

PEDIATRIC COVID VACCINES



Ages 5-11 years

Disclaimer: The following information was compiled from the Pfizer training webinars prior to product release. This information is subject to change and you should stay up-to-date with the most recent CDC guidelines.

Authorized for Emergency Use

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. The emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Source: covidvaccine-us.com

[EUA Fact Sheet for Providers](#)



[EUA Fact Sheet for Recipients and Caregivers](#)

Reminder that caregivers should be provided the vaccine information prior to immunization and should be offered the information to take home. The 5-11 y/o vaccine has a different EUA Fact Sheet.

NDC and CPT Codes

Cap	Vaccine Code	Vaccine Administration Code(s)	NDC 10/NDC 11 Labeler Product ID (Vial)
Purple (Ages 12+)	91300	0001A (1st Dose) 0002A (2nd Dose) 0003A (Third Dose for Immunocompromised) 0004A (Booster Dose)	59267-1000-1 59267-1000-01
Orange (Ages 5 through 11)	91307	0071A (1 st Dose) 0072A (2 nd Dose)	59267-1055-1

Pfizer Vaccine Characteristics

Vial Cap & Label Border Colors	PURPLE 	ORANGE 
Description	<i>Dilute Before Use</i>	<i>Dilute Before Use</i>
Age Group	12 years and older	5 through 11 years
Dose	30 mcg	10 mcg
Dose Volume	0.3 mL	0.2 mL
Amount of Diluent* Needed per Vial	1.8 mL	1.3 mL
Doses per Vial	6 doses per vial (after dilution)	10 doses per vial (after dilution)
Storage Conditions		
ULTFreezer (-90°C to -60°C)	9 months**	6 months***
Freezer (-25°C to -15°C)	2 weeks	DO NOT STORE
Refrigerator (2°C to 8°C)	1 month	10 weeks
Room Temperature (8°C to 25°C)	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture
After First Puncture (2°C to 25°C)	Discard after 6 hours	Discard after 12 hours

The purple cap vaccine can NOT be used to provide a dose to a child 5 through 11 years of age.

Product Packaging Overview

Pack Size Overview

10-pack, 25-pack, and 195-pack carton thermal shipping containers store the vaccine at -90°C to -60°C

Applicable to the following cap colors:
PURPLE (Ages 12+)
ORANGE (Ages 5 thru 11)

10-PACK CARTON



The Single-Use Thermal Shipping Container **cannot** be used for temporary storage.

The single use shipper should be disposed of after unpacking the vaccine. However, the **Controlant monitor will need to be returned**.

25-PACK CARTON



Thermal shipping container **should not** be used as temporary storage for 25-pack carton.

Thermal shipping container included with the 25-pack cartons should be returned within 10 days of delivery.

195-PACK CARTON



If an ultra-low temperature freezer is not available for the 195-pack cartons, the thermal container may be used as **temporary** storage for up to 30 days from delivery when consistently refilled to the top of the container with dry ice.

Note: The Orange top vaccine can only be stored in a Ultra-cold freezer (-90 to -60 C) or the refrigerator (2-8 C) for up to 10 weeks. It is not to be stored in a regular freezer. The single use shipper can not be used for storage, but the medium 195-pack carton can be used if consistently replenished with dry ice. Once the vial has been thawed, do not refreeze.

Process Overview:

Receipt of Single-use Thermal Shipping Container

Applicable to the following cap colors:

ORANGE (Ages 5 thru 11)

1. Receive Shipment & Open Container



- Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation.
- Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, resulting in asphyxiation.
- Use caution when lifting the shipping container, as it may be heavy. Depending on the amount of vaccine ordered, the shipping container can weigh approximately 15 kg.
- Do not place anything on top of the thermal shipping container.
- In a well-ventilated area, open the Outer Corrugated Shipper by cutting the tape on the outside.

2. Stop Shipment Temperature Monitoring



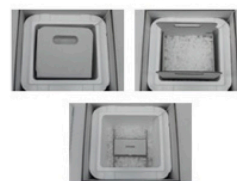
- When you open the thermal shipping container, you will see a temperature monitoring device embedded in the foam lid. The temperature monitoring device continuously tracks the temperature during shipment to ensure the frozen vaccine product has been maintained at the required temperatures during transport.
- Press and hold the stop button for 5 seconds on the Controlant Monitor.
- Once stop button is pressed, Pfizer is no longer monitoring the product
- The Controlant monitor will need to be removed from the container because it must be returned.

