~ FINAL PROGRAM PLAN ~

Manitoba's 2019/20 Seasonal Influenza Immunization Program

JULY 2019*

Manitoba Health, Seniors and Active Living
Population 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 of this Interim Program Plan.

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Acronyms

ACIP	Advisory Committee on Immunization Practices
AEFI	Adverse event following immunization
CI	Confidence interval
DPIN	Drug Programs Information Network
FNIHB	First Nations and Inuit Health Branch
GBS	Guillain-Barré syndrome
IIV	Inactivated influenza vaccine
ILI	Influenza-like illness
LAIV	Live attenuated influenza vaccine
LTCF	Long-term care facility
MDV	Multi-dose vial
MHSAL	Manitoba Health, Seniors and Active Living
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 authority
VE	Vaccine effectiveness
WHO	World Health Organization

Purpose

The purpose of this Program Plan is to provide **all** health care providers and regional health authorities (RHAs), including the First Nations and Inuit Health Branch (FNIHB), that participate in the annual Manitoba Seasonal Influenza Immunization Program, with the provincial program details for the upcoming 2019/20 influenza (flu) season.

2019/20 Program Dates

- **February/March 2019:** World Health Organization released the three initial recommended strains for the 2019/20 northern hemisphere influenza vaccines in February, and the subsequent strain 6 weeks later.
- **May 28:** The National Advisory Committee on Immunization's (NACI's) *"Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2019/20"* is posted on the Government of Canada, National Advisory Committee on Immunization website at: www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2019-2020.html.
- **August 15 - September 13:** Health care providers can 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 1:** 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.
- **September 4:** Deadline for health care providers and regions to submit their clinic dates, times and locations for inclusion on the Manitoba Health, Seniors and Active Living (MHSAL) website and/or through Health Links–Info Santé. Please email information to: Vaccines@gov.mb.ca.
- **October 1:** MHSAL 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 and who have never received a dose of Pneu-P-23 vaccine.
- **1st week of October (exact date TBD):** Launch of the provincial 2018/19 Seasonal Influenza Immunization Program advertising campaign.

Provincial Eligibility Criteria and Recommendations for Use

For the 2019/20 season, the seasonal flu vaccine is available free-of-charge to all Manitobans aged six months and older, and 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 women
- health care workers and first responders
- 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 MHSAL coverage. Please report all doses administered to non-Manitoba residents using the appropriate forms (www.gov.mb.ca/health/publichealth/cdc/div/docs/miifp.pdf for Pharmacies and www.gov.mb.ca/health/publichealth/cdc/div/docs/iifhcp.pdf for all other providers), and indicate on the data entry forms/fields, “no personal health identification number (PHIN)”. Please ensure to provide as much information on the person being immunized 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, 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 influenza vaccines can be given at the same time as, or at any time before or after administration of, other live attenuated or inactivated vaccines. NACI recognizes that some heath care providers may choose to give LAIV and other live vaccines simultaneously or separated by at least four weeks to avoid any possibility of immune interference. Alternatively, an IIV may be given.

Pregnant women and their newborn infant, once born, 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 women are recommended to receive the flu vaccine at any stage of pregnancy.

Influenza vaccination provides benefits to health care workers and to the patients to whom they provide care. Being immunized against influenza is an essential component of the standard of care for all health care workers for the protection of their patients. 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 and who are vulnerable to influenza-related complications. 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. (**Note:** NACI and MHSAL recommend IIV, instead of LAIV, for health care workers).

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.

Every year, NACI updates its recommendations regarding the use of the seasonal flu vaccine. MHSAL 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 2019/20** is available online (www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2019-2020.html) and MHSAL's **Seasonal Influenza Management Protocol** is also available online at www.manitoba.ca/health/flu/pro.html.

Annual vaccination is required because the specific strains in the vaccine are reviewed each year by WHO and often changed 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, with higher efficacy demonstrated against laboratory-confirmed influenza than clinically defined outcomes. Immunization has been shown to reduce the number of physician visits, hospitalizations and deaths in high-risk adults.

Please refer to the NACI website for the most up-to-date data on efficacy and effectiveness: www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html

Vaccine Safety

Influenza vaccines are safe and well tolerated. Data from post marketing surveillance of influenza vaccines in Canada (Canadian Adverse Events Following Immunization Surveillance System) have shown seasonal influenza vaccines to have a safe and stable adverse event following immunization (AEFI) profile with no unexpected events.

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 used as a preservative to keep the product sterile. Large cohort studies of health databases have demonstrated that there is no association between childhood vaccination with 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.

Note: For the 2019/20 influenza season, LAIV nasal spray will not be available in Canada.

