

Frequently Asked Questions: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies

December 22, 2023

This document accompanies the most recent Executive Officer (EO) Notice on the Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies available on the ministry website.

Participating pharmacies administering publicly funded COVID-19 vaccines must adhere to their COVID-19 Vaccine Agreement with the ministry respecting COVID-19 administration and use of the provincial COVID-19 vaccine solution-COVAX_{ON}. This document primarily relates to the public funding of pharmacy administration of COVID-19 vaccines and is not intended to provide information about the requirements in the COVID-19 Vaccine Agreement.

Additional information:

- COVID-19 Vaccine Guidance
- COVID-19 vaccine immunization in Ontario
- Health Network System claims issues, pharmacy staff may contact the ministry's Ontario Drug Benefit (ODB) Help Desk and refer to the <u>Ontario Drug Programs</u> Reference Manual
- Injection training and scope of practice, pharmacy staff should contact the <u>Ontario</u>
 College of Pharmacists (OCP)

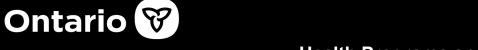


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Overview

1. What is the role of pharmacies in the administration of the publicly funded COVID-19 vaccine?

Participating pharmacies play an important role in the administration of publicly funded COVID-19 vaccines. Pharmacy staff, including pharmacists, registered pharmacy students, interns and pharmacy technicians who are members of the Ontario College of Pharmacists (OCP) and have completed the required injection training in accordance with OCP guidance, may administer publicly funded COVID-19 vaccines in participating pharmacies to eligible individuals. Participation by pharmacies is voluntary. For more information about the criteria for participating refer to the most recent *EO Notice:* Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies.

2. Who can get a publicly funded COVID-19 vaccine at a pharmacy?

Individuals 6 months of age and older who live, work or study in Ontario or are visiting Ontario from another province / territory or another country may be eligible to receive the COVID-19 vaccine at a participating pharmacy. For all vaccine doses, when eligibility is defined by age, individuals must be the respective age of eligibility on the day of the vaccine administration. For more information refer to the most recent *EO Notice:*Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies.

3. How will the public know which pharmacies in Ontario are administering publicly funded COVID-19 vaccines?

Individuals may visit the ministry's <u>online location finder</u> to find participating pharmacies that administer publicly funded COVID-19 vaccines and book an appointment.

4. Which publicly funded COVID-19 vaccines are available in pharmacies?

Refer to the most recent EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies. Inclusion of a product in the EO Notice does not guarantee continued supply of the product through the participating pharmaceutical distributors.

5. What type of identification do individuals need to provide at the pharmacy to have a COVID-19 vaccine administered?

Individuals should provide a valid Ontario health card number to the pharmacy. Individuals who do not have an Ontario health card number may still receive a publicly funded COVID-19 vaccine and should provide an alternate identification to the pharmacy that includes the individual's date of birth and contact information.

Alternative forms of identification include:



- Birth Certificate
- Driver's License
- First Nations ID
- Out of Province ID
- MRN (Medical Record Number)
- Passport

Pharmacy Participation

6. Do all Ontario pharmacies provide publicly funded COVID-19 vaccines?

Only participating pharmacies that have been selected by the ministry and who meet the criteria in the EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies are eligible to provide publicly funded COVID-19 vaccines.

Pharmacy criteria include but are not limited to:

- Have a valid HNS Subscription Agreement with the ministry
- Have a valid COVID-19 Vaccine Agreement
- Be enrolled in the current Universal Influenza Immunization Program (UIIP)

Note: A valid COVID-19 Vaccine agreement is in respect of a particular pharmacy operator operating at a specific pharmacy location. Where a pharmacy is sold, or where a pharmacy operator relocates, a new COVID-19 Vaccine Agreement is required to reflect the new pharmacy operator or location. Similarly, enrollment in the UIIP is in respect of a particular pharmacy operator operating at a specific pharmacy location. Where a pharmacy is sold, or where a pharmacy operator relocates, new enrollment in the UIIP is required to reflect the new pharmacy operator or location.

Other considerations include:

- pharmacies should have the capacity and ability to accept and administer vaccine supply quickly and effectively
- other factors such as high-risk areas, regional population distribution, pharmacy patient base and performance in the UIIP.

7. Are all Ontario pharmacists able to administer COVID-19 vaccines to eligible individuals?

Only Part A pharmacists, registered pharmacy students, interns and registered pharmacy technicians who are members of the OCP and who have completed an approved training program in accordance with OCP guidance can administer publicly funded COVID-19 vaccine in participating pharmacies. The eligible OCP members who have registered the required injection training are listed on the OCP's member registry website.

Reference information:



- OCP guidelines including appropriate infection control measures
- OCP website for more information on injection training
- Ontario Pharmacists' Association <u>Playbook</u> and <u>FAQs</u>
- Ministry Guidance documents provided to clinicians available here.

8. Can a participating pharmacy employ other health care providers (e.g., registered nurse) to administer COVID-19 vaccines in the pharmacy?

