

Universal Influenza Immunization Program Manual

**Public Health Protection and Prevention Branch
Public Health Division
Ministry of Health and Long-Term Care
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Acknowledgements

The Vaccine Program would like to thank Ontario's 36 boards of health and other community stakeholders involved in the Universal Influenza Immunization Program (UIIP) who have contributed a great deal to program development over the last decade. We would like to acknowledge the enthusiastic contributions and professional experiences that have contributed to the creation of, and the content in, a program manual for the UIIP.

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Section 1: Introduction and Background

The purpose of this document is to provide the necessary resources and support for all participants of the Universal Influenza Immunization Program (UIIP) throughout Ontario jurisdictions. Each year the UIIP in Ontario is based on recommendations from the World Health Organization (WHO) and the National Advisory Committee on Immunization (NACI) as well as recommendations from the federal Vaccine Supply Working Group (VSWG).

Many different strains of influenza viruses circulate throughout the world, and the strains vary from year to year. Immunization against influenza must be given annually in order to provide optimal protection with vaccine that contains the most current circulating strains. Immunization is especially important for those at high risk of complications from influenza, particularly for young children, pregnant women, people with chronic health conditions and the elderly. If people in high-risk groups get sick with influenza, the immunity provided by the vaccine can reduce the severity of the illness and possibly save lives.

The first program of its kind in the world, the UIIP was officially launched in the fall of 2000 as part of the commitment to protect and promote the health of Ontarians. The objectives of the UIIP are to provide individual protection against influenza, reduce the number and severity of influenza cases, reduce the impact on the health care system during the influenza season (including reducing the annual impact of influenza on emergency room overcrowding and the utilization of other health care facilities), and decrease the economic impact of influenza during the influenza season.

Eligible Ontarians can receive publicly funded influenza vaccination from their physicians and through community influenza clinics offered by health units, community health centres, community care access centres, hospitals, long-term care homes, pharmacy-based clinics and workplace clinics across the province.

Disclaimer

This program manual is intended to support boards of health, and in particular, participants in the UIIP. This document is intended for informational purposes only, and is not intended to provide legal advice or to be a substitute for the professional judgment of public health or UIIP staff. Public health and UIIP staff should consult with legal counsel as appropriate. Where there is a conflict between this document and the Ontario Public Health Standards (OPHS), the Health Protection and Promotion Act (HPPA), or its regulations, the OPHS, HPPA or regulations, as the case may be, prevail.

Section 2: The Prequalification Process

Health care agencies, retirement homes and workplaces that receive the publicly-funded influenza vaccination are required to complete the prequalification process in order to participate in the UIIP each influenza season.

By signing the *Prequalification Form for Organizations Requesting Influenza Vaccine*, the agency, retirement home or workplace is agreeing to abide by all terms and conditions as stated on the *Prequalification Form*. The *Prequalification Form*, when signed, is a legally binding agreement between the agency, retirement home or workplace and the ministry.

The prequalification process involves the following steps:

- 1) Health care agencies, retirement homes, and workplaces must submit the **completed and signed** *Prequalification Form* and **proof of liability insurance** to the ministry on or before the deadline specified for the specific influenza season. *Prequalification Forms* and liability insurance submitted after the deadline each year will **not** be accepted and the agency, retirement home or workplace will **not** be permitted to participate in the UIIP that influenza season.
- 2) In the event that a health unit receives *Prequalification Forms* and/or liability insurance certificates, the documents must be forwarded to the ministry for review and approval. Health units cannot process and approve the prequalification forms.
- 3) The ministry will review all *Prequalification Forms* and corresponding liability insurance certificates that are received on or before the specified deadline. Following the review process the ministry will forward a list to each health unit of agencies, retirement homes and workplaces that will require a cold chain inspection by the health unit.
- 4) Agencies, retirement homes and workplaces who submitted incomplete prequalification packages to the ministry will be informed of this in writing and they will not be included on cold chain inspection list that is provided to the health unit.
- 5) Once the cold chain inspection(s) has been completed at the health care agencies, retirement homes and/or workplaces the **health unit** will notify the ministry regarding the results (pass/fail) of these inspections by email (uiip.moh@ontario.ca), as they are completed for the current influenza season.
- 6) As per the *Vaccine Storage and Handling Protocol* influenza vaccine should only be provided to locations that have received a documented fridge inspection with a "passing" grade.

- 7) Once the ministry has received confirmation from the health units regarding the results of the cold chain inspection(s) a final list will be completed and distributed to all agencies, retirement homes, workplaces and health units. This list will include formal notification to agencies, retirement homes and workplaces indicating they have been approved to participate in the UIIP for the current season.
- 8) If approved, health care agencies, retirement homes and workplaces will receive a short letter from the ministry with specific information about the UIIP for the current season.
- 9) Agencies, retirement homes and workplaces will be notified in writing by the ministry if they have not been approved to participate in the UIIP as a result of their cold chain inspection.
- 10) Approved agencies are able to obtain influenza vaccine. If the health care agency, retirement home or workplace is not on the email list the health unit received from the ministry, influenza vaccine should not be released.

Cold Chain Inspections

Health units are responsible for assessing conditions and making recommendations regarding cold chain maintenance in premises within the health unit jurisdiction where publicly-funded vaccines are stored. All such premises should be inspected at least once annually for adherence to the minimum requirements according to the ministry's [Vaccine Storage and Handling Protocol](#). Publicly-funded influenza vaccine cannot be stored in commercial pharmacy fridges or in fridges in personal residences. Bar-style fridges, although permitted with appropriate modifications to ensure the safety and quality of the vaccine, are not recommended.

