

Pediatric Pfizer COVID-19 Vaccine Update

October 21, 2021

Agenda

- Providing Access
- Packaging/Vial Size
- Initial Allocation and Ordering
- Special Considerations
- New Pediatric Order Form Walk Through
- Q&A

Pediatric Pfizer Vaccines

- FDA VRBPAC Committee scheduled to meet on Pfizer 5-11 data on October 26th
- CDC's ACIP is then scheduled to meet November 2nd and 3rd
- **Initial pediatric vaccine deliveries will begin the week of November 1st**
- Providing as many COVID-19 pediatric providers as possible with vaccine is critical to achieving equitable vaccine access during product roll out
- Even if ordering a small amount of vaccine, avoiding missed opportunities is critical during vaccine roll out



Pediatric Pfizer: Packaging/Diluent

- The packaging configuration will be 10-dose vials in cartons of 10 vials each (**100 doses total**) pending FDA authorization
- The product will be delivered refrigerated (2 to 8°C) during these initial weeks, and should not be re-frozen
- Based on current information, its anticipated that once a vial is opened, doses must be used within 6 hours
- **COVID-19 pediatric vaccines will require diluent**
 - The diluent will be provided with ancillary supplies which are configured specifically for use in children. NOTE – reconstitution of the product for use on 5–11-year-olds uses a different volume of diluent than the adult formulation

Pediatric Pfizer Vials

Pfizer-BioNTech COVID-19 Vaccines

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Description	Current Adult/Adolescent Formulation (1170 and 450 packs)	Future Pediatric Formulation
	<i>Dilute Prior to Use</i>	<i>Dilute Prior to Use</i>
Age Group	12 years and older	5 to <12 years**
Vial Cap Color	PURPLE 	ORANGE 
Dose	30 mcg	10 mcg
Injection Volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 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		
ULT Freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

Q: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

Purple Cap – Adult/Adolescent: Authorized only for aged 12 years and older



Orange Cap – Pediatric: Future authorization for aged 5- to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.



Please note: the age limit is 5-11 years for the orange cap.

NOTE: Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS

**The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old

Pediatric Pfizer: Second Doses

- Pediatric Pfizer doses will not have an automatic second dose sent 3 weeks later, as occurred with initial adult vaccine allocation
- LA also does not know what our future allocation of pediatric vaccine will look like so providers should order enough doses to cover 1st and 2nd doses
- Ex. If you expect to vaccinate 100 individuals in the first 2-3 weeks of pediatric vaccine availability, you will need to submit an order for 200 doses of vaccine (100 for first doses, and 100 which you will store for 3 weeks for second doses)
- At this time, we expect pediatric Pfizer second doses to be due 3 weeks (or 21 days) after the first dose was administered

Pediatric Pfizer: Minimum Pre-Order

- *The minimum direct order size will be 300 doses for the first week and 100 doses in subsequent weeks*
- **LDH will not require this large of a minimum order – M& D will be filling all orders the first couple weeks**
- By shipping our entire initial allocation to M&D, we will continue our low and wide approach/allow providers to pre-order **as little as 20 doses of vaccine** (1 vial for first doses, 1 for second doses so 20 dose minimum order size)
- **“Pre-ordering” has begun this week in LINKS and will be open through 5:00 p.m. Wednesday, October 27**

The next 3 slides explain how the **vaccine will be delivered in minimum doses of 100** after the first wave of deliveries is completed. Vaccine will not be delivered like this initially to provider sites, as M & D will be repackaging all vaccine for refrigerated delivery during the first wave.

