Updated: Questions and Answers for: Administration of Publicly Funded COVID-19 Vaccine in Ontario Pharmacies

This Questions and Answers document accompanies the most recent Executive Officer (EO) Notices on the Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies available on the ministry website. This Questions and Answers document also replaces any previous version on the same topic on the ministry website.

Participating pharmacies administering the publicly funded COVID-19 vaccine must be familiar with their agreement with the ministry respecting COVID-19 administration and use of the provincial COVID-19 vaccine solution-COVAX$_{ON}$ (COVID-19 Vaccine Agreement)[1]. These Questions and Answers primarily relate to the public funding of pharmacy administration of the COVID-19 vaccine and are not intended to provide information about the requirements in the COVID-19 Vaccine Agreement.

For more information on:

- 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 Ontario Drug Programs Reference Manual
- Injection training and scope of practice, pharmacy staff should contact the Ontario College of Pharmacists (OCP)

[1] The COVID-19 Vaccine Agreement includes requirements respecting vaccine ordering, storage and handling (such as cold chain requirements and incident management) and access to and use of the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$ (if access to the Solution has been granted to the pharmacy).

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Overview

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

Pharmacists and other members of the Ontario College of Pharmacists (OCP) play an important role in the administration of the publicly funded COVID-19 vaccine. Part A pharmacists, registered pharmacy students, interns and pharmacy technicians who are members of the OCP, have completed the required injection training and in accordance with OCP guidance can administer the publicly funded COVID-19 vaccine to eligible individuals in participating pharmacies. Please refer to the Executive Officer Notice for more information about the criteria for participating pharmacies. Participation by pharmacies is voluntary.

2. What are the publicly funded COVID-19 vaccines that are available to pharmacies?

Please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Billing**".

Inclusion of a product in the EO Notice does not guarantee continued supply of the product through the participating pharmaceutical distributors.

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

Pharmacies that provide the COVID-19 vaccine will be listed on the ministry website at this link.

4. How do pharmacies obtain the publicly funded vaccines?

Pharmacies selected by the ministry to participate in the vaccine rollout with an HNS Subscription Agreement and COVID-19 Vaccine Agreement will receive the publicly funded COVID-19 vaccines (at no cost) through a designated pharmaceutical distributor. Some vaccines may only be available through your local public health unit. Vaccine ancillary supplies (e.g., needles, syringes) will be provided based on the vaccine allocation to the distributors. Note that supplies may not arrive at the same time due to different delivery requirements.

5. Are vaccinations at pharmacies available by walk-in or pre-booked appointments?

COVID-19 vaccination at pharmacies are recommended to occur **by pre-booked appointment**; however, some pharmacies may choose to offer walk-in appointment. Pharmacies are able to implement a booking procedure that best suits their business's operations.

Pharmacies that choose to offer walk-in appointments are reminded of their responsibility for informing and educating the public on COVID-19, including promoting infection prevention and control measures. See Question #27 for further details on other procedures that must be followed during the COVID-19 pandemic.

Patients will be directed to visit the ministry's online location finder to find their local pharmacy and pre-book an appointment or inquire about the pharmacy's procedures related to walk-in appointments.

6. **Are pharmacies able to operate and administer COVID-19 vaccines 24 hours a day / 7 days a week?**

There are no restrictions that limit the hours of operations and pharmacies are strongly encouraged to support the administration of the COVID-19 vaccine 24 hours a day / 7 days a week, where permissible.

Eligibility

7. **Are all individuals eligible for the publicly funded COVID-19 vaccine administered at a pharmacy?**

No. Appropriately trained pharmacy staff can only administer the publicly funded COVID-19 vaccine in pharmacies to eligible individuals in accordance with the manufacturer's directions and according to the province's vaccine rollout plan. Please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**".

Patient eligibility criteria at the pharmacy is expected to change as COVID-19 vaccine supply fluctuates and the pandemic situation evolves.

8. **Are patients required to provide consent before pharmacists administer the COVID-19 immunization?**

Yes. Completion of a consent form is required by the patient or the patient's authorized representative or substitute decision maker prior to administering the COVID-19 vaccine.

NOTE: an additional consent form, "COVID-19 Vaccine Information for Individuals who received a first dose of the AstraZeneca COVID-19 vaccine/COVISHIELD", is required prior to the administration of a second dose with any vaccine. An additional consent form is not required for individuals who received an mRNA vaccine for their first dose. However, patients must provide informed consent to receive a second or subsequent dose of an mRNA vaccine, including an mRNA vaccine that is different from the mRNA vaccine as their first dose, for any reason.

9. Can a person who does not have an Ontario health card number still receive the publicly funded COVID-19 vaccine at a pharmacy?

Yes. Appropriately trained pharmacy staff can administer the publicly funded COVID-19 vaccine to someone ***without*** an Ontario health card number provided they have other valid documentation and they live, work, or study in Ontario or they are visiting Ontario from another province / territory or another country, and if they meet the applicable vaccine eligibility criteria. Please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**".

See Question #36 for further details on the claims submission process.

10. Can a patient be an ODB recipient and not have an Ontario health card number?

Yes. There may be circumstances when a patient who is an eligible ODB recipient does **not** have an Ontario health card number, such as an individual who is issued a temporary health number by the Ministry of Children, Community and Social Services that is used until the official Health Card is issued, or an individual who is not eligible for an Ontario health card number but has a paper Drug Benefit Eligibility Card. In these cases, the temporary eligibility number must be used for the HNS claim submission.

11. Can a pharmacist still submit a claim for payment for the administration of the COVID-19 vaccine if a patient forgot to bring his/her Ontario health card number?

No. If the patient has an Ontario health card number, then the pharmacist needs the patient's Ontario health card number in order to submit the claim for payment through the HNS.

12. What forms of identification and other information are required for patients who do not have an Ontario health card number?

If a pharmacy has been granted access to the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$, then the COVID-19 Vaccine Agreement requires documentation of alternate forms of identification to confirm date of birth if the patient does **not** have an Ontario health card number. Pharmacy staff must document the alternate form of ID on the vaccine record. Other forms of patient identification noted in that system may include:

- Birth Certificate

- Employee ID
- First Nations ID
- Passport
- MRN (Medical Record Number)
- Out of Province ID
- Driver's Licence

13. What if a patient received their first dose (or more than one dose) of a vaccine outside of Ontario or Canada? Are they considered fully vaccinated and up to date?

Fully vaccinated:
The 'fully vaccinated' definition may continue to be used in some settings. In Ontario, an individual is considered fully vaccinated if they have received:

- The full series of a COVID-19 vaccine authorized by Health Canada, or any combination of such vaccines,
- One or two doses of a COVID-19 vaccine not authorized by Health Canada, followed by one dose of a COVID-19 mRNA vaccine authorized by Health Canada, or
- Three doses of a COVID-19 vaccine not authorized by Health Canada; and
- They received their final dose of the COVID-19 vaccine at least 14 days ago.

