VFC Update
Vaccines for Children Program

August 23, 2024

Vaccine Supply Updates, myCAvax Order Statuses, Temperature Excursion Reporting, and Call Center Closure

COVID-19 Vaccine Ordering Temporarily Paused – Awaiting Newly Authorized Updated COVID-19 Vaccines

On August 21, 2024, the U.S. Food and Drug Administration approved and granted emergency use authorization (EUA) for updated mRNA COVID-19 vaccines (2024-2025 formula) to include a monovalent (single) component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2. The mRNA COVID-19 vaccines have been updated with this formula to more closely target currently circulating variants and provide better protection against serious consequences of COVID-19, including hospitalization and death. These actions relate to updated mRNA COVID-19 vaccines manufactured by Moderna^{TX} Inc. and Pfizer Inc.

As a result, the previous 2023-2024 COVID vaccine formulations are no longer available to order through the VFC Program, and we have temporarily paused COVID-19 ordering until the newly authorized vaccines are available. Once the California VFC Program has received allocations and supply of the updated 2024-2025 COVID-19 vaccines, we will resume COVID-19 ordering.

Deauthorization of the Previous 2023-2024 mRNA COVID-19 vaccines:

- For 12 years and older:
  - There is no specific FDA language against the use of the licensed mRNA 2023-2024 vaccines (Comirnaty and Spikevax). Previously, FDA did not release explicit language ceasing the use of the prior licensed vaccine.
  - CDPH recommends that providers stop using the licensed 2023-2024 mRNA COVID-19 vaccines (Comirnaty and Spikevax), as the FDA package label only refers to the 2024-2025 formula.
- For children under 12 years:
  - mRNA COVID-19 vaccines for children under 12 years have been formally deauthorized by FDA and should no longer be used:
- Moderna Letter: https://www.fda.gov/media/144636/download?attachment

- Pfizer Letter: https://www.fda.gov/media/150386/download?attachment

CDC and CDPH guidance documents will be updated in coming weeks. For more information refer to the FDA Press Release, August 22, 2024.

Return Any Remaining 2023-2024 COVID-19 Vaccines

Providers should note the following regarding the 2023-2024 COVID-19 vaccine formulation to minimize risk of vaccination errors:

- Please remove the product from your inventory, and report them as expired, regardless of expiration date and return to McKesson. Please click here for instructions.
- Providers can no longer order the 2023-2024 COVID-19 vaccine formulation on myCAvax.
- Orders that have been placed prior to this announcement and are in flight and any order that has been placed but not approved or sent to CDC will be rejected and will not ship.
- Orders submitted and approved to CDC or your LHD for fulfillment are in transit. Upon receiving, please report as expired and return to McKesson.

Once supply becomes available, Providers should begin ordering and administering the 2024-2025 COVID-19 vaccine formulation.

Flu and RSV Immunization Ordering Coming Soon!

VFC Flu vaccine ordering for the 2024-2025 flu season is expected to begin in late August/early September. The VFC Program will allocate doses to VFC Providers based on approved pre-book amounts, or available supply if a provider did not pre-book, as supply is received at McKesson. Once doses are allocated, providers will be able to request flu vaccine on their routine VFC order form. Please note, the VFC Program will NOT automatically ship flu orders. Providers will be expected to actively go in and submit a flu vaccine request. More information about flu ordering and timelines will be communicated.

RSV immunizations is expected to be available for ordering in September. More information about RSV ordering and timelines will also be communicated soon!

New MenQuadfi Presentation and NDC

As part of updates to CDC's vaccine contract, Sanofi's MenQuadfi (MenACWY) 5-pack of single dose vials (NDC: 49281-0590-05) is no longer available for ordering. Only the 10-pack of MenQuadfi single dose vials (NDC: 49281-0590-10) is available for vaccine requests. McKesson is currently working on fulfilling the MenQuadfi 5-pack requests that were previously on backorder and will be delivering those this week. For the backorders that could not be fulfilled, providers who had recently requested the 5-pack of MenQuadfi will

have their orders automatically updated to the 10-pack presentation. If the vaccine request was in multiples of 5, it will be rounded up to the nearest 10th.

Td Vaccine Supply

Historically, two tetanus and diphtheria (Td) vaccine products have been available for use in the United States:

- TdVax™, manufactured by MassBiologics
- Tenivac®, manufactured by Sanofi

As previously communicated to VFC Providers on March 26, 2024, MassBiologics has discontinued production of TdVax™, which is exclusively distributed by Grifols. TdVax™ will remain available for ordering until supply is depleted. Sanofi, manufacturer of Tenivac®, is taking steps to augment their available supply of Td for the US and will be implementing ordering controls until the supply has increased. It is anticipated that the supply of Td vaccine in the US market will be constrained through the rest of 2024.

As a result, CDC has put allocations into place for all Td products. Due to the limited allocations, providers can only request up to 10 doses of Td vaccine with your routine VFC vaccine order. We have currently reached our monthly allocation limits for Tenivac® and TdVax™. Supply availability may change in the coming months.