With intramuscularly injected (needle) vaccines (Fluzone® Quadrivalent, Flulaval® Tetra, Afluria® Tetra, and Fluzone® High-Dose), injection site reactions are common but are generally classified as mild and transient. Fluzone® High-Dose 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 and that the risk of GBS associated with influenza illness is larger (about 17 cases per million influenza-coded health care encounters, which are a proxy for influenza illness) than that associated with influenza vaccination. 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 found during the 2000/01 flu season; few cases have been reported since then. ORS is not considered to be an allergic response. Persons who have a 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-immunized with influenza vaccine. Persons who experienced ORS with lower respiratory tract symptoms should have an expert review. 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 any of the seasonal influenza vaccines available as part of Manitoba's Seasonal Influenza Immunization Program without prior influenza vaccine skin test and with the full dose, irrespective of a past severe reaction to egg, and without any extraordinary precautions, but ensuring that immunizers be prepared with the necessary equipment, knowledge and skills to respond to a vaccine emergency.

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 seasonal quadrivalent influenza vaccines, inactivated and attenuated, for the 2019/20 season in the northern hemisphere contain:

- **A/Brisbane/02/2018 (H1N1)pdm09-like virus;**
- **A/Kansas/14/2017 (H3N2)-like virus;** [1]
- B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage); and
- B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage)*.

*Of the four strains indicated, this strain is not included in the high-dose influenza vaccine for the 2019-20 season.

The decision to include specific flu vaccines as part of Manitoba's Seasonal Influenza Immunization Program depends on a multitude of factors. For the 2019/20 season, MHSAL will offer the following flu vaccines as part of its annual Seasonal Influenza Immunization Program (product composition to be confirmed following national allotment finalization):

1. **Fluzone® Quadrivalent (Sanofi Pasteur):** a quadrivalent IIV in MDV and PFS for intramuscular (IM) injection (needle), supplied in 5.0mL, 10-dose MDV as well as single-dose (0.5mL) PFS in packages of ten. The vaccine is to be kept at 2° to 8° Celsius. Once punctured, the MDV can be used to the expiry date indicated.
2. **Flulaval® Tetra (GlaxoSmithKline):** a quadrivalent IIV in MDV for IM injection (needle), supplied in 5.0mL, 10-dose MDV. The vaccine is to be kept stored at 2° to 8° Celsius. **Once punctured, the MDV should be discarded within 28 days**.

[1] The **two bolded strains** are different from last year's seasonal influenza vaccine.

3. **Afluria® Tetra (Seqirus):** a quadrivalent IIV in MDV for IM injection (needle), will be supplied in singe dose (0.5ml) PFS in packages of 10. The vaccine is to be kept stored at 2°to 8° Celsius. Use the product before the expiration date on the packaging.
4. **Fluzone® High-Dose (Sanofi Pasteur):** a trivalent IIV in PFS for intramuscular injection (needle) supplied in a single 0.5mL/dose. The vaccine is to be kept at 2° to 8° Celsius. Use the product before the expiration date. *More detailed information provided below.*

Note: For the 2019/20 influenza season, LAIV nasal spray will not be available in Canada.

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 who is authorized under that act to administer vaccines.

The ever-present possibility of antigenic drift, which may occur in one or more influenza virus strains, requires seasonal flu vaccines to be reformulated and administered annually.

Characteristics of influenza vaccines available for use in Manitoba, 2019/20

	Fluzone® Quadrivalent	**Flulaval® Tetra**	**Afluria® Tetra**	**Fluzone® High-Dose**
Vaccine Preparations	QIV	QIV	QIV	TIV
Formats available	MDV and PFS	MDV	Single dose prefilled syringe	Single dose prefilled syringe
Authorized ages for use	≥ 6 months	≥ 6 months	5 years and older	≥ 65 years ¥
Adjuvant	No	No	No	No
Antigen content (each of strains)	15 µg haemagglutinin (HA) /0.5 mL dose	15 µg HA /0.5 mL dose	15 µg HA /0.5 mL dose	60 µg HA /0.5 mL dose
Thimerosal	Yes - MDV No - PFS	Yes	No	No
Antibiotics	None	None	Neomycin and Polymixin B	No
Latex	None	None	None	None
Other clinically relevant non-medicinal ingredients	• Egg protein • Formaldehyde • Triton X-100 • Sucrose	•Egg protein •α-tocopheryl •hydrogen succinate •polysorbate 80 •formaldehyde •ethanol •sodium deoxycholate	• Egg protein • Calcium chloride • Monobasic potassium phosphate • Monobasic sodium phosphate • Potassium chloride	• Formaldehyde • Sodium Phosphate-buffered • Isotonic sodium chloride solution • egg protein

