

# Updated: Questions and Answers for: Administration of Publicly Funded COVID19 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 <u>ministry website</u>. 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<sub>ON</sub> (COVID-19 Vaccine Agreement)<sup>1</sup>. 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 <u>Ontario Drug Programs</u> Reference Manual
- Injection training and scope of practice, pharmacy staff should contact the <u>Ontario</u>
   College of Pharmacists (OCP)

<sup>&</sup>lt;sup>1</sup> 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<sub>ON</sub> (if access to the Solution has been granted to the pharmacy).



#### **Table of Contents**

Overview	2
Eligibility	4
Ministry Payment	6
Pharmacist Training	7
Pharmacy Participation	9
Documentation Guidelines	12
Claim for payment through the Health Network System	15
Adverse Drug Reactions	17
Restrictions	19
Vaccine Storage and Handling	26

#### **Overview**

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

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. 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 <u>online location finder</u> 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 <a href="ministry website">ministry website</a> 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. For youth age 12 to 17 years, including youth who are turning 12 at anytime during 2021, there is a specific consent form.

NOTE: an <u>additional consent form</u>, "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 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 <u>not</u> 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.

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

## 10. Can a patient be an ODB recipient and <u>not</u> have an Ontario health card number?

Yes. There may be circumstances when a patient who is an eligible ODB recipient does <u>not</u> 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 <u>not</u> have an Ontario health card number?

If a pharmacy has been granted access to the Provincial COVID-19 Vaccine Solution-COVAX<sub>ON</sub>, then the COVID-19 Vaccine Agreement requires documentation of alternate forms of identification to confirm date of birth if the patient does <u>not</u> 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. Can the pharmacy administer a second dose of a COVID-19 vaccine to a patient who received their first dose outside of Ontario or Canada? Which COVID-19 vaccine should I give?

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 <u>public</u> <u>health unit</u> in order to be registered in the system.

Once that process is complete, these individuals will be able to book their second 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.

Please refer to the <u>guidance</u> posted on the ministry's website regarding COVID-19 vaccine second doses for those who received a first dose outside Ontario/Canada.

### **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-COVAX<sub>ON</sub> 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 Ontarians?

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 <u>Ontario College of Pharmacists</u>.



## 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. 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 <a href="Executive Officer Notices and Questions & Answers documents">Executive Officer Notices and Questions & Answers documents</a> ("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 COVAX<sub>ON</sub> 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 COVAX<sub>ON</sub> system.
- Evidence that the other HCP has a clear understanding of Vaccine Storage and Handling Guidelines and required protocols

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

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-COVAX<sub>ON</sub> database that holds all the COVID-19 vaccination information.

Resource information regarding the Provincial COVID-19 Vaccine Solution-COVAX<sub>ON</sub> including support, training, forms and reference materials for pharmacies are available. Pharmacies should contact their head office or the <a href="Ontario">Ontario</a> <a href="Pharmacists Association">Pharmacists Association</a> for these resources.

Do not contact the COVAX<sub>ON</sub> 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-COVAX<sub>ON</sub>.

### **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 included but not limited to:

- currently enrolled and in good standing in the 2020/2021 Universal Influenza Immunization Program (UIIP)
  - reminder to pharmacies to <u>enroll in the 2021/22 UIIP</u> to continue participating in administering COVID-19 vaccines
- must have the capacity and ability to accept and administer vaccine supply quickly and effectively (for example an average of 30 - 40 injections per day)
- other factors may include high risk areas, regional population distribution, pharmacy patient base and performance in the UIIP.

Please refer to the <u>ministry website</u> for the most recent EO Notice. For detailed information on pharmacy site selection please refer to the ONEMail notice "DDD Notice No. 21037 Posted March 22, 2021: UPDATES EO Notices and FAQs on COVID-19 Vaccine Immunization through Ontario Pharmacies"



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

The Provincial COVID-19 Vaccine Solution-COVAX<sub>ON</sub> 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<sub>ON</sub>.

The requirements for accessing and using the Provincial COVID-19 Vaccine Solution-COVAX<sub>ON</sub> 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<sub>ON</sub> by the ministry.

It is important that pharmacies correctly document vaccine administration and inventory management in the Provincial COVID-19 Vaccine Solution-COVAX<sub>ON</sub>. While vaccine administration to the patient should occur PRIOR to completing the entry in COVAX<sub>ON</sub>, pharmacy staff must be diligent in accessing COVAX<sub>ON</sub> 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<sub>ON</sub> must be corrected immediately.