3. Determine if Product has had a Temperature Excursion



- If the Shipment Status LED blinks **green**, this indicates there was no temperature deviation outside of pre-defined limits
- If the Shipment Status LED blinks **red**, this means the product may be affected by temperature excursions. Do not use the product until you have received further information from Controlant advising on further use
- A shipment quality report email will be sent. This report will indicate whether there was a temperature excursion or not and further instructions

4. Remove the Foam Lid and Remove Dry Ice Pod



- Remove the foam lid.
- Note: Take caution when opening the thermal shipping containers.
- Once the foam lid is removed the dry ice pod will be seen as illustrated above.
- While wearing insulated (thermal) gloves, take out the Dry Ice Pod. There will also be dry ice in compartments in the container that surround the box that holds the product cartons.

5. Open Box That Holds The Product Cartons And Remove Product Cartons



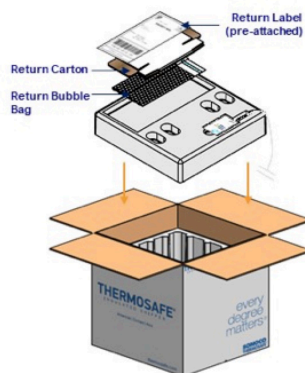
- Open the box that holds the product cartons and remove the bag containing the product cartons.
- Carefully remove the product cartons.
- Leave the box containing the cartons inside the thermal shipping container when accessing or removing the product cartons.

Single-Use Shipper Logger Return Process*

Applicable to the following cap colors:

ORANGE
(Ages 5 thru 11)

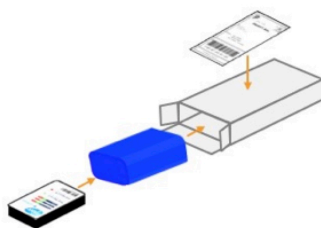
1. Sites will receive vaccines in Single-Use Shipper with Logger Return Kit embedded within lid of shipper



2. Site removes Logger from thermal shipper and places it inside of Bubble Bag

Site place Bubble Bag into Return Carton

Return Label applied to Return Carton (or may come pre-attached)



**Single-Use Thermal Shipper will not be returned, solely the Logger*

3. Logger Return Carton collected at site or dropped off for return to Controlant Service Center



**FedEx
UPS
United States Postal Office**

Ancillary Kits are similar to purple top kits except they contain 25G x 1" needles for vaccinating children. Note the diluent vial is the same for both the purple and orange cap vials but the volumes are different. The remaining volume should be discarded after use.

General Conditions for Storage



During storage, **minimize exposure to room light**. Avoid exposure to direct sunlight and ultraviolet light



Vials are glass and **should be handled with care**



Vials should always remain **upright in cartons** during storage



Do not touch frozen vials until there is a need to remove them from the carton for use or transfer



Product should be **retained in the original vial cartons** until ready for use



Protective gloves allowing manual dexterity should be worn while handling frozen vials

Potential Transportation Options

Applicable to the following cap colors:
ORANGE
 (Ages 5 thru 11)

If local redistribution is needed, undiluted Orange Cap vials may be transported



Individual vials or full cartons at **refrigeration temperature**

2°C to 8°C

OR



Individual vials or full cartons at **ultra cold temperature**

-90°C to -60°C

- Do not re-freeze thawed vials
- If vials are delivered at 2°C to 8°C, vaccine needs to stay at 2°C to 8°C.
- Check that the carton has been updated to reflect the 10-week refrigerated expiry date.

If local redistribution is used, ensure there is one vial of diluent (sterile 0.9% Sodium Chloride Injection, USP) for each vial of the vaccine and ancillary supplies.

For Orange Caps

Once removed from shipper, if transferring orange vial cartons to a ULT freezer, unopened cartons may be at room temperature (< 25°C) for up to 5 minutes.

