

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

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 <u>ministry website</u>. This Frequently Asked Questions document replaces the previous version of Questions and Answers for Pharmacies as well as Questions and Answers for Patients 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:

- <u>COVID-19 vaccine immunization</u> 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> <u>Reference Manual</u>
- Injection training and scope of practice, pharmacy staff should contact the <u>Ontario</u> <u>College of Pharmacists (OCP)</u>



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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 vaccine. 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 vaccine in participating pharmacies to eligible individuals. Participation by pharmacies is voluntary. For more information about the criteria for participating refer to the most recent <u>EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies</u>.

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 <u>EO Notice:</u> 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. What publicly funded COVID-19 vaccines are available in pharmacies?

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

5. What do individuals need to provide at the pharmacy to get 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. Are all Ontario pharmacies providing publicly funded COVID-19 vaccines?

Only participating pharmacies that have been selected by the ministry and who meet the criteria in the <u>EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario</u> <u>Pharmacies</u> 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 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:

- pharmacy 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 <u>guidelines</u> 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.

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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 <u>Executive Officer Notice and Frequently</u> <u>Asked Questions documents</u> ("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</u> <u>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.



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 Ontario College of Pharmacist (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 of Public Health Units.

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 LTC homes within these settings?

Pharmacies are required to work with their local Public Health Unit 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 Public Health Units. 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 <u>EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies.</u>



Ministry of Health Health Programs and Delivery Division

The roles of each entity are outlined below:

Public Health Unit	Retirement Home,	Pharmacy
	Congregate Setting or LTC Home	
 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 COVAX_{ON} 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

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.



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

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 Ontario College of Pharmacist (OCP) 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 <u>EO Notice</u>: <u>Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies</u> 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 guidelines/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 Ontario College of Pharmacist (OCP) 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 <u>https://www.ppesupply.ontario.ca/</u>. Access to this portal has been provided by MPBSD to

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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all pharmacies administering COVID-19 vaccines. If your pharmacy is having difficulties or cannot access the portal, please contact <u>sco.supplies@ontario.ca.</u>

As of March 31, 2023, the Remedy online intake form is no longer available.

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.

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 during the COVID-19 pandemic?

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 <u>Ontario College of Pharmacists</u> website as well as <u>Ministry Guidance at this website</u>.



Vaccine Ordering and Inventory Management

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

Pharmacies selected by the ministry to participate in the COVID-19 vaccination program must meet these requirements before ordering publicly funded COVID-19 vaccines at no cost through a designated pharmaceutical distributor:

- HNS Subscription Agreement
- COVID-19 Vaccine Agreement*
- Cold chain inspection
- COVAXON registration and training

Some vaccines may only be available through your local public health unit.

Pharmacies that are suspended by a Public Health Unit (PHU) will have their COVID-19 vaccine orders cancelled for the week in which the suspension was put in place by the PHU. Once a suspension has been lifted by a PHU, pharmacies may resume ordering and receiving vaccines.

The ministry may reduce or cancel a pharmacy's COVID-19 vaccine order based on information in COVAX_{ON} that indicates low vaccine administration rates and/or high vaccine inventory. Pharmacies must maintain accurate inventory and administration records in COVAX_{ON} to avoid disruptions in vaccine ordering.

Vaccine ancillary supplies (e.g., needles, syringes) may also be ordered from vaccine distributors. Note that supplies may not arrive at the same time due to different delivery requirements.

* When a pharmacy is sold or the pharmacy operator relocates, a new COVID-19 Vaccine Agreement is required to reflect the new pharmacy operator or location. An outdated agreement may delay COVID-19 vaccine ordering and delivery for the pharmacy.

16. Are pharmacies able to order and administer Nuvaxovid[™] (Novavax Inc.) or viral vector vaccines (Janssen)?

Nuvaxovid[™] and Janssen vaccines are available through Public Health Units (PHUs). Pharmacies are not able to order them from the distribution centres, and therefore, should contact their local PHU to determine how eligible individuals may receive these vaccines.



17. What is the Provincial COVID-19 Vaccine Solution-COVAXON?

COVAX_{ON} is the database that holds all COVID-19 vaccine administration for the province. 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.

It is important that pharmacies correctly document vaccine administration and inventory management in the Provincial COVID-19 Vaccine Solution-COVAX_{ON.}

While vaccine administration to the patient should occur PRIOR to completing the entry in COVAX_{ON}, pharmacy staff must be diligent in accessing COVAX_{ON} 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 COVAX_{ON} must be corrected immediately.

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

Pharmacy staff must complete training to use COVAX_{ON}. Pharmacies should contact their head office or the <u>Ontario Pharmacists Association</u> for resource information related to COVAX_{ON} including support, training, forms and reference materials. **Do not contact the COVAX_{ON} support channel directly.**

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 COVAX_{ON}.