Up to Date:
Being 'up to date' means a person has completed their primary series and has received a COVID-19 vaccine within the last six months.

Doses outside of Canada:
Individuals who received a COVID-19 vaccine outside of Ontario or Canada are required to provide proof, such as a vaccination receipt or certificate, to their public health unit in order to be registered in the system.

Once that process is complete, if an additional dose is required, these individuals will be able to book their subsequent dose appointment through the provincial booking system, public health units that use their own booking system or participating pharmacies and primary care settings at an interval that aligns with Ontario's vaccine strategy.

Individuals who received a COVID-19 vaccine outside of Ontario or Canada who contact their local Public Health Unit will have their COVID-19 vaccine history verified and uploaded into the COVAX system. Depending on how many doses and which vaccines were

previously administered (please refer to the COVID-19 Vaccine Guidance located on the ministry's website), pharmacies may administer an additional dose of an mRNA monovalent vaccine or a bivalent mRNA vaccine if applicable, if required to complete the vaccine series or as a booster.

Please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**".

Ministry Payment

14. How much does the ministry pay pharmacy immunizers to administer the COVID-19 vaccine?

The ministry pays the pharmacy $13.00 for the costs associated with services when administering an injectable publicly funded COVID-19 vaccine, when a claim for payment is submitted through the HNS. Services include:

- Providing the patient with details of the process and answering any questions related to the vaccination.
- Obtaining the consent of the patient or their substitute decision-maker prior to vaccine administration
- Administering the COVID-19 vaccine.
- Providing the patient with proper monitoring and written vaccine information as well as after-care instructions following vaccine administration.
- Providing the patient with a written receipt of the vaccination with the pharmacy contact information; a pharmacy may wish to issue an electronic receipt as well (see Question #30 below for more information) (Note: a written receipt can be printed from COVAX ON)
- Mandatory scheduling of the second dose
- Complying with any requirements to access and use the Provincial COVID-19 Vaccine Solution-COVAXON under the COVID-19 Vaccine Agreement, provided that the pharmacy has been granted access to the Solution.

15. 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 pharmacies the acquisition cost (no mark-up, dispensing or service fee) of approved epinephrine auto-injection products up to the total amount reimbursed (i.e., see Table 2 of the EO Notice) when used in this circumstance.

See Question #36 for further details on the claims submission process.

16. Does the ministry pay the pharmacist directly or the pharmacy?

The ministry pays the participating pharmacy.

Pharmacist Training

17. Are all Ontario pharmacists able to administer the 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 and in accordance with OCP guidance can administer the publicly funded COVID-19 vaccine by injection in participating pharmacies. The eligible OCP members who have registered the required injection training are listed on the OCP's member registry website.

For more information on pharmacist, pharmacy student, intern, and pharmacy technician injection training please contact the Ontario College of Pharmacists.

Pharmacy professionals who decide to administer COVID-19 vaccines to infants and young children may require additional education and/or training as needed. Please visit the OCP website for Guidance and Reference information.

18. Can I employ other health care providers (e.g., registered nurse) to provide COVID-19 vaccines in my pharmacy?

Other health care providers (HCPs) who have the authority to administer the COVID-19 vaccine by injection under Ontario law and who have injection training may also administer the 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 the COVID-19 vaccine in the pharmacy, the pharmacy must comply with all terms and conditions in the Ministry's

Notices and Questions & Answers documents ("Ministry Policies"), and the user agreement for the COVAXON 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 health care professionals. All respective HCPs whether pharmacist, intern, registered pharmacy student, pharmacy technician or other HCP must identify themselves as the vaccinator in the COVAXON system and on the vaccine receipt provided to the patient.

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

19. Besides injection training, is there other training involved when administering the COVID-19 vaccine to eligible individuals?

In addition to injection training for pharmacy vaccinators as outlined by the Ontario College of Pharmacists, pharmacy staff must also go through general training to use the Provincial COVID-19 Vaccine Solution-COVAXON database that holds all the COVID-19 vaccination information.

Resource information regarding the Provincial COVID-19 Vaccine Solution-COVAXON including support, training, forms and reference materials for pharmacies are available. Pharmacies should contact their head office or the Ontario Pharmacists Association for these resources.

Do not contact the COVAXON support channel directly.

20. Are there on-boarding resources available for pharmacies?

Yes. Pharmacies will be provided with an on-boarding resource package that outlines the overall process and descriptions of user profiles for the Provincial COVID-19 Vaccine Solution-COVAXON.

Pharmacy Participation

21. Will all Ontario pharmacies provide the publicly funded COVID-19 vaccine?

No. Only participating pharmacies that have been selected by the ministry and who meet the criteria in the most recent version of the EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**", are eligible to provide the publicly funded COVID-19 vaccine.

Pharmacy criteria include but are not limited to:

- Have a valid HNS Subscription Agreement with the ministry
- Have a valid COVID-19 Vaccine Agreement
- Currently enrolled and in good standing 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:

- 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.

Please refer to the ministry website for the most recent EO Notice.

*Due to the rapid spread of the Omicron variant and to increase access to vaccination services to as many eligible individuals as possible, as of January 13, 2022, the ministry opened enrollment in the COVID-19 vaccination program to pharmacies that are not enrolled in the current UIIP on an exceptional and temporary basis. Pharmacies that are

interested in administering publicly funded COVID-19 vaccines but not currently enrolled in the current UIIP should email the ministry at: OPDPInfoBox@ontario.ca with their store name, address and ON Provider #. In addition to having a valid HNS Subscription Agreement and a valid COVID-19 Vaccine Agreement, such pharmacies will be required to pass an inspection by their local public health unit (PHU), including a cold chain inspection, and comply with all storage and handling guidelines for vaccines. Please note that conducting inspections will be at the sole discretion of the local PHUs and their resources and timelines.

22. What is the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$?

The Provincial COVID-19 Vaccine Solution-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 information as well as inventory supply in this system. The fee paid to pharmacies for administering the COVID-19 vaccine includes pharmacy services relating to accessing and using the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$.

The requirements for accessing and using the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$ can be found in the COVID-19 Vaccine Agreement. Access to and use of the Solution is conditional on the pharmacy being granted access to the Provincial COVID-19 Vaccine Solution-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 their first 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.

Please refer to the Job Aids in the resource information provided. regarding the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$ including support, training, forms and reference materials for pharmacies are available. Pharmacies should contact their head office or the Ontario Pharmacists Association for these resources.

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).

23. What happens if there is a system failure and the pharmacy is not able to enter vaccine or inventory information in the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$?

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 the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$.

For example, at a minimum, pharmacies should ensure there is supply of consent forms, vaccine information forms and daily patient rosters printed in the event the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$ system is not available.

24. What type of personal protective equipment (PPE) do pharmacists need in order to administer the COVID-19 vaccine?

Resources and guidance for PPE can be found on the Ontario College of Pharmacists website.