Prequalification Agreement Violations

Health units are requested to complete a *Prequalification Form Violation Report* to document any violations of the prequalification agreement as indicated on the *Prequalification Form*. A separate "violation report" form should be completed for every violation that occurs in the jurisdiction of the responsible health unit. Completed forms should be forwarded to the UIIP Coordinator by fax (416-327-0984) or via email (uiip.moh@ontario.ca).

Section 3: The Influenza Vaccine

In Ontario, influenza vaccine is publicly funded for the immunization of anyone aged 6 months or older if they live, work or attend school in the province.

Each year the National Advisory Committee on Immunization (NACI) publishes a statement about the influenza vaccine and its use for the corresponding influenza season. The information provided in the [National Advisory Committee on Immunization \(NACI\) statement](#) is used to establish program requirements, including target groups, for the UIIP during the current season.

UIIP participants should at minimum be familiar with the information listed in table 1 below regarding the current supply of influenza vaccine and its administration.

Table 1. Seasonal Influenza Vaccine Supply for the Current UIIP Season	
Vaccine Strain	See current season's NACI statement Information will be provided by the ministry
Target Groups	See current season's NACI statement Information will be provided by the ministry
Vaccine Products	Information will be provided by the ministry
Thimerosal-Free	See current season's product monograph for each vaccine
Single Dose Format	Information will be provided by the ministry
Latex-Free	See current season's product monograph for each vaccine
Antibiotic-Free	See current season's product monograph for each vaccine
Formaldehyde Use	See current season's product monograph for each vaccine
Egg-proteins	See current season's product monograph for each vaccine
Other vaccine components	See current season's product monograph for each vaccine
Groups vaccine is licensed for	See current season's product monograph for each vaccine Information will be provided by the ministry
Other	See current season's product monograph for each vaccine Specific program information will be provided in a letter from the ministry See current season's NACI statement

Product Monograph

A new product monograph will be available for each influenza vaccine that is developed for each influenza season and informs medical directives. All UIIP participants should be familiar with the product monograph that corresponds with the specific influenza vaccine they are providing to the general public each season.

Vaccine Availability

Delivery of seasonal influenza vaccine to all provinces and territories is determined by many factors that include: delivery of seed stock strains to Canada's manufacturers, growth of the recommended strains, vaccine production, clinical trials and release of vaccine lots by the regulatory body of Health Canada known as the Biologics and Genetic Therapies Directorate (BGTD). When all of these systems are working effectively all provinces and territories receive a percentage of their overall influenza vaccine orders for the season in phased deliveries.

Once influenza vaccine lots have been released by BGTD, the Canadian influenza vaccine manufacturers begin to deliver percentages of requested orders in phases to the provinces and territories. As Ontario does not receive the full quantity of requested vaccine in the initial delivery to Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS), the ministry must ensure that influenza vaccine is distributed fairly to all health unit jurisdictions in the province, and therefore, distributes the vaccine as it is delivered from the manufacturers to the OGPMSS.

Health units are notified by the ministry when influenza vaccine is available in Ontario. The first shipment of influenza vaccine is generally expected to arrive at OGPMSS sometime in September/October each season. Because the influenza vaccine is received to OGPMSS on an incremental basis the ministry recommends the vaccine delivery is prioritized for the immunization of individuals at high risk of influenza-related complications, those capable of transmitting influenza to individuals at high risk of complications, and to individuals who provide essential community services first.

Once the vaccine is widely available across the province the ministry will make the recommendation when the vaccine may be available to the general public. In order to facilitate fair allocation and access of influenza vaccine across Ontario, UIIP participants should not begin providing influenza vaccine until season specific information is received from the ministry.

Health Unit Jurisdictional Boundaries

Publicly funded influenza vaccine for use in the UIIP cannot cross health unit jurisdictional boundaries. All UIIP vaccine must be administered to clients in the jurisdiction where it is stored and monitored under cold chain conditions as per *Vaccine Storage and Handling Guidelines*.

Vaccine Returns

Spoiled or expired vaccine should be returned to the vaccine supply source it was ordered from; either the health unit or OGPMSS as applicable. All unused vaccine should be returned by the deadline established by the ministry for the current influenza season. If required, health units can keep up to 0.5% of their total influenza vaccine order for late



outbreaks or travelers. All other organizations must return all unused UIIP vaccine as per the established deadlines for the current influenza season.

All vaccine product that cannot be used due to a defect (e.g. cracked vial, etc.) must be returned to the organization it was ordered from (health unit/OGPMSS) and not directly to the manufacturer. Please contact the organization where the influenza vaccine was ordered (health unit/OGPMSS) to arrange for the return of the defective vaccine product and explain the problem encountered. Organizations contacting OGPMSS directly should contact the OGPMSS Customer Service department (contact information is on the UIIP vaccine order form). All problems related to vaccines are recorded and forwarded to the vaccine manufacturer. The reports are tracked from all jurisdictions in Canada and this information often helps to quickly identify defective lot numbers or common issues with particular vaccine products.

All appropriate staff should be aware of this information and the protocol for returning defective vaccine products.

Section 4: UIIP Immunization Clinics

UIIP Clinics

There are two distinct types of UIIP clinics that are currently offered in Ontario, they are most commonly referred to as “reimbursable” and “non-reimbursable”. UIIP participants may offer a “reimbursable” influenza clinic if they are an established organization that currently receives transfer payments from the ministry and this clinic is widely communicated and open to the public, as specified in the prequalification agreement. All other UIIP participants may offer “non-reimbursable” clinics.