Pediatric Pfizer Shipping Container

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Tris/Sucrose* Formulation Packaging Overview

(Primary, Secondary, Tertiary)

Vial	10-Pack, 25-Pack	Thermal Shipper
 Pfizer-BioNTech Multi-dose vial	<p>10-Pack</p> <p>Single carton holds 10 vials</p>  <p>25-Pack</p> <p>Single carton holds 25 vials</p> <p><i>Phasing out product configuration end of 2021</i></p> 	<p>Single-Use Shipper</p> <ul style="list-style-type: none">• Real-time data monitoring• 10-packs and 25-packs• Return the logger, but not the box 

Note: M&D will be shipping all initial orders of pediatric COVID-19 vaccine so vaccine may arrive in a different shipper than below (particularly if you are ordering in quantities less than 100):

NOTE: The Pfizer-BioNTech COVID-19 Vaccine cap color, carton, and artwork will differ based on the manufacturing location, supplier, and/or indication. The images above are illustrative and shows the carton for the New COVID-19 Vaccine Ages 12+ Presentation for Q4 2021/2022. The estimated size of the plastic boxes are subject to change based on plant of manufacture.

*The new formulation name is under review and is subject to change.



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business secrets of Pfizer and BioNTech

MD From Megan Deming to Everyone

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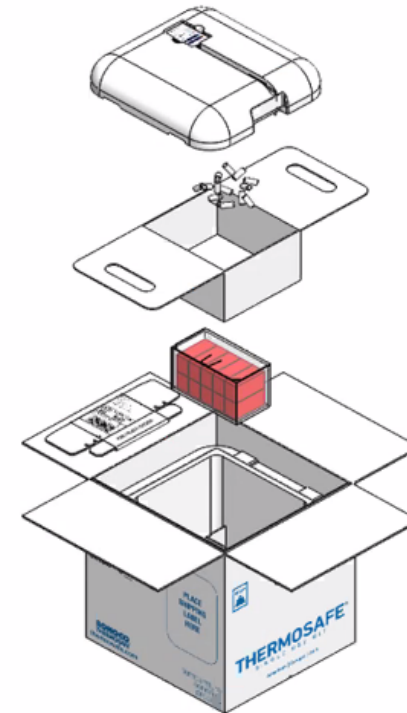
Pediatric Pfizer Shipping Container

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

New Single-Use Shipper

SINGLE-USE SHIPPER

Key Considerations*	
Controlant Logger/Monitoring	Real-time Data Monitoring
Pack Options	10-pack
Shipper Duration	3 Days
Shipper Return	Not Applicable – Destroyed per procedure
Controlant Logger Return	Returned without Shipper in provided return envelope
Thermal System	Dry Ice – 10kg
POU Considerations	<ul style="list-style-type: none">• Not Reusable• Not designed for on-site storage• Vials must be transferred to ULT or refrigerator upon receipt



Note: No vaccine is to be stored in these shipping containers as you are doing with current supply. These shippers are to be thrown away.

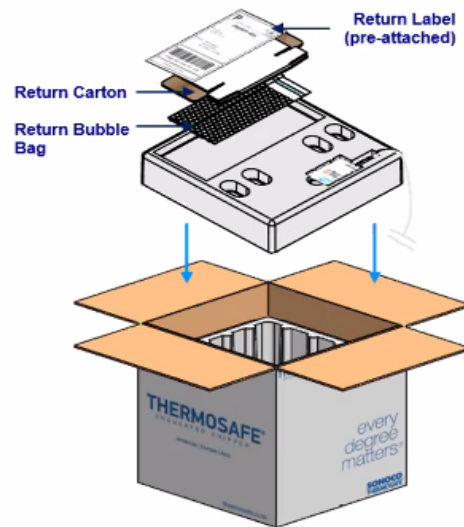
*Note: for pediatric doses, product should not be stored in single-use or medium ULT

Pediatric Pfizer Shipping Container

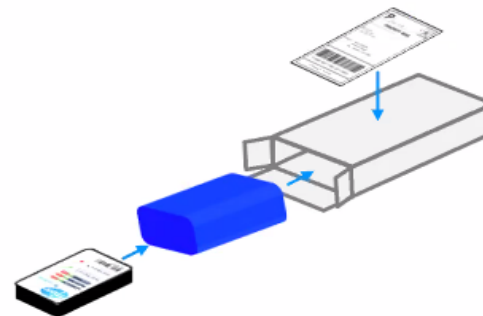
PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

Single-Use Shipper Logger Return Process*

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



- 2**
- POU removes Logger from thermal shipper and places it inside of Bubble Bag
 - POU places 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 POU or dropped off for return to Controlant Service Center



Note: Only the controlant temperature monitor is to be returned in a prepacked box that will be included.