25. Is PPE available for pharmacies that administer the COVID-19 vaccines?

Yes. The ministry has a dedicated supply of PPE that is available through the provincial stockpile for participating pharmacies that administer the publicly funded COVID-19 vaccine.

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.

26. How do I access the ministry supply of PPE to support the administration of the COVID-19 vaccine?

Pharmacies may order PPE by accessing the Remedy online intake[2] form at this link: https://ehealthontario.on.ca/en/health-care-professionals/ppe-intake?a=ppe-intake

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, the access for PPE is the same as for accessing for the UIIP program. Pharmacies may use the same form / process.

27. 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 Ontario College of Pharmacists website as well as Ministry Guidance at this website.

Please also refer to Vaccine and Storage Handling section at the end of the Qs & As.

28. Is it mandatory to schedule the patient's appointment for the second or subsequent dose?

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

Pharmacy staff should schedule the appointment dates and times for the second or subsequent doses as applicable. The appointment date and time can be hand-written on the printed receipt-of-vaccine that is provided to the patient as per documentation requirements (Note: a written receipt can be printed from COVAX$_{ON}$).

Patients are strongly urged to return to the same pharmacy for the second dose.

Pharmacy staff must provide patients with information on the arrangements for the second or other subsequent dose scheduling (if applicable) including how the patient may reach the pharmacy should there be a need for rescheduling as well as potential situations that may require the pharmacy to re-schedule for reasons such as issues with vaccine supply.

In the event that a patient requests a dose at your pharmacy – without having had their first or primary series doses at your pharmacy – pharmacies are permitted to administer the vaccine dose. Patients should be reminded to cancel any appointments they may have booked at other pharmacy or mass clinic locations.

29. What is the procedure if the patient does not show up for the scheduled dose or there are doses left at the end of the day?

Pharmacists may use their professional judgement in the event that a patient does not show up for their vaccine appointment. For example:

- They may contact the patient to make inquiries on their timing, situation;
- They may re-schedule the patient or move them in the queue as appropriate;
- They may reallocate the dose to another eligible or soon-to-be eligible patient with a future scheduled appointment or a patient on their waiting list if no other patient is available and document the rationale.

Pharmacists should ensure to the best of their ability that no vaccine is wasted.

All sites administering the COVID-19 vaccine, including pharmacies, are expected to follow the eligibility criteria determined by the province in alignment with the framework.

Documentation Guidelines

30. What are pharmacists required to document when providing the COVID-19 immunization vaccine to eligible patients?

For the purpose of post-payment verification, pharmacists must keep a record of the following:

- Record of name and address of patient.
- Record of the patient's health number or alternate ID with contact information if applicable.
- In the case of patients who receive the Novavax COVID-19 vaccine (Nuvaxovid™) or AstraZeneca / COVISHIELD vaccine due to an allergy to an mRNA vaccine, the COVID-19 Vaccination: Allergy Form. (refer to question #40)
- In the case of immunocompromised individuals eligible to receive booster dose(s) after a 3-dose primary series, as applicable,[3] a copy of the referral letter from their health care provider OR pharmacist documentation that the patient is taking an immunosuppressive medication listed here, based on the pharmacist's examination of the patient's recent prescription label or prescription receipt or their medication profile (refer to question # 61)
- Record of name of vaccine administered, dose (including half-dosing if applicable), lot number, expiry date, time, date, route and site of administration.
- Record of pharmacy name, pharmacy address and name and signature of individual who administered the vaccine.
- Record of location of administration (e.g. pharmacy or pharmacy parking lot, or within the retirement home, congregate setting, long-term care home, or location of a mobile clinic, if applicable) See Questions #46 to 48 for more information.
- Evidence of the provision of a written and electronic record (if applicable) of the COVID-19 immunization record to the patient, which includes the pharmacy's contact information and date and time for the second scheduled dose at the

[3] For more information on when this documentation is required, see the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility".

same pharmacy location. Note: date and time of the second dose may be hand-written on the written record provided to the patient.

- Record of any serious adverse events following immunization that result in the administration of epinephrine, and the circumstances relating to the administration of the substance.
  - Please refer to question #38 and #39 regarding reporting requirements for adverse events following immunization.
- Records documenting compliance with any requirements to access and use the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$ under the COVID-19 Vaccine Agreement. Note: All respective health care providers whether pharmacist, intern, registered pharmacy student, pharmacy technician or other health care provider must identify themselves as the vaccinator in the COVAX$_{ON}$ system and on the vaccine receipt provided to the patient.

31. How long must I keep the COVID-19 immunization and/or an epinephrine auto-injector 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 patient'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 patient, or until 10 years after the day on which the patient 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.

32. What will happen if I forget to document or misplace the documentation?

If there is no documentation, incorrect or incomplete documentation, the administration fee that is claimed may be subject to recovery by the ministry. Documentation is also important in the event of an adverse reaction following an immunization or if a patient follows up with the pharmacy for their COVID-19 vaccine record.

33. What documentation must pharmacists provide to the patient after administration of the COVID-19 vaccine?

To help patients keep track of their COVID-19 vaccine, pharmacists must provide a written record (i.e., paper based) of the COVID-19 immunization product administered, including the date and name of the pharmacy. A pharmacy may wish to also provide an electronic record containing this information.

Pharmacy staff should also schedule with the patient the day and time for the subsequent COVID-19 vaccine doses as applicable at the same pharmacy. They must also give the patient instructions on how they can reach the pharmacy in the event they need to reschedule as well as let the patient know how they will reach them should there be a need to reschedule due to issues such as vaccine supply.

Patients should keep the vaccine record in a safe place, and it must also be readily available on file at the pharmacy.

Pharmacies must inform and provide written documentation to patients of 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.

34. What documentation does the ministry require for an epinephrine auto-injector claims submission?

The HNS claim for the epinephrine auto-injector will follow the claim for the COVID-19 vaccine. Documentation to support the claim includes:

- Name, pharmacy address and signature of the pharmacist (or other health care provider) who administered the epinephrine auto-injector.
- Name, strength/dose (where applicable) and quantity of the epinephrine auto-injector administered.
- Name and address of the patient.
- Time and date the epinephrine auto-injector was administered.
- Cross-reference with the claim for the publicly funded COVID-19 vaccine administered to the same patient.

Pharmacies must keep a record when the epinephrine auto-injector was administered for emergency use due to a pharmacist-administered COVID-19 vaccine.

Claim for payment through the Health Network System

35. When should the pharmacist submit the claim for payment for administration of the publicly funded COVID-19 vaccine?

Date of service for the claim submitted to the HNS must reflect the date the publicly funded COVID-19 vaccine was administered[4].

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. 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.

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).