Reimbursable UIIP Clinics

The ministry will provide monetary reimbursement for each dose of influenza vaccine administered through community clinics in the current influenza season. In order for community clinics to be eligible for reimbursement by the ministry the following criteria must be met:

- The community clinic must be run by a previously established organization with the ministry that is in current receipt of transfer payments (e.g. public hospitals, LTCHs, CCACs, CHCs) for the UIIP. Exceptions may be made for specific organizations identified in the prequalification agreement (i.e. pharmacy-based clinics).
- Pharmacy based clinics must be held within the physical boundaries of the pharmacy;
- Pharmacy based clinics must retain the use of a health care agency that has been approved by the ministry through the current season’s prequalification process to participate in the UIIP.
- All clinics must be open to the public (i.e. open and accessible to any recommended vaccine recipient who lives, works or attends school in Ontario)
- Widely advertised in the community (e.g. local newspaper, posters, etc.).
- Publicly funded vaccine must be used.
- Influenza immunization must be provided free of charge to the vaccine recipients.
- The ministry must not be billed for these immunizations through any other mechanism.

Non-Reimbursable UIIP Clinics

All other clinics, including workplace clinics, are not eligible for reimbursement. No clinic is eligible to be reimbursed unless it meets the criteria listed in the above section, and has been notified in advance that it may provide a reimbursable clinic by the ministry. The ministry does not provide any retroactive approvals for reimbursable UIIP clinics.

Health care agencies, retirement homes and workplaces may be approved through the prequalification process to provide “non-reimbursable” UIIP clinics.



Note that workplace clinics are not eligible for reimbursement by the ministry even if they are provided by organizations that are eligible to provide “reimbursable” clinics (e.g. an organization will not be reimbursed for the provision of publicly funded influenza vaccine to their staff and/or outsiders such as staff family members).



Section 5: Retaining an External Health Care Agency

All external health care agencies retained by an organization to administer UIIP vaccine must have completed the prequalification process for the current influenza season and be approved by the ministry to participate in the UIIP.

The vaccine should be provided by the public health unit/OGPMSS directly to the agency/organization that will be administering the vaccine to clients.

Physicians and the Retaining of External Health Care Agencies

- Occupational health physicians who have a permanent practice at a workplace may retain an external health care agency to assist with influenza vaccine delivery.
- All billing for vaccine administration under the direct supervision of the physician must be billed to the Ontario Health Insurance Plan (OHIP).
- Any external health care agency that is retained by the physician must work under the direct supervision of the physician using medical directives for influenza vaccine administration by the physician.
- The physician cannot bill the ministry or the public health unit for costs incurred by retaining the external health care agency.

If there are questions or concerns about retaining an external health care agency to assist with the UIIP please contact the ministry at uiip.moh@ontario.ca for information about this practice.

Section 6: Influenza Vaccine Ordering

UIIP vaccine order forms for the various providers are available on the [Ontario forms repository](#). The influenza vaccine must be ordered from each of the jurisdictions in which the influenza immunization clinics will be held. The influenza vaccine cannot be taken or stored outside the jurisdictional area from where the vaccine was obtained.

Ordering UIIP Vaccine: Inside the “M” Postal Code

Health Units and Physicians, Public Hospitals, Long-Term Care Homes, Family Health Teams, and Community Health Centres **within the “M” postal code** that receive vaccine directly from OGPMS usually receive pre-allocated initial quantities of UIIP vaccine based on order history from the previous influenza season.

In most influenza seasons health units and providers in the “M” postal code receive *two* shipments of pre-allocated vaccine. Once the pre-allocated vaccine shipments are complete, health units and “M” postal code providers will be able to re-order vaccine from the OGPMS as required unless otherwise informed by the ministry.

Ordering UIIP Vaccine: All Others

Health units are responsible for determining the local distribution of the initial allotment of influenza vaccine to UIIP participants, based on the recommendations from the ministry. Health units may base the influenza vaccine allocation decisions by comparing actual usage from previous years and subtracting returns for that year. If an external health care agency is retained to administer the UIIP vaccine the vaccine should be ordered by the agency that will be administering the vaccine.

Section 7: Influenza Immunization Reporting Forms

Vaccine Utilization Invoice and Report Forms

Vaccine utilization invoice forms and/or vaccine utilization report forms are available on the [Ontario forms repository](#). There are two types of vaccine utilization forms that UIIP participants use to provide UIIP vaccine administration information to the ministry; “Vaccine Utilization Invoice” for reimbursable clinics, and “Vaccine Utilization Report” for non-reimbursable clinics. All deadlines for the completion of forms used in the UIIP will be provided in a letter sent to participants from the ministry for the current influenza season.

“Reimbursable” Clinic Forms

A “Vaccine Utilization Invoice” must be filled out for **each** reimbursable influenza clinic in order to both provide aggregate immunization data to the ministry and to receive reimbursement for the doses of UIIP vaccine administered. “Vaccine Utilization Invoices” must be signed and completed and then forwarded to the local public health unit in the jurisdiction where the clinic was located. The responsible health unit is required to review, sign-off, and forward all vaccine utilization invoice forms to the ministry. All forms must be received by the ministry before the end of the specified deadline for the current year’s influenza season.

“Non-Reimbursable” Clinic Forms

A “Vaccine Utilization Reports” as stipulated in the prequalification agreement, must be filled out for **each** non-reimbursable influenza clinic in order to provide aggregate immunization data to the ministry as a result of influenza vaccine doses administered through participation in the UIIP. “Vaccine Utilization Reports” must be signed and completed and then forwarded to the local public health unit in the jurisdiction where the clinic was located. The responsible health unit is required to review, sign-off, and forward this form to the ministry. All forms must be received by the ministry before the end of the specified deadline for the current year’s influenza season.

