Executive Officer Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies

Effective September 26, 2023

Certain eligible pharmacies can administer publicly funded COVID-19 vaccines to eligible individuals (see Pharmacy Eligibility below).

The purpose of this Executive Officer (EO) Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies (EO Notice), and the accompanying Frequently Asked Questions (FAQs) document, is to set out the terms and conditions for a participating pharmacy's submission of claims for payment (claims) for administering injectable COVID-19 vaccines to eligible individuals. Each document is a Ministry of Health (ministry) policy that pharmacy operators must comply with under section 3.2 of the Health Network System (HNS) Subscription Agreement for Pharmacy Operators. Participating pharmacies must comply with all of the terms and conditions set out in the EO Notice and FAQs.

The EO Notice and the accompanying FAQs document are not intended to describe a pharmacy operator's obligations in respect of administering injectable COVID-19 vaccines under applicable legislation, other agreements with the Province of Ontario, or policies of the Ontario College of Pharmacists (OCP). Pharmacy operators with questions about their legal obligations outside of the HNS Subscription Agreement should refer to the applicable legislation, other agreement, or OCP policy as appropriate.

This EO Notice replaces the previous EO Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies that was effective July 7th, 2023.

Pharmacy Eligibility

In order to be eligible to submit claims for administering a publicly funded COVID-19 vaccine, a pharmacy operator (also referred to in this document as a "participating pharmacy") must be authorized by the ministry and meet the following requirements:

- Have a valid HNS Subscription Agreement with the ministry
- Have a valid agreement[1] with the ministry respecting COVID-19 vaccine administration and the use of the Provincial COVID-19 vaccine solution (the "COVID-19 Vaccine Agreement"); and
- Be enrolled in the current Universal Influenza Immunization Program (UIIP)[2].

This eligibility criteria may be updated from time to time. Please refer to the ministry website for the most recent version of this notice.

Individual Eligibility

The following rules apply to the interpretation of the eligibility criteria in the summary table below for any COVID-19 vaccine doses.

An individual is eligible to receive a publicly funded COVID-19 vaccine if 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 eligibility criteria in the table below. For all vaccine doses, when eligibility is defined by age, individuals must be the respective age of eligibility on the day of the vaccine administration.

Residents of long-term care homes, residents of retirement homes, and persons living in other congregate settings (e.g. assisted-living facilities, naturally occurring congregate retirement settings/seniors apartment buildings, congregate settings for people with developmental disabilities, mental health and addictions issues, etc.) who meet the eligibility criteria in the table below are only eligible to receive a pharmacy-administered vaccine dose when pharmacy staff administer the dose (using pharmacy vaccine supply) at the long-term care home, retirement home or other congregate setting. Staff, support workers, essential caregivers, volunteers and contractors who are working at the long-term care home, retirement home or other congregate settings are also eligible for pharmacy-administered vaccine doses either at the pharmacy or when the pharmacy staff visit the home / congregate setting, provided that they meet the applicable eligibility criteria in the table below. Pharmacies must coordinate any vaccine administration at a long-term care

[1] A valid 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.
[2] 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.

home, retirement home or congregate setting with the local public health unit and the proprietor of the home/setting.

Informed consent is required to administer any COVID-19 vaccine to an eligible individual.

On September 22, 2023, the MOH updated the COVID-19 Vaccine Guidance . Highlights from the recent guidance updates are below:

To align with the National Advisory Committee on Immunization (NACI), the ministry is moving away from using the terms 'primary series' and 'booster dose(s)'. This document refers to an individual's vaccination status as **'previously vaccinated'** (i.e. having completed their primary series and are eligible for a booster dose) and **'not previously vaccinated'** (i.e. require initiation of a primary series)

Vaccine Recommendation

1. Consistent with NACI, the ministry recommends a dose of the XBB.1.5-containing COVID-19 mRNA vaccine for individuals in the authorized age group (i.e. 6 months and older) who have been **previously vaccinated** against COVID-19, if it has been 6 months from the previous COVID-19 vaccine dose or known SARS-CoV-2 infection (whichever is later) as outlined in Table 1. NACI also notes that a shorter interval (3 to < 6 months) can be used to support fall program implementation

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

2. Individuals who **have NOT been previously vaccinated,** may use the XBB.1.5 containing COVID-19 vaccine to initiate the series as outlined in Table 2. NACI recommendations on vaccine interchangeability can apply to XBB.1.5 containing COVID-19 vaccines if used to complete a vaccine series started with a different formulation (either original monovalent wild type-containing or bivalent vaccine). Regardless of which product is offered to start a vaccine series, the previous dose should be counted, and the series need not be restarted.