36. How are claims for COVID-19 vaccine submitted through the HNS?

Claims submission requirements for Ontario Drug Benefit (ODB)-eligible recipients and Non-ODB recipients are as follows:

For ODB-eligible recipients

The claim submission follows the usual process (See Section 5 of the Ontario Drug Program Reference Manual) for submitting claims on the HNS with the following additional information:

- Intervention code 'PS': (Professional Care Services)
- Drug Identification Number (DIN): as per the publicly funded COVID-19 vaccine administered
- Valid Pharmacist ID

[4] Note that the HNS can process online transactions for publicly funded services on any 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).

For Non-ODB recipients

When submitting a claim for a person who does not have ODB coverage, pharmacists must submit the following information:

- Patient Gender: 'F' = female; 'M' = male
- Patient Date of Birth: Valid YYYYMMDD
- Patient's Ontario Health Card number*
- Intervention codes:
  - PS: Professional Care Services
  - ML: Established eligibility coverage (i.e., 1 day of the Plan 'S' coverage)
- Carrier ID: 'S'
- Drug Identification Number (DIN): as per the publicly funded COVID-19 vaccine administered
- Valid Pharmacist ID

***For patients without an Ontario health number**

When submitting a claim for any eligible person who does not have an Ontario health number, pharmacists must submit the following information:

- First Name: Patient's first name
- Last Name: Patient's last name
- Patient Gender: 'F' = female; 'M' = male
- Patient Date of Birth: Valid YYYYMMDD
- Proxy patient ID: 79999 999 93
- Intervention codes:
  - PS: Professional Care Services
  - PB: Name entered is consistent with card
- Valid Pharmacist ID

Pharmacist must ensure that the patient's date of birth, Ontario health number / proxy patient ID and name (as it appears on the health card / document) are entered as part of the HNS claims submission. Failure to do so may impact the ability to submit future claims

for these patients. In addition, by identifying the date of birth, pharmacists can align the appropriate vaccine to the patient's age group.

37. When submitting the claim for the epinephrine auto-injector due to an adverse reaction from the COVID-19 injection, I notice the payment appears in the "dispensing fee" field – is that correct?

Yes, the payment appears in the "dispensing fee" field of the claim submission.

Adverse Drug Reactions

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 Ontario Adverse Events Following Immunization Reporting Form and sent to the local public health unit[5].
In addition, it is mandatory for pharmacies to document the adverse event due to the vaccine administration in the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$.

For additional information, please contact your local public health unit. Refer to the ministry website for a list of Ontario public health units.

39. If a patient 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.

[5] For complete reporting requirements, please refer to the pharmacy's *COVID-19 Vaccine Agreement* for adverse events. For additional information, please contact your local public health unit. Refer to the ministry website for a list of Ontario public health units.

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.

For claims submission purposes, the ministry requires the patient's Ontario health number (or proxy patient ID) and pharmacist identification for the use of an epinephrine auto-injector after an adverse reaction to the administered COVID-19 vaccine.

40. Can an individual get Nuvaxovid™, Covifenz® or a viral vector vaccine (AstraZeneca/Janssen) vaccine if they are allergic to the mRNA vaccines?

At this time the Province has a limited supply of Nuvaxovid™, Covifenz® and viral vector vaccines (for example, the AstraZeneca/COVISHIELD/Janssen vaccines). Pharmacies should work with their public health unit to determine how eligible individuals can receive one of these vaccines, if required.

Pharmacists should direct individuals with known or suspected allergies to components of the mRNA vaccines or AEFI with a COVID-19 vaccine to their primary care provider or local public health unit (PHU) for a referral to an appropriate physician / nurse practitioner (or a relevant specialist related to the AEFI that occurred). The appropriate physician / nurse practitioner will complete an assessment and Allergy Form to develop a vaccination care plan with the individual which will determine the method for possible (re)administration of a COVID-19 vaccine, such as Nuvaxovid™ or Covifenz®. A viral vector vaccine (Janssen or AstraZeneca / COVISHIELD vaccine) should only be offered when all other authorized COVID-19 vaccines are contraindicated and with informed consent. The assessment will also determine whether vaccine administration can be safely provided in a general PHU vaccine clinic, pharmacy, or primary care office. People who experienced a severe immediate allergic reaction after a first dose of an mRNA COVID-19 vaccine may safely receive future doses of the same or another mRNA COVID-19 vaccine after consulting with an appropriate physician / nurse practitioner.

See NACI's recommendations on the use of COVID-19 vaccines for more information.

The Allergy Form and patient vaccine administration care plan completed by an appropriate physician / nurse practitioner must be provided to the identified vaccine clinic for inclusion in the individual's medical record. The vaccination care plan must also include the parameters a clinic should meet to provide the safe administration of vaccine, including: availability of advanced medical care; details/severity of the previous allergic episode(s); confirmation

that appropriate counselling on the safe administration of vaccine was provided; date, clinician's name, signature and contact information; and the individual's name and date of birth. A copy of the Allergy Form and patient vaccine care plan must be maintained by the administering clinic. PHUs may coordinate with participating pharmacies and/or primary care offices to assist in vaccine administration, including transferring Nuvaxovid™ or Covifenz® (or a viral vector vaccine if applicable) to the site, as required

Please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**" for further information, including dosing intervals for second doses as well as third / booster doses.

Restrictions

41. Can pharmacy immunizers submit claims for providing the publicly funded COVID-19 vaccine to residents of long-term care homes or hospital in-patients?

With respect to hospitals, the answer is no. Pharmacy staff administration of the publicly funded COVID-19 vaccine to hospital in-patients is **not** eligible for payment under this initiative.

With respect to long-term care home residents, pharmacies can submit claims for providing the publicly funded COVID-19 vaccine to residents of long-term care homes at the location of the long-term care home or other congregate setting in collaboration with the public health unit, if certain conditions are met. See Questions #64-70 for more information.

In addition, staff, support workers, essential caregivers, volunteers and contractors who are working within congregate settings are eligible for COVID-19 vaccine doses when pharmacy staff visit the home / congregate setting to administer the vaccine to residents, provided that they meet all eligibility requirements noted in the most recent Executive Officer Notice – Administration of COVID-19 vaccine in Ontario Pharmacies.

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

No. The ministry does not accept paper claims for the publicly funded COVID-19 vaccine unless 3 intervention codes are required in order to process the claim. All claims must be submitted electronically using the HNS.

43. Can pharmacists submit a claim for the epinephrine auto-injector when it is provided to the patient to take home after the COVID-19 vaccine was administered?

No. Claims submitted for epinephrine auto-injector that are associated with the publicly funded COVID-19 vaccine emergency use are ***only*** reimbursed when the injection is given by the pharmacist (or other regulated health care provider) as emergency first aid or temporary assistance as needed right after administering the COVID-19 vaccine to a patient.

44. Can pharmacists submit a claim for epinephrine auto-injector for a patient without a valid Ontario health card number?

Yes. Pharmacists may submit claims for payment using the ministry's HNS for epinephrine auto-injectors administered to individuals without a valid Ontario health card number for emergency use after administering the COVID-19 vaccine by using the proxy patient ID.

