



# Pennsylvania COVID -19 Vaccine Program

MAY 4TH, 2023

## Disclaimer

Information presented in these slides and on today's webinar is based on the most current guidance and is subject to change.

## Agenda

HHS Announcements  
PHE Ends May 11  
Updated Recommendations

## Speakers

Tracy Radtke  
**Public Health Program Manager**  
COVID Vaccine Program

Vaccination Schedule  
Vaccine Products  
Resources  
V-safe  
Inventory Management

Sri Parajuli  
**Program Coordinator**  
COVID Vaccine Program

**Q&A Session**

DOH Team

# ➤ HHS Bridge to Access Program

On April 18<sup>th</sup>, 2023, HHS announced the **‘HHS Bridge Access Program For COVID-19 Vaccines and Treatments Program’ (“Program”)** to maintain broad access to COVID-19 vaccines for millions of uninsured Americans. The program will create a unique \$1.1 billion public-private partnership to help maintain uninsured individuals’ access to COVID-19 care at their local pharmacies, through existing public health infrastructure, and at their local health centers.

The program has two major components:

- First, provide support for the existing public sector vaccine safety net, which is implemented through local health departments (LHDs) and Health Resources and Services Administration (HRSA) supported health centers.
- Second, create a novel, funded partnership with pharmacy chains that will enable them to continue offering free COVID-19 vaccinations and treatments to the uninsured through their network or retail locations as has been done during the COVID-19 Public Health Emergency (PHE).

[Fact Sheet: HHS Announces ‘HHS Bridge Access Program For COVID-19 Vaccines and Treatments’ to Maintain Access to COVID-19 Care for the Uninsured | HHS.gov](#)

# PHE Ends May 11, 2023

Based on current COVID-19 trends, the Department of Health and Human Services (HHS) is planning for the federal Public Health Emergency (PHE) for COVID-19, declared under Section 319 of the Public Health Service (PHS) Act, to expire at the end of the day on May 11, 2023.

It is important to note that the Administration's continued response to COVID-19 is not fully dependent on the COVID-19 PHE, and there are significant flexibilities and actions that will not be affected as we transition from the current phase of this response.

- **Access to COVID-19 vaccinations and certain treatments, such as Paxlovid and Lagevrio, will generally not be affected.**
- **FDA's EUAs for COVID-19 products (including tests, vaccines, and treatments) will not be affected.**
- **Reporting of COVID-19 laboratory results and immunization data to CDC will change.**
- **Public Readiness and Emergency Preparedness (PREP) Act liability protections for countermeasure activities that are NOT related to any USG agreement may be impacted. - Please contact respective Board of Licensing at PA Department of State to confirm your scope of immunization after PHE ends.**



# HHS Intent to Amend PREP Act Declaration

## Some of the key features that will not change under the amended declaration include:

- **No immediate impact on USG distributed COVID-19 countermeasures.** As noted above, the amended PREP Act declaration will not have any immediate impact on COVID-19 vaccines, treatments, and tests currently distributed by the USG—either now or when the COVID-19 PHE ends on May 11.
- **No change to coverage for certain prescribing and dispensing of COVID-19 oral antivirals.** The PREP Act will continue to offer liability immunity for pharmacists, pharmacy technicians, and pharmacy interns dispensing COVID-19 treatments, in accordance with a U.S. Food and Drug Administration (FDA) authorization, such as the oral antiviral treatments Paxlovid and Lagevrio. In the case of Paxlovid, pharmacists are permitted to prescribe the treatment under certain circumstances. These oral antiviral treatments are available at over 40,000 provider locations, including over 35,000 retail pharmacies.
- **No change to the “Test to Treat” program.** Pharmacists and other providers prescribing tests in the [“Test to Treat”](#) program will continue to receive liability protection under the PREP Act.

[CMS PHE Fact Sheet](#)

[CMS PHE FAQs](#)

[Fact Sheet: HHS Announces Intent to Amend the Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 | HHS.gov](#)

[FAQ - Commercialization of COVID-19 Medical Countermeasures \(hhs.gov\)](#)

## Key changes that Secretary Becerra plans to make under the upcoming amended declaration include:

- **Extending coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.** PREP Act immunity from liability will be extended through December 2024 to pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals three and over, consistent with other requirements), and COVID-19 tests, regardless of any USG agreement or emergency declaration.
- **Extending coverage through December 2024 for Federal agreements.** This includes all activities related to the provision of COVID-19 countermeasures that are 1) provided based on a Federal agreement (including the vaccines and treatments purchased and provided by the USG), or 2) directly conducted by the USG, including by Federal employees, contractors or volunteers.
- **Ending of coverage for certain activities.** Once products are no longer distributed under a USG agreement, PREP Act coverage will no longer extend to the following activities:
  - COVID-19 vaccination by non-traditional providers (e.g., recently retired providers and students); and
  - COVID-19 vaccinations across state lines by licensed providers and pharmacists and pharmacy interns.
- **Ending of coverage for routine childhood vaccinations.** Once there is no emergency in effect, PREP Act coverage will no longer extend to all routine childhood vaccinations by pharmacists, pharmacy interns, and pharmacy technicians.

