

HHS COMMERCIALIZATION TRANSITION GUIDE

SUNSETTING THE US GOVERNMENT COVID-19 VACCINE DISTRIBUTION PROGRAM

COVID-19 PROGRAM BACKGROUND

On June 15, 2023, independent experts on the Food and Drug Administration’s (FDA’s) Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to publicly discuss whether a change to the current vaccine strain composition of COVID-19 vaccines is necessary for the 2023-2024 fall/winter season. The VRBPAC voted to update the vaccine composition, and FDA subsequently advised those manufacturers planning to offer COVID-19 vaccines that they should develop vaccines with a monovalent XBB.1.5 composition. The anticipated availability of such vaccines is mid to late September 2023. These vaccines will be the first COVID-19 vaccines to be available directly from the manufacturers as part of the commercial market, rather than through the United States Government (USG).

This guide provides direction to those participating in the COVID-19 Vaccination Program as the USG stops distributing COVID-19 vaccines through its current ordering system and the vaccines transition to the commercial market. This guide aims to help jurisdictions and providers: (1) plan to transition away from USG ordering; (2) understand how to place orders after current full-scale USG ordering transitions to request based ordering; (3) understand how to manage inventory and disposal of current COVID-19 vaccine products, including continued reporting requirements of remaining USG inventory; and (4) provide a summary of information about programs implemented by the Centers for Disease Control and Prevention (CDC) to provide access for uninsured individuals once COVID-19 vaccines become commercially available. **This guide is for planning purposes only based on potential, future action by FDA and CDC should they authorize and recommend the new vaccines this fall.** Details may change.

FALL COVID-19 VACCINE TRANSITION

The following summary table provides an estimated sequence of events based on the VRBPAC that took place on June 15, 2023.

Projected Timeline (All subject to change)	Action/Event
Present – 08/03/2023	Vaccines ordered from USG on a continuing basis
06/15/2023	VRBPAC meeting held, committee recommended updated fall vaccine composition
06/16/2023	FDA statement on XBB.1.5 as recommended fall vaccine composition
08/03/2023	Vaccine thresholds for partners will be set to 0 in anticipation of decreased demand Note: Jurisdictions, Federal agencies, and other partners may make out of cycle requests for vaccines from USG if needed
TBD (expected in mid to late September)	FDA decisions and amendments to Emergency Use Authorizations (EUAs) / Biologics License Applications (BLAs)
TBD (concurrent with FDA decision)	USG discontinues distribution of current COVID-19 vaccine composition
TBD (pending FDA decision)	Advisory Committee on Immunization Practices (ACIP) discussion on COVID-19 epidemiology and vaccine effectiveness and CDC recommendation
TBD (pending FDA decision, CDC recommendation, and manufacturer readiness)	Fall vaccine availability for administration begins across all age groups with traditional pathways for procurement, distribution, and payment

EXCEPTIONAL ORDERS AFTER FULL-SCALE ORDERING CLOSES

While many individuals may wait to receive a COVID-19 vaccine until the updated version is released, as it is expected to provide more robust protection against currently circulating variants, certain individuals may need or desire a COVID-19 vaccine prior to the anticipated release of the updated vaccine in the fall. While overall demand for the current vaccine is expected to significantly decrease in the general population in late summer, it is important that access points to the current vaccines remain available across all age groups.

It is anticipated that USG will stop the regular threshold/replenishment ordering mechanism for all COVID-19 vaccines and ancillary supplies on **August 3, 2023, at 4:00 PM ET**, by setting ordering thresholds to zero for all COVID-19 vaccines. Jurisdictions, Federal agencies, and other partners should work with their providers/sites to place sufficient orders prior to that date to maintain their COVID-19 vaccine inventory and access points while these vaccines are still authorized.

Providers are encouraged to place necessary orders prior to the cutoff date of August 3, 2023. If a provider requires additional supply to be responsive to demand after USG closes the current ordering mechanism, COVID-19 vaccines will continue to be available for ordering via the established out-of-cycle request process. Requests received after August 3, 2023, will be processed twice every week, following the below schedule:

- Out of cycle orders received between Friday 8:00 AM ET and Wednesday 8:00 AM ET will be processed on Wednesday by 11:59PM ET
- Out of cycle orders received between Wednesday 8:00 AM and Friday 8:00 AM ET will be processed by Friday by 11:59PM ET

The public will continue to be directed to [Vaccines.gov](https://www.vaccines.gov) to find providers offering COVID-19 vaccine. After receiving vaccine orders, providers should report their inventory to Vaccines.gov as soon as possible. Providers are also strongly encouraged to report the minimum age (in months and years) for whom a location can administer vaccine.

GUIDANCE ON INVENTORY AND DISPOSAL MANAGEMENT

COVID-19 Vaccines

It is anticipated that USG will stop the traditional threshold/replenishment ordering mechanism on August 3, 2023, at 4:00 PM ET. Providers should maintain their inventories of EUA and/or BLA vaccines until the vaccine exceeds its shelf life, or the FDA announces a change to EUAs and/or BLAs, whichever occurs first.

Any vial of vaccine that exceeds the shelf-life indicated by the manufacturer should be disposed of as regulated medical waste in consultation with the manufacturer. The [COVID-19 Vaccination Provider Agreement](#) states that providers should dispose of COVID-19 vaccine waste in accordance with local regulations and processes currently being used to dispose of regulated medical waste. This agreement requires providers to report wastage, including doses disposed of due to expiration, to CDC's [Vaccine Tracking System \(VTrckS\)](#).