45. If the pharmacist recommends to a physician that a patient 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.

46. Do I 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. Refer to Question #47
- as a mobile clinic in other locations (e.g., community centres, apartment complexes, etc.). Refer to Question #48.

- in retirement homes, congregate settings and long-term care homes under the direction of Public Health Units. Refer to questions # 64-70.

Reference information:

- Ontario College of Pharmacists guidelines including appropriate infection control measures to ensure patients remain safe.
- Ontario Pharmacists' Association Playbook and FAQs as a reference for much of the overall operational aspects of providing COVID-19 vaccines to your patients.
- Ministry Guidance documents provided to clinicians available here.

47. Am I allowed to administer the COVID-19 vaccine to a patient in their private home for example if they are not physically mobile?

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 patient's private home (i.e., one-on-one; not a congregate setting) to administer the COVID-19 vaccine provided the patient has requested a home visit by the pharmacist and provides a reason such as due to the patient being immobile, and this request and rationale is documented by the pharmacy in writing. In exceptional circumstances, a single dose of Pfizer or Moderna vaccines may be transported in a syringe whilst adhering to the storage and handling guidelines regarding transport of vaccines. 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. See Questions #64-70 below for more information. As per Question #48, pharmacies are also allowed to administer as mobile clinics.

The pharmacy must also ensure public safety, vaccine handling and storage requirements (e.g. specific references to transferring vaccines and vaccine specific references at this link) 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.

This documentation must be retained in a readily retrievable location for a period of at least 10 years from the last recorded pharmacy service provided to the patient, or 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer.

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

As a response to the Omicron variant, as of December 20, 2021, pharmacies may conduct off-site mobile clinics in collaboration with their local Public Health Unit. All patient eligibility requirements in the most recent version of the Executive Officer Notice – Administration of COVID-19 Vaccine in ON Pharmacies apply to the mobile clinic.

Participating pharmacies must notify the ministry in advance if they plan to operate a mobile clinic. Emails are sent to OPDPInfoBox@ontario.ca. Pharmacy emails must include the pharmacy ON#, pharmacy name and address of the pharmacy responsible for the mobile clinic. In addition, pharmacies must provide the proposed date and location of the mobile clinic.

In addition, 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 days[6].
- Participating pharmacies are responsible for all aspects of running the mobile clinic including staffing, supplies, communication, signage and other logistics.

[6] 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).

- Participating pharmacies must comply with applicable law, including with respect to waste management with consideration for any added insurance requirements respecting operations off-site.

Following the pharmacy mobile clinic, pharmacies must complete within 7 calendar days, the Pharmacy Mobile Clinic Form at this link: https://forms.office.com/r/iNc4bXFcL8

The participating pharmacy must also ensure public safety, vaccine handling and storage requirements (e.g. specific references to transferring vaccines and vaccine specific references at this link) as well as adhere to relevant Ministry policy / direction, the COVID-19 Vaccine Agreement (including insurance and indemnity requirements), 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 at the mobile clinic.

This documentation must be retained in a readily retrievable location for a period of at least 10 years from the last recorded pharmacy service provided to the patient, or 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer.

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 Notices and Qs and As, they should refer to the applicable legislation, other agreements, or OCP policy as appropriate.

49. Can the COVID-19 vaccines be mixed / switched – one vaccine used for the first dose and the other for the second dose?

For primary COVID-19 vaccine series:

The National Advisory Committee on Immunization (NACI) guidelines has recommended interchangeability of vaccines (or vaccine mixing) which means a patient could receive one vaccine product for the first dose and a different vaccine product for the second dose to complete the two-dose vaccine series.

Persons who received a first dose of the AstraZeneca/COVISHIELD vaccine should receive an mRNA vaccine (Pfizer-BioNTech (12+ formulation) or Moderna) for their second dose, unless contraindicated. According to NACI, an mRNA vaccine is now preferred as the

second dose for individuals who received a first dose of the AstraZeneca/COVISHIELD vaccine, based on emerging evidence of a potentially better immune response from this mixed vaccine schedule and to mitigate the potential risk of VITT associated with viral vector vaccines.
The Nuvaxovid™ COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine to complete the primary series.

Persons who received a first dose of an mRNA vaccine (Pfizer-BioNTech or Moderna) should be offered the same mRNA vaccine for their second dose. If the same mRNA vaccine is not readily available* or unknown, another mRNA vaccine can be considered interchangeable and should be offered to complete the vaccine series. This is consistent with recommendations provided by the NACI and the practices of many jurisdictions. Provision of a second dose of vaccine should not be significantly delayed in order to complete a vaccine series using the same mRNA product, unless clinically indicated. Note: An mRNA vaccine followed by a second AstraZeneca vaccine is not an acceptable interchangeable vaccine series unless the individual has a contraindication to the mRNA vaccines. *Note, readily available means easily available at the time of vaccination without delay or vaccine wastage[7]

Based on advice from the Ontario Immunization Advisory Committee (OIAC), and in alignment with NACI, the Ministry of Health has issued a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 5-29 years of age if receiving a primary series dose, or 5 – 17 years of age if receiving a booster dose.** This recommendation stems from an observed increase in the number of reports in Ontario of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in children, adolescents and young adults, particularly among males. Although risk of myocarditis/pericarditis with the Moderna (50 mcg) vaccine in children 6 to 11 years of age is unknown, with a primary series in adolescents and young adults the rare risk of myocarditis/pericarditis with Moderna (100 mcg) was higher than with Pfizer-BioNTech (30 mcg). See COVID-19 Vaccine Guidance for more details on administering to special populations.

Note: Informed consent is required for those age 5 to 29 who wish to receive the Moderna vaccine, as it is whenever administering a vaccine.

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

[7] Q&A for Health Care Providers on Mixed COVID-19 mRNA Vaccine Schedules

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. There is no preferred product for individuals 6 months to 4 years of age.

Please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**" for further information about eligibility criteria for second doses, including vaccine mixing.

50. Question intentionally deleted as of November 3rd, 2021 update.

51. Question intentionally deleted as of September 12, 2022 update.

52. Question intentionally deleted as of November 3rd, 2021 update.

Why has the province paused the use of the AstraZeneca vaccine for first dose administration?

As of May 11, 2021, following the advice of Ontario's Chief Medical Officer of Health Dr. David Williams, the province has paused the rollout and administration of first doses of the AstraZeneca vaccine.

This decision was made out of an abundance of caution due an observed increase of vaccine-induced immune thrombotic thrombocytopenia (VITT) linked to the AstraZeneca vaccine.

As of May 12, 2021, the Public Health Agency of Canada (PHAC) has estimated the rate of VITT in Canada to be 1 in 83,000 doses administered (of the first dose of AstraZeneca/COVISHIELD vaccine). However, as investigations continue, the rate could be as high as 1 in 55,000. The rate of VITT in the UK, after the second dose of AstraZeneca vaccine, is estimated to be approximately 1 in 600,000 (17 cases out of 10.7 million second doses administered). It should be noted that with increased observation times, VITT rates have generally increased.[8] (Refer to Q#40 for information regarding administration of AstraZeneca/COVISHIELD vaccine)

Please refer to the Executive Officer Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility for more information.