Pediatric Pfizer Shipping Container



Note: real packages will have Orange-cap vials for age 5-11 vaccine. NOT grey cap vials. This is just a model picture of the 10-pack carton.

Pediatric Pfizer: Initial Allocation

- Federal Government currently has enough pediatric doses on hand for entire 5-11 US population, but doses will be allocated initially to prevent stockpiling/over ordering relative to demand
- Louisiana will receive an initial first week allocation of vaccine, split into three Waves (to avoid a strain on the federal supply chain)
- We will then receive a weekly allocation for at least the first 3 weeks

Pediatric Pfizer: Initial Allocation

- Please submit your initial order of vaccine through LINKS any time before **5:00 p.m. on Wednesday October 27th**
- Even though doses will not ship until later this month/early November, **all initial COVID-19 vaccine orders need to be submitted this week**
- Depending on the quantity of provider orders, and quantity of our state allocation, your order submission may be adjusted
- The Immunization Program will make every effort to ensure every provider who orders vaccine receives vaccine in this initial roll-out

Pediatric Pfizer: Initial Allocation

- Providers will be notified of their approved pediatric order quantity via email on 10/29, so they can begin any necessary planning
- Pending timely delivery from the federal government, vaccine deliveries will begin prior to ACIP/CDC recommendation
- Providers should prepare to receive and store doses early **but not begin administration** until full CDC and LDH authorization is given
- “Projected” pediatric vaccine administration start date is **Thursday November 4th**
- Reminder – do not set appointments until vaccines are physically received
- Deliveries involved in this initial pre-order wave of vaccines could arrive into the week of November 8

Pediatric Pfizer: Other Planning Considerations

- Holidays occurring in November and December.
- The PREP Act has expanded scope of practice for pharmacists and pharmacy technicians nationwide to allow for provision of COVID-19 and influenza vaccinations to children ≥ 3 years old

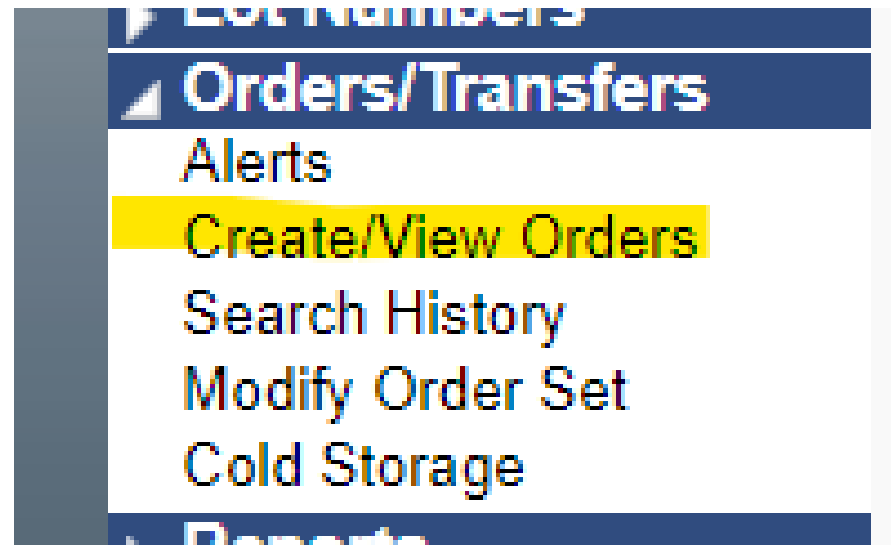
Pediatric Pfizer: Other Planning Considerations