Other health care providers (HCPs) who have the authority to administer COVID-19 vaccine under Ontario law and who have injection training may also administer publicly funded COVID-19 vaccine in participating pharmacies including if that pharmacy is operating a Pharmacy Mobile Clinic. Should it be necessary that a pharmacy retain the services of other HCPs to administer COVID-19 vaccine in the pharmacy, the pharmacy must comply with all terms and conditions in the Ministry's Executive Officer Notice and Frequently Asked Questions documents ("Ministry Policies"), and the user agreement for the COVAX_{ON} system (the "User Agreement") in relation to the HCP's vaccine-related activities in the pharmacy. For clarity, all terms and conditions in Ministry Policies and the User Agreement respecting the vaccine-related activities of a pharmacist, intern, registered pharmacy student or pharmacy technician apply equally to the other HCP that has been retained by the pharmacy to administer the vaccine.

A Part A pharmacist must be identified in the prescriber field on the claim through the HNS for vaccines administered by other HCPs. All respective HCPs whether pharmacist, intern, registered pharmacy student, pharmacy technician or other HCP must identify themselves as the vaccinator in the COVAX_{ON} system and on the vaccine receipt provided to the individual.

The Designated Manager should also consider the following non-exhaustive list of requirements that would be needed to comply with Ministry Policies and the User Agreement:

- Satisfaction that the HCP has the competency to administer COVID-19 vaccine injection such as a proof of registration as such under the respective regulatory body (e.g., College of Nurses)
- List of all vaccination details administered by the other HCP including those that must be entered in the COVAX_{ON} system

Evidence that the other HCP has a clear understanding of <u>Vaccine Storage and Handling Guidelines</u>, the <u>COVID-19</u>: <u>Vaccine Storage and Handling Guidance</u> document on the ministry's <u>website</u> and required Ministry guidance and protocols.

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9. Does a pharmacy have to administer the COVID-19 vaccine within the walls of the pharmacy?

Participating pharmacies must administer publicly funded COVID-19 vaccine within the pharmacy premises, unless otherwise permitted as follows:

- in a nearby location (e.g., pharmacy parking lot) as long as they adhere to public safety and relevant Ministry policy / direction (including infection prevention and control measures), the COVID-19 Vaccine Agreement, and any OCP standards, polices or guidelines.
- for home-bound patients in their private home.
- as a mobile clinic in other locations (e.g., community centres, apartment complexes, etc.).
- in retirement homes, congregate settings and long-term care homes under the direction and in collaboration with the local Public Health Unit and the home.

Note: Pharmacy staff administration of publicly funded COVID-19 vaccine to hospital inpatients is not eligible for payment.

10. What is the process for pharmacies when administering doses for residents of retirement homes, elderly living in other congregate settings or residents of Long-Term Care (LTC) homes within these settings?

Pharmacies are required to work with their local Public Health Unit (PHU) and the retirement home, LTC home or congregate setting for administering COVID-19 vaccines to residents of these places. Pharmacies will be contacted by their local PHU or the retirement home, LTC home or congregate setting if their services are required. The list of retirement homes is available for pharmacies through their Office 365 email account for verification purposes only.

Note: Trained community pharmacy staff may administer and submit claims for COVID-19 vaccine doses to residents in LTC homes, retirement homes and other congregate settings under the direction of PHU. In addition, trained community pharmacy staff may administer and submit claims for COVID-19 vaccine doses for staff, support workers, essential caregivers, volunteers, and contractors who are working within congregate settings when the pharmacy staff visits the home / congregate setting to administer vaccines to residents. All individuals receiving the vaccine must be eligible for their dose as per the requirements noted in the most recent EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies.

The roles of each entity are outlined below:



Public Health Unit	Retirement Home, Congregate Setting or LTC Home	Pharmacy
Identifies retirement homes, congregate settings or LTC home that have residents who are eligible for a COVID-19 vaccine dose that will be administered by a pharmacy If available, provides pharmacy with 'Clinic in a Box' (IPAD¹ for accessing COVAXoN on site at the retirement home, congregate setting or LTC home) if required	 Works with the public health unit to determine best method of vaccine administration Establishes a partnership with a local pharmacy if needed Works with the pharmacy to provide guidance on the number of doses needed and support for scheduling dose administration / clinic days including which mRNA vaccine to be administered For congregate settings, determine number of elderly residents or staff (and others noted above) that require a vaccine dose 	 Administers mRNA COVID-19 as per arrangements between PHU and retirement home, congregate setting or LTC home Pharmacy administers COVID-19 vaccine from own supply and transports doses to the retirement home, congregate setting or LTC home as per storage and handling guidelines Pharmacy accesses COVAXON on site using 'Clinic in a Box' for required documentation and issuing of patient receipts if needed Upon return to pharmacy, submits claim through the HNS as soon as possible within one business day Comply with applicable law, including with respect to waste

11. Can a pharmacy offer COVID-19 vaccine administration services to a patient in their private home?

¹ Participating pharmacies providing COVID-19 vaccines outside the pharmacy in congregate settings or mobile clinics should be prepared to use their own IPADs or tablets to access the COVAX_{ON} system.



There is an expectation that pharmacies are administering the COVID-19 vaccine within the pharmacy premise where vaccine storage requirements can be maintained.