[8] NACI rapid response: Interchangeability of authorized COVID-19 vaccines

54. Are pharmacies able to order and administer Nuvaxovid™ (Novavax Inc.), Covifenz® (Medicago Inc.) or viral vector vaccines?

Pharmacies will not be ordering Nuvaxovid™, Covifenz® or viral vector vaccines (AstraZeneca/COVISHIELD and Janssen COVID-19 vaccines) from their distribution centres at this time due to the limited quantities available in the province. Should patients approach pharmacies for Nuvaxovid™, Covifenz® or a viral vector vaccine, pharmacies should work in collaboration with their local Public Health Unit (PHU) on a case-by-case basis to determine eligibility when an mRNA vaccine is declined or for allergy situations (refer to Q#40). Nuvaxovid™, Covifenz® and viral vector vaccines will primarily be available through PHUs. In very limited situations, a PHU may engage a pharmacy to assist with administration. See also Q# 61 for other vaccine available only through PHUs at this time.

55. What is the recommended scheduling for second doses of mRNA vaccines in Ontario for individuals who received an mRNA vaccine for their first dose?

The recommended dosing interval is 8 weeks for mRNA vaccines. For more information please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**".

56. What is the recommended scheduling for second doses of the Nuvaxovid™ vaccine in Ontario for individuals who received Nuvaxovid™ vaccine for their first dose?

The recommended dosing interval is 8 weeks for the Nuvaxovid™ vaccine. For more information please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**".

57. What is the recommended scheduling for second doses of the Covifenz® vaccine in Ontario for individuals who received Covifenz® vaccine for their first dose?

The recommended dosing interval is 8 weeks for the Covifenz® vaccine. For more information please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**".

Note: Currently the supply for Covifenz® in Ontario is uncertain.

58. What is the recommended scheduling of second doses for individuals who received the AstraZeneca/COVISHIELD vaccine for their first dose?

Refer to Q#40 for more information regarding administration of AstraZeneca / COVISHIELD vaccine for a second dose.

The recommended dosing interval for individuals who received their first dose of the AstraZeneca/COVISHIELD vaccine and who are receiving an mRNA vaccine (Pfizer-BioNTech (12+ formulation) or Moderna) or Nuvaxovid™ / Covifenz® for their second dose (if not contraindicated) is at least 8 weeks.

For more information please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**".

59. What is the dose regimen of the Janssen COVID-19 vaccine?

The Janssen COVID-19 vaccine generally requires a single dose. However, individuals who received the single dose Janssen vaccine are eligible for a supplementary or booster dose in accordance with the EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility. For more information, please refer to the ministry website for the most recent of that EO Notice.

60. Which of the Pfizer vaccines (adult strength or pediatric strength) is recommended for children who are 11 years of age and turning 12 by the time they are eligible for their second dose or booster dose?

Children should receive the formulation that is recommended for their age at the time of administration. For example, children who receive the Pediatric Pfizer vaccine for their first dose and who have turned 12 by the time the second dose is due may receive for their second dose of the Pfizer vaccine (12+ formulation) that is authorized for individuals aged 12 years and over to complete their primary series.

Note: At this time, only the Pediatric Pfizer BioNTech COVID-19 vaccine, orange cap (10mcg) is authorized as a booster dose for children aged 5 – 11 years.

61. How do pharmacies obtain the Moderna COVID-19 vaccine (0.10mg/mL) and Infant Pfizer COVID-19 vaccine (3mcg) for infants/children?

Pharmacies are able to access the Moderna COVID-19 vaccine (0.10mg/mL) and the Infant Pfizer COVID-19 vaccine (3mcg) from their Distribution Centre.

62. Can the Moderna COVID-19 vaccine (0.10mg/mL) be used for older children (i.e., 6 to 11 years) or as a booster for those 18+?

Although the lower concentration (0.10mg/mL) format of the Moderna COVID-19 vaccine can be used to administer a 50mcg dose for children aged 6 to 11 years or to those 18+ as a booster, due to limited vaccine supply, this format is reserved for completing a primary series for infants/children aged 6 months to 5 years at this time.

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

Based on NACI recommendations, use of pediatric Pfizer BioNTech COVID-19 vaccine (10 mcg) is preferred to the Moderna COVID-19 vaccine (25 mcg). The Moderna COVID-19 vaccine (25 mcg) may be given to children 5 years of age as an alternative with informed consent and discussion of risks and benefits with the health care provider.

Children who have received Moderna COVID-19 vaccine (25 mcg) for a previous dose and turn 6 prior to completing their primary series are recommended to receive Moderna COVID-19 vaccine (50 mcg) to complete their primary series. If the primary series was completed with Moderna COVID-19 vaccine (25 mcg) or with Pfizer-BioNTech COVID-19 vaccine (10 mcg), the dose should be considered valid and the series complete.

Note: At this time, only the Pediatric Pfizer BioNTech COVID-19 vaccine, orange cap (10mcg) is authorized as a booster dose for children aged 5 – 11 years.

64. When is a third or booster dose recommended after being infected with COVID-19?

Individuals 5 years of age and older who are eligible to receive a booster dose and who are infected with COVID-19 after their primary series (but before their booster dose), are recommended to receive their booster dose 3 months after symptom onset or positive test (if asymptomatic) but 6 months may provide better immune response, provided that they

meet the applicable dosing interval after completing their primary vaccine series. As per NACI, emerging evidence indicates that a longer interval between SARS-CoV-2 infection and vaccination is associated with improved antibody responses to COVID-19 vaccines. With informed consent, individuals may receive a booster dose once they are no longer infectious (asymptomatic and have completed their isolation) and are otherwise eligible for the booster dose.

Pharmacies should be informed and stay current with the vaccine's official indications in accordance with Health Canada's approved product monograph, including information regarding the recommended dosing. Ontario is funding third doses or booster doses, based on recommendations of the Chief Medical Officer of Health, OIAC and NACI.

Note: the Janssen COVID-19 vaccine series involves a single dose. However, individuals who received the single dose Janssen vaccine are eligible for a supplementary or booster dose in accordance with the EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility. References in the remainder of this document to individuals who have already received two doses of a COVID-19 vaccine shall be interpreted to include individuals who received the single dose Janssen vaccine. In addition, for immunocompromised individuals who received the single dose Janssen vaccine, references in the remainder of this document to a third dose shall be interpreted to mean a second dose.

65. What is the difference between a third dose and a booster dose?

Historically in other vaccine programs, it takes years of post-marketing surveillance to determine the optimal interval between doses and dose number to complete a primary series to sustain long-term protection.