Please refer to the Job Aids in the resource information provided. regarding the Provincial COVID-19 Vaccine Solution-COVAX<sub>ON</sub> 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<sub>ON</sub>, immunizers <u>must</u> 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<sub>ON</sub>?

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<sub>ON</sub>.

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<sub>ON</sub> 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 <u>Ontario College of</u> 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<sup>2</sup> form at this link: <a href="https://ehealthontario.on.ca/en/health-care-professionals/ppe-intake?a=ppe-intake">https://ehealthontario.on.ca/en/health-care-professionals/ppe-intake?a=ppe-intake</a>

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.

#### 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 <a href="Ontario College of Pharmacists">Ontario College of Pharmacists</a> website as well as <a href="Ministry Guidance at this website">Ministry Guidance at this website</a>.

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

<sup>&</sup>lt;sup>2</sup> Note, the access for PPE is the same as for accessing for the UIIP program. Pharmacies may use the same form / process.



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

Yes. Pharmacy staff must schedule the appointment date and time for the second dose. 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<sub>ON</sub>).

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 dose scheduling 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 second dose at your pharmacy – without having had their first dose at your pharmacy – pharmacies are permitted to administer the second 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. Priority for second doses should be given to those at highest risk of severe illness and death from COVID-19 disease after or concurrent with first doses for all remaining eligible populations.

The province has an <u>Ethical Framework</u> in place to guide COVID-19 vaccine prioritization and distribution. 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.
- Record of name of vaccine administered, dose, 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 location of administration (e.g. pharmacy or pharmacy parking lot).
   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 same pharmacy location. Note: date and time of the second dose may be hand-written on the written record provided to the patient.
- Record 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<sub>ON</sub> 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<sub>ON</sub> system and on the vaccine receipt provided to the patient.

#### 31. 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 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 must also schedule with the patient the day and time for the second dose 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 <a href="Ontario Pharmacists Association">Ontario Pharmacists Association</a>.

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



#### 34. What documentation does the ministry require for an epinephrine autoinjector 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 autoinjector 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 <u>must</u> reflect the date the publicly funded COVID-19 vaccine was administered<sup>3</sup>.

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<sub>ON</sub>, immunizers <u>must</u> identify their individual health professional status (i.e., they must use their own User ID).

<sup>&</sup>lt;sup>3</sup> 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).



#### 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 <u>Section 5</u> 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

#### 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

o 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 <a href="Ontario Adverse">Ontario Adverse</a>



<u>Events Following Immunization Reporting Form</u> and sent to the local <u>public health</u> unit<sup>4</sup>.

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<sub>ON</sub>.

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

## 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.

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 the AstraZeneca vaccine for their first shot if they are allergic to the mRNA vaccines?

At this time there is a pause on administering the AstraZeneca vaccine as a first dose in pharmacies is per the May 11, 2021 Executive Officer Communication that is based on the Provincial direction. However, if an individual requires the AstraZeneca vaccine due to a confirmed allergy to components of the mRNA vaccines or if an individual has had a severe allergic reaction or anaphylaxis to a

<sup>&</sup>lt;sup>4</sup> 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.



previous dose of a COVID-19 vaccine, they should not receive a COVID-19 vaccine in a general vaccine clinic including a pharmacy until they have been assessed by an allergist-immunologist.

According to ministry guidance, a referral to an allergist / immunologist is recommended for these individuals. Pharmacists should direct patients to their primary care provider or their local public health unit (PHU) for referral. An allergist-immunologist assessment is required to assess the method for possible (re)administration of a COVID-19 vaccine.

The Province has distributed a list of designated allergists to all Public Health Units and Primary Care Providers that are specifically seeing patients with reactions to the COVID-19 vaccines. The allergist-immunologist is required to complete an Allergy Form for this purpose - COVID-19 Vaccination: Allergy Form and determine the course of action for these patients.

The Allergy Form and patient vaccine administration care plan that is completed by the allergist-immunologist must be provided to the immunization clinic, which could include a participating pharmacy for inclusion in the individuals record when the assessment determines that immunization can be safely provided in a general vaccine clinic or pharmacy. The vaccination plan must include what types of parameters the clinic should meet to provide safe vaccination administration, including for example availability of advanced medical care, details/severity of the previous allergic episode(s), confirm that appropriate counselling on the safe administration of vaccine was provided, and include the date, the clinician's name, signature and contact information, as well as the individual's name and date of birth.