However, an exception may be allowed for the pharmacist to visit the individual's private home (i.e., one-on-one) to administer the COVID-19 vaccine provided the eligible individual has requested a home visit by the pharmacist and provides a reason such as due to the individual being immobile, and this request and rationale is documented by the pharmacy in writing. In addition, trained community pharmacy staff may administer COVID-19 vaccine doses in long-term care homes, retirement homes and other congregate settings under the direction of Public Health Units.

The pharmacy must ensure public safety, vaccine handling and storage requirements (e.g., <u>specific references</u> to COVID-19 Vaccine Storage and Handling Guidance for transferring vaccines) as well as adhere to relevant Ministry policy / direction, the COVID-19 Vaccine Agreement, and any <u>OCP</u> standards, polices or guidelines. In addition, the pharmacist documentation must include the geographical location of the vaccine administration if not conducted within the pharmacy.

12. How can my pharmacy participate in delivery of COVID-19 vaccines via mobile clinics? What are the requirements / parameters?

Pharmacies may conduct off-site mobile clinics in collaboration with their local Public Health Unit. All individual eligibility requirements in the most recent version of the EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies apply to the mobile clinic.

The following conditions apply:

- Participating pharmacies must contact their local PHU to notify them of future mobile clinics that they intend to operate. It is recommended that mobile clinics be within the geographic region of the local PHU.
- The mobile clinic must be aligned with Ontario's vaccine distribution plan in cooperation with local PHU planning and may be informed by outreach and engagement possibly coordinated with community partners.
- Trained pharmacy staff from the participating pharmacy must administer COVID-19 vaccine from their own supply and transport doses to the mobile clinic as per storage and handling guidelines
- Pharmacy staff from the participating pharmacy would need to ensure infection prevention and control measures are followed and other quidelines/policies if applicable.



- Pharmacy staff from the participating pharmacy must access COVAX_{ON} on site at the mobile clinic location for required documentation of vaccine administration and issuing of patient receipts
- Upon return to the location of the participating pharmacy, the pharmacist from the participating pharmacy must submit claims through the HNS for reimbursement as soon as possible and within 7 calendar days².
- Participating pharmacies are responsible for all aspects of running the mobile clinic including staffing, supplies, communication, signage and other logistics.
- Participating pharmacies must comply with applicable law, including with respect to waste management with consideration for any added insurance requirements respecting operations off-site.

The participating pharmacy must ensure public safety, vaccine handling and storage requirements (e.g. <u>specific references</u> to COVID-19 Vaccine Storage and Handling Guidance for transferring vaccines) as well as adhere to relevant Ministry policy / direction, the COVID-19 Vaccine Agreement, and any <u>OCP</u> standards, polices or guidelines. In addition, the pharmacist documentation must include the geographical location of the vaccine administration if not conducted within the pharmacy.

Individual pharmacists, interns, pharmacy students and pharmacy technicians with injection training may also participate in administering COVID-19 vaccine in an alternate clinic setting organized and hosted by another authorized organization (e.g., PHU or hospital-led mass immunization clinic). In these instances, as it falls outside the parameters of the Executive Officer Notice, they should refer to the applicable legislation, other agreements, or OCP policy as appropriate.

13. Is personal protective equipment (PPE) available for pharmacies that administer COVID-19 vaccines?

Pharmacies that administer COVID-19 vaccines may order PPE by accessing the Ministry of Public and Business Service Delivery (MPBSD) PPE Supply Portal at https://www.ppesupply.ontario.ca/. Access to this portal has been provided by MPBSD to all pharmacies administering COVID-19 vaccines. If your pharmacy is having difficulties or cannot access the portal, please contact sco.supplies@ontario.ca.

Pharmacies that belong to a banner or chain corporation should work through their corporate head office, who may centrally coordinate order and facilitate distribution. Independent pharmacies may order directly from the website.

² Note that the HNS can process online transactions for publicly funded services on any of the most recent seven calendar days, including the current date. This means that a claim for the COVID-19 vaccine could be submitted today for a service date in the past (as long as it is within the past 7 days).

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Note that there is an allocation framework in place depending on the current supply and not all orders for PPE may be filled. The ministry's supply of PPE must ONLY be used to support the activity of pharmacies administering the publicly funded COVID-19 vaccine.

14. What other procedures must be followed to ensure the safe administration of COVID-19 vaccines?

Pharmacy professionals should continue to follow the guidelines set out by public health officials. Pharmacies have a shared responsibility for informing and educating the public on COVID-19, including promoting infection prevention and control measures. Resources can be found on the Ontario College of Pharmacists website as well as Ministry Guidance at this website.

Vaccine Ordering and Inventory Management

15. How do pharmacies obtain publicly funded COVID-19 vaccines?

Before ordering publicly funded COVID-19 vaccines, pharmacies must meet these requirements to participate in the COVID-19 Vaccine Program:

- 1. Hold a valid HNS Subscription Agreement
- Hold a valid COVID-19 Vaccine Agreement*
- 3. Pass a cold chain inspection conducted by the local PHU
- 4. Complete COVaxon registration and training
- * When a pharmacy is sold or the pharmacy is relocated, a new COVID-19 Vaccine Agreement is required to reflect the new pharmacy operator or location's new OCP Accreditation number and updated ON# of the pharmacy. An outdated agreement may delay COVID-19 vaccine ordering and delivery for the pharmacy. Pharmacy owners may contact the ministry to obtain an application for updating at OPDPInfoBox@Ontario.ca.

