries. This information is extremely important and will ensure an efficient and timely delivery schedule. Locations that have complicated or restrictive delivery timelines may result in delayed deliveries.

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/or COVID-19 vaccines that covers all providers in the facility.

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

For information on the distribution model, how to register for the program, please go to www.manitoba.ca/fludistribution. All 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 using the *Manitoba Health's Return Policy and Procedure* available at: https://www.gov.mb.ca/health/publichealth/cdc/div/docs/vbrpp.pdf.

Monitoring the Safety of Vaccines

Vaccines are generally safe and well tolerated. In addition to data from pre-marketing trials showing vaccine safety, steps are undertaken by national and provincial vaccine programs to monitor their use in post-marketing for any new safety issues that might emerge. In addition to routine passive surveillance, every year during the seasonal influenza and COVID-19 vaccination campaigns, PHAC conducts expedited reporting of AEFIs with current influenza and COVID-19 vaccines in order to identify vaccine safety signals in a 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 annual flu and COVID-19 immunization campaigns. This involves a systematic, near-real-time assessment of an identified risk associated with the use of the vaccine 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 <u>provincial immunization program standards</u>. 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 the Public Health Information Management System (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/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 the public.

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

b. Data Entry

Health care providers and facilities 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, who 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 who 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). For more information, refer to https://phimsmb.ca/files/provider-recorded.pdf.
 - Pharmacists are required to enter flu and COVID-19 vaccines that they administer directly into PHIMS.
- If you do not have access to PHIMS, are unable to enter information directly into PHIMS

 (i.e. Private Flu Clinic) and don't use the claims processing system, complete and submit for the doses administered using
 - www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf.
 - For doses administered to persons **without** a PHIN, complete and submit www.gov.mb.ca/health/publichealth/cdc/div/manual/docs/vaccine-admin-reporting-no-phin-letter.pdf and fax to Manitoba PHIMS Quality Assurance at 204-945-6482.
 - All doses 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 respiratory surveillance reports. Reports for 2025-26 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: manitoba.ca/respiratoryviruses/resources-public.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 2° to 8° Celsius. In the event that vaccines have been exposed to temperatures outside of 2° to 8° 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 2025-2026 available online at https://manitoba.ca/respiratoryviruses/resources-hcp.html#resources.

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 will be available to order, free of charge, from the Materials Distribution Agency, and will also be posted on MHSLTC's Vaccine-Preventable Respiratory Illnesses website at https://www.gov.mb.ca/respiratoryviruses/resources-hcp.html#print where they can be downloaded electronically.

The flu and COVID-19 promotional/educational resources are expected to be updated for the 2025-26 season. Confirmation will be broadly communicated once the updated resources are available.

The Order Form to order promotional and educational resources is available here:

https://www.gov.mb.ca/health/jmc/index.html

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

https://www.gov.mb.ca/respiratoryviruses/vaccinefinder.html

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 to be included in the Flu and COVID-19 Vaccine Provider Map.