In the event that a patient is directed to a pharmacy for safe COVID-19 vaccine administration as per an allergist-immunologist assessment and patient care plan, a listing of pharmacies that carry the AstraZeneca vaccine can be located on the Ministry website at this link: <a href="COVID-19">COVID-19</a> pharmacy vaccine locations (ontario.ca)

#### Restrictions

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

No. Pharmacy staff administration of the publicly funded COVID-19 vaccine to long-term care home residents or hospital in-patients is **not** eligible for payment under this initiative.



## 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. 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?

There is an expectation that pharmacies are administering the COVID-19 vaccine within the pharmacy premises. The pharmacy is permitted to administer publicly funded vaccines 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) and any Ontario College of Pharmacist (OCP) standards, polices or guidelines.\*

\* See Question #48 for information regarding pharmacy participation in mobile clinics in other locations (e.g., community centres, apartment complexes, etc.).

#### Reference information:

- Ontario College of Pharmacists <u>guidelines</u> including appropriate infection control measures to ensure patients remain safe.
- Ontario Pharmacists' Association <u>Playbook</u> and <u>FAQs</u> 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 <u>here.</u>

## 47. Am I allowed to administer the COVID-19 vaccine to a patient in their private home 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 (Pfizer, Moderna or second doses of AstraZeneca/COVISHIELD at this time) provided the patient has requested a home visit by the pharmacist 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 vaccine may be transported in a syringe whilst adhering to the <a href="storage">storage</a> and handling quidelines regarding transport of vaccines.

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 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 withing 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?

At this time, pharmacies are not part of the province's mobile clinic activity. The ministry will keep pharmacies / pharmacy operators current if / when mobile clinic operations apply to the pharmacy vaccine rollout clinic model.

However, individual pharmacists, interns, pharmacy students and pharmacy technicians with injection training may participate in administering COVID-19 vaccine in an alternate clinic setting (e.g., PHU-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?

NACI guidelines now recommend 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. For example:

- Persons who received a first dose of the AstraZeneca/COVISHIELD vaccine may receive either AstraZeneca/COVISHIELD vaccine or an mRNA vaccine (Pfizer-BioNTech 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.
- 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 recently provided by the <a href="NACI">NACI</a> 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. \*Note, readily available means easily available at the time of vaccination without delay or vaccine wastage<sup>5</sup>

Please refer to the <u>ministry website</u> 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. I have a patient who wants to get their second dose earlier (i.e., earlier than the current 16 week interval recommendation) – can I give it to them?

With the increase of COVID-19 vaccine supply in Canada, second doses should be offered as soon as possible (subject to minimum dosing intervals), with priority given to those at highest risk of severe illness and death from COVID-19 disease after or concurrent with first doses for all remaining eligible populations.

Due to the increased vaccine supply that is now available in Ontario, the province is accelerating the second dose intervals. Please refer to the Executive Officer Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility for more information.

Note: The Ministry provides second dose interval guidance documents on the ministry's <u>website</u>. These documents outline the appropriateness of extending the second dose interval up to 4 months, and also discuss special populations (like cancer or transplant patients) in which shortening the second dose interval may be recommended.

## 51. How do individuals with health conditions who may require a second dose sooner book their second dose appointment or change the date of their appointment?

Individuals with health conditions are eligible to receive a second dose at an accelerated interval. Please refer to the ministry website for the most recent EO

<sup>&</sup>lt;sup>5</sup> Q&A for Health Care Providers on Mixed COVID-19 mRNA Vaccine Schedules



Notice entitled "Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility" for further information about accelerated dosing intervals.

It is recommended that these individuals, present a letter from their healthcare provider at their first and second dose appointments.

If an individual has already had their first dose, the individual can contact the public health unit, pharmacy, vaccine clinic, or primary care practice at which they received their first dose and indicate they are eligible for the shortened second dose to get booked for their second dose. The patient will need to bring the letter to their appointment.

Assistance with bookings are outlined on the ministry website (see links below):

- Phase 2 mass delivery of vaccines: <a href="https://covid-19.ontario.ca/ontarios-covid-19-vaccination-plan#phase-2">https://covid-19.ontario.ca/ontarios-covid-19-vaccination-plan#phase-2</a>
- COVID-19 vaccine, getting your second dose: <a href="https://covid-19.ontario.ca/covid-19-vaccines-getting-your-second-dose">https://covid-19.ontario.ca/covid-19-vaccines-getting-your-second-dose</a>

## 52. Who qualifies as a high-risk health care worker eligible to receive their second dose of the COVID-19 vaccine at a shortened interval? When will they be eligible, and how can they book their appointment?