Pharmacy staff must also be registered with the updated ON# as per the updated COVaxoN agreement. After these requirements are fulfilled, pharmacies may order publicly funded COVID-19 vaccines at no cost through a designated pharmaceutical distributor. Some vaccines may only be available through the local public health unit (PHU). Vaccine ancillary supplies (e.g., needles, syringes) may also be ordered from vaccine distributors; however, these supplies may not arrive at the same time due to different delivery requirements.

Vaccine Storage and Handling Guidelines:

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Pharmacies storing publicly funded vaccines are required to submit temperature records to the local PHU on a regular basis. If a pharmacy fails to submit temperature records to the PHU or if there is a cold chain incident at a pharmacy, the local PHU will inform the vaccine distributor to temporarily suspend vaccine ordering for that pharmacy. Once a pharmacy is suspended by the local PHU, the distributor will cancel any vaccine order for the week in which the suspension is issued by the PHU and the distributor will not deliver vaccines to that pharmacy until the PHU determines that the pharmacy has met the storage requirements, and the suspension may be lifted. When the suspension is lifted by the local PHU the pharmacy and distributor will be notified to allow vaccine ordering and delivery to resume.

COVaxon Inventory Management:

Pharmacies are required to maintain accurate weekly vaccine inventory and administration records in COVaxon. A pharmacy's COVaxon records are reviewed by the ministry when the pharmacy orders vaccine from the distributor to ensure proper allocation and prevent wastage of available vaccine supply. The ministry may reduce or cancel a pharmacy's vaccine order based on the pharmacy's current inventory on hand recorded in COVaxon compared to the average vaccine administration recorded in COVaxon over the last 14 days.

To minimize disruptions in vaccine ordering and delivery, it is important for pharmacies to follow the Vaccine Storage and Handling Guidelines, provide the required information to their local PHU in a timely manner, and maintain accurate inventory and administration records in COVaxon.

16. Are pharmacies able to order and administer Nuvaxovid™ (Novavax Inc.) XBB vaccine?

On December 5th, 2023, Novavax Nuvaxovid XBB.1.5 was approved by Health Canada for use as an authorized COVID-19 vaccine. The Novavax XBB vaccine can be offered to individuals 12 years and older who are not able or willing to receive a recommended mRNA COVID-19 vaccine.

Ontario has a supply of Novavax XBB.1.5 vaccine and will be collaborating with Ontario pharmacies for administration of doses to eligible Ontarians. Pharmacies that have patient demand for Novavax XBB.1.5 can submit an order for a limited quantity of Novavax XBB through their distributor's exceptional order process. Please include all relevant rationale in the exceptional order submission.

17. What is the purpose of the COVaxon system?

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COVax_{ON} is the database that holds all COVID-19 vaccine inventory and administration information for Ontario. It is separate from the HNS and all pharmacies are required to enter patient vaccine administration details and maintain up to date inventory information in this system. The fee paid to pharmacies for administering the COVID-19 vaccine includes pharmacy services relating to access and use of COVax_{ON}.

The requirements for accessing and using $COVax_{ON}$ can be found in the COVID-19 Vaccine Agreement. Access to and use of the system is conditional on the pharmacy being granted access to $COVax_{ON}$ by the ministry.

Pharmacy staff must complete training to use COVaxon. Pharmacies should contact their Pharmacy Trainer (i.e., first-line support) – either a corporate office (for pharmacy chains), or the Ontario Pharmacists Association (for independent pharmacies) for resource information related to COVaxON including support, training, forms and reference materials. Do not contact the COVaxon support channel directly.

It is important that pharmacies accurately and regularly document vaccine inventory and administration data in COVaxon. Pharmacies should contact their trainer for questions on data entry and resolving inventory discrepancies in COVaxon. Pharmacy trainers are your corporate office. The trainer for independent, unaffiliated pharmacies is the Ontario Pharmacists Association (acatapano@opatoday.com or jdeschenes@opatoday.com); an OPA membership is not required.

