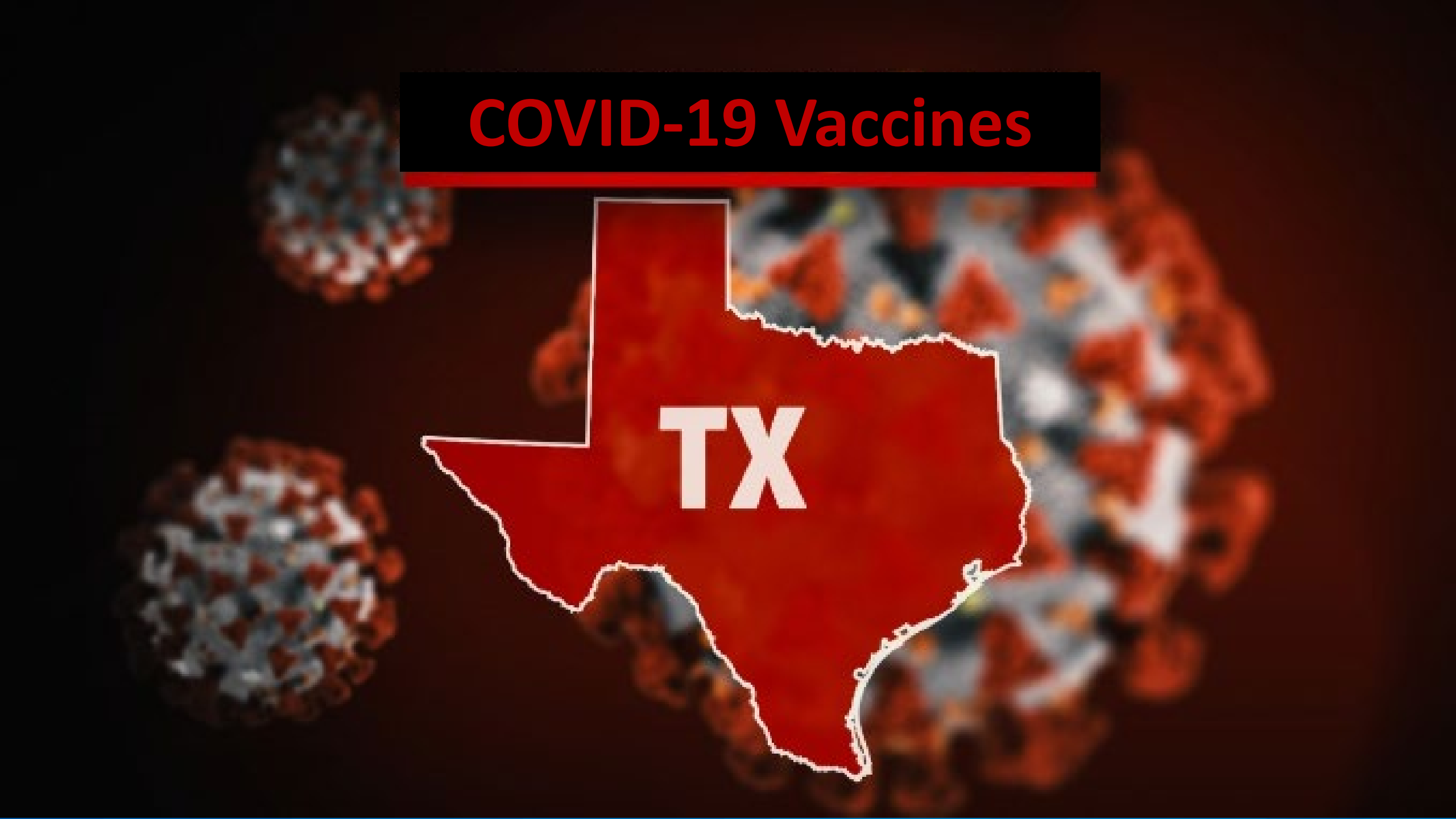
TEXAS
Health and Human Services

Texas Department of State Health Services


COVID-19 Vaccines
TX

Texas Vaccine Providers Webinar

April 25, 2023

Discussion Topics

Opening Remarks – Garrett Cottom
COVID-19 Updates – Saroj Rai, PhD, MPH
Live Q&A
Clinical Reminders – Cheryl Garcia, RN, BSN CCM
COVID-19 Vaccine Product Ordering Updates – Oscar Paz
ImmTrac2 Updates – Lisa Marie Pawelczak
Live Q&A