		•sucrose	• Sodium chloride • Sodium taurodeoxycholate • Beta-propiolactone	• Triton X-100
**For more information, see Appendix A, Characteristics of influenza vaccines available for use in Canada, 2019-20 of the Statement on Seasonal Influenza Vaccine for 2018-19: www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2018-2019.html*				

For product information as well as other manufacturer-developed tools and resources, please visit:

- Sanofi Pasteur (Fluzone® Quadrivalent):
  - http://products.sanofi.ca/en/fluzone-qiv.pdf
  - www.sanofipasteur.ca/
- GSK (Flulaval® Tetra Quadrivalent)
  - https://pdf.hres.ca/dpd_pm/00051583.PDF
  - https://health.gsk.ca/
- Seqirus (Afluria® Tetra):
  - https://pdf.hres.ca/dpd_pm/00051323.PDF
  - https://www.seqirus.ca/
- Sanofi Pasteur (Fluzone® High-Dose):
  - http://products.sanofi.ca/en/fluzone-hd.pdf
  - www.sanofipasteur.ca/

Fluzone® High-Dose

MHSAL is continuing to offer the high-dose inactivated influenza vaccine (Fluzone® High-Dose) to residents of long-term care facilities (LTCFs) aged 65 years and older, including chronic care residents. Clients in interim/transitional care beds, respite care clients as well as new, unimmunized residents admitted to a LTCF during the flu season are also eligible. *Staff of LTCFs and residents of LTCFs less than 65 years of age should be immunized with standard-dose IIV.*

Residents of LTCFs 65 years of age and older are at higher risk of complications from the flu, and the immune response to flu vaccines in this population is thought to be less effective than that seen in younger populations. In order to elicit a stronger and more effective immune response among elderly individuals, Fluzone® High-Dose is being offered because it contains four times the amount of influenza virus antigen per strain (60 µg vs. 15 µg) compared to the standard-dose IIV. Fluzone® High-Dose is a *trivalent* IIV and protects against three (2A + 1B) of the influenza strains predicted to be circulating in North America during the 2018/19 season. Given the burden of influenza A(H3N2) disease and evidence of better efficacy in this age group, it is expected that Fluzone® High-Dose will provide superior protection compared with standard-dose IIV.

The higher antigen concentrations contained within Fluzone® High-Dose 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, but serious adverse events were similar in frequency between the high- and standard-dose IIV. Fluzone® High-Dose has been authorized for use in Canada since 2015.

Two randomized controlled trials (RCTs) and one retrospective cohort study measured the relative efficacy of Fluzone® High-Dose compared to a standard-dose IIV in adults 65 years of age and older. Relative efficacy of high-dose versus standard-dose IIV against lab-confirmed symptomatic influenza was 12.5% (95%, CI: -141 to 66%) in one RCT during the 2009-10 season, in which the pandemic A(H1N1) flu virus predominated and represented a vaccine strain mismatch. Canadian authorization of the high-dose vaccine was based on a second, larger RCT conducted over two seasons (2011/12, 2012/13) in which the relative efficacy was 24% (95% CI: 10 to 36%) compared to standard-dose IIV. In the retrospective cohort study of Medicare beneficiaries in the USA, Fluzone® High-Dose was estimated to be 22% (95% CI: 15 to 29%) more effective than standard-dose IIV in preventing probable influenza-related illness, and 22% (95% CI: 16 to 27%) more effective than standard-dose IIV in preventing hospital admission due to an influenza diagnosis.

Vaccine Distribution

Manitoba uses a mixed provider delivery model for the Manitoba Immunization Program, with public health nurses, nurses, nurse practitioners, midwives, physicians, physician assistants and pharmacists administering vaccines in private and public health settings. It is important for all health care providers to take this into consideration when they are ordering influenza vaccine because unused vaccines in a health care provider's fridge cannot be returned to the Provincial Distribution Warehouse and redistributed. All health care providers must order based on the amount administered and recorded in Manitoba's Immunization Registry last year to reduce wastage. **Failure to reconcile vaccine doses ordered with administered (and reported) may result in health care providers receiving fewer vaccine doses than ordered.** It is therefore critical that all influenza vaccine doses administered be reported to MHSAL (see **Documentation - Data Entry** for more information on how to report administered vaccine doses). **Influenza vaccine wastage should be less than 10% at the end of the influenza season.** Subsequent orders can be placed with the Provincial Distribution Warehouse (at no penalty to the health care provider), while supplies last.