Inventory Data:

- It is important for pharmacies to maintain real-time data entry in COVaxon to avoid vaccine order cancellations/reductions.
- Pharmacies should conduct a weekly inventory reconciliation of physical doses onhand compared to reported COVaxon doses before placing a vaccine order.
- Pharmacies may access the <u>Inventory Reconciliation Report</u> in COVaxon and discrepancies must be investigated and resolved (e.g., wastage events, inventory adjustments) in a timely manner in COVaxon. Please contact your pharmacy trainer if required.
- To align with the COVID-19 vaccine ordering process, inventory should be reconciled and updated in COVaxon one day prior to the weekly pre-book ordering process.
- Here are four common inventory discrepancies in COVaxon:
 - 1. Doses appearing as available from expired lots, or surpassed maximum refrigeration time, should be adjusted as wastage with the appropriate wastage reason.
 - 2. Doses appearing as available from completed lots should be adjusted with the appropriate wastage reason (if known). If the reason for the discrepancy



- is unknown, complete an inventory adjustment and add the note "record is part of a remediation effort to clear available doses from completed lot".
- 3. Doses appearing as available from suspended lots should be adjusted as either a wastage or excursion event and add the note "record is part of a remediation effort to clear available doses from suspended lot".
- 4. Doses appearing as available from lots that are not physically present should be investigated and remediated. Where physical inventory is not onhand for a particular lot number, and the nature of discrepancy is unknown, complete an inventory adjustment and add the note "record is part of a remediation effort to clear available doses from lots not physically present".

Administration Data:

- While vaccine administration to the individual should occur prior to completing the
 entry in COVaxon, pharmacy staff must be diligent in accessing COVaxon to
 confirm when the patient received the vaccine dose (if applicable) including
 verifying which vaccine and the appropriate time interval between doses before
 administering the vaccine. Incorrect entries in COVaxon must be corrected
 immediately.
- When entering information in COVax_{ON}, immunizers must identify their individual health professional status (i.e., they must use their own User ID).

Please also ensure that the information in COVaxON is accurate and up-to-date based on the patient's health card. For example, a patient may choose to change their name after getting married or if they are trans or non-binary.

In the event of system failure, pharmacies must ensure a manual contingency plan is in place for keeping track of COVID-19 vaccine administration and future logging in COVaxoN (e.g., at a minimum, pharmacies should ensure there is supply of consent forms, vaccine information forms and daily patient rosters printed.)

18. What is the process to transfer COVID-19 vaccines between participating pharmacies?

Pharmacies that need to transfer vaccine to another participating pharmacy must adhere to the COVID-19: Vaccine Storage and Handling Guidance that includes specific information on individual COVID-19 vaccine requirements. Only unused vials (i.e., not punctured) can be transferred. Doses can only be transferred within their local public health region.

Doses that are transferred must also be logged into the COVAX_{ON} system for proper system-wide inventory management.



Typically, pharmacy transfers are between pharmacies; however, if a public health unit (PHU) has confirmed that they will accept or supply vaccines, the same process for storage and handling would apply to transferring vaccine to or from a PHU as well.

Pharmacies arranging to transfer / or accept transfers of vaccine from primary care providers should contact their local public health unit for assistance in logging the transfer in COVAX_{ON}. if the primary care provider does not have their own AO (Authorized Organization) within the COVAX_{ON} system.

Pharmacies are no longer required to contact the ministry for approval of vaccine transfers.

19. How do pharmacies dispose of expired or wasted COVID-19 vaccines?

Pharmacies must document wastage, extra doses from vaccine vials and temperature excursions into the COVAX_{ON} system for proper inventory management.

After wastage is documented in COVAX_{ON}, pharmacies must follow disposal practice protocols including:

- COVID-19: Vaccine Storage and Handling Guidance
 - Do NOT return expired or unused COVID-19 vaccines to the local public health unit; and
 - Ontario College of Pharmacist (OCP) guidelines, such as <u>Policy on Medication</u> Procurement and Inventory Management
 - This would include how to properly dispose of expired or wasted vaccine.
 Pharmacies may wish to contact the OCP for further advice as destruction of vaccine and drug wastage is included as part of the pharmacy's usual disposal practice protocols.

Individual Eligibility

20. Can an individual who does <u>not</u> have an Ontario health card number still receive publicly funded COVID-19 vaccine at a pharmacy?

Yes. Appropriately trained pharmacy staff can administer publicly funded COVID-19 vaccine to individuals *without* an Ontario health number provided the patient presents with valid ID for documentation (refer to Question #5) and meet the eligibility criteria. Refer to the most recent EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies for eligibility criteria, and billing process.



Note: For individuals who have a valid Ontario health number, pharmacies need the Ontario health number to submit the claim for payment. This would apply even if the individual forgot to bring the Ontario health number to the appointment.

21.Is an individual who received vaccine outside of Ontario or Canada considered fully vaccinated and up to date?

Refer to the most recent <u>COVID-19 Vaccine Guidance</u> for information on out of province vaccines and staying up to date. The definition for fully vaccinated in Ontario is available at this <u>website</u>.

22. How are the terms primary series, booster dose, unvaccinated or previously vaccinated defined?

To align with the National Advisory Committee on Immunization (NACI) and the product monographs, as of Fall 2023 the ministry is moving away from using the terms 'primary series' and 'booster dose(s)'. Individuals' vaccination status may be identified as not previously vaccinated and previously vaccinated. Table A (below) provides additional details on the previous and current terminology:

Table A. COVID-19 Vaccination Status Terminology

Previous Terminology	New Terminology	Explanation	Fall 2023 COVID-19 Vaccine Eligibility
Eligible for primary series – age 6 months and older	Not previously vaccinated	These patients have never received any type of COVID-19 vaccine	These patients are eligible to receive the authorized XBB schedule for their age if it has been 6 months (minimum 3 months) since their last confirmed SARS-CoV-2 infection.
Booster Dose – age 5 and older	Previously vaccinated	These patients are 5 years of age or older and have received at least one dose of any COVID-19 vaccine to date.	All individuals who are 5 years of age and older and who have received at least one dose of any COVID-19 vaccine are eligible to receive at least one XBB dose this fall.