- Pharmacies in the Federal Retail Pharmacy Program will be able to order vaccine to select pharmacy locations, increasing the # of locations children may get vaccinated
- To support increased logistics needed to push out large number of pediatric doses during the first week, no direct orders for Pfizer adult vaccine shipments (1170 product configuration) will be distributed during the pediatric product launch.
 - However, direct orders will be filled by M&D during this time/there should not be any delays to adult/adolescent vaccine distribution in Louisiana

Pediatric Pfizer COVID-19 Vaccine New LINKS Order Form Walkthrough

Ordering COVID Pediatric Vaccines Through LINKS

- Log in to LINKS
- Go to the navigation menu. Click **Orders/Transfers**, then click **Create/View Orders**.



Ordering COVID Pediatric Vaccines Through LINKS

- Click on **Create Order**. This will bring you to your reconciliation page.
- Before you can proceed you will need to reconcile your inventory. Once completed, click **Submit Monthly Inventory**.

Reconcile										
Vaccine	Number		Quantity on Hand	Physical Inventory	Adjustment (+/-)	Category	Reason	Funding Source	Inactive	Add Row
COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose (Covid-19 0.3 (Pfizer))	25256645	10/31/2021	10	<input type="text" value="10"/>	0.0	--No Category Required v	--No Reason Required-- v	PUB	<input type="checkbox"/>	<input type="button" value="+"/>
MMR	1234567	06/20/2022	10	<input type="text" value="10"/>	0.0	--No Category Required v	--No Reason Required-- v	PUB	<input type="checkbox"/>	<input type="button" value="+"/>

[Inventory Last Submitted: 10/19/2021](#)

Ordering COVID Pediatric Vaccines Through LINKS

- Once you submit your monthly inventory, your Create Order page will be visible.
- Select your *Order Set* (for this case will be COVID-19 Pediatric/Distributor). Enter the *Order Quantity* (For COVID-19 pediatric vaccine, the minimum is 10). Select the *Vaccine Name*.
- Click **Submit Order**.
- It will take you to the Order/Transfer List and show; ex **Order 529475 Successfully created and Pending State Approval**. You will know your order has been completed and is awaiting approval.

Create Order

Organization: TEST IRMS
Facility: TEST FACILITY
Phone Number: (318)222-6666
Phone Extension:
Email: ADRIENNE.MERCADEL@LA.GOV

First Name: JANE
Middle Name:
Last Name: PIGGY
Address: 560 MOCCASIN LANE
City: NEW ORLEANS
State: LA
Zip: 70112

Monday: ☒ 08:00 ▾ 12:00 ▾ 13:30 ▾ 17:00 ▾
Wednesday: ☐ 09:00 ▾ 12:00 ▾ 13:00 ▾ 17:00 ▾
Friday: ☐ 09:00 ▾ 12:00 ▾ 13:00 ▾ 17:00 ▾

Tuesday: ☒ 09:00 ▾ 12:00 ▾ 13:30 ▾ 17:00 ▾
Thursday: ☒ 08:00 ▾ 11:00 ▾ 13:00 ▾ 17:00 ▾

PIN: 88TEST
Order Date: 10/20/2021
Submitter: JUDI GREENE (JGREENE)
Comments:

Instructions:
Order Status: In Progress

Inventory Last Submitted: 10/20/2021
Last Order Submitted: 10/20/2021 01:30:11 PM
Order Set: COVID-19 PEDIATRIC / Distributor ▾

Inventory Transaction Report

Lot Number Summary

Edit Temperature

Order Frequency: Order Timing:
Order Schedule:

Order Details

Vaccine	Vaccine Name	Funding Source	Dose Used Last Month	Physical Inventory	Order Quantity	Urgent	Priority Reason	Comments
COVID-19, mRNA, LNP-S, PF, 10 mcg/0.2 mL dose, tris-sucrose	Covid Ped ▾	PAN	0	0	10 ▾	<input type="checkbox"/>	--select-- ▾	<input type="text"/>

Cancel

Save Order

Submit Order

Q&A