For example, 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 <u>COVID-19</u>: <u>Vaccine Storage and Handling Guidance</u> 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:

- <u>COVID-19: Vaccine Storage and Handling Guidance</u> (specifically Appendix B).
 - 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> <u>Procurement and Inventory Management</u>
 - 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 they have other valid documentation and meet the eligibility criteria. Refer to the most recent <u>EO Notice:</u> <u>Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies</u> for a list of other valid documentation, eligibility criteria, and billing process.

Note: For individuals who have a valid Ontario health number, pharmacies need the Ontario health number in order 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. What is recommended for a primary series of COVID-19 vaccine?

For a primary series, NACI continues to preferentially recommend that a complete primary series of a monovalent mRNA COVID-19 vaccine (Pfizer-BioNTech, Moderna) should be offered to individuals in the authorized age group without contraindications to the vaccine.

Novavax may be offered to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive a mRNA COVID-19 vaccine.

Janssen may be offered to individuals who are 18 years and older without contraindications to the vaccine who are not able or willing to receive either a mRNA vaccine or a Novavax vaccine. Informed consent is required to ensure appropriate communication about the risk of thrombosis with thrombocytopenia syndrome which may be life-threatening. Informed consent is always required for vaccines under the Health Care Consent Act and express consent is required when a vaccine is being offered as an alternative to the recommended one.

For a quick reference guide on mRNA vaccines, refer to Appendix B of the ministry's most recent <u>COVID-19 Vaccine Guidance</u>.

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23. What is recommended for COVID-19 vaccines for individuals who are immunocompromised?

An extended primary series, which constitutes administration of an additional dose to complete the primary series, is recommended for certain moderately to severely immunocompromised individuals.

Pharmacies may administer additional doses as part of a primary series for immunocompromised individuals subject to eligibility rules in the most recent Executive Officer Notice and may only submit claims as such for doses of the COVID-19 vaccine using a mRNA vaccine unless contraindicated.

As per <u>NACI</u>, moderately to severely immunocompromised children 6 months to 4 years of age should receive a three-dose primary series of monovalent Moderna (25 mcg) as the preferred product. This preferential recommendation is not related to any product safety concerns and is only due to the feasibility of series completion using three instead of four doses. If monovalent Moderna (25 mcg) is not readily available, a four-dose primary series of monovalent Pfizer (3 mcg) may be offered.

A four-dose primary series of monovalent Pfizer (3 mcg) may have feasibility challenges, including the need to schedule four separate appointments and space appointments appropriately relative to other childhood vaccination appointments. Vaccine providers should also consider the total length of time it will take to complete a four-dose primary series at the recommended intervals (12 to 24 weeks) compared to a three-dose primary series (8 to 16 weeks), and the risk associated with incomplete protection during this period.

There is no preference between monovalent Pfizer-BioNTech (3 mcg) or monovalent Moderna (25 mcg) for immunocompetent children 6 months to 4 years of age.

An extended primary series of mRNA COVID-19 vaccines is recommended for the following populations eligible for vaccination with the vaccine product authorized for their age group:

- Individuals receiving dialysis (hemodialysis or peritoneal dialysis)
- Individuals receiving active³ treatment (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies
- Recipients of solid-organ transplant and taking immunosuppressive therapy

³ Active treatment includes patients who have completed treatment within 3 months. Active treatment is defined as chemotherapy, targeted therapies, immunotherapy, and excludes individuals receiving therapy that does not suppress the immune system (e.g., solely hormonal therapy or radiation therapy). See Ontario Health/Cancer Care Ontario's <u>Frequently</u> <u>Asked Questions</u> for more information.



- Recipients of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Individuals with moderate to severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- HIV with AIDS-defining illness in last 12 months before starting vaccine series, or severe immune compromise with CD4 count <200 cells/uL or CD4 percentage <15%, or without HIV viral suppression
- Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies⁴ (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the <u>Canadian Immunization Guide</u> for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.

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

24. When is it recommended that an entire vaccine series be re-initiated?

It is recommended that a re-vaccination with a repeat COVID-19 vaccine primary series (plus booster dose, if applicable) 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.⁵

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

25. Can different COVID-19 vaccine products be used to complete an individual's primary series (i.e., one vaccine product for the first dose and a different product for the subsequent dose(s))?

Individuals who received a first dose of a mRNA vaccine (Pfizer-BioNTech or Moderna) should be offered the same mRNA vaccine for their second dose. If the same mRNA vaccine is not available at the time of vaccination without delay or vaccine wastage, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series.

⁴ Active treatment for patients receiving B-cell depleting therapy includes patients who have completed treatment within 12 months

⁵ As per the <u>Canadian Immunization Guideline</u>, HSCT recipients should be viewed as vaccine naïve (i.e. never immunized) and require re-immunization after transplant.