Previous Terminology	New Terminology	Explanation	Fall 2023 COVID-19 Vaccine Eligibility
			See Tables 1-2 in COVID-19 Vaccine Guidance for appropriate intervals
Booster Dose – age 6 months to 4 years	Previously vaccinated	These patients are 6 months to 4 years of age and have received at least 1 dose of any COVID-19 vaccine to date.	The vaccine schedule recommendations differ based on whether or not the child has previously completed either a 2 dose-series (i.e., Monovalent or Bivalent Moderna) or a 3 doseseries (i.e., Monovalent Pfizer). See Tables 1 in COVID-19 Vaccine Guidance.

See page 15 of the COVID-19 Vaccine Guidance for suggested intervals between SARS-CoV-2 Infection and COVID-19 Vaccination

The guidance also contains additional details and guidance to aide with clinical decision making.

23. What COVID-19 vaccine is recommended for individuals NOT previously vaccinated?

Individuals who have NOT been previously vaccinated against COVID-19:

- I. Those 5 years and older who are previously unvaccinated should be vaccinated. The XBB.1.5-containing COVID-19 mRNA vaccine (XBB) formulations are recommended Please refer to Table 1 in COVID-19 Vaccine Guidance for schedule guidelines
 - The recommendation for unvaccinated individuals 12-29 years to receive a Pfizer COVID-19 vaccine rather than a Moderna COVID-19 vaccine is no longer a recommendation with the XBB formulation. Unvaccinated individuals in this age range may receive either the Pfizer or Moderna XBB vaccine.



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- II. Those 6 months to 4 years who are previously unvaccinated and who are at high risk of severe illness due to COVID-19, should be vaccinated. The XBB formulations are recommended. Please refer to Table 1 for schedule guidelines.
- III. Those 6 months to 4 years who are previously unvaccinated and are not known to be at high risk of severe illness due to COVID-19, may be vaccinated. The XBB formulations are recommended. Please refer to Table 1 for schedule guidelines.

24. For individuals who are immunocompromised, which COVID-19 vaccine is recommended?

Individuals 6 months and older who are moderately to severely immunocompromised are recommended to receive at least one dose of the XBB mRNA vaccine formulation this fall. Please see Table 1 in COVID-19 Vaccine Guidance for appropriate schedule based on number of previous doses received.

The ministry preferentially recommends the Moderna XBB vaccine over the Pfizer XBB vaccine for individuals 6 months – 4 years who are moderately to severely immunocompromised. This product preference reflects acceptability and feasibility considerations for implementing a 3 dose (Moderna) vs. 4 dose (Pfizer) series and greatly likelihood of series completion in high-risk individuals, with fewer doses required in the Moderna schedule.

The safety and efficacy of the Novavax COVID-19 vaccine has not been established in individuals who are immunocompromised due to disease or treatment. As such, eligible individuals who choose to be immunized with the Novavax COVID-19 vaccine should be informed that there is currently limited evidence for use of these vaccines in this population. Individual clinical discretion should be used when offering an additional dose of Novavax to immunocompromised individuals.

Individuals who are moderately to severely immunocompromised, 6 months and older, who have NOT been previously vaccinated or who are recommended by their clinician to restart the vaccination series should receive the authorized XBB schedule for their age and are recommended to receive one additional dose of XXB.1.5. Refer to Table 1 in the ministry's COVID-19 Vaccine Guidance.

25.In what clinical scenario would re-initiation of the entire COVID-19 vaccine series be required?

It is recommended that re-vaccination with a new COVID-19 vaccine series be initiated post-transplantation for hematopoietic stem cell transplant (HSCT), hematopoietic cell transplants (HCT) (autologous or allogeneic), and recipients of CAR-T-cell therapy given



the loss of immunity following therapy or transplant.³ Optimal timing for re-immunization should be determined on a case-by-case basis in consultation with the clinical team. For additional information on organ transplantation, consult the <u>Canadian Society of</u>

Transplantation statement on COVID-19 vaccination.

For more information, refer to the ministry's most recent COVID-19 Vaccine Guidance.

26. If a child (6 months – 4 years old) received Moderna bivalent or Pfizer monovalent for their first dose, what should they receive for their second dose?

Refer to Table 1 and Appendix B for COVID-19 mRNA Vaccine Scenarios for Individuals 6 months-4 years in the ministry's most recent <u>COVID-19 Vaccine Guidance</u>. Vaccine schedule recommendations differ based on whether or not the child has previously initiated either a 2 dose-series (i.e., Monovalent or Bivalent Moderna) or a 3 dose-series (i.e., Monovalent Pfizer).

Children who have not completed an initial 2 or 3 dose series (as appropriate depending on product), should complete the series using the appropriate number of doses using an XBB vaccine. Please see in the COVID-19 Vaccine Guidance Table 1 and Appendix B for authorized and recommended intervals for this population and specific scenarios.