Submission of Vaccine Utilization Invoice and Report Forms

As a condition of receiving and administering publicly-funded influenza vaccine, specific information, as indicated on the current forms for each season, **must** be reported to the ministry **for each clinic**. Specific reporting instructions for each influenza season are available on the current form.

Examples of the aggregate information the ministry requests from UIIP participants:

- All vaccine doses administered **and** wasted; and
- Gender and age breakdown by priority group (high priority group or general population).



All completed *Vaccine Utilization Invoice* and *Vaccine Utilization Report* forms must be sent to the health unit or OGPMSS (if in the "M" postal code) where the vaccine was ordered and **must** be reviewed, signed off and faxed, by the health unit/OGPMSS, to the ministry as directed on the form, this information is requested on a **weekly basis**.

Review of Completed Vaccine Utilization Invoices and/or Reports

Health units/OGPMSS are responsible for reviewing all *Vaccine Utilization Invoice* and *Vaccine Utilization Report* forms that are submitted within their health unit jurisdiction. Health unit/OGPMSS staff should review each form for accuracy and completeness, and cross-reference the quantities of vaccine ordered and utilized during the community clinic and also that the vaccine reported was obtained from their health unit, to ensure that:

- (a) the number of doses administered does not exceed the number of doses that the health unit provided;
- (b) the organization/agency is not over-ordering;
- (c) vaccine wastage is minimized; and
- (d) ensure all sections of the invoice are complete and then sign off the form before forwarding the invoice or report to the ministry.

Submission of Vaccine Utilization Invoices and/or Reports to the Ministry

Health unit invoices should be entered on the Web-Based Reporting System (contact UIIP.MOH@ontario.ca for access to the URL) as soon as possible as per the instructions on the form. Usually the ministry requests receipt of this information no more than **10 working days** after the clinic was held.

Invoices must be received at the ministry before the established deadline for the current influenza season (usually the end of February) in order to be eligible for reimbursement. Invoices received after the deadline will not be processed for payment.

If UIIP clinics are held after the current influenza season deadline records should be retained and the ministry should be contacted (UIIP.MOH@ontario.ca).

Specific UIIP participants may have different deadlines depending on the type of UIIP clinic that is offered. Organizations participating in the UIIP should be aware of all applicable deadlines pertaining specifically to them.



Section 8: Health Unit Vaccine Distribution Survey

Health units are requested to track UIIP vaccine distribution to the following providers:

- Community Care Access Centres (CCAC)
- Community Health Centres (CHC)
- Correctional Facilities and Youth Justice Facilities
- Health Units Clinics
- Health Care Agencies (nursing agencies - includes health care agencies retained by workplaces or pharmacies to provide immunizations)
- Long-Term Care Homes (LTCH)
- Physician's Offices
- Public Hospitals
- Retirement Homes
- Workplaces (with occupational health departments that do not hire an outside agency to provide immunizations)

The *Influenza Vaccine Distribution Survey* should be completed by the responsible health unit and submitted electronically on the first working day of each month during the influenza season to UIIP.MOH@ontario.ca.

Section 9: UIIP Related Materials and Information

General Influenza Information

UIIP information from the ministry will be posted on the [ministry's website](#) each influenza season with regular updates as required. UIIP participants should review this website on a regular basis for new information.

Communications/Promotional Materials

Communication and promotional materials for the UIIP can be viewed and ordered through [ServiceOntario](#).

UIIP Forms

All forms necessary for use by UIIP participants will be available on the [Ontario Forms Repository website](#). The forms are updated for each influenza season.

Management of Anaphylaxis

This information is included in the [Canadian Immunization Guide \(2006\)](#).

Proof of Immunization Documentation

The purpose of an immunization record is to ensure that people receiving influenza vaccine from immunizers in your community have documentation to carry with them. Providing a written record of immunization according to the Standards of the Regulated Health Professions Act (RHPA) and the professional college to which the immunizer belongs is required for each vaccine recipient. This is also recommended by NACI and stipulated in the prequalification agreement.

Documentation

In general, when influenza (or other) vaccine is administered to a client, it should be recorded in three different locations:

- the client's personal immunization record (provided directly to the client for their permanent record)
- the record of the health care provider who gave the influenza vaccine
- the local immunization registry

In each instance, influenza immunization records, at minimum, should include the following:

- the trade name and manufacturer of the product
- the disease which it protects against (i.e. influenza)
- the date administered (day, month, year)



- the dose
- the site and route of administration
- the lot number
- name and title/professional designation of the person administering the vaccine

Further information about the recording of immunization records is available from:

[The Canadian Immunization Guide, 7th Edition, 2006 \(page 55\)](#)

[The College of Nurses of Ontario: Medication Practice Standard, 2008](#)

[The College of Physician's and Surgeons of Ontario: Medical Records Policy, 2006](#)

Appendix 1: Controlled Acts and Medical Directives

*“While the College’s **Delegation of Controlled Acts** policy requires that delegation must usually occur in the context of doctor-patient relationship, it also indicates exceptions in circumstances where the delegation is made in the context of a program that provides good public protection even without a traditional physician-patient relationship. The College affirms that influenza vaccination programs fall into such exceptions so long as all of the appropriate safety, patient screening and consent measures are in place.”*

Source: College of Physician’s and Surgeons of Ontario (CPSO (2009). Controlled acts, medical directives. Dialogue, 5(4), pp22. Retrieved from www.cpso.on.ca.

Organizations may consult the College of Physicians and Surgeons of Ontario (CPSO) policies and the College of Nurses of Ontario (CNO) Nursing Standards to guide in the development of medical directives for the administration of influenza vaccine. Your organization should also have a protocol present at the clinic that is clearly visible and easily accessible for the management of anaphylaxis and fainting. Both Registered Nurse’s (RN) and Registered Practical Nurse’s (RPN) can be delegated controlled acts and work under medical directives. The RN and/or RPN must have the necessary knowledge, skills, and judgment to guide their practice.