3. For individuals who are not able or willing to receive an mRNA COVID-19 vaccine, NACI recommends the **Novavax COVID-19 vaccine** be offered. An **XBB.1.5 formulation of Novavax COVID-19 vaccine** is expected later this fall. Individuals requesting the Novavax vaccine should be made aware of the upcoming availability of an updated formulation. NACI guidance on the XBB.1.5 formulation of Novavax is

anticipated after authorization. In the interim, individuals who are not able or willing to receive an mRNA COVID-19 vaccine may be offered the Novavax COVID-19 vaccine targeting the original COVID-19 strain. Those 12 years and older who have not been previously vaccinated may use the Novavax COVID-19 vaccine to complete a two-dose series; an additional dose may be needed for individuals who are immunocompromised. Previously vaccinated individuals, 18 years and older, who are not able or willing to receive an mRNA COVID-19 vaccine may be offered a Novavax dose.

4.

Note: Immunization with the **bivalent COVID-19 vaccine formulation** that was approved by Health Canada last fall, is still available. Pharmacists may refer to the COVID-19 Vaccine Guidance (see Appendix C and D on bivalent use and recommendations) for individuals who wish to receive a dose of this formulation.

Recommendations for Moderately to Severely Immunocompromised Individuals

Individuals who are moderately to severely immunocompromised who have been **previously vaccinated are strongly recommended to receive an XBB.1.5 COVID-19 vaccine this fall** if it has been 6 months[5] since their previous dose or confirmed SARS-CoV2 infection. Moderately to severely immunocompromised individuals, **6 months to 4 years, who have not been previously vaccinated or who may need to restart the vaccination series, should receive the 2-dose schedule** as outlined in Table 1. **Those 5 years and older who are moderately to severely immunocompromised should receive one dose of the XBB.1.5 COVID-19 vaccine** (Table 1). NACI guidance on whether an additional dose is recommended for these populations in the context of the newly authorized schedules for the Moderna XBB.1.5 product is pending.The ministry will update this guidance for this population once further NACI recommendations are released.

Refer to the COVID-19 Vaccine Guidance for more information on moderately to severely immunocompromised populations as well as recommendations regarding re-vaccination with a new COVID-19 vaccine series post transplantation.

Staying Up to Date:

- Individuals 6 months and older are considered up to date with their COVID-19 vaccines if they have received a Fall 2023 COVID-19 dose.

Refer to the Qs+As for information on Co-Administration of vaccines

Summary Table[3] - COVID-19 Vaccines Individual Eligibility Criteria

Table 1: Individuals who have previously received a COVID-19 vaccine

Age	Vaccine Product	Recommended Vaccine Dosing[4] for Immunocompetent & Immunocompromised Individuals
6 months to 4 years	Moderna **Spikevax *XBB. 1.5* 0.1mg/mL (25mcg/0.25mL dose)** Royal blue cap / coral blue label (DIN 02541270)	1 dose, six months (168 days) after last dose or confirmed SARS-CoV-2 infection
5 to 11 years	Moderna **Spikevax *XBB. 1.5* 0.1mg/mL (25mcg/0.25mL dose)** Royal blue cap / coral blue label (DIN 02541270) Pfizer-BioNTech **Comirnaty *Bivalent (BA. 4/5) 0.05mg/mL*** (10mcg/0.2mL dose) orange cap / orange label (DIN 02533197) **DILUTE** Moderna **Spikevax *Bivalent (BA. 4/5)* 0.1mg/mL** (25mcg/0.25mL) blue cap / grey label (DIN 02532352)	1 dose, six months (168 days) after last dose or confirmed SARS-CoV-2 infection

[3] For more information on COVID-19 vaccines refer to the ministry's most recent COVID-19 Vaccine Guidance.
[4] For more information on recommended and minimum intervals between doses refer to the ministry's most recent COVID-19 Vaccine Guidance.