As announced on May 10, 2021, high-risk health care workers will be eligible for the shortened second-dose interval (earlier than 16 weeks, but not less than 21 days where Pfizer-BioNTech is a first dose if supply allows and 28 days where a Moderna COVID-19 vaccine is a first dose<sup>6</sup>). See the list <u>here</u>.

Most health care workers will be able to book their second doses through where they received their first vaccine, with timing dependent on supply availability. The Ministry is working with public health units and hospitals on a plan to ensure all health care worker second doses are completed as soon as possible, while ensuring that already-scheduled first dose appointments are respected.

<sup>&</sup>lt;sup>6</sup> For more information refer to the *Q&A for Health Care Providers on Mixed COVID-19 mRNA Vaccine Schedules* at this <u>link</u> and *COVID-19 Vaccine Series Second Dose Eligibility Quick Reference* located at this <u>link</u>. Note that an interval of 28 days for Pfizer may be considered for operational feasibility.



## 53. 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.<sup>7</sup>

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

Please also refer to Question 40 for information about individuals who are exempt from this pause in the administration of first doses of the AstraZeneca vaccine due to allergies to mRNA vaccines.

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

The ministry has outlined a schedule for eligibility to book a second dose appointment for the Pfizer or Moderna vaccines for individuals who received those vaccines for their first dose. The schedule is subject to vaccine product availability and can be accessed on the ministry website at this <u>link</u>.

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

<sup>&</sup>lt;sup>7</sup> NACI rapid response: Interchangeability of authorized COVID-19 vaccines



## 55. What is the scheduling of second doses for individuals who received the Astrazeneca/COVISHIELD vaccine for their first dose?

Individuals who received their first dose of the AstraZeneca/COVISHIELD vaccine are eligible to receive a second dose of the AstraZeneca/COVISHIELD vaccine at an interval of at least 8 weeks, unless they are eligible for an accelerated dosing interval.

Individuals who received their first dose of the AstraZeneca/COVISHIELD vaccine at any time and who choose to receive an mRNA vaccine (Pfizer-BioNTech or Moderna) for their second dose (if not contraindicated), are eligible to receive a second dose at an interval of at least 8 weeks, unless they are eligible for an accelerated dosing interval, depending on vaccine availability.

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

#### **Vaccine Storage and Handling**

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

Pharmacies must continue to follow the requirements outlined in the <u>Vaccine Storage and Handling Guidelines</u> 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 <u>public health unit</u> 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.

Pharmacies must also document wastage, extra doses from vaccine vials and temperature excursions in the Provincial COVID-19 Vaccine Solution-COVAX<sub>ON</sub>.



Once wastage is documented in the Provincial COVID-19 Vaccine Solution-COVAX<sub>ON.</sub>, pharmacies may dispose as per usual disposal practice protocols. 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 no wastage.

#### 57. Does the COVID-19 vaccine require reconstitution?

Currently, the PFIZER-BIONTECH COVID-19 VACCINE requires reconstitution using a diluent that is supplied with the vaccine. For more information on the vaccines please refer to the product monograph and the resource information on the ministry website.

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

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

As noted in the COVAX<sub>ON</sub> 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 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 vaccine storage and handling guidelines as well as <u>specific references</u> to transferring the vaccine. 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 COVAX<sub>ON</sub> 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 the vaccines, this information can apply to transferring vaccine to a PHU as well.

Pharmacies arranging to transfer / or accept transfers of vaccine from primary care providers or their local public health units must also follow this process and await ministry approval.

## 59. Is there updated information on the expiry date of certain lot numbers of the AstraZeneca COVID-19 vaccine?

Yes. Health Canada <u>announced</u> on May 29, 2021 that it has approved an extension to the expiry dates of two lots (MT0055 and MT0056) of the AstraZeneca COVID-19 vaccine by 30 days, from May 31, 2021, to July 1, 2021. The approval to extend the shelf life was supported by scientific evidence.

#### **Additional Information:**

#### For pharmacy billing:

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



#### For Support for Provincial COVID-19 Vaccine Solution-COVAXON

Please contact your pharmacy head office or the <u>Ontario Pharmacists Association or the Neighbourhood Pharmacy Association of Canada</u>

#### For COVID-19 vaccine rollout in pharmacy:

Please email the ministry at: <a href="mailto:OPDPInfoBox@ontario.ca">OPDPInfoBox@ontario.ca</a>

#### 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.