The [CNO Practice Guideline for Directives](#) are available on the CNO website.

[Information from the CPSO about medical directives](#) is available on the CPSO website.

Appendix 2: Emergency Services Workers Administering Influenza Vaccine

The Emergency Health Services Branch of the Ministry of Health and Long-Term Care has provided the following information as guidance to ambulance services, base hospitals and paramedics regarding Seasonal Influenza Vaccine Clinics:

“In general there is no legal prohibition against paramedics providing influenza vaccination services at a seasonal clinic. However, these services should be provided only where **ALL** of the following conditions have been met:

1. The paramedics are “off-duty” or not otherwise performing, or not “on-call” to perform ambulance service or related duties. A paramedic should not participate in the administration of the influenza vaccine where such participation would prejudice or may prejudice the proper provision of ambulance services.
2. The controlled act in question (i.e. the administration of vaccinations) has been legally delegated by a physician who is not acting, in his or her capacity, as a Base Hospital physician under the *Ambulance Act*. A Base Hospital physician does not have the authority to delegate or purport to delegate a controlled act to a paramedic that is outside the scope of the regulations under the *Ambulance Act* to a paramedic as part of the physician’s and the paramedic’s official roles in providing ambulance services. Any such delegation is outside the ambit of the *Ambulance Act* and regulations, and outside of the Performance Agreement with the Base Hospital; and therefore, such delegation would be outside the ambit of his or her role as a BH physician. The Base Hospital Program must not be associated with such delegation in anyway.
3. There is full compliance with the College of Physicians and Surgeons of Ontario (CPSO) policies – Physicians must comply with the CPSO’s policies concerning delegation of controlled acts, particularly as they apply to the administration of influenza vaccines as part of programs operated under the authority of a Medical Officer of Health (MOH), documentation practices and responding to Adverse Events Following Immunization (AEFI’s).

Disclaimer

The Ministry of Health and Long-Term Care is not responsible for the accuracy or completeness of the information in this appendix. It is not to be considered legal advice. The Ministry is not responsible for any liability whatsoever for the information above. Please consult with your legal counsel, local Medical Officer of Health or professional licensing body if you have any questions regarding any of the contents above.

Appendix 3: Adverse Events Following Immunization (AEFI)

As required under the *Health Protection and Promotion Act, 1990*, all AEFIs need to be reported to the medical officer of health at the local health unit using the **National Adverse Event Following Immunization (AEFI) Reporting Form**. The [AEFI reporting form and its user guide](#) are available from the Public Health Agency of Canada (PHAC).

Under section 38 of the *Health Protection and Promotion Act*, physicians or other persons authorized to administer an immunizing agent, are required to inform the person who consents to immunization of the importance of immediately reporting to a physician or registered nurse in the extended class any reaction that may be a reportable event.

Also, under section 38 of the *Health Protection and Promotion Act*, a physician, a member of the College of Nurses of Ontario or a member of the Ontario College of Pharmacists who, while providing professional services to a person, recognizes the presence of a reportable event and forms the opinion that it may be related to the administration of an immunizing agent must report the “reportable event” to the local medical officer of health (i.e. the medical officer of health of the health unit where the professional services are provided), **within seven days** after the reportable event is recognized.

A “reportable event” means:

- (a) persistent crying or screaming, anaphylaxis or anaphylactic shock occurring **within 48 hours** after the administration of an immunizing agent,
- (b) shock-like collapse, high fever or convulsions occurring **within three days** after the administration of an immunizing agent,
- (c) arthritis occurring **within 42 days** after the administration of an immunizing agent,
- (d) generalized urticaria, residual seizure disorder, encephalopathy, encephalitis or any other significant occurrence* occurring **within 15 days** after the administration of an immunizing agent, or
- (e) death occurring at any time and following upon a symptom described in clause (a), (b), (c) or (d).

* Significant occurrences which are unexpected or unusual in severity including reactions such as oculorespiratory syndrome (ORS), Guillain-Barré Syndrome (GBS).

To report an adverse event following immunization, please call [your local health unit](#).



Once the health unit has reviewed the AEFI, it should be entered into the Integrated Public Health Information System (iPHIS) within the required reporting time.

Appendix 4: Influenza Vaccine Storage and Handling Guidelines for Health Care Agencies, Retirement Homes, Workplaces, and Other Organizations Participating in the UIIP

Every effort must be made to ensure that the vaccine cold chain is maintained. The potency and efficacy of influenza vaccine may be compromised if the vaccine cold chain is not maintained. Clients who are immunized with exposed vaccines may need to be recalled by the health care practitioner and re-immunized to ensure that they are protected against the disease.

Vaccines are sensitive biological substances that can lose their potency and effectiveness if they are frozen or exposed to heat and/or light. The vaccine cold chain includes all of the materials, equipment and procedures used to maintain vaccines in the required temperature range of **+2°C to +8°C** from the time of manufacture until the vaccines are administered to individuals.

Health care agencies and workplaces play a critical role in protecting the health of Ontarians by ensuring that the administered influenza vaccines retain their potency and that vaccine wastage is reduced. In preparation for and during immunization clinics, proper vaccine storage and handling practices must be followed when storing, packing, transporting, and administering vaccines at the clinic.