NACI recommendations on vaccine interchangeability apply to XBB COVID-19 vaccines if used to complete a vaccine series started with a different formulation (either original monovalent wild type-containing or bivalent vaccine). Regardless of which product is offered to start a vaccine series, the previous dose should be counted, and the series need not be restarted.

27. Can an individual get Novavax (Nuvaxovid) vaccine if they are allergic to the mRNA vaccines?

People who have experienced a severe immediate allergic reaction after a dose of an mRNA COVID-19 vaccine can safely receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an allergist/immunologist or another appropriate physician.

See the Canadian Immunization Guide for more information.

Individuals with known allergies to components of the vaccines may speak with an appropriate physician or nurse practitioner (NP) for evaluation.

For more information, refer to the ministry's most recent COVID-19 Vaccine Guidance.

³ As per the <u>Canadian Immunization Guide</u>, HSCT recipients should be viewed as vaccine naïve (i.e., never immunized) and require re-immunization after transplant.

Frequently Asked Questions - Administration of COVID-19 Vaccines in Ontario Pharmacies



28. Can pharmacies administer the COVID-19 vaccine at or around the same time as the flu vaccine?

Individuals 6 months and older, may receive a COVID-19 vaccine simultaneously with (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines). If vaccines are co-administered, immunization on separate limbs is recommended, however if the same limb must be used, the injection sites should be separated by at least 2.5 cm (1 inch).

There are two exceptions. COVID-19 vaccines should not be co-administered with the Imvamune vaccine (for mpox) and the Arexvy vaccine for Respiratory Syncytial Virus (RSV). Refer to the COVID-19 Vaccine Guidance for more information.

29. What is recommended for individuals who have been previously vaccinated against COVID-19?

Consistent with NACI, the Ontario MOH recommends a dose of an XBB mRNA vaccine for individuals in the authorized age group (i.e., 6 months and older) who have been previously vaccinated against COVID-19, if it has been 6 months from the previous COVID-19 vaccine dose or known SARS-CoV-2 infection (whichever is later) as outlined in Table 1_in the most recent COVID-19 Vaccine Guidance. NACI notes that a shorter interval (3 to < 6 months) can be used to support fall vaccine program implementation.

Immunization is particularly important for those at increased risk of COVID-19. The Ontario MOH strongly recommends that individuals at high-risk from COVID-19, including those with a potential for greater impact from infection, receive a dose of an XBB mRNA vaccine this fall, if it has been six months since their last COVID-19 vaccine dose or confirmed SARS-CoV-2 infection (see Fall 2023 COVID-19 Vaccine Program).

For more information on product preferences and dosing intervals, refer to the most recent COVID-19 Vaccine Guidance.

30. How many COVID-19 vaccine doses can an individual receive and how often?

At this time, the seasonality of COVID-19 is not known, and it has not yet been determined whether people will need an additional COVID-19 vaccine dose at a set time period (e.g., every 6 months). The current Ministry COVID-19 Vaccine Guidance outlines current recommendations, based on age and health status. For more information on dosing intervals, refer to Table 1 in the most recent COVID-19 Vaccine Guidance.



Pharmacy Payment for Vaccine Administration

For Health Network System (HNS) claims issues, pharmacy staff may contact the ministry's Ontario Drug Benefit (ODB) Help Desk and refer to the Ontario Drug Programs Reference Manual.

31. How much does the ministry pay a pharmacy to administer COVID-19 vaccines?

The ministry will reimburse the pharmacy \$13.00 when a claim for payment is submitted through the HNS for the costs associated with services related to administering publicly funded COVID-19 vaccine. Refer to the most recent EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies for details on the services that must be provided to eligible individuals.

Date of service for the claim submitted to HNS must reflect the date that the publicly funded COVID-19 vaccine was administered. HNS can process online transactions for the most recent seven calendar days, including the current date. This means that a claim for the COVID-19 vaccine could be submitted today for a service date in the past as long as it is within the past 7 days. A Part A pharmacist must be identified in the prescriber field on the claim through the HNS for vaccines administered by other health care providers.

Registered pharmacy students, interns and pharmacy technicians that have valid injection training may administer the COVID-19 vaccine; however, the respective injection-trained supervising pharmacist must submit the claim for payment through the HNS using their Pharmacist ID.

Note: When entering information in the Provincial COVID-19 Vaccine Solution-COVAX_{ON}, immunizers <u>must</u> identify their individual health professional status (i.e., they must use their own User ID).

32. How much does the ministry pay a pharmacy if the immunizer is required to inject epinephrine as emergency treatment for patients experiencing a serious adverse drug reaction due to the publicly funded COVID-19 vaccine?

The ministry will reimburse the pharmacy the acquisition cost (no mark-up, dispensing or service fee) of approved epinephrine auto-injection products up to the total amount reimbursed when used in this circumstance.

Refer to the most recent EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies and Section 6.15 of the Ontario Drug Programs Reference Manual for details on the claim submission process.