Per NACI's interim guidance on booster COVID-19 vaccine doses in Canada, the intent of a **booster dose** is to restore protection that may have decreased over time to a level that is no longer deemed sufficient in individuals who initially responded adequately to a complete primary vaccine series. This is distinguished from the intent of a **third dose** which might be added to the standard primary vaccine series with the aim of enhancing the immune response and establishing an adequate level of protection for individuals who developed no or sub-optimal immune response to a single or 2-dose primary series.

While the term "booster dose" is used in this guidance, NACI continues to monitor the emerging scientific data on whether this dose is indeed a booster dose (to stimulate the memory response once protection has truly waned), or should be considered part of the primary series (to establish strong immune response and memory). NACI will adjust the terminology as required. See NACI interim guidance for more information.

With respect to **third doses**, certain populations may demonstrate a suboptimal immune response to a single or two-dose COVID-19 vaccine series due to underlying health conditions. In these populations, a third dose of the current mRNA COVID-19 vaccines is recommended for certain populations as described in the ministry guidance document, COVID-19 Vaccine Booster Recommendations.

The use of third or booster doses of mRNA COVID-19 vaccines is based on evidence and recommendations from the NACI located at this website, and OIAC.

66. Are pharmacies permitted to administer third doses of the COVID-19 vaccine?

Pharmacies may administer **third doses** as part of a 3-dose primary series for immunocompromised groups with the vaccine product authorized for the eligible individuals age group (these recommendations also apply to children aged 6 months – 11 years of age) and may only submit claims for third doses of the COVID-19 vaccine using a mRNA vaccine (i.e., Moderna [both strengths] or Pfizer-BioNTech [Pediatric or 12+ Formulations]) unless contraindicated or, in the case of Nuvaxovid™, the person (age 18+) receiving the third dose in a primary series is unable or unwilling to receive an mRNA vaccine; or, in the case of Covifenz® the person (age 18 to 64 years of age) receiving the third dose in a primary series is unable or unwilling to receive an mRNA vaccine (Refer to Q#40), to the HNS that are administered to:

- Individuals 6 months of age and older from the following moderately to severely immunocompromised population groups that provide a referral letter from their health care provider or are taking an immunosuppressant medication listed here, as verified by the pharmacy, at a minimum of **2 months or 56 days** following their second dose or at an interval of at least 28 days if directed in writing by their health care provider:
    - Individuals receiving dialysis (hemodialysis or peritoneal dialysis)
    - Individuals receiving active[9] treatment (e.g., chemotherapy, targeted therapies, immunotherapy) for solid tumour or hematologic malignancies
    - Recipients of solid-organ transplant and taking immunosuppressive therapy

[9] 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 Frequently Asked Questions 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).
- Individuals with HIV with prior AIDS defining illness **or** prior CD4 count ≤ 200/mm3 **or** prior CD4 fraction ≤ 15% **or** (in children 5-11 years) perinatally acquired HIV infection
- Individuals receiving active treatment with the following categories of immunosuppressive therapies: anti-B cell therapies[10] (monoclonal antibodies targeting CD19, CD20 and CD22), high-dose systemic corticosteroids (refer to the Canadian Immunization Guide for suggested definition of high dose steroids), alkylating agents, antimetabolites, or tumor-necrosis factor (TNF) inhibitors and other biologic agents that are significantly immunosuppressive.

A copy of the referral letter from the health care provider is required as part of the documentation for administration of the third vaccine dose in the pharmacy to the immunocompromised groups above, **except where a pharmacist assessed an individual's eligibility in accordance with the following note:**

Note: Pharmacists may verify whether a patient is eligible for a third dose of a COVID-19 vaccine based on the patient's use of an immunosuppressant medication listed here by referring to a patient's recent prescription label or prescription receipt or their medication profile. If an individual presents a prescription of a medication that is not listed here, they should be directed to their health care provider to receive a referral form/letter for a third dose of the COVID-19 vaccine.

67. Are pharmacies permitted to administer booster doses of the COVID-19 vaccine?

A booster dose with an mRNA vaccine is recommended for eligible individuals, to obtain stronger and longer-lasting protection regardless of which vaccine was used in the primary series.

See question 74 for information on primary series.

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

Eligibility Criteria for Non-Bivalent Booster Dose Administration after a primary series

Individuals aged 12 years or older are eligible for a booster dose, if at least 6 months (168 days)* have passed since they received their last dose.

- * Note: With informed consent, individuals aged 12 or older may receive the booster dose in less than 6 months as long as 3 months have passed since they received their last dose.

Individuals aged 5 to 11 years, are eligible for a booster dose, if at least 6 months (168 days) have passed since completing a primary COVID-19 vaccine series, including those who are moderately to severely immunocompromised who have completed a 3-dose primary vaccine series[11]),

- Note: With informed consent, individuals aged 5 to 11 years may receive their booster dose in less than 6 months (168 days) as long as 3 months have passed since completing their primary COVID-19 vaccine series.
- Only the Pediatric Pfizer-BioNTech COVID-19 vaccine (orange cap) is authorized as a booster dose for individuals aged 5 to 11 years.

Eligibility Criteria for Bivalent Booster Dose Administration after a primary series

Individuals aged 18 years and older may receive a COVID-19 bivalent (Moderna) booster dose, if at least six months (168 days)*, have passed since the individual's last dose, regardless of the number of booster doses received.

- Individuals who are 12 years and older with an underlying medical condition that places them at risk of COVID-19
    - For adolescents 12-17 years of age with moderately to severely immunocompromising conditions and/or who have biological or social risk factors that place them at high risk of severe outcomes of COVID-19, a booster dose of the bivalent Moderna COVID-19 vaccine may be offered off-label based on clinical discretion.

***Note:** With informed consent, individuals listed above may receive the COVID-19 bivalent (Moderna) booster dose in less than 6 months as long as 3 months have passed since they received their last dose.

[11] Individuals (12 years of age and older) who were receiving active treatment necessitating a three dose primary series, are eligible for a booster dose, even if not receiving active treatment currently.

For more information please refer to the ministry website for the most recent EO Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**".

68. Question deleted as of December 17, 2021 update.

69. Should individuals receiving a booster dose with an mRNA vaccine receive the full dose?

For individuals age 18 and over who are recommended to receive a fall (2022) booster dose, NACI and the Ministry **recommends that the authorized dose of a bivalent Omicron-containing mRNA COVID-19 vaccine should be offered** subject to eligibility rules in the most recent Executive Officer Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility". If the bivalent Omicron-containing mRNA COVID-19 vaccine is not readily available, an original mRNA COVID-19 vaccine should be offered to ensure timely protection. The Moderna Bivalent COVID-19 vaccine 0.10mg/mL is a 50mcg dose.

70. 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 ONEMail account for verification purposes only.

Note: Effective November 25, 2021 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.

As of December 17, 2021, 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 Executive Officer Notice – Administration of COVID-19 vaccine 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' (IPAD[12] 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 COVAX$_{ON}$ 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

[12] 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.

