

# Federal Retail Pharmacy Program Updates

**Federal Retail Pharmacy Partnership for COVID-19 website** Find up to date information and newsletters on our <u>website</u> for the Federal Retail Pharmacy Partnership for COVID-19.

Sitio web en Español para participantes del programa de vacunas COVID

General updates

# Action required: Data reconciliation requirement and process

Pharmacies that participate in the Federal Retail program (FRPP) received US government purchased COVID-19 vaccine and ancillary supplies for administration to individuals. As the Federal program begins to wind down, pharmacies must be able to account for all vaccines received. Please also preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local or territorial law.

To aid you in this data reconciliation process, we have started communicating with pharmacies who have unaccounted for doses for each NCPDP that is part of the program. This communication has included targeted emails, as well as phone call outreach. All questions should be directed to COVIDvaccines@amerisourcebergen.com.

It is important that pharmacies account for these doses accurately in the outlined processes, as they may be asked to provide additional documentation on data discrepancies for vaccine administrations or waste data that has been reported to the CDC. Be sure your pharmacy is doing the following:

• Reporting on hand doses in VaccineFinder

- Processing all vaccine administrations through your pharmacy system
- Reporting waste in ABC Order
- <u>Reporting any transfers</u>

Failure to comply with reconciliation process may result in your pharmacy being placed in a HOLD status and you will not be able to request COVID Vaccine allocation.

Your pharmacy may be asked to provide additional documentation on vaccine administrations if there are data discrepancies on vaccine administrations or other data that has been reported to the CDC.

We appreciate and thank you for all you are doing for your patients.

# Reporting waste

When reporting waste, it's important to complete all the required fields. Incomplete reports will need to be resubmitted. Please report waste as accurately as possible. Once waste is reported it cannot be edited or changed. All questions should be directed to <u>COVIDvaccines@amerisourcebergen.com</u>.

## Attestations due soon

# Quarterly attestations due July 21

The week of July 10 your pharmacy will receive quarterly attestations to sign and return. Please note that there are different attestations for the vaccine and therapeutics programs, so you may receive two attestations that need to be signed and returned. Please email <u>COVIDvaccines@AmerisourceBergen.com</u> if you need the attestation(s) to be resent. Please include your NCPDP and pharmacy name in all inquiries. The attestations must be signed quarterly to remain in compliance with the Federal Retail Pharmacy Partnership programs and continue to order product through the program. If your pharmacy's attestation(s) are not returned, your pharmacy will be placed on hold and will be unable to request product until the attestation(s) are returned.

### **Required: Data Reconciliation Attestation**

In the month of July, you'll receive an email from Elevate Provider Network containing the COVID-19 VACCINATION PROGRAM PROVIDER ATTESTATION FOR VACCINE **DATA RECONCILIATION**. You'll need to read in its entirety, sign and return it immediately. Note there will be 2 pages to the document; the last page should be completed and signed by the authorized signer.

This attestation is **separate** from your standard quarterly attestations and must be completed in addition to your quarterly attestations.

# Vaccine program updates

# CDC updates clinical considerations for COVID-19 vaccines

After updates to CDC recommendations, the <u>Interim Clinical Considerations for Use of</u> <u>COVID-19 Vaccines Currently Authorized in the United States</u> have been updated to reflect changes that allow people who are moderately or severely immunocompromised to receive additional COVID-19 bivalent vaccine doses to help restore protection that may wane over time.

CDC's updated guidance provides healthcare providers with the flexibility to administer an additional COVID-19 mRNA vaccine dose to their <u>immunocompromised patients</u> who have previously received an updated (bivalent) COVID-19 vaccine dose at least two months ago.

Individuals can also self-identify about their eligibility and receive doses anywhere vaccines are offered without a prescription or documentation of medical condition. This will help ensure there are no additional barriers to access for this population.

Paxlovid is still authorized under EUA and continues to be available from the federal government at no cost.

# Therapeutics updates

# Reminder: COVID-19 therapeutic product expiration dates

#### No oral antivirals have expired

Please do not dispose of product based on labeled expiration dates. A searchable database of <u>COVID-19 Therapeutic Product Expiration Dates</u> is available.

- User the search box to find a specific item OR
- Select which product you are interested in and sort by lot number, labelled expiry, or extended expiry

Pfizer is maintaining a <u>searchable expiry</u> data for Paxlovid (nirmatrelvir co-packaged with ritonavir). ASPR's expiry webpage includes the link to that site.

# When will the COVID-19 therapeutic products currently procured and distributed by the USG transition to the commercial marketplace?

At this time, we have not been provided specific dates to share for when the therapeutics will transition to the commercial market; however, we will certainly keep pharmacies informed as the strategy is further developed. Lagevrio (molnupiravir) is expected to transition to the commercial marketplace in Q4 2023. CDC/ASPR is developing the timeline for Paxlovid and understands that sites administering/dispensing these products will need time to develop transition plans, and are committed to providing advance notice to support state/territorial planning efforts. Information on the commercialization of COVID-19 Medical countermeasures can be found <u>HERE</u>.

# How does the FDA approval affect pharmacist prescribing of Paxlovid, which was previously outlined in the Paxlovid EUA?

Although different presentations of PAXLOVID are now FDA-approved for the treatment of mild to moderate COVID-19 in certain adults, there are not sufficient quantities of the approved PAXLOVID available for distribution to this population in its entirety at the time of reissuance of this EUA. To ensure continued access to the U.S. government's supply for Paxlovid and fully meet the public health need before commercial launch of the approved product, the EUA continues to include the patient population now approved under the NDA for Paxlovid. The use of Paxlovid under the EUA must be consistent with the terms and conditions of the authorization. More information can be found on the <u>Paxlovid FAQ</u>.

# Resources

# Lagevrio Expiration Date Extension to 36 months

- On June 14, 2023, FDA <u>announced authorization of an additional extension</u> to the shelf life for the Merck antiviral therapy, Lagevrio (molnupiravir) capsules from 30 months to 36 months.
- FDA granted this extension following a thorough review of data submitted by Merck.
- As a result of this extension, certain lots of Lagevrio capsules may be stored for an additional 6 or 12 months from the original labeled date of expiry.
- As required by the emergency use authorization, unopened cartons of Lagevrio capsules must be appropriately held in accordance with storage conditions detailed in the authorized <u>Fact Sheet</u> for Health Care Providers
- The lot numbers have been updated in the <u>ASPR searchable expiry database</u>.

# Expiry checking

Efforts should be made to verify expiration dates for all extended vaccines and therapeutics before administration/dispensing to patients. Pharmacies can check the expiration date using the manufacturer expiration date tool. It is best practice for pharmacies to develop their own process for removing expired vaccines/therapeutics within a reasonable time. Please ensure all team members review this process and are updating inventory.

- 1. Pfizer-BioNTech COVID-19 Vaccine Expiry
- 2. Moderna Vial Expiration Date Look Up Tool
- 3. Janssen COVID-19 Vaccines Expiry Checker
- 4. Paxlovid Expiry Dates by Batch Number
- 5. Novavax Expiry Date Checker
- 6. CDC's COVID-19 Vaccine Lot Number and Expiration Date Report

# Updated Implementation and Allocation Guides

- Therapeutics Allocation guide
- <u>Therapeutics implementation guide</u>
- Vaccine implementation guide
- Vaccine allocation guide

# COVID-19 marketing materials

Let your patients know that you have the latest booster shot available at your pharmacy with new print and digital marketing materials. Visit the "COVID-19 Vaccine" library in <u>Brand Central Station</u> and <u>SOCi</u> to access the materials.

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