Infants and children are recommended to be administered the same vaccine product for all doses in a primary series, using the dose that is correct for their age at the time of appointment. This is particularly important for children aged 6 months to under 5 years of age who are eligible to receive the Moderna 25 mcg or Pfizer 3 mcg vaccine, due to the difference in the number of doses in the primary series between the two products. For more information on switching vaccine products, refer to the Appendix in the most recent <u>COVID-19 Vaccine Guidance</u>.

26. Can an individual get Nuvaxovid or Janssen vaccine if they are allergic to the mRNA vaccines?

People who 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.

27. What is the recommendation for children who are 5 years old? Which COVID-19 vaccine should they receive?

For the primary series, children who are 5 years of age are eligible for either the monovalent Moderna (25 mcg) or monovalent Pfizer-BioNTech (10 mcg) vaccine. The use of the monovalent Pfizer-BioNTech vaccine (10 mcg) is preferred to the monovalent Moderna (25 mcg) for those 5 years. However, per NACI, monovalent Moderna (25 mcg) may be offered to children who are 5 years as an alternative to the monovalent Pfizer-BioNTech vaccine (10 mcg), with informed consent and discussion of risks and benefits with the child's healthcare provider.

The bivalent Pfizer-BioNTech (10 mcg) vaccine is the only authorized bivalent booster for children aged 5 to 11 years.

CAUTION: Please read labels carefully and ensure the correct product is administered. The bivalent Pfizer 10 mcg and monovalent Pfizer 10 mcg vials have the same ORANGE cap colour.



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

With the exception of individuals who may have been administered Imvamune® vaccine provided for monkeypox, 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). Informed consent should include a discussion of the benefits and risks given the limited data available on administration of COVID-19 vaccines at the same time as, or shortly before or after, other vaccines. If vaccines are co-administered, immunization on separate limbs is recommended to minimize the risk of interaction.

Refer to the <u>COVID-19 Vaccine Guidance</u> for more information.

29. What is recommended for booster doses of COVID-19 vaccine?

All Ontarians aged five years and older are eligible to receive booster doses after completing a primary series. Infants and children aged 6 months to 4 years are not eligible for booster doses at this time.

At this time, the seasonality of COVID-19 is not known, and it has not yet been determined whether eligible individuals will need a COVID-19 vaccine booster at a set time period (e.g., every 6 months). COVID-19 clinical vaccine guidance may change as emerging evidence comes forward to inform recommendations closer to Fall 2023.

Individuals 5 years of age and older who have not yet received a booster dose since September 1, 2022, remain recommended to receive a booster dose if it has been at least six months since the last dose or confirmed COVID-19 infection. A confirmed COVID-19 infection is characterized by a positive test or after having symptoms post contact with someone who had a positive test (refer to Table 3 in the COVID-19 Vaccine Guidance).

If booster doses have been received on or after September 1, 2022 (either monovalent or bivalent), there is no current evidence that substantiates the need for an additional dose, beyond the high-risk groups mentioned below.

Individuals in specific high-risk populations are recommended to receive a spring⁶ booster dose if at least six months (168 days) have passed since the last dose or confirmed COVID-19 infection. The following groups are recommended to receive a booster dose this spring:

• Individuals aged 65 years and older

⁶ In Ontario, April 6, 2023, marks the start of the spring booster dose campaign



- Residents of long-term care homes, retirement homes, elder care lodges, and other congregate living settings for seniors
- Individuals aged 18 years and older living in congregate care settings for people with complex medical care needs
- Pregnant individuals
- Individuals aged 18 years and older are moderately to severely immunocompromised
- Individuals aged 55 years and older who identify as First Nations, Inuit, or Métis and their non-Indigenous household members aged 55 years and older.

In Ontario, individuals outside of the above groups may opt to receive another booster dose during the spring of 2023, if at least 6 months (168 days) have passed since the previous dose or confirmed COVID-19 infection. However, it should be communicated that there is no current evidence that substantiates the need for an additional dose if a booster was already received on or after September 1, 2022.

While the recommended interval is at least 6 months, vaccine administrators can use their discretion to decide on administration prior to the 6-month interval, primarily as a result of operational considerations. The closer the timing is to the optimal interval, the better; evidence shows that the antibody response is higher with longer intervals between infection and vaccination and with longer intervals between vaccination doses.

Individuals are recommended to receive a mRNA vaccine for their booster dose(s). Bivalent boosters (in authorized age groups) are recommended over monovalent boosters.