Disposal of Vaccine Vials and Packaging

Applicable to the following cap colors:
PURPLE | **ORANGE**
 (Ages 12+) | (Ages 5 thru 11)

Vulnerability is greatest at point-of-use



- Vaccination sites play a critical role during and after injection
- Ensure the safety of the vaccine vials by limiting access to authorized personnel only and by locking the storage location
- After the vials have been used, and before disposal, continue to treat empty vials as if they were still full to minimize the risk of unauthorized access

Disposal



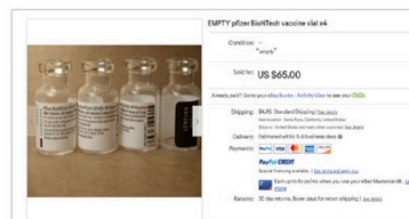
Vials:

- **Option 1 (Preferred Method):** Treat vial disposal as medical waste disposal, and place in red sharps container
- **Option 2:** Deface or safely crush vials so they cannot be reintroduced or reproduced

Vial Cartons:

- Deface or safely crush vial cartons so they cannot be reintroduced or reproduced. After the vial cartons are sufficiently defaced, dispose with regular waste

Sale of used vials for criminal purposes is in violation of federal or state laws



Empty vaccine vials sold on eBay (USA)

Safe disposal of empty vials protects patient safety

Dilution



- The vaccine **does not contain preservative** and is provided as a **multiple dose vial**
- The vaccine **must be diluted with sterile 0.9% Sodium Chloride Injection, USP** before administering the vaccine.
 - ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent.
 - Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- After dilution with 1.3 mL of 0.9% Sodium Chloride Injection, USP **the vial contains 10 doses of 0.2 mL (10 mcg)**
 - Do not add more than 1.3 mL of diluent

IMPORTANT: regardless of the volume of the diluent vial, it must be used for **ONE TIME** dilution (after 1.3mL withdrawal, the remaining diluent must be discarded)

Storage and Timing Considerations



- **Undiluted** orange cap vaccine may be stored at room temperature (8°C to 25 °C) for a total of **12 hours prior to dilution**.
- **Diluted** vials should be stored between **2°C to 25°C** (35°F to 77°F)
- Any vaccine remaining in vials (or syringes) **should be discarded 12 hours after dilution***
- During storage, **minimize exposure to room light**, and avoid exposure to **direct sunlight and ultraviolet light**

*Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (5 through 11 years of age) supersedes the number of hours printed on vial labels and cartons

Do not freeze

Dose Preparation

Supplies needed per vial

- **1 Vial 0.9% Sodium Chloride Injection, USP**
- Other materials such as alcohol swabs, gloves, PPE



*Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Bacteriostatic saline or other diluents must NOT be used.

For diluent withdrawal and mixing

- **ONE 3 mL syringe** (optimal size) or 5 mL syringe to withdraw:
 - **Orange:** 1.3 mL of 0.9% Sodium Chloride Injection, USP from each diluent vial
- **ONE 21 gauge or narrower needle** should be used to withdraw the diluent. Use the same needle to add the diluent to the vial.



For vaccine administration (intramuscular injection)

- **TEN 1mL syringes**
- **TEN 25-gauge needles** for intramuscular injection
 - Needle lengths appropriate for varied body sizes – 5/8", 1", 1 1/2"



Preparation Instructions



✓ Orange plastic cap and label with orange border.

- Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states "Age 5y to < 12y."
- Vaccine intended for individuals ages 12 years and older should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.



Store in the refrigerator for up to 10 weeks prior to use.

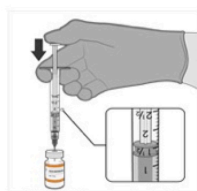
Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:

- Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)].
 - A carton of 10 vials may take up to 4 hours to thaw.
 - Thawed vials can be stored in the refrigerator for up to 10 weeks.
- Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.



Gently × 10

- Before dilution, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.



Add 1.3 mL of sterile 0.9% sodium chloride injection, USP

- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.



Use within 12 hours after dilution.