12 years and older	Moderna **Spikevax *XBB. 1.5* 0.1mg/mL (50mcg/0.5mLdose)** Royal blue cap / coral blue label (DIN 02541270) Pfizer-BioNTech **Comirnaty *Bivalent* 0.1mg/mL** (30mcg/0.3mLdose) grey cap / grey label (DIN 02531461) Moderna **Spikevax *Bivalent* (BA.4/5) 0.1mg/mL** (50mcg/0.5mL dose) blue cap / grey label (DIN 02532352)	1 dose, six months (168 days) after last dose or confirmed SARS-CoV-2 infection
	Novavax **Nuvaxovid** (see Note 1) 5 mcg/0.5mL dose (DIN 02525364)	For those not able or willing to receive a Pfizer-BioNTech or Moderna vaccine. Note: A new XBB formulation is expected later this fall

Table 2: Individuals who have NOT previously received COVID-19 vaccine or those who are candidates for re-vaccination

Age	Vaccine Product	Recommended Vaccine Dosing[5]
6 months to 4 years	Moderna **Spikevax *XBB. 1.5* 0.1mg/mL** (25mcg/0.25mL dose) Royal blue cap / coral blue label (DIN 02541270)	Immunocompetent Moderna XBB 1.5 2 doses, 56 days apart Moderna Bivalent 2 doses, 56 days apart

[5] For more information on recommended and minimum intervals between doses refer to the ministry's most recent COVID-19 Vaccine Guidance.

Age	Vaccine Product	Recommended Vaccine Dosing[5]
	Moderna **Spikevax** ***Bivalent (BA. 4/5)*** **0.1mg/mL** (25mcg/0.25mL dose) blue cap / grey label (DIN 02532352) Moderna **Spikevax 0.1mg/mL** (25mcg/0.25mL dose) blue cap / purple label (DIN 02527685)	Immunocompromised Moderna XBB 1.5 2 doses, 56 days apart. Note: Further recommendations for immunocompromised are pending from NACI Moderna Bivalent 3 doses, 56 days apart
5 to 11 years	Moderna **Spikevax** ***XBB. 1.5*** **0.1mg/mL** **(25mcg/0.25ml dose)** Royal blue cap / coral blue label (DIN 02541270) Pfizer-BioNTech **Comirnaty** ***Bivalent (BA. 4/5) 0.05mg/mL*** (10mcg/0.2mL dose) orange cap / orange label (DIN 02533197) * *DILUTE** Moderna **Spikevax** ***Bivalent (BA. 4/5)*** **0.1mg/mL** (25mcg/0.25mL dose) blue cap / grey label (DIN 02532352) Moderna **Spikevax** **0.1mg/mL** (50mcg/0.5mL dose) blue cap / purple label (DIN 02527685)	Immunocompetent Moderna XBB.1.5 1 dose schedule Pfizer / Moderna Bivalent 2 doses, 56 days apart Immunocompromised Moderna XBB.1.5 1 dose schedule Note: Further recommendations for immunocompromised are pending from NACI Pfizer / Moderna Bivalent 3 doses, 56 days apart

Age	Vaccine Product	Recommended Vaccine Dosing[5]
12 years and older	Moderna **Spikevax XBB. 1.5 0.1mg/mL** (50mcg/0.5ml dose) Royal blue cap / coral blue label (DIN 02541270) Pfizer-BioNTech **Comirnaty *Bivalent* 0.1mg/mL** (30mcg/0.3mL dose) grey cap / grey label (DIN 02531461) Moderna **Spikevax *Bivalent (BA. 4/5)* 0.1mg/mL** (50mcg/0.5mL dose) blue cap / grey label (DIN 02532352)	Immunocompetent Moderna XBB.1.5 (50 mcg) 1 dose schedule Pfizer / Moderna Bivalent 2 doses, 56 days apart Immunocompromised Moderna XBB.1.5 1 dose schedule Note: Further recommendations for immunocompromised are pending from NACI Pfizer / Moderna Bivalent 3 doses, 56 days apart
	Novavax **Nuvaxovid** (see Note 1) 5 mcg/0.5mL dose (DIN 02525364)	2 doses, 56 days apart For those not able or willing to receive a Pfizer-BioNTech or Moderna vaccine. Note: A new XBB formulation is expected later this fall.