Vaccine Storage prior to Clinics

- A hard-sided, insulated container with ice and/or gel packs and a temperature monitoring device (e.g. digital maximum-minimum thermometer, data logger) is required to pick up the vaccines from the vaccine supply source.
- To retain their potency and to be effective, vaccines must be stored and handled between **+2°C to +8°C** at all times.
- Always store vaccines on the middle shelves of the refrigerator and away from the walls, floors and cold-air vents.
- Never store vaccines in refrigerator door shelves or drawers as vaccines may be exposed to warmer temperatures.

Packing a Cooler for Vaccine Transport to Clinics

- A hard-sided, insulated container is required for vaccine transport and temporary storage to ensure that the vaccines are maintained between **+2°C to +8°C**.
- Icepacks come out of the freezer at a temperature of approximately **-20°C**. Keeping the icepacks at room temperature for a period of time (approximately 30-60 minutes) allows the ice at the core of the icepack to rise to **0°C**. This process is called "conditioning".

- An icepack is adequately “conditioned” as soon as beads of water cover its surface. The conditioning process usually takes 20 to 30 minutes. Vaccines are vulnerable to freezing if icepacks have not been correctly “conditioned”.
- Only pack the amount of vaccine you expect to use during the influenza immunization clinic.
- Pre-chill the insulated container by placing conditioned ice and/or gel packs inside for at least one hour.
- When packing the insulated container, ensure that the vaccines are packed with a temperature monitoring device.
- If a digital maximum-minimum thermometer is used, the probe/sensor must be placed in the centre of a vaccine box to get an accurate temperature reading.

Transporting Vaccines in the Community (Outside the Office Setting)

- A hard-sided, insulated container (which maintains the internal temperature within the +2°C to +8°C range with icepacks) are required for transporting vaccine to community clinics.
- Vaccine must never be transported in the trunk of a car due to the risk of exposure to temperature extremes.

Protecting Vaccines during Influenza Immunization Clinics

- Temperature readings in the insulated container should be monitored to ensure that temperatures are maintained within +2°C to +8°C. Record temperatures:
 - a) Before leaving the office with the insulated container,
 - b) Upon arrival at the clinic location, but prior to the immunization clinic,
 - c) At one hour intervals (however it is strongly encouraged to record temperatures hourly) during the immunization clinic, ,
 - d) On completion of the clinic; however, before transport back to the office, and
 - e) After return to the office, but before the vaccines are put back in the refrigerator.
- The temperature monitoring device thermometer should also be visually inspected each time the insulated container is opened.
- Every effort should be taken to minimize the number of times that the insulated container is opened during the immunization clinic.
- As most insulated containers can only maintain the required temperature range for a maximum 4 hours, transport of vaccine for longer than 4 hours will require the ice and/or gel packs to be replaced with new frozen conditioned ice and/or gel packs during the immunization clinic.

Following these practices will ensure that the vaccine cold chain is maintained, and that unused vaccines that are returned to the refrigerator have not been exposed to temperatures below +2°C or above +8°C.

Contact your local health unit immediately for assistance whenever your influenza vaccine has been exposed to temperatures below +2°C or above +8°C. The health unit will assess all provincially funded vaccines that have been exposed to determine whether they can be used.

Please refer to the [Vaccine Storage and Handling Guidelines](#) for additional information.

Appendix 5: UIIP Questions & Answers

The following are a list of frequently asked questions for the UIIP:

Q: Do I have to complete the prequalification process if my organization would like to participate in the seasonal UIIP?

A: Yes. All organizations that wish to participate in the seasonal UIIP, unless otherwise exempt (e.g. health units, physician offices, long-term care homes) must complete the prequalification process.

Q: Does a retirement home at the same location as a long-term care home need to prequalify?

A: If the publicly funded influenza vaccine is stored and monitored in the long-term care home, and *not* in the retirement home, then the retirement home would not be required to prequalify.

Q: My organization is not planning to store or monitor any influenza vaccines, but we would still like to host a workplace influenza clinic. What should we do?

A: Organizations not storing and/or administering must hire an approved organization that has completed the prequalification process or a physician that can administer the influenza vaccines and has completed and passed the required annual vaccine refrigerator inspection.

Q: I am a retirement home/workplace/ other organization, and we have arranged for a physician to provide immunizations for our residents and/or employees; we are planning to store the vaccine on site. Do I need to prequalify?

A: Yes. As of 2010, if a retirement home is planning to store and monitor publicly funded influenza vaccine on site they are required to prequalify.

Q: I am a retirement home/workplace/ other organization, and we have arranged for a physician to provide immunizations for our residents and/or employees; the physician is bringing the vaccine from their private practice, and our organization will NOT be storing any vaccine. Do I need to prequalify?

A: No. If the physician is bringing the vaccine from their private practice and administering the vaccine to the residents and/or employees then the retirement home/workplace does not need to prequalify.

Q: Can we partner with another organization, or physician and lease/rent space in their vaccine refrigerator to store influenza vaccine?

A: No. As per the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine*:

- Leasing of space inside a refrigerator (i.e. shelves in a refrigerator) is not permitted.

Q: Our employee works for our organization and for another organization, can we store our organization's vaccine in the other organization's refrigerator if our employee is responsible for monitoring the refrigerator?

A: No. As per the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine*:

I/we understand that our vaccine refrigerator(s) must meet the following requirements:

- physically located within our organization's premises;

Q: Our organization provides occupational health services for another organization. Can this vaccine refrigerator be used to store vaccine for all of our influenza immunization clinics?