# Updated COVID –19 Vaccine Clinical Recommendations

Following the Food and Drug Administration's regulatory action on April 19th, 2023, the Centers for Disease Control and Prevention (CDC) has approved simplification of COVID-19 vaccine recommendations and allows more flexibility for people at higher risk who want the option to receive an additional COVID-19 vaccine dose.

- **Monovalent (original) COVID-19 mRNA vaccines (Pfizer and Moderna) are no longer recommended for use in the U.S.**

**Note:** non-mRNA COVID-19 vaccines (Novavax and Johnson and Johnson) are not affected by this change and remain available as alternatives for people who cannot or will not receive an mRNA vaccine

# Updated Recommendations



# COVID-19 Vaccine Schedule for General Population



Age*	Vaccines	If Unvaccinated				If received movovalent doses, give bivalent doses	
6m- 4yrs	Pfizer BV	Dose 1	3-8 weeks ^	Dose 2	≥8 weeks	Dose 3	If received 2 MV doses, then give BV dose ≥8 weeks  If received 1 MV dose, then complete series with 2 BV doses.
6m- 5yrs	Moderna BV	Dose 1	4-8 weeks ^  Use blue cap vial (0.25ml)	Dose 2	≥2 months		If received 2 MV doses, then give a BV dose (pink cap, 0,2 ml) ≥2 months  If received 1 MV dose, then give a BV dose (blue cap, 0.25 ml) after 4-8 weeks
6+ yrs	Moderna BV	Dose 1	≥4 months  Use blue cap vial (0.25ml)	Optional 2 <sup>nd</sup> BV dose if age (in yrs) = 65 +	}		
5 - 11yrs	Pfizer BV	Dose 1					
12+ yrs	Pfizer BV	Dose 1	≥4 months	Optional 2 <sup>nd</sup> BV dose if age (in yrs) = 65+		Give BV dose (Moderna/Pfizer) at least 2 months after last dose ( of any of the 4 vaccine brands)	
12+ yrs	Novavax MV	Dose 1	3-8 weeks ^	Dose 2			
18+ yrs	Janssen MV**	Dose 1					

\* Please see [schedules for children in transition from a younger to older age group](#).

\*\* Although use of mRNA COVID-19 and Novavax vaccines is preferred, the Janssen vaccine may be offered in some situations.

† For people who have not received any booster doses and are unable or unwilling to receive bivalent booster vaccine, [the monovalent Novavax booster may be administered as a single booster dose at least 6 months after completion of the primary series to people 18 years and older](#).

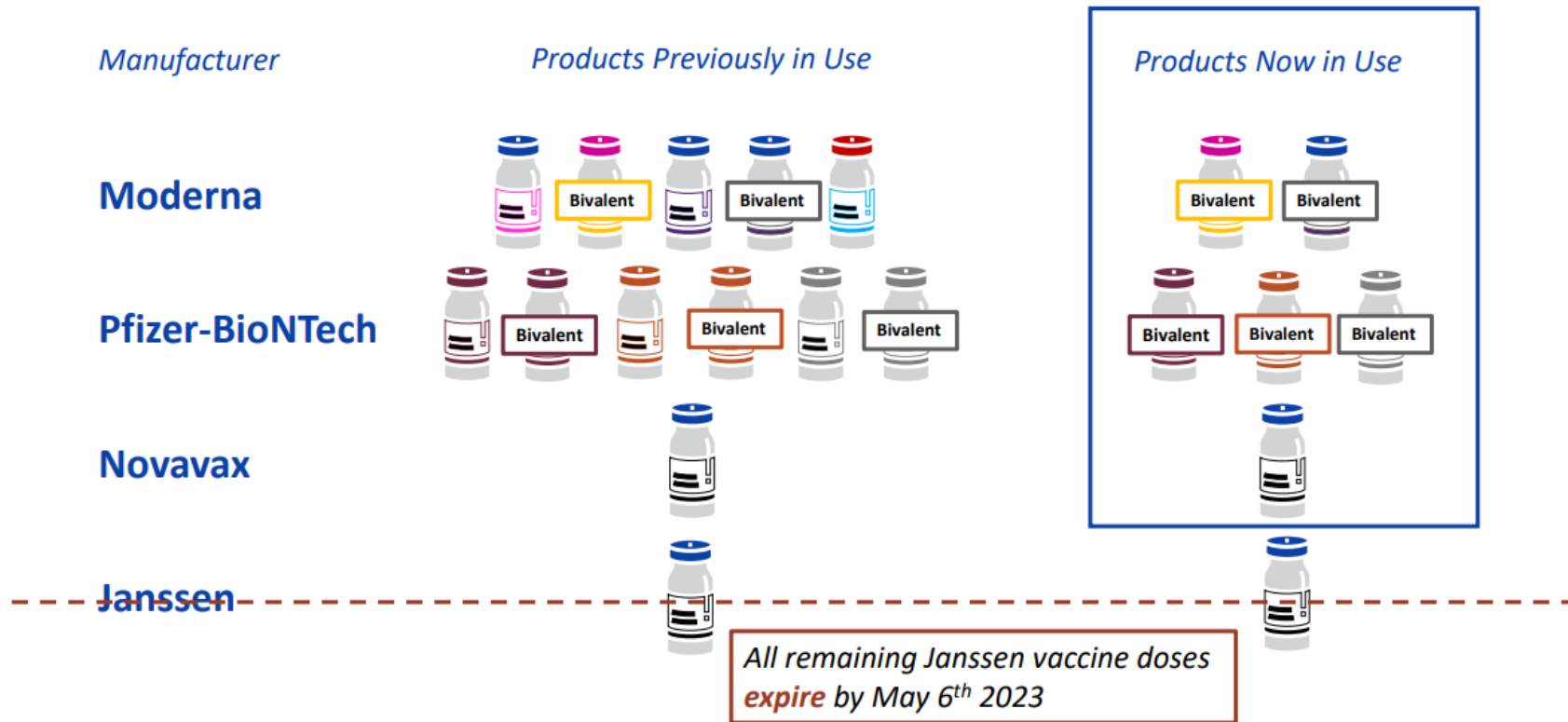
^ An 8-week interval may be preferable for some people, especially for males 12-39 years.