There is no preferential recommendation between Moderna Bivalent (50 mcg) or Pfizer-BioNTech Bivalent (30 mcg) as a bivalent booster dose for individuals **18 years of age and older.**

For individuals aged **12 to 17 years**, a bivalent **Pfizer-BioNTech** (30 mcg) COVID-19 vaccine booster dose is preferred. The bivalent **Moderna BA.1** (50 mcg) may be offered as a booster to individuals aged **12 to 17 years** of age with informed consent.

For individuals aged **5 to 11 years** a bivalent **Pfizer-BioNTech** (10 mcg) COVID-19 vaccine booster dose is preferred. The bivalent **Moderna BA.1** (25 mcg) may be offered as a booster to individuals aged **6 to 11 years** with informed consent.

Note: As of March 6, 2023, bivalent Moderna supply is being switched over to the bivalent Moderna BA.4/5 product and the bivalent Moderna BA.1 product will begin to be phased out. Although the indication for use of bivalent Moderna BA.1 as a booster was expanded to those 6 - 17 years on February 17, 2023, Ontario will not order more supply once the current supply has been depleted.



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

30. How many booster doses can an individual receive and how often?

After completion of a full primary series, booster dose(s) are recommended for some populations based on the ongoing risk of infection due to waning immunity, the ongoing risk of severe illness from COVID-19, and the adverse impacts on health system capacity from the COVID-19 pandemic.

- Individuals 6 months to 4 years of age are considered up to date if the primary series is complete.
- Individuals 5 years of age and older are considered up to date if the primary series is complete and one monovalent or bivalent booster dose was received on or after September 1, 2022.
- Individuals in the high-risk populations are considered up to date if the primary series is complete and one monovalent or bivalent booster dose was received within the last six months.

Individuals 5 years of age and older may receive another booster dose if it has been six months (168 days) since the previous COVID-19 vaccination (e.g., monovalent or bivalent booster dose) or confirmed SARS-CoV-2 infection.

There is no current recommendation for individuals to receive ongoing vaccine booster doses every few months. Individuals may receive repeated booster doses however the dosing interval between a booster dose and previous COVID-19 vaccine or confirmed infection is six months. Vaccine administrators may use their discretion to provide a booster dose prior to the 6-month interval, primarily for operational reasons (e.g., an individual cannot come back) and using a short grace period (e.g., a few days) or based on the dosing interval noted in the specific vaccine's product monograph. The closer the timing is to the six month booster vaccine dosing interval, the stronger and more durable the antibody response.

For more information on dosing intervals, refer to Table 1 in the most recent <u>COVID-19</u> <u>Vaccine Guidance</u>.



31. Can anyone receive a spring booster dose?

Starting April 6, 2023, individuals in specific high-risk populations are recommended to receive a spring booster dose if at least six months (168 days) have passed since the last dose or confirmed COVID-19 infection. The following groups are recommended to receive a booster dose this spring:

- Individuals 65 years of age and older
- Residents of long-term care homes, retirement homes, elder care lodges, and other congregate living settings for seniors
- Individuals 18 years of age and older living in congregate care settings for people with complex medical care needs
- Pregnant individuals
- Individuals 18 years of age and older are moderately to severely immunocompromised
- Individuals 55 years of age and older who identify as First Nations, Inuit, or Métis and their non-Indigenous household members aged 55 years and older.

Other individuals 5 years of age and older may choose to receive another booster dose in the spring 2023, if at least six months (168 days) have passed since the previous dose or confirmed COVID-19 infection. However, it should be communicated that there is no current evidence that substantiates the need for an additional dose if a booster was already received on or after September 1, 2022.

Note: A confirmed COVID-19 infection means one that is confirmed by testing (including a rapid home test) or one in which an individual develops symptoms and lives with someone who has a COVID-19 infection confirmed by testing. If the individual is unsure if they have had a COVID-19 infection or not, it is better to get the vaccine rather than wait six months.

For more information on spring booster doses, refer to the Spring 2023 Campaign Flow Chart in Appendix D of the most recent <u>COVID-19 Vaccine Guidance.</u>



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 <u>Ontario Drug Programs Reference</u> <u>Manual.</u>

32. 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 <u>EO Notice: Administration of Publicly</u> <u>Funded COVID-19 Vaccines in Ontario Pharmacies</u> 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).

33. 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 <u>EO Notice: Administration of Publicly Funded COVID-19 Vaccines</u> <u>in Ontario Pharmacies</u> and Section 6.15 of the <u>Ontario Drug Programs Reference Manual</u> for details on the claim submission process.



34. 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.

35. 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

36. 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.

37. 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 aftercare 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 <u>Ontario Pharmacists Association</u>. Resources can also be found on the <u>Ontario College of Pharmacists</u> website as well as <u>Ministry Guidance at this website</u>.

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

38. 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 <u>Record Retention</u>, <u>Disclosure and Disposal Guidelines</u>.



39. 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.

40. 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.

41. 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</u> <u>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.