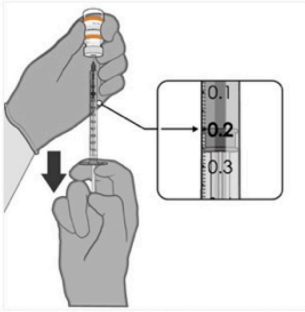
- Record the date and time of first vial puncture on the vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine **12 hours* after dilution.**

*Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in the EUA Fact Sheet (5 through 11 years of age) supersedes the number of hours printed on vial labels and cartons

Preparation of Individual 0.2mL Doses for Administration

Applicable to the following cap colors:
ORANGE
(Ages 5 thru 11)

REMINDER: Prior to withdrawing each dose, check the vaccine vial label for recorded dilution date and time to ensure the vaccine has been diluted and that vial has not reached the **12-hour post-dilution*** expiration



Withdraw 0.2 mL dose of vaccine.

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be a white to off-white suspension. During the visual inspection:
 - Verify the final dosing volume of 0.2 mL
 - Confirm there are no particulates and that no discoloration is observed.
 - Do not administer if vaccine is discolored or contains particulate matter.
- Administer immediately.

**How to
Administer IM
and SC**

Second doses should be given at least 3 weeks after the first. Be sure to tell parents the 2nd dose is important for full immunity and to schedule their 2nd dose appointment. Question: if a child turns 12 before their second dose, you have the choice to give either the orange or purple top vaccine. Dosing is only based on age not weight.

Important Safety and Other Considerations

- Do not administer to individuals with known history of a severe allergic reaction (anaphylaxis) to any component of the vaccine.
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event of an acute anaphylactic reaction occurs following administration of the vaccine.
- Monitor vaccine recipients for the occurrence of immediate adverse reactions according to the CDC guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).
- Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose.
- Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.
- The vaccine may not protect all vaccine recipients.
- Before administration of the vaccine, please see the full Prescribing Information and EUA fact sheets for vaccination providers linked on the front page of this document.

Adverse Reactions in Clinical Trials

Applicable to the following cap colors:

PURPLE (Ages 12+)

ORANGE (Ages 5 thru 11)

Primary Series Adverse Events

- In clinical studies (30 mcg modRNA) of participants **16 through 55 years of age**, the most commonly reported adverse reactions ($\geq 10\%$) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).
- In clinical studies (30 mcg modRNA) of participants **56 years of age and older**, the most commonly reported adverse reactions ($\geq 10\%$) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).
- In a clinical study (30 mcg modRNA) of adolescents **12 through 15 years of age** adverse reactions following the administration of the primary series, included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).
- In a clinical study (10 mcg modRNA) in children **5 through 11 years of age**, adverse reactions following administration of any primary series dose included pain at the injection site (84.3%), fatigue (51.7%), headache (38.2%), injection site redness (26.4%), injection site swelling (20.4%), muscle pain (17.5%), chills (12.4%), fever (8.3%), joint pain (7.6%), lymphadenopathy (0.9%), nausea (0.4%), rash (0.3%), malaise (0.1%), and decreased appetite (0.1%).

Booster Dose Adverse Events

- In a clinical study (30 mcg modRNA) of participants **18 through 55 years of age**, adverse reactions following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%).

Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS online at <https://vaers.hhs.gov/reportevent.html>

US Customer Service Information

General Product Inquiries



(877) 829 2619

8am – 11pm ET
7 days/week

Pfizer Medical Information



(800) 438 1985

www.PfizerMedInfo.com

8am – 8pm ET
5 days/week (M-F)
Subject to change

US Shipment Support



(800) 666 7248

8am – 8pm ET
5 days/week (M-F)

Controlant Customer Support



(701) 540 4039

24/7

McKesson Support



(833) 272 6634

SNSSupport@McKesson.com

7:30am – 7:30pm ET

US Customer Service Contact Information also available at www.cvdvaccine-us.com



Before administration of the vaccine, please see full Prescribing Information (16+ years of age) and EUA Fact Sheets for Vaccination Providers:

12+ years of age (DILUTE BEFORE USE/Purple Cap), 12+ years of age (DO NOT DILUTE/Gray Cap) and 5 through 11 years of age (DILUTE BEFORE USE/Orange Cap).