Note 1:
There is limited supply of Novavax vaccines. Contact your local public health unit to determine how individuals who are not able or willing to receive an mRNA COVID-19 vaccine may receive this vaccine. The safety and efficacy of Novavax vaccines for immunocompromised individuals due to disease or treatment have not been established. As such, individuals who choose to be immunized with Novavax vaccines should be informed that there is currently limited evidence of the safety and efficacy of these vaccines in this population. Clinicians should use clinical discretion to offer an additional dose for an extended primary series with Novavax to immunocompromised individuals. For additional

information, refer to the ministry COVID-19 Vaccine Guidance.

Claims for Payment

- There is no cost to eligible patients who receive the COVID-19 vaccine when administered at a pharmacy.
- For each valid claim submitted, a pharmacy will receive $13.00 as payment for providing the following services:
    - Providing the patient with details of the process and answering any questions related to the vaccination.
    - Obtaining the consent of the patient or their substitute decision-maker prior to vaccine administration
    - Administering the COVID-19 vaccine.
    - Providing the patient with proper monitoring and written vaccine information as well as after-care instructions following vaccine administration.
    - Providing the patient with a written receipt of the vaccination with the pharmacy contact information **after** the vaccine is administered (see Pharmacy Documentation Requirements section below); a pharmacy may wish to issue an electronic receipt as well. (Note: a written receipt can be printed from COVAX$_{ON}$).
    - Complying with any requirements to access and use the Provincial COVID-19 Vaccine Solution-COVAX$_{ON}$ under the COVID-19 Vaccine Agreement.
- Pharmacies may access personal protective equipment (PPE) from the ministry's dedicated supply, if needed, to administer the COVID-19 vaccine. The ministry's supply of PPE must ONLY be used to support the activity of pharmacies administering the publicly funded COVID-19 vaccine.
- The table above lists the publicly funded COVID-19 vaccines that are available to pharmacies and are billable, including any restrictions on administering the vaccine (e.g., age groups).

Exclusions and Restrictions

- If a patient does not have a valid Ontario health card number, pharmacy staff can still administer the publicly funded COVID-19 vaccine, provided that the patient provides an alternate identification confirming their name and date of birth. In such cases, pharmacies must use the proxy patient ID: 79999 999 93.

- Administration of non-publicly funded COVID-19 vaccines that are privately purchased by the pharmacy does not qualify for payment.
- Vaccine administration must occur at the location of the participating pharmacy premises, unless otherwise indicated. The pharmacy is permitted to administer publicly funded vaccines supplied by their distributor in a nearby location (e.g., an adjacent pharmacy parking lot) and retirement homes, elderly congregate settings, long-term care homes, or mobile clinic locations as long as they are able to ensure adherence 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. See the most recent version of the accompanying FAQs for more information.
- The role of pharmacists, pharmacy students, interns or pharmacy technicians administering the COVID-19 vaccine in initiatives led by other authorized organizations that have entered into COVID-19 Vaccine Agreements with the Ministry (e.g., public health units or hospitals that organize mass immunization clinics) that are not billed through the HNS is excluded from this notice.
- A pharmacist's recommendation to a prescriber that a patient should receive a COVID-19 vaccine is not a billable service under the Pharmaceutical Opinion Program.

Billing Procedures – Summary

- Claims for administering the publicly funded COVID-19 vaccine can only be submitted electronically using the HNS (see "Billing Procedures - Detailed" below). No manual paper claims will be accepted unless 3 intervention codes are required in order to process the claim.
- The Part A pharmacist who administers the vaccine or who is overseeing other pharmacy staff administering the vaccine must be identified in the prescriber field on the claim. Each claim must include the Drug Identification Number (DIN) corresponding to the publicly funded COVID-19 vaccine that was administered to the eligible individual (see Summary Table).
- The person submitting the claim must ensure that the eligible individual's date of birth, Ontario health number and name (as it appears on the health card / document) are included in the claim. Failure to do so – especially for non-Ontario Drug Benefit (ODB) Program recipients – may impact the ability to submit future claims for these individuals.