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

The COVID-19 vaccines may be given with, or at any time before or after, other vaccines, including the influenza vaccine with the exception of children aged 6 months to under 5 years of age.

For children who are 6 months to under 5 years of age, it is recommended to wait for a period of at least 14 days BEFORE or AFTER the administration of another vaccine before administering a COVID-19 vaccine to prevent erroneous attribution of an AEFI to one particular vaccine or the other. However, this suggested minimum waiting period between vaccines is precautionary and therefore concomitant administration or a shortened interval between COVID-19 vaccines and other vaccines may be warranted on an individual basis in some circumstances.

These include:

- when there is a risk of the individual being unable to complete an immunization series due to the limited access to health services or being unlikely to return at a later date;
- when an individual may not return to receive a seasonal influenza vaccine;
- when another vaccine is required for post-exposure prophylaxis;
- when individuals require accelerated vaccination schedules prior to immunosuppressive therapy or transplant; and
- at the clinical discretion of the healthcare provider

For those individuals age 5 years and older who are eligible for co-administration, if given by injection at the same time, separate limbs should be used if possible. Alternatively, the injections may be administered into the same muscle separated by at least 2.5 cm (1”). Different immunization equipment (needle and syringe) must be used for each vaccine.

Please see COVID-19 Vaccine Guidance for more information.

72. 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.[13] Optimal timing for re-immunization should be determined on a case-by-case basis in consultation with the clinical team.

A re-vaccination series includes first, second, third and (if applicable) booster dose intervals based on a referral letter from a health care provider.

73. What course of action should be followed if the pharmacy has administered an incorrect dose to a patient or used the wrong vaccine according to the patient's age or experienced other errors or lapse of judgement when administering COVID-19 vaccines?

Pharmacists should refer to Health Canada's COVID-19 Vaccine Guide for basic information 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.

74. What is the recommendation of a primary series of COVID-19 vaccine administration?

For a primary series

1. 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.
2. Novavax or Medicago may be offered to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine.

[13] As per the Canadian Immunization Guideline, HSCT recipients should be viewed as vaccine naïve (i.e. never immunized) and require re-immunization after transplant.

3. A complete primary series of a viral vector Janssen COVID-19 vaccine may be offered to individuals in the authorized age group without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated.

For more information, refer to the COVID-19 Vaccine Guidance.

Vaccine Storage and Handling

75. What are the some of the requirements for pharmacies around vaccine storage and handling?

Pharmacies must continue to follow the requirements outlined in the Vaccine Storage and Handling Guidelines (with the exception of the process for 'returning vaccine' noted on page 21 – refer to Q #76) regarding temperature log monitoring and managing cold-chain incidents. For example, pharmacies must:

- reach out to their public health unit about temperature logging and reporting. The frequency of temperature log monitoring / submissions will vary across public health units.
- notify their public health unit immediately should they experience any cold chain incidents in which the publicly funded vaccine is exposed to temperatures outside the +2 degrees C and +8 degrees C.
- contact their public health unit when adding new equipment (refrigerator) so that it can be inspected.

This includes any wasted product as a result of an investigated temperature excursion, if applicable.

Pharmacies should also be aware of the different storage guidelines (before/after dilution, before/after vial puncture, etc.) of each vaccine and be mindful when booking appointments to ensure there is minimal wastage.

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

For wastage and disposal of COVID-19 vaccine, pharmacies must document wastage, extra doses from vaccine vials and temperature excursions in the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$.

Once wastage is documented in the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$., pharmacies must follow disposal practice protocols including:

- referral to the COVID-19: Vaccine Storage and Handling Guidance document on the ministry's website for information on how to dispose of expired or wasted vaccine (specifically Appendix B). **Note that pharmacies are NOT to return expired or unused COVID-19 vaccines to their local public health unit as they currently do with the influenza vaccine;** and

- adherence to Ontario College of Pharmacist (OCP) Policy and Guidance for example, the OCP *Policy on Medication Procurement and Inventory Management* to ensure there is a "method for identifying products that are outdated, deteriorated, recalled, obsolete, or hazardous, and that such products are disposed of in a safe, legal, and environmentally sound manner".

    - 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.

77. Does the COVID-19 vaccine require reconstitution?

Currently, the Infant Pfizer-BioNTech, maroon cap, (DIN 02530325), Pediatric Pfizer-BioNTech COVID-19 vaccine, orange cap (DIN 02522454) and the Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, purple cap (DIN: 02509210) require reconstitution using a diluent that is supplied with the vaccine. The Pfizer-BioNTech COVID-19 (12+ formulation) vaccine, grey cap (DIN: 02527863) does NOT require reconstitution.
For more information on the vaccines please refer to the product monograph and the resource information on the ministry website: COVID-19 Vaccine Information and General COVID-19: Vaccine Storage and Handling Guidance.

Pharmacies should ensure that they have adequate space for preparing the injection for administration while adhering to proper infection prevention and control measures.

78. What is the process if my pharmacy needs to transfer COVID-19 vaccine supply to another participating pharmacy?

As noted in the COVAX$_{ON}$ Agreement, pharmacies that need to transfer COVID-19 vaccine stock to another participating pharmacy require an authorization from the ministry. Stores are not allowed to transfer their vaccine supply to another store (even if the stores have the

same owners) without authorization from the ministry and will only be allowed in exceptional circumstances (i.e., where there is risk of unused vaccine wastage).

NOTE: The Pfizer-BioNTech COVID-19 vaccine (all formulations) and the Moderna COVID-19 vaccine can only be transferred in exceptional circumstances and MUST be ministry approved prior to any transfer.

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 and the transferring pharmacy must notify the ministry by sending an email that includes:

- the pharmacy contact information (including ON Provider #) of the site transferring the doses,
- pharmacy contact information of the site (including ON Provider #) receiving the transfer
- number of doses to be transferred,
- vaccine name, lot # and expiry date, and
- reason for the transfer

Emails are sent to OPDPInfoBox@ontario.ca.

Doses that are transferred must also be logged into the COVAXON system for proper system-wide inventory management.

Pharmacies transferring vaccine must ensure that they include needles and syringes with the shipments.

Typically, pharmacy transfers are between pharmacies; however, if a public health unit (PHU) has confirmed that they will accept or supply vaccines, this information can 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 COVAXON. if the primary care provider does not have their own AO (Authorized Organization).

Pharmacies arranging to transfer or accept transfers of vaccine must also follow this process and await ministry approval.

79. Question intentionally deleted as of November 3rd, 2021 update.

Additional Information:

For pharmacy billing:

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For Support for Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$

Please contact your pharmacy head office or the Ontario Pharmacists Association or the Neighbourhood Pharmacy Association of Canada

For COVID-19 vaccine rollout in pharmacy:

Please email the ministry at: OPDPInfoBox@ontario.ca

For Ministry COVID-19 Vaccine-Relevant Information and Planning Resources

Please access this website

For all other Health Care Providers and the Public:

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282.