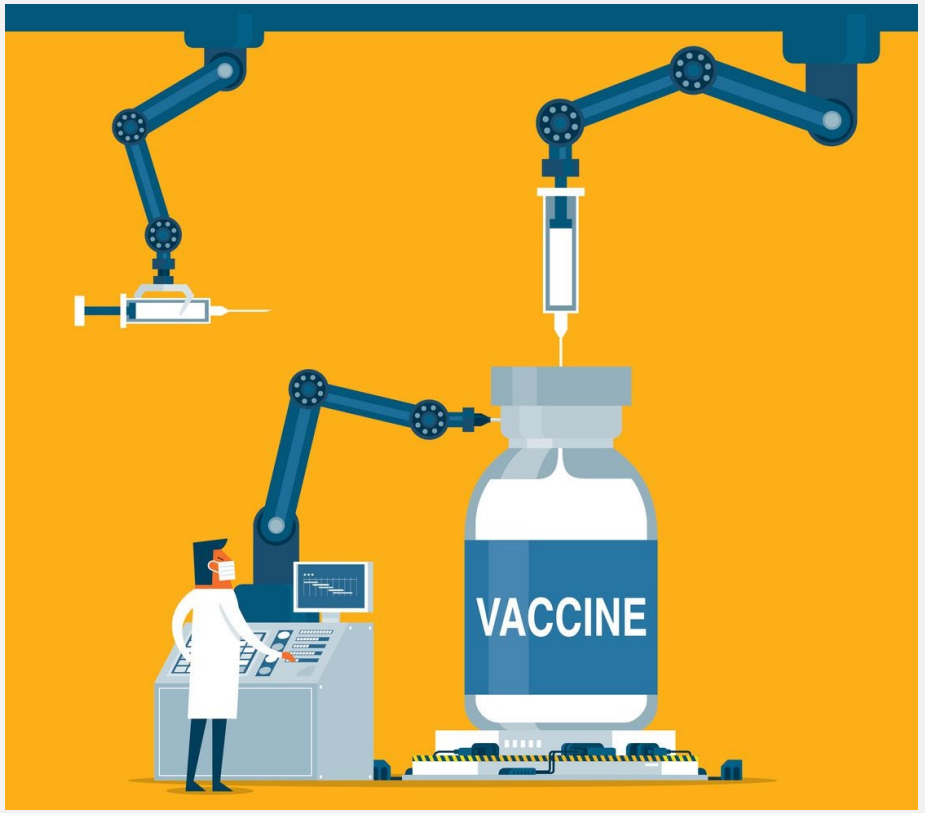
Welcome

Garrett Cottom

Vaccine Operations Group Interim Director/Immunization Section

Spring COVID-19 Updates-April:

Existing Monovalent Pfizer and Moderna authorization has been removed by the FDA



TEXAS Health and Human Services

Texas Department of State Health Services

Spring COVID-19 Updates-April:

Zeroing Out Inventory in VAOS

FAQ:

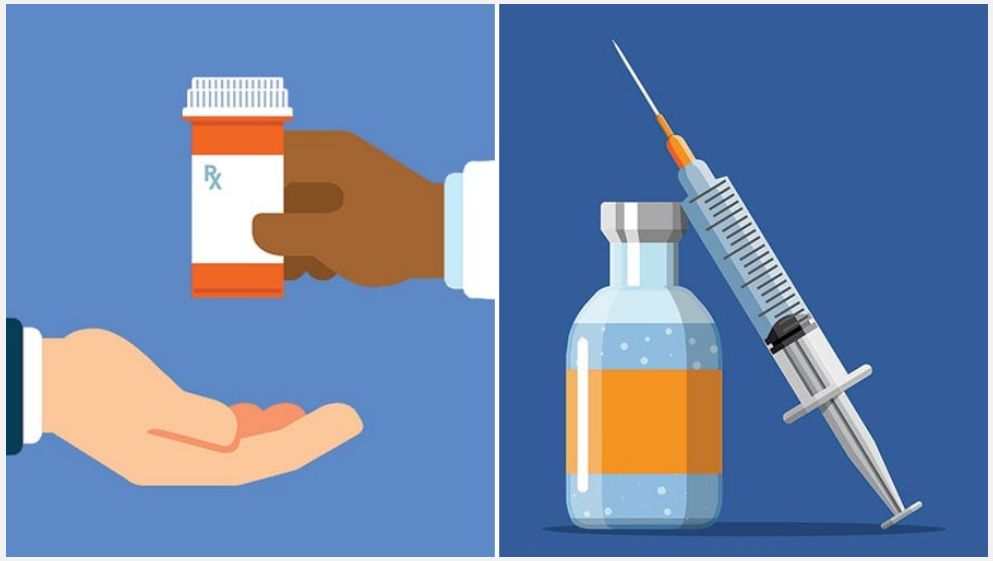
Q: Can the whole vial be thrown away?

A: Yes. Throw it all away and report it.

Spring COVID-19 Updates-April:

Commercialization and Transition of COVID-19 Vaccines

What is Commercialization?



TEXAS Health and Human Services

Texas Department of State Health Services

TEXAS
Health and Human Services

Texas Department of State Health Services

COVID-19 Vaccine Update

Saroj Rai, PhD, MPH

Senior Scientific Advisor

Office of the Chief State Epidemiologist

Texas Department of State Health Services

April 25, 2023

DISCLAIMER

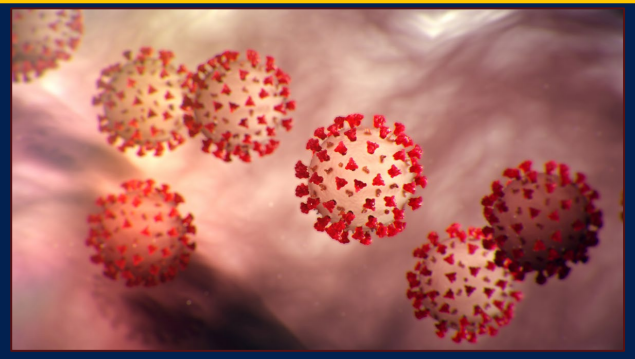
The information presented today is based current preliminary data and on CDC's recent guidance. Information is subject to change.