COVID-19 Ancillary Kits

It is anticipated that USG will continue providing ancillary supplies for vaccine orders placed after the cessation of the traditional threshold/replenishment ordering mechanism for vaccines on August 3, 2023, at 4:00 PM ET. Providers should maintain inventory of ancillary kits to continue administration of vaccinations to anyone who is eligible and wants an authorized vaccination. Providers are reminded that they can opt out of receipt of COVID-19 Ancillary Kits. For Awardees, opt-out instructions can be found in the VTrckS library at: <https://vtrcks-library.cdc.gov/gm/folder-1.11.17315>. Federal Agencies/Commercial Partners can opt-out in HPoP.

The expiration date printed on the exterior box of the ancillary kit does not apply to all the items contained in the kit. The expiry date found on the external label is based on the earliest expiry of any of the kit components. Providers may exercise discretion and continue using unexpired components (e.g., needles and syringes) until

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expiry of the component. Providers should dispose of expired components in accordance with local, state, and Federal requirements.

Unexpired ancillary kits or items contained within can be shared domestically, at no charge, with other immunization programs within the practice, clinics and other sites offering healthcare services, or veterinary clinics. Ancillary kits cannot be donated outside of the U.S. or to organizations that will use the supplies outside the U.S.

DATA REPORTING REQUIREMENTS

In accordance with the COVID-19 Vaccination Program Provider Agreement, providers are responsible for adhering to all requirements outlined in the Agreement, including updated recommendations, requirements, and other guidance provided in the footnoted web links incorporated in the Agreement.

As the USG further plans for the end of the COVID-19 vaccine distribution program, direction will be forthcoming on activities to complete prior to the program ending. Providers are expected to provide reporting of all USG doses that they received and should refer to the [CDC website](#) for updates to inventory, administration, and disposal reporting requirements.

While providers will no longer be required to report inventory to Vaccines.gov after vaccines transition to being available on the commercial market, they will continue to be encouraged to report voluntarily. CDC will continue its efforts to make sure that all people have access to COVID-19 medical countermeasures and know where to find product in the future.

CDC PROGRAMS FOR UNINSURED INDIVIDUALS

CDC will provide access to COVID-19 vaccines for uninsured individuals once COVID-19 vaccines become commercially available.

Uninsured children will be able to receive COVID-19 vaccines through the existing Vaccines for Children (VFC) program implemented in 1994. This program helps provide routinely recommended vaccines to children whose parents or guardians may not be able to afford them. Children eligible for VFC include those who are younger than 19 years of age and are Medicaid-eligible, uninsured, or underinsured with respect to vaccination (when served at Federally Qualified Health Centers or Rural Health Clinics) or are American Indian or Alaska Native. More information about the VFC program can be found online at: [VFC: Vaccines for Children Program | CDC](#).

Uninsured adults will be able to receive COVID-19 vaccines through a new temporary program called the Bridge Access Program for COVID-19 Vaccines and Treatments. This program consists of two components: the first component utilizes existing public health infrastructure including state immunization programs, local health departments, and HRSA-supported health centers to provide COVID-19 vaccines to uninsured adults. The second component will be implemented through contracts with pharmacy chains that will enable them to continue offering free COVID-19 vaccinations to the uninsured through their network or retail locations as has been done during the COVID-19 public health emergency.

More information about the Bridge Access Program for COVID-19 Vaccines and Treatments can be found online at: [Fact Sheet: HHS Announces 'Bridge Access Program For COVID-19 Vaccines and Treatments' to Maintain Access to COVID-19 Care for the Uninsured. Addition information will follow shortly from CDC.](#)

ANTICIPATED VACCINE SCHEDULE FOR FALL

Detail on the current recommended vaccine schedules for each age group can be found on the [CDC website](#).

An updated recommendation for all age groups is expected in the mid to late September timeframe after anticipated FDA regulatory authorizations or approvals of an updated COVID-19 vaccine composition. We anticipate that jurisdictions and providers will be able to order and receive updated COVID-19 vaccines shortly thereafter for administration.

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PLANNING CONSIDERATIONS

As with previous planning guides, jurisdictions and providers continue to be encouraged to adopt strategies to minimize unnecessary wastage; however, they should not miss any opportunities to vaccinate every eligible person who requests a vaccination, even if it means puncturing a multidose vial to administer vaccine without having enough people available to receive each dose in the vial.

Jurisdictions will be responsible for assuring vaccines remain available, especially in communities where uptake of the COVID-19 vaccine is lower.

Public Readiness and Emergency Preparedness Act (PREP Act) Declaration

The [PREP Act and the PREP Act Declaration](#) issued by the Secretary of the U.S. Department of Health and Human Services authorize and provide liability protections to licensed providers and others identified in the declaration to administer COVID-19 vaccines authorized or approved by FDA, including COVID-19 vaccines authorized for administration to children. In accordance with the recent PREP Act Amendment 11, neither the end of the COVID-19 public health emergency on May 11, 2023, nor the discontinuation of USG COVID-19 vaccine distribution, affect the protections of the PREP Act declaration for COVID-19 vaccines.

This authorization preempts state requirements that would otherwise prohibit, or effectively prohibit, these providers from administering the vaccine. The PREP Act Declaration authorizes certain providers listed in the Declaration to administer vaccines regardless of state requirements.