A: No, a refrigerator may not be used as a "hub" to store vaccine for other community/workplace influenza clinics. The vaccine must be stored in a fridge that is monitored by the staff of your organization. Your organization must prequalify to administer seasonal influenza vaccine, and must have office space (rented or owned) in the jurisdictions where influenza clinics will be provided. In each instance the organization responsible for storing and monitoring the vaccine must have their own fridge designated to influenza vaccine and have *their own* staff dedicated to monitoring and administering the vaccine to clients. The organization that prequalifies for the vaccine must:

- a. take sole responsibility for the vaccine and any potential results for storing and administering the influenza vaccine; and
- b. physicians and/or nurses hired through the organization for purposes of storing and administering the vaccine must be working under the capacity of the organization that is solely responsible for the vaccine through the prequalification process.

Q: Our organization is owned by or owns a Long-Term Care Home. Can this vaccine refrigerator be used to store, monitor or transport vaccine for all our community or workplace influenza immunization clinics?

A: No, a refrigerator in the Long Term Care Home may not be used as a “hub” and store vaccine for other community/workplace influenza clinics (this fridge can only be used to store vaccine that will be administered to residents/staff in the LTCH *and to retirement home residents if applicable*). Your organization must prequalify to administer seasonal influenza vaccine, and must have office space (rented or owned) in the jurisdictions where influenza clinics will be provided. In each instance the organization responsible for storing and monitoring the vaccine must have their own fridge designated to influenza vaccine and have *their own* staff dedicated to monitoring and administering the vaccine to clients. The organization that prequalifies for the vaccine must:

- a. take sole responsibility for the vaccine and any potential results for storing and administering the influenza vaccine; and
- b. physicians and/or nurses hired through the organization for purposes of storing and administering the vaccine must be working under the capacity of the organization that is solely responsible for the vaccine through the prequalification process.

Q: Our organization would like to provide seasonal influenza immunizations in a jurisdiction where we do not have a vaccine refrigerator. Will we be able to obtain vaccines from that jurisdiction to provide our influenza immunization clinics?

A: No. As per the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine*:

I/we understand that if our organization does NOT have a refrigerator in the health unit's jurisdiction, we will not be able to obtain vaccine from the health unit and will not be able to provide seasonal influenza immunization clinics in that jurisdiction.

Q: Our organization has satellite or branch offices located in private dwelling house(s). Can we use this location to store vaccines?

A: No. As per the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine*:

I/we understand that our vaccine refrigerator(s) must meet the following requirements:

- not located in a private dwelling house or garage.

Q: Can our staff transport influenza vaccine from our approved and inspected vaccine refrigerator and store the vaccine in a refrigerator in a private dwelling house?

A: No. As per the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine*:

Publicly-funded seasonal influenza vaccines are not to be stored in refrigerators located in a private dwelling house. The vaccines will only be stored in the approved refrigerator(s) as listed on the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine*.

Q: My organization is not planning to store or monitor any influenza vaccines, but we would still like to host a workplace influenza clinic. What should we do?

A: Organizations who do not have an occupational health department storing and/or administering seasonal vaccines must hire an approved organization that has completed the prequalification process or a physician that can administer the influenza vaccines and has completed and passed the required annual vaccine refrigerator inspection.

Q: Will we need to contact our health unit for a vaccine refrigerator (cold chain) inspection?

A: No. Once the ministry receives a list of your organization's vaccine refrigerators we will forward this information to the health unit(s) for a cold chain inspection.

Q: Does our organization need to provide the ministry with a copy of our cold chain inspection results and/or temperature logs?

A: No. The ministry will receive the results of your cold chain inspection from the health unit. The health unit may request your temperature logs as a 'vaccine storage and handling' requirement.

Q: If our organization's insurance is not effective from October 1 to March 31, of the current influenza season can we still participate in the program?

A: No. As per the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza and H1N1 Vaccine*:

The policy of insurance must:

- be effective during the time period from October 1 to March 31 of the current influenza season.

NOTE: If the insurance expires during this time period, the renewed insurance certificate must be submitted to the ministry.

Q: Will the ministry notify us if they have received our *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine* and proof of liability insurance?

A: No. As per the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine*:

I/we understand that the ministry will *not* notify our organization if our prequalification package was received.

Q: Will I be able to participate in the seasonal *UIIP* if the ministry receives our *Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine* after the deadline for the current influenza season and/or the form is incomplete and/or we did not submit my proof of liability insurance?

A: No. As per the *UIIP and Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine*:

I/we understand that the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine* and proof of insurance received after the deadline for the current influenza season will NOT be processed and/or will NOT be accepted;

I/we understand that it is our responsibility to ensure that the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine* is complete (this includes initialing the bottoms of all pages) and the proof of insurance policy is submitted along with the *UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine* to the ministry. The ministry will not process incomplete prequalification packages (*UIIP Prequalification Form for Organizations Requesting Seasonal Influenza Vaccine* and insurance certificate) and will not contact us if the prequalification package is incomplete.

Q: If my organization has multiple locations across the province, can my organization submit one (1) *Prequalification Agreement for Organizations Requesting Seasonal Influenza Vaccine* for the current season to cover all locations?

A: Yes. One *Prequalification Agreement for Organizations Requesting Seasonal Influenza Vaccine* for the current season may be submitted to cover multiple locations of the same organization, permitting that all refrigerator locations are listed on the form, all locations are covered under the same insurance policy, and that the prequalification is complete.

Q: If my organization has successfully prequalified for the UIIP, what is the process to follow for vaccinating Ontarians?

A: Upon satisfactory completion and approval (as determined by the ministry) of the *Prequalification Agreement for Organizations Requesting Seasonal Influenza Vaccine for the current season*; you are eligible to store, monitor and administer the seasonal influenza vaccines. If you have made the decision to administer the seasonal influenza vaccines, please do so in adherence with the ministry's recommended approach for the current season.

Please also ensure you monitor the [ministry's website](#) for information.