Please view [Interim Clinical Considerations for Use of COVID-19 Vaccines for](#) details. Schedule is subject to change.

## ➤ Schedule for Moderately to Severely Immunocompromised

- [Clinical Guidance for COVID-19 Vaccination | CDC](#)
- [COVID Vaccine Dosing\\_Quick Reference.pdf \(aap.org\)](#)

## Fewer COVID-19 Vaccine Products in Use



Accessed from: [CDC Presentation](#)

# Resources

Updated CPT Codes	<p>American Medical Association (AMA) updated the CPT codes for COVID vaccines on May 1, 2023 to accommodate all new updated clinical recommendations.</p> <p><a href="#">Appendix Q: COVID-19 Vaccines   AMA (ama-assn.org)</a></p>
Updated Education and Training	<p>Moderna- <a href="#">Moderna Covid19 Vaccine (modernatx.com)</a></p> <p>Pfizer - <a href="#">Pfizer Medical Information - US</a></p> <p>Novavax - <a href="#">Meeting Registration - Zoom</a></p> <p>Janssen - <a href="#">COVID-19 Education and Training   Johnson &amp; Johnson (jnj.com)</a></p>
Updated EUA Fact Sheets	<p><a href="#">Pfizer-BioNTech COVID-19 Vaccines   FDA</a></p> <p><a href="#">Moderna COVID-19 Vaccines   FDA</a></p> <p><a href="#">Novavax HCP Fact Sheet 03282023 (fda.gov)</a></p> <p><a href="#">Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers 03132023 (fda.gov)</a></p>
Updated Pre-vaccination checklist	<p><a href="#">Prevaccination Guidance for COVID-19 Vaccines Information for Healthcare Professionals (cdc.gov)</a></p>
Upcoming COCA Call	<p>May 11, 2023</p> <p>Link: <a href="#">Calls/Webinars   Clinician Outreach and Communication Activity (COCA)(cdc.gov)</a></p>

# ➤ V-safe After Vaccination Health Checker

Enrollment in v-safe will be closed on May 19, 2023.

Follow up will continue until June 30th, 2023, on reports of medically attended health events.

Next generation v-safe is under development.

# Inventory Management

- Check all vaccine storage units and remove monovalent Moderna and Pfizer vaccines.
- **Providers receiving state allocation only:**
  - Dispose of all inventory and report wastage in PA SIIS ([QRS PA SIIS 2001 - Documenting Wasted or Expired Vaccine](#))
  - Update inventory in PA SIIS regularly.
- **Providers receiving state + federal or only federal allocation:**
  - Dispose of all inventory and report wastage in PA SIIS.
  - Deauthorized monovalent products should be removed from Vaccines.gov and on-hand inventory should be zeroed out.
  - Update/zero out inventory regularly on PA SIIS as well as on vaccines.gov to avoid turning away customers.
- **Providers must keep vaccine usage and wastage data for 3 years.**
- **Practice first in/first out inventory management.**
  - Store older vaccines to the front of the refrigerator or freezer unit.
  - Dispose of any expired vaccine according to state and local regulations.
- **Providers no longer participating in COVID-19 vaccination must zero out inventory.**
- For more information, please refer to [Vaccines.gov Provider Resources](#).



# QUESTIONS??

**For general questions related to COVID-19 vaccine**

email: [RA-DHCOVIDVAX@pa.gov](mailto:RA-DHCOVIDVAX@pa.gov)

**For PA-SIIS related questions**

email: [RA-DHPASIIS@pa.gov](mailto:RA-DHPASIIS@pa.gov)

**For inquiries related to COVID-19 therapeutics and monoclonal antibodies**

email: [covidtherapeutics@pa.gov](mailto:covidtherapeutics@pa.gov)