33. Can pharmacists submit claims for COVID-19 vaccine administration manually to the ministry, using a paper claim?

The ministry does not accept paper claims for administration of publicly funded COVID-19 vaccine unless 3 intervention codes are required to process the claim. All claims must be submitted electronically using the HNS.

34. If the pharmacist recommends to a physician that an eligible individual should get their COVID-19 vaccine, is the recommendation billable under the Pharmaceutical Opinion Program?

No. All eligible individuals are encouraged to receive the COVID-19 vaccine. In addition, because its administration is within the pharmacist's scope of practice (when administered in accordance with this initiative) and requires no permission from a primary care provider, such a recommendation does not meet the criteria of the Pharmaceutical Opinion Program.

Documentation and Reporting Requirements

35. Are individuals required to provide consent before the COVID-19 vaccine is administered in the pharmacy?

Yes. Informed consent, verbally or in writing, must be obtained prior to vaccine administration and should include a discussion of risks and benefits when applicable.

A consent form is available for vaccine administrators or individuals, if preferred.

36. What must be documented in the pharmacy when providing COVID-19 vaccines to eligible individuals?

Pharmacies must inform and provide written documentation to eligible individuals for after-care instructions, any potential adverse effects they may experience following the vaccination and when to contact their health care provider.

For more information on forms and resource materials pharmacies should contact their head office or the Ontario Pharmacists Association. Resources can also be found on the Ontario College of Pharmacists website as well as Ministry Guidance at this website.

For details on the documentation required for post-payment verification, refer to the most recent EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies.

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Ministry of Health Health Programs and Delivery Division

37. How long must I keep the COVID-19 immunization and/or an epinephrine autoinjector administration record on file?

As for any HNS claim, pharmacies must keep a record of the required documentation. All pharmacy documentation records relating to the administration of the COVID-19 vaccine claim (and epinephrine auto-injector, if applicable) are part of the individual's medication record and must be maintained in a readily retrievable format for the appropriate record retention period of at least 10 years from the last recorded professional pharmacy service provided to the individual, or until 10 years after the day on which the individual reached, or would have reached, the age of 18 years, whichever is longer. Such records must also be maintained for the same period of time for the purposes of post-payment verification.

In addition, pharmacists are expected to review and adhere to the Ontario College of Pharmacists Record Retention, Disclosure and Disposal Guidelines.

38. What are the reporting requirements for an adverse event following immunizations?

All adverse events following immunization must be reported to the local Medical Officer of Health within seven business days, per section 38 of the *Health Protection and Promotion Act*.

Written record of any adverse events following immunization (AEFIs) that may or may not result in the administration of epinephrine, and the circumstances relating to the administration of the substance should be reported using the <u>Ontario Adverse Events</u> <u>Following Immunization Reporting Form</u> and sent to the local public health unit. For additional information, contact your local public health unit and refer to Ministry <u>COVID-19</u> <u>Vaccine Guidance</u>. The ministry website has a list of <u>Ontario public health units</u>.

In addition, it is mandatory for pharmacies to document the adverse event due to the vaccine administration in COVAX_{ON}. For complete reporting requirements, refer to the pharmacy's COVID-19 Vaccine Agreement.

39. If an individual has an adverse reaction to the COVID-19 vaccine, who is responsible for administering the epinephrine auto-injector?

Should the adverse reaction occur after the administration of the COVID-19 vaccine, the pharmacist (or the other health care provider) who administered the COVID-19 vaccine must administer the epinephrine auto-injector.

Under the *Regulated Health Professions Act, 1991,* the administration of a substance by injection is a controlled act which unauthorized persons are prohibited from performing.



Where the administration of a substance by injection is done for the purposes of rendering first aid or temporary assistance in an emergency, individuals are exempted from the prohibition of performing this activity. However, it is advisable to speak with the Ontario College of Pharmacists if you have any additional questions about your responsibilities and/or accountabilities in this regard.

40. What course of action should be followed when the pharmacy has administered an incorrect dose or vaccine to an individual?

Pharmacists should refer to Ministry <u>COVID-19 Vaccine Guidance</u> (Errors and Deviations section) on the management of inadvertent vaccine administration errors. This guidance document is intended to assist healthcare providers by providing them with suggested actions to take after an inadvertent immunization error has occurred to support consistent and optimal management of vaccine administration incidents. A vaccine administration error is a preventable event that may cause or lead to incorrect use of a vaccine and/or patient harm. Pharmacists should also be following their usual Standards of Practice when an error occurs including notifying the patient and any follow-up that is required.

This response provides basic information only. This response is not intended to take the place of medical advice, diagnosis or treatment, or legal advice.

Additional Information:

For pharmacy billing call ODB Pharmacy Help Desk at 1-800-668-6641.

For Support for Provincial COVID-19 Vaccine Solution-COVAX_{ON} contact your pharmacy head office or the <u>Ontario Pharmacists Association</u> or the <u>Neighbourhood Pharmacy Association of Canada.</u>

For COVID-19 vaccine rollout in pharmacy email the ministry at OPDPInfoBox@ontario.ca.

For Ministry COVID-19 vaccine information and planning resources refer to this website.

Other health care providers and the public may call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282.