For the most recent prescribing information and fact sheets, please visit www.cvdvaccine-us.com

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines

In addition to information that may be found in the EUA Fact Sheet or Full Prescribing information, the CDC provides interim clinical guidance, which includes information regarding topics including but not limited to:

- Co-administration of COVID-19 vaccines with other vaccines
- Vaccination of people with prior or current SARS-CoV-2 infection
- Vaccination of people with certain underlying medical conditions
- Considerations involving pregnancy, lactation, and fertility
- Considerations for COVID-19 vaccination in moderately and severely immunocompromised people
- Considerations for use of a COVID-19 booster dose
- COVID-19 vaccine administration errors and deviations
- Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects



Check this site or the [MMWR](#) regularly for the most updated information

Visit <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html> for more information

Training for Vaccinating Pediatric Patients - optional

[Pharmacy-Based Immunizations for Pediatric Patients](#)

<https://www.pharmacist.com/Education/eLearning/Advanced-Training/Immunizations-for-Pediatric-Patients>

APhA Advanced Training Continuing Education (\$39 members/ \$59 non-members)

Program Description

Pharmacy-based Immunizations for Pediatric Patients is a two-hour, application-based learning activity. The program is designed to meet the needs of pharmacists and pharmacy technicians in states where the PREP Act allows for pharmacists and pharmacy technicians to administer vaccinations to children as young as 3 years of age. The program provides a thorough review of topics related to immunizing pediatric patients including parent and patient preparation, immunization administration techniques for children and documentation of pediatric vaccinations.

It is important to refer the children to receive their well-child visit with their pediatrician or primary care physician. A majority of Arkansas children are enrolled in Medicaid and get their vaccines provided by the Vaccines for Children program. We encourage more pharmacies to become enrolled as VFC providers, but it is not required for COVID-19 reimbursement under Medicaid.

Ordering Vaccine

To place your vaccine orders, contact the administrator in the Local Health Units

<https://www.healthy.arkansas.gov/health-units>

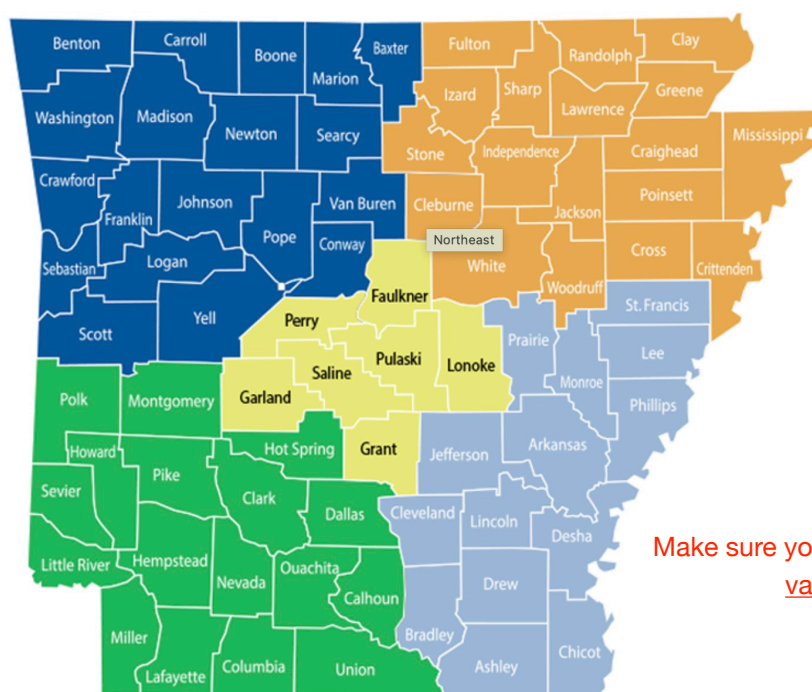
Include which vaccine, quantity and when it is needed.

HEALTH UNITS

**Due to COVID-19 each local health unit new operating hours are: 8:00 am – 4:30 pm Daily
Except Tuesdays, General Clinic on Tuesday 9:30 AM TO 6:00 PM.**

Click [here](#) for a list of Local Health Units that are partially or fully closed. All other health units not listed are fully open.
The list is subject to change on a day to day basis.

- [CLPH COVID-19 Testing Locations](#)



Make sure your location is listed on
vaccines.gov

Pfizer Pediatric COVID-19 Vaccine Distribution Plan

We are assured that there will be plenty of vaccine available in the state. You can contact other providers to see if they need to transfer inventory they are not able to fully utilize.

Thank you for your ongoing effort to fight this pandemic. You are saving lives!