Q: Will my application be accepted if it is late?

A: No. Late applications, received after the deadline for the current influenza season will not be accepted.

Q: Can I submit my application by email or fax?

A: No. Applications that are received by fax or e-mail will not be accepted. Applications must be mailed to the ministry, and they must be received by the ministry on/or before the deadline for the current influenza season.

Q: Do I need a medical directive to administer the Seasonal influenza vaccines?

A: Yes, if you/your organization must have set medical directives specifically written for the administration of the seasonal influenza vaccines:

- *The medical directive delegates the controlled act of giving influenza vaccines to any registered nurse*
- *Operation under this medical directive requires that:*
 - *an Emergency Bag be present at all times;*
 - *a protocol for managing fainting and anaphylaxis be available at all times;*
 - *nurses present at a clinic must be trained in fainting and anaphylaxis management and be familiar with the medical directive and utilization of the emergency bag; and,*
 - *a land telephone is readily available for contacting emergency services.*

Q: What does the ministry consider to be an "Emergency Bag"?

A: An Emergency Bag is a bag that contains the necessary emergency equipment to manage anaphylaxis at immunization clinics. Some of the contents that are expected to be in this bag include:



- Epinephrine, Benadryl and medical directive for administration
- A blood pressure cuff that would suit the needs of clients of all ages and sizes that will be present at your clinic,
- A stethoscope,
- First aid equipment in case there are falls, injuries, or fainting at the clinic, and
- Any other emergency equipment needed to manage health emergencies that may arise at your influenza immunization clinics.

It may be helpful for your organization to consult the College of Nurses of Ontario (CNO) Nursing Standards to guide you in ensuring you have the correct equipment in this bag. Your organization should also have a protocol present at the clinic that is clearly visible and easily accessible for the management of anaphylaxis and fainting.

Q: “The medical directive delegates the controlled act of giving seasonal influenza vaccines to any registered nurse.” Does this mean Registered Nurses (RN) only or does it include Registered Practical Nurses (RPN’s) as well?

A: Both RPN’s or RN’s can be delegated controlled acts and work under medical directives. The RN and/or RPN must have the necessary knowledge, skills, and judgment to guide their practice.

Q: Do I have to report adverse events following immunization (AEFI) to my local health unit?

A: Yes, as with every immunization, vaccine delivery agents are required to document and report any adverse event following immunization (AEFI) according to section 38 of the *Health Protection and Promotion Act*, within 7 days.

To report an adverse event to your local health unit, vaccine delivery agents must fill out the [AEFI report form located on the Public Health Agency of Canada’s website](#).

A [list of public health units](#) can be found at the ministry’s website.

Q: What additional resources are available to me/my organization?

A: [The Canadian Immunization Guide, 7th Edition](#) provides recommendations about the management of anaphylaxis on page 82.

The College of Nurses of Ontario provides practice guidelines for:

- [Influenza Vaccinations](#)
- [Preparing for an Influenza Pandemic](#)

The ministry provides guidelines for the storage and handling of vaccine:



- [Vaccine Storage and Handling Guidelines](#)

Q: Can our organization co-administer different types of seasonal influenza vaccines at our clinics?

A: Yes, your organization may co-administer different types of seasonal influenza vaccine at workplace clinics provided appropriate medical directives exist for all vaccine administered. The vaccines should be prepared in separate syringes and should be labelled in order to identify which vaccine each syringe contains.

Further information about providing multiple injections is available from:

- [The Canadian Immunization Guide, 7th Edition](#) provides recommendations about multiple injections, page 41
- [The College of Nurses of Ontario Practice Standard: Medication, 2008](#)
- [The World Health Organization: best practices for injections and related procedures toolkit, 2010](#)

Q: Are there a minimum number of vaccinations an organization must be prepared to administer to qualify to participate in the seasonal UIIP?

A: No. There is no minimum number of vaccinations required to participate in the seasonal UIIP.

Q: Who can our organization contact if we have additional questions?

A: Please email all questions relating to the prequalification process to UIIP.MOH@ontario.ca. Due to the large volume of emails, you will receive a response in 3 to 5 business days.

Please monitor the [ministry's website](#) for important information and updates.

You may also contact your local public health unit for details regarding the prequalification process and/or the UIIP in your jurisdiction.

Q: Do post secondary education institution with an onsite health and wellness services need to prequalify?

A: The answer depends on the following:

- i) No. If the health and wellness service of your institution has a physician that provides influenza immunizations to the students (similar to a Doctor's Office) then you do not need to prequalify.

- ii) Yes. If your institution is holding a mass influenza immunization clinic (similar to a workplace flu clinic open to all eligible Ontarians), by regulated healthcare professionals under a medical directive, then you are required to prequalify.

Q: My organization does not bill OHIP. Can we still participate in the UIIP?

A: Yes. However, your organization must prequalify and meet the requirements outlined in the Prequalification Form and pass all steps involved in the prequalification process.

Q: Do private hospitals that receive ministry funding have to prequalify?

A: Yes. All private hospitals must prequalify. The ministry does not distinguish between private hospitals that receive ministry funding or private hospitals that do not receive ministry funding.

Q: Can base hospital physicians of paramedic services sign the Prequalification Form?

A: No. As indicated in the Prequalification Form:

I/we agree that if our organization is defined as "Emergency Medical Services" (EMS) or "First Responders" or "Paramedics," the base hospital physician is not permitted to be the Affiliated Physician.

Therefore, the base hospital physician cannot sign the Prequalification Form.

Q: Can private hospitals host reimbursable community influenza clinics?

A: No. Private hospitals cannot be reimbursed for community influenza clinics because they do not receive transfer payments