However, Tetanus, diphtheria, and acellular pertussis (Tdap) vaccines are available without supply constraints at this time. The limited supply of Td vaccine needs to be preserved for those with a contraindication to receiving pertussis-containing vaccines. To assist vaccination providers, CDC has developed the following guidance:

- **Transition to use of Tdap** vaccine in lieu of Td vaccine whenever possible **while Td vaccine supplies are constrained.**
- Tdap vaccine **is an acceptable alternative** to Td vaccine, including when a tetanus booster is indicated for wound management.
- Tdap vaccine **isn't an acceptable alternative** only when a person has a specific contraindication to pertussis-containing vaccines, which is very rare.

This guidance will remain in place until the period of temporary ordering controls for Td vaccine ends**.**

myCAvax Order Statuses

Thank you for your continued patience as the VFC Program has been working hard to review and approve the influx of orders received for back-to-school alongside our transition to myCAvax. As you submit your VFC vaccine request, you will notice several order statuses. These statuses will help guide you on where your order is at in the process:

- **Draft** – Orders that have been started, but not submitted to the VFC Program.
- **Submitted** – Orders that have been submitted for review through the VFC Program.
- **Pending** – If an order is pending, further review/action is needed from the CDPH team prior to order processing. For example, an order may be pending if there is an "Order Hold" that needs field representative approval prior to processing.
- **Corrections Needed** – The order has been sent back to the Vaccine Coordinator and Backup Vaccine Coordinator to correct any accountability issues. Please respond by making corrections to your on-hand inventory or doses used. Some tips to prevent accountability issues:
    - Refer to your previous order to account for doses received.
    - Report any doses transferred/returned/wasted in myCAvax prior to submitting your order.
    - Conduct a physical vaccine inventory to get an accurate vaccine count in your storage units.
    - Review physical vaccine inventory count against your "Provider Inventories" in myCAvax to ensure they match. Note: "Provider Inventories" can be accessed through the "Vaccine Inventories" tab under your VFC Program Location.
    - Run a report from the Immunization Registry (CAIR/Healthy Futures) to determine the number of doses administered since your last order.
- **Approved** – The VFC Program has approved your vaccine request and will process it shortly to be sent to CDC.
- **Ready for VTrckS** – After the order has been approved, the order file is being prepared to be sent to CDC. An email will be sent to the Primary and Backup Vaccine Coordinators notifying them that their order has been approved.
- **VTrckS File Written** – The order has been processed and sent to CDC. This is similar to the "Fulfilment Pending" status.
- **Fulfilment Pending** – CDC has sent the order to the distributor (McKesson for most vaccines, Merck for Varicella-containing products, and Pfizer for their COVID-19 vaccines) for packing and shipment.
- **Complete** – The vaccine order has been shipped for delivery.

Temperature Excursion Reporting in myCAvax

Updates have been made to the myCAvax excursion report that will triage whether you can continue vaccination services or should contact vaccine manufacturers to determine vaccine viability, depending on the temperature and timeframe of the excursion(s) reported. This message will populate under the file upload prompt once the excursion information is inputted to help inform providers on next steps. Follow the guidance provided by myCAvax when submitting the excursion report.

1. If no further action is needed, an orange message will populate, and the Excursion table will be greyed out.

2. If further action is needed, a red message will populate with instructions to contact the manufacturer to determine stability information, and this information will need to be entered in the Excursion table.
3. If temperatures were not recorded, a red message will populate with instructions to label the vaccines as 'Do not use', and the 'Affected Inventory' column of the Excursion table will need to be filled out.
4. If vaccines were not stored in the unit during an excursion, you now have the option to indicate this on the report. Once selected, the excursion report will not prompt you to select the vaccines involved and you can proceed with documenting that an excursion occurred for the unit, but no vaccines were stored at the time.

Current Policy on Temperature Excursion Reporting:

- Providers do not need to wait for CDPH review of excursions unless it was a "temperatures not recorded" situation.
    - If temperatures were not recorded, CDPH will review the incident and provide follow-up guidance.
- If you are directed to contact the manufacturer(s), follow their guidance regarding vaccine stability and report results on the excursion form.
- If vaccines are spoiled, submit a return / waste form.
- If vaccines are okay to be used, continue vaccination services. No need to wait for CDPH.

VFC's Customer Service Center Closure

The VFC Customer Service Center will be closed on the following date:

- Monday, September 2, 2024 (Labor Day Holiday)

Normal business hours will resume on Tuesday, September 3, 2024. For any questions, please contact the VFC Program at (877) 243-8832 or MyVFCVaccines@cdph.ca.gov or visit our website for important VFC Program communications and information.

CDPH Immunization Branch Updates for Providers Webinar

The CDPH Immunization Branch conducts a webinar for all providers every other Friday. These webinars provide useful information such as clinical updates, as well as updates on vaccine supply, vaccine management and VFC Program information. Please join the next webinar on Friday September 6, 2024, from 9:00am – 10:30am.

- Register for the next session: Friday September 6, 2024, 9:00am – 10:30am (PT)

To view our archived webinars, please visit our Webinars page on EZIZ!

Thank you,

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