April 25, 2023

TEXAS
Health and Human Services

Texas Department of State Health Services

COVID-19 Vaccine Update



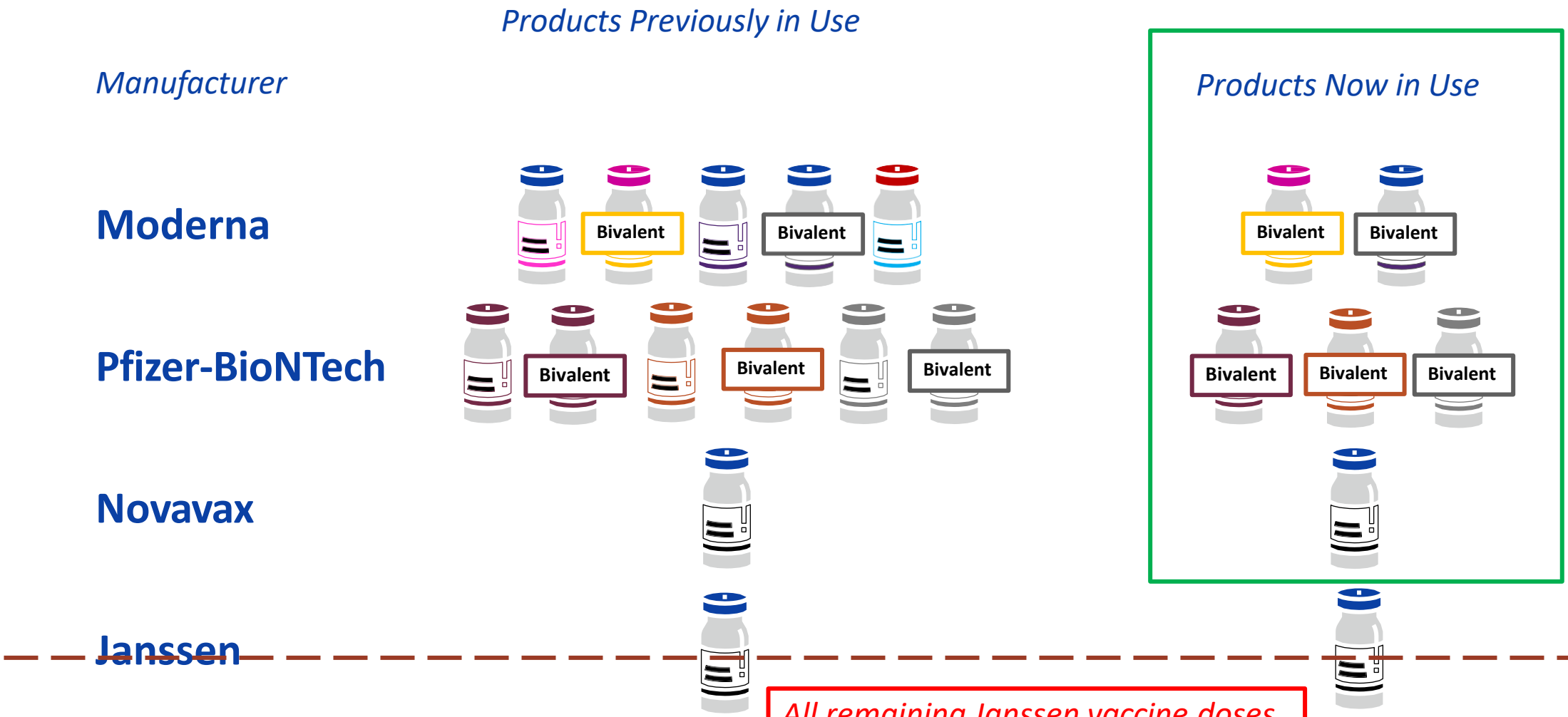
Updated COVID-19 Vaccine Clinical Recommendations

TEXAS
Health and Human Services
Texas Department of State Health Services

- Following the Food and Drug Administration's 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.

Pfizer HCP FS 04182023 (fda.gov)
Pfizer Recipient and Caregiver FS 04182023 (fda.gov)
Moderna Recipients and Caregivers Fact Sheet 6m+ 04182023 (fda.gov)
Moderna HCP Fact Sheet 6m+ 04182023 (fda.gov)

Fewer COVID-19 Vaccine Products in Use



Adapted from: CDC Presentation, accessed 4/24/2023

Updated COVID-19 Vaccine Clinical Recommendations

TEXAS Health and Human Services
Texas Department of State Health Services

- The CDC now recommends that everyone ages 6 years and older receive a bivalent mRNA COVID-19 vaccine, regardless of whether they previously completed their (monovalent) primary series.
  - Individuals ages 6 years and older who have already received a bivalent mRNA vaccine do not need to take any additional shot at this time, *unless they are 65 years and older or immunocompromised.*
    - Individuals ≥65 years who have received a single dose of a bivalent vaccine may receive one additional dose at least four months following their initial bivalent dose.
    - Individuals ≥ 6 years who are immunocompromises and have received a bivalent COVID-19 vaccine may receive an additional dose of a bivalent COVID-19 vaccine at least 2 months following a dose of a bivalent COVID-19 vaccine, and additional doses may be administered at the discretion of their health care provider.

