



## **Rhode Island Department of Health Pharmacy Standing Order**

**Effective September 12, 2025**

### **Off Label Administration of COVID-19 Vaccines at Rhode Island Pharmacies**

#### **Purpose/Background:**

In August 2025, the Food and Drug Administration (FDA) authorized the 2025-2026 COVID-19 vaccines, but limited their use to people aged 65 and older and others at high risk for serious illness from COVID-19. This authorization is narrower than the recommendation from the Centers for Disease Control and Prevention (CDC) for the 2024-2025 COVID-19 vaccine, and it is narrower than the recommendations issued by several established medical organizations for the 2025-2026 COVID-19 vaccine. These medical organizations include the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), and/or the American College of Physicians (ACP).

Rhode Island law establishes the Rhode Island Department of Health (RIDOH) as the sole authority to make vaccine recommendations to Rhode Islanders (R.I. Gen. Laws § 23-1-18). Reference is also made to H5427 Sub A and S166 Sub B, an amendment to R.I. Gen. Laws § 5-19.1-3, signed into law by Governor McKee on July 2, 2025. This Act authorizes pharmacies to administer COVID-19 immunization to individuals between the ages of three (3) years and eighteen (18) years, inclusive.

RIDOH remains fully committed to providing safe and appropriate immunization recommendations and vaccines to Rhode Islanders. To ensure access to the COVID-19 vaccine, I am issuing the following “off-label” Standing Order. This Standing Order authorizes Rhode Island Pharmacies/Qualified Immunizing Pharmacists and Qualified Level II Technicians to administer the COVID-19 vaccine “off-label.” This standing order is consistent with the recommendations of the AAP, AAFP, ACOG, and the ACP. AAP recommends COVID-19 vaccination for all children ages 6-23 months and for high-risk children through 18 years; as well as for those 2 through 18 whose parent/guardian desires their protection. AAFP recommends COVID-19 vaccination for those 18 and older. ACOG recommends COVID-19 vaccination for all pregnant women.

Pharmacists are some of the most accessible healthcare practitioners, uniquely positioned to help support public health initiatives and assist in addressing public health issues. In addition to the

many services pharmacists provide, the administration of vaccines has benefited public health. Under Rhode Island law, qualified pharmacists, pharmacy interns, and certified pharmacy technicians (Technician II) can administer vaccines. 216 RICR 40-15-1.11

### **Immunizing Pharmacist(s) Qualifications**

Pharmacist(s) shall possess an active Rhode Island pharmacist(s) license in good standing and be qualified and trained as qualified to administer vaccines pursuant to 216 RICR 40-15-1.11. Pharmacists who are qualified to administer vaccines shall also adhere to best practices set forth by their employers.

### **Prescriber of Record for Statewide Standing Order**

As the Director of the Rhode Island Department of Health, I serve as the prescribing physician and authorize the “off label” use of COVID-19 vaccines for Rhode Islanders ages 3 and over.

### **Pharmacy visits**

The general Rhode Island public may visit a participating pharmacy on a walk-in or appointment basis (as determined by participating pharmacies) to receive the off-label administration of COVID-19 vaccinations. Prior to receiving the vaccination, customers must adhere to the participating pharmacy’s practices.

### **Sites and Settings**

All Rhode Island pharmacies willing and qualified to participate.

### **Scope of disease(s) managed**

Mitigation of effects of COVID-19.

### **Protocol**

The general Rhode Island public may visit a participating pharmacy on a walk-in or appointment basis to receive COVID-19 vaccines. Prior to purchasing the vaccines, customers shall provide all requisite contact and insurance/payor information.

Vaccinating Pharmacists/Technician Dispensing and Administration of COVID-19 Vaccine:  
2025-2026

#### **Procedure**

- 1) Assess for Need/Eligibility of Vaccination.
- 2) Screen for Contraindications and Precautions.  
Contraindications:
  - A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the COVID-19 vaccine or to a component of the COVID-19 vaccine

Precautions:

- A diagnosed non-severe allergy to a component of the COVID-19 vaccine.
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of one COVID-19 vaccine type, if receiving the same vaccine type.
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine.
- Moderate to severe acute illness, with or without fever.

3) Provide Vaccine Information Statements.

4) Prepare to Administer Vaccine.

- Verify that the label on the vaccine states 2025-2026 Formula.
- Choose the needle gauge, needle length, and injection site.

5) Administer COVID-19 Vaccine

**For intramuscular administration**

- MNEXSPIKE (COVID-19 Vaccine, mRNA) injectable suspension, 2025-2026 Formula  
Dispense single 0.2 mL dose for:
  - Individuals 12 years of age and older
  - For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of MNEXSPIKE at least 3 months after the last dose of COVID-19 vaccine

Directions for use: Administer MNEXSPIKE as a single 0.2 mL dose

**OR**

- SPIKEVAX (COVID-19 Vaccine, mRNA) injectable suspension, 2025-2026 Formula
  - a. Individuals 6 months of age through 11 years of age  
Dispense single 0.25 mL dose, irrespective of COVID-19 vaccination status.
    - For individuals previously vaccinated with any COVID-19 vaccine, administer the dose  $\geq 2$  months after the last dose of COVID-19 vaccine

Direction for use: Administer SPIKEVAX 0.25 mL dose

**OR**

- b. Individuals 12 years of age and older  
Dispense single 0.5 mL dose, irrespective of COVID-19 vaccination status.
  - For individuals previously vaccinated with any COVID-19 vaccine, administer the dose  $\geq 2$  months after the last dose of COVID-19 vaccine

Direction for use: Administer SPIKEVAX 0.5 mL dose

**OR**

- COMIRNATY (COVID-19 Vaccine, mRNA) injectable suspension, 2025-2026 Formula
  - a. Individuals 5 years of age through 11 years of age  
Dispense single 0.3 mL dose supplied in vials with blue caps and labeled with blue borders

- For individuals previously vaccinated with any COVID-19 vaccine, administer the dose at least 2 months after the last dose of COVID-19 vaccine

Directions for use: Administer COMIRNATY as a single 0.3 mL dose

**OR**

- b. Individuals 12 years of age and older  
Dispense single 0.3 mL dose supplied in prefilled syringes labeled with gray borders
  - For individuals previously vaccinated with any COVID-19 vaccine, administer the dose at least 2 months after the last dose of COVID-19 vaccine

Direction for use: Administer COMIRNATY as a single 0.3 mL dose

**OR**

- NUVAXOVID (COVID-19 Vaccine, Adjuvanted) injectable suspension, 2025-2026 Formula

Dispense single 0.5 mL dose for:

- Individuals 12 years of age and older
  - For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of NUVAXOVID at least 2 months after the last dose of COVID-19 vaccine

Directions for use: Administer NUVAXOVID as a single 0.5 mL dose

- 6) Document the Vaccination.
- 7) Be Prepared to Manage Medical Emergencies.
- 8) Report Adverse Events to the Vaccine Adverse Event Reporting System (VAERS).

**Physician's Name and RI License No.** (print legibly): Jerome Larkin, MD; 11946

Authorized Signature of Physician



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Jerome Larkin, MD, MPH

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September 12, 2025

DATE