Health care providers may order influenza vaccine starting August 15, 2019, and up to 4 p.m. on September 13, 2019, in order to be placed in their respective distribution groups, which have been outlined below. Any orders placed after 4 p.m. on September 13th will be placed in the last distribution group. Where possible, health care providers at the same facility should submit one order for flu vaccine (that covers all providers in the facility) to expedite orders and reduce the number of individual orders that are being shipped to one location.

To place an order for influenza vaccine, please submit an order online or via fax/email using the Influenza and Pneumococcal *Vaccines Order Form*: www.manitoba.ca/health/publichealth/cdc/protocol/influpnevcorderform.pdf, or as directed through the Public Health Information Management System (PHIMS).

Note: For the 2019/20 influenza season, LAIV nasal spray will not be available in Canada.

If you are a LTCF or are ordering on behalf of a LTCF, please complete and submit the *2019/20Influenza and Pneumococcal Vaccine Order Form for Long-Term Care Facilities:* http://www.gov.mb.ca/health/publichealth/cdc/protocol/influpnevcorderform_ltcf.pdf.

Provided flu vaccine manufacturers meet delivery timelines as per the contractual obligations for the 2019/20 season, all flu vaccine orders will be shipped according to the following schedule:

1. hospitals, LTCFs and First Nations communities
2. providers/facilities with Client ID (Holding Point #) ending in 7, 8 or 9
3. providers/facilities with Client ID (Holding Point #) ending in 0, 1, 2 or 3
4. providers/facilities with Client ID (Holding Point #) ending in 4, 5 or 6
5. providers/facilities that order after 4:00pm on September 13, 2019

Within each of these groups, orders will be processed in the sequence in which the order is received by the Provincial Distribution Warehouse (on or after the vaccine ordering start date).

If one or more flu vaccine manufacturers fail to deliver flu vaccine on time, distribution could be substantially delayed or product substitutions may take place. In the event that this occurs, MHSAL will communicate important flu vaccine distribution and delivery information to immunization providers in a timely manner and post it on the “Vaccine Distribution and Supply” website: www.manitoba.ca/health/flu/distribution.html.

Documentation

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

a. Adverse Events Following Immunization (AEFI)

In accordance with The Public Health Act, health care providers 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.

MHSAL 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 including FNIHB **MUST ACCOUNT FOR EVERY DOSE OF VACCINE ORDERED AND ADMINISTERED, INCLUDING FLU VACCINE,** by ensuring that doses are recorded in the client's electronic public health record. Immunizations are entered into a client's electronic public health record via the Manitoba Immunization Registry (PHIMS) in one of three ways:

1. Data entry by PHIMS users.
    - Health care providers who have access to PHIMS can enter the immunization data directly into PHIMS if their permissions allow for data entry. For those who do not have access to PHIMS and in instances where a health care provider is unable to enter information directly into PHIMS (i.e. Private Flu Clinic), as well as for instances where the individual does not have a PHIN (or the PHIN is unknown), health care providers are to complete the *Immunization Inputting Form for Health Care Providers* and submit it to the local Public Health office where it will be entered manually into Panorama by regional staff.
        - This form can be accessed online at: www.manitoba.ca/health/publichealth/cdc/div/docs/iifhcp.pdf
        - The listing of public health offices in Manitoba is located at: www.manitoba.ca/health/publichealth/offices.html
        - **Note:** Pharmacies are to report immunizations provided to those with no PHIN using the *Pharmacist Immunization Inputting Form for Patients without a Valid*

PHIN located at www.manitoba.ca/health/publichealth/cdc/div/docs/miifp.pdf and send the completed forms into MHSAL based on the directions on the form.

2. Uploaded from the Drug Programs Information Network (DPIN) system when administered by pharmacists.
3. Uploaded from the Claims Processing System (Physician Billing) when administered by fee-for-service physicians and other health care providers that shadow bill (e.g. regional nurse practitioners).

Surveillance of influenza immunization uptake is included in the weekly and end of season influenza surveillance reports. Reports for 2019/20 as well as the previous nine seasons can be accessed online at: www.manitoba.ca/health/publichealth/surveillance/reports.html.

c. Consent

As per MHSAL's *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 MUST report the adverse storage condition incident to MHSAL. Please complete/submit the online form (www.manitoba.ca/health/publichealth/cdc/docs/ccf.pdf) or submit the required information directly through PHIMS. **MHSAL does not allow the use of bar fridges to store vaccines and regular mercury thermometers are not be used to monitor the fridge temperature.** Fridges should only contain vaccines. No food or other biologics should be kept in the vaccine 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 MHSAL's Seasonal Flu website (www.manitoba.ca/health/flu/index.html). The flu promotional/educational resources may be updated for the 2019/20 season resulting in all new promotional materials. 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, MHSAL will communicate with health care providers including RHAs and FNIHB 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 (exact date TBD).