- **For eligible individuals without an Ontario health number, pharmacies must use the proxy patient ID: 79999 999 93 (see below for further details).**

Billing Procedures – Detailed

The claim submission follows the usual process (See Section 5.1 of the Ontario Drug Program Reference Manual) for submitting claims in the HNS with the following additional information:

Fields required for all claims for pharmacist administered COVID-19 vaccines

ODB recipients and non-ODB recipients

- Intervention code 'PS': (Professional Care Services)
- Drug Identification Number (DIN): as per the publicly funded COVID-19 vaccine administered (see table above)
- Valid Pharmacist ID
- Professional fee: $13.00

Additional fields required for non-ODB recipients with an Ontario health number

When submitting a claim for an eligible individual who does not have ODB coverage, submit the following additional information:

- Patient Gender: 'F' = female; 'M' = male
- Patient Date of Birth: Valid YYYYMMDD
- Patient's Ontario Health 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

Additional fields required for non-ODB recipients without an Ontario health number

When submitting a claim for an eligible individual who does not have an Ontario health number, submit the following additional 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

Payment for epinephrine auto-injector for emergency treatment after administration of the COVID-19 vaccine

If there is an adverse event resulting immediately after pharmacy staff administers a publicly funded COVID-19 vaccine, the ministry will reimburse pharmacies for the acquisition cost of the epinephrine auto-injector up to the total amount reimbursed.

Emergency treatment must take place in the pharmacy or where the vaccine was administered, for example an adjacent pharmacy parking lot, retirement home, long-term care home, other congregate setting, or mobile clinic location, if applicable.

The claim submission process is the same as the one followed for the publicly funded UIIP. Refer to Section 6.15 of the Ontario Drug Program Reference Manual for billing information.

Pharmacy Documentation Requirements

Pharmacies must keep a record of every dose of publicly funded COVID-19 vaccine administered.

Pharmacists shall keep records consistent with their obligations under the *Pharmacy Act, 1991*, the *Drug and Pharmacies Regulation Act*, the COVID-19 Vaccine Agreement, and any instructions or guidelines provided by the OCP or the ministry.

For purposes of post-payment verification, pharmacy records related to claims for administering a publicly funded COVID-19 vaccine must be maintained in a readily available format for the purpose of ministry inspection for a minimum of 10 years from the last recorded 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.

Overpayments due to inappropriate claim submissions are subject to recovery.

Pharmacy documentation must be maintained in a readily retrievable format and record requirements are:

- Record of name and address of patient.
- Record of patient's Ontario health number or alternate ID with contact information if applicable.
- 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 (inside pharmacy, pharmacy parking lot or within the retirement home, elderly congregate setting, long-term care home or location of a mobile clinic if applicable)
- Evidence of the provision of a written and electronic (if applicable) record (post administration) 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 of any serious adverse events following immunization that result in the administration of epinephrine, and the circumstances relating to the administration of the substance.
- 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.

Prior EO Notices

Updates relating to this Executive Officer Notice were, prior to April 6, 2023, communicated as two (2) separate EO Notices (Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Eligibility**; Administration of the Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – **Billing**) on the effective dates listed below.

EO Notices in 2023				
March 6	April 6	July 7	**September 26**	
EO Notices in 2022				
January 13	April 7	July 28	September 12	November 8
February 18	May 2	August 8	September 26	December 21
March 25	July 14	September 1	October 17	
EO Notices in 2021				
March 10	May 11	June 4	September 1	December 2
March 22	May 13	June 14	September 8	December 17
April 1	May 18	June 17	October 1	December 20
April 19	May 21	June 25	October 8	
April 30	May 23	July 5	November 3	
May 6	May 31	August 18	November 25	

Additional Information:

For pharmacy billing:

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

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.