

Federal Retail Pharmacy Program Updates

Vaccine 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.

<u>Sitio web en Español</u> para participantes del programa de vacunas COVID

General updates

Action required for pharmacies part of FRPP

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. All questions should be directed to <u>COVIDvaccines@amerisourcebergen.com</u>.

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.

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>.

Payer COVID-19 coverage updates

Elevate Provider Network has received updates from Prime and Caremark regarding COVID-19 vaccine and oral antiviral coverage.

- <u>Prime notice</u> regarding their COVID-19 vaccine coverage update.
- <u>Caremark notice</u> regarding their COVID-19 oral antiviral update.

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.

As a reminder, CDC will host a <u>COCA Call</u> on Thursday, May 11, 2023, to discuss updated COVID-19 vaccine recommendations. Questions regarding the Interim Clinical Considerations should be directed to <u>NIPINFO@cdc.gov</u>.

J&J is now expired

This is a reminder that **all remaining doses of J&J/Janssen COVID-19 vaccine in the United States expired on May 6, 2023**. All channels should clear their COVID-19 vaccine inventory of J&J/Janssen and discontinue further administration of this vaccine.

The CDC COVID-19 Vaccination Program Agreement specifically requires providers to:

- dispose of expired COVID-19 vaccine in accordance with local regulations and processes regulating medical waste, and
- report disposed as wastage in VTrckS.

Monovalent vaccines are no longer authorized by the CDC

As of April 19, 2023, CDC no longer recommends the use of monovalent mRNA COVID-19 vaccine. In anticipation of this recommendation, monovalent orders were placed on hold beginning on April 13, 2023 to avoid the delivery of unauthorized vaccine. All pending orders for monovalent mRNA vaccines in VTrckS will be canceled by CDC. No action is required on your part. You will receive notification of canceled orders in the coming days. Bivalent vaccine orders are not impacted by this action.

CDC now recommends the use of bivalent vaccine for all recommended mRNA COVID-19 vaccine dose(s). To minimize the risk of administration errors, providers should:

- Remove all monovalent mRNA vaccine from storage units immediately, even if they are not expired. This includes both EUA and BLA products (Comirnaty and Spikevax).
- Once all inventory is fully accounted for, remove monovalent mRNA COVID-19 vaccine from the vaccine inventory in your Immunization Information System. (Jurisdictions only.)
- Dispose of **all monovalent mRNA COVID-19 vaccine vials** in accordance with local, state, and federal regulations.
- Report all disposed inventory as wastage.

For additional information, including a table listing the mRNA monovalent COVID-19 vaccines that should be removed from your inventory, see <u>IIS COVID-19 Vaccine</u> <u>Related Code | CDC</u>.

FDA EUA changes

On, April 18, 2023, the FDA amended its emergency use authorizations (EUAs) (<u>FDA</u> <u>announcement</u>) to authorize bivalent Moderna and Pfizer-BioNTech COVID-19 vaccines to be used for all doses administered to individuals 6 months of age and older. The

monovalent Moderna and Pfizer-BioNTech COVID-19 vaccines are no longer authorized for use in the United States.

FDA retiring monovalent vaccines

The FDA is retiring the monovalent COVID-19 vaccines. The products below have been removed from ABC Order and any orders will be canceled. Read the <u>FDA press release</u>.

- Pfizer Pediatric (6 Mos 4) 59267-0078-04
- Pfizer Pediatric (5-11)
- 59267-1055-04
- Moderna Pediatric (6 Mos 5) 80777-0279-99

Novavax 5-dose vials now available to order

Pharmacy participants can now place orders for the 5-dose vial presentation of Novavax COVID-19 vaccine (Unit of Sale NDC: 80631-0102-10). Each carton contains ten 5-dose vials. The minimum order quantity of the new Novavax vaccine is 100 doses or 2 cartons. This number of doses matches the number of doses supported by existing ancillary kits. You may still opt-out of receiving ancillary kits. The expiration date of this new Novavax presentation is October 31, 2023.

You can no longer place orders for the 10-dose vial presentation of the Novavax COVID-19 vaccine (Unit of Sale NDC: 80631-0100-10) has now ended. Please note that all viable doses of Novavax currently in the field have an expiration date of April 30, 2023. There will be no shelf-life extensions for this product.

Providers should remember to:

- Remove expired vaccine vials immediately from storage units to avoid inadvertently administering them. Expired vaccine should NEVER be administered.
- Discard the vaccine according to the manufacture's guidance, state, and federal regulations.
- Update their inventory of Novavax in VaccineFinder. The current NDC of this vaccine should no longer be listed as in stock in after April 30, 2023 (i.e., available doses should be zero).

Remember, thresholds of Novavax monovalent vaccines have been lifted. You may order as many doses as you need. CDC anticipates Novavax COVID-19 vaccine will continue to serve as an alternative to mRNA COVID-19 vaccines into the foreseeable future. Novavax can be ordered by emailing a request to COVIDvaccines@AmerisourceBergen.com.

Preparedness (PREP) Act

On April 14, 2023, Secretary Becerra announced that in the coming weeks, he will issue an amendment to the declaration under the PREP Act for medical countermeasures against COVID-19.

- Extending coverage for COVID-19 vaccines, seasonal influenza vaccines and COVID-19 tests
- Extending coverage through December 2024 for federal agreements
- No immediate impact on USG-distributed COVID-19 countermeasures

Learn more

Therapeutics updates

Shelf-life extension for specific lots of Paxlovid

View the <u>COVID-19 Therapeutic Product Expiration Dates Database</u> for the most recent shelf-life extension and product expiration information.

The COVID-19 pandemic is rapidly evolving, and new updates are issued frequently. To view a full list of HHS/ASPR's updates related to COVID-19 monoclonal antibody therapeutics, please see our <u>full list of updates</u>.

Learn more

Resources

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
- Therapeutics implementation guide
- Vaccine implementation guide
- Vaccine allocation guide

COVID-19 Treatment 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.