Available at: Clinical Guidance for COVID-19 Vaccination | CDC accessed 4/24/2023

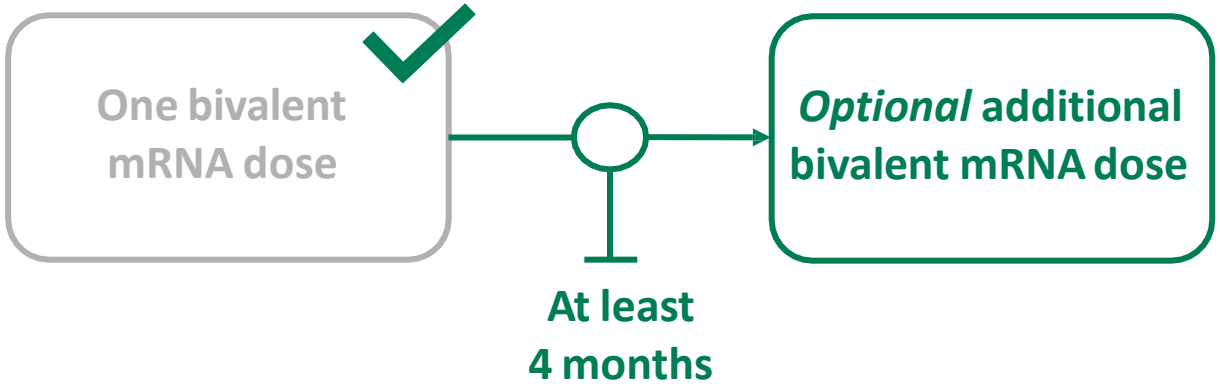
New recommendations for aged ≥6 years without immunocompromise who have already received a bivalent mRNA dose

Vaccination is complete.
No doses are indicated at this time.

Available at: CDC Presentation, accessed 4/24/2023

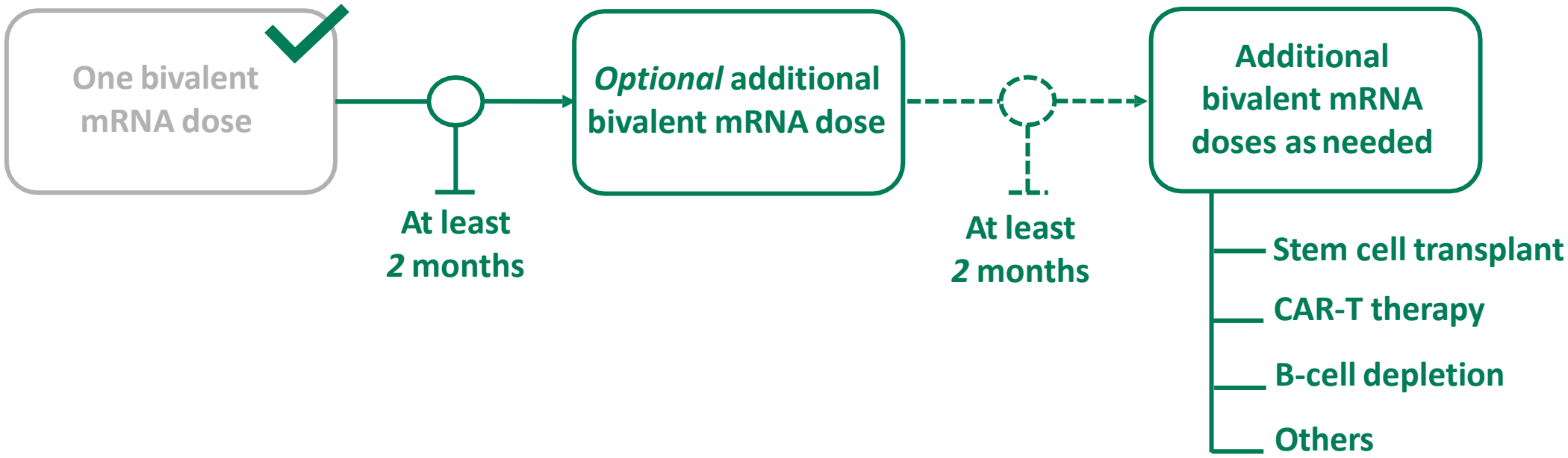
Flexible for people at higher risk of severe COVID-19:

People aged ≥65 years who have already received a bivalent mRNA dose



Available at: CDC Presentation, accessed 4/24/2023

New flexibility for people at higher risk of severe COVID-19: People aged ≥6 years *with immunocompromise** who have already received a bivalent mRNA dose



*Including those with imminent immunocompromise (e.g., prior to organ transplant; other causes.)

Available at: CDC Presentation, accessed 4/24/2023

Non-mRNA COVID-19 Vaccines (Novavax)

Novavax COVID-19 Vaccine

People ages 12 years and older who previously received 1 or more doses of Novavax COVID-19 Vaccine are recommended to receive 1 bivalent mRNA vaccine dose.

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses
1 or more doses of Novavax vaccine	Moderna *or* Pfizer BioNTech	1	0.5 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose
People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.5 mL/50 ug (dark blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border).					

Novavax COVID-19 Vaccine remains authorized to provide:

- A 2-dose primary series to people ages 12 years and older. The primary series doses are separated by 3–8 weeks. An 8-week interval between the first and second primary series doses might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with this vaccine.
- A booster dose in limited situations to people ages 18 years and older who previously completed primary vaccination using any FDA-approved or FDA-authorized COVID-19 vaccine; have not received any previous booster dose(s); and are unable (i.e., mRNA vaccine contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose. The monovalent Novavax booster dose is administered **at least 6 months** after completion of any primary series.

Available at: Clinical Guidance for COVID-19 Vaccination | CDC accessed 4/24/2023

Non-mRNA COVID-19 Vaccines (Johnson & Johnson/Jannsen)

Previous vaccination with Janssen COVID-19 Vaccine

People ages 18 years and older who received the Janssen COVID-19 Vaccine primary series dose are recommended to receive 1 bivalent mRNA vaccine dose (Moderna or Pfizer-BioNTech) at least 2 months after completion of the primary series dose (for people who have not previously received any booster doses), or at least 2 months after the last monovalent booster dose.

Available at: Clinical Guidance for COVID-19 Vaccination | CDC accessed 4/24/2023

mRNA COVID-19 Vaccines(Moderna & Pfizer) for People who are NOT Moderately or Severely Immunocompromised

Ages 12 years and older

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses*
Unvaccinated	Moderna ___or___ Pfizer BioNTech	1	0.5 mL/50 ug	Dark blue cap; gray label border	—
		1	0.3 mL/30 ug	Gray	—
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna ___or___ Pfizer BioNTech	1	0.5 mL/50 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.3 mL/30 ug	Gray	At least 8 weeks after last monovalent dose
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

People ages 65 years and older have the option to receive 1 additional bivalent mRNA vaccine dose at least 4 months after the first dose of a bivalent mRNA vaccine. If Moderna is used, administer 0.5 mL/50 ug (dark blue cap and label with a gray border); if Pfizer-BioNTech is used, administer 0.3 mL/30 ug (gray cap and label with a gray border).

Abbreviation: NA = not authorized

*An 8-week interval between the first and second doses of Moderna and Pfizer-BioNTech COVID-19 vaccines might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

†FDA EUA requires that children who transition from age 4 to 5 years during the Pfizer-BioNTech vaccination series receive the 0.2 mL/3 ug dosage (maroon cap and label with a maroon border) for all doses.

Available at: Clinical Guidance for COVID-19 Vaccination | CDC accessed 4/24/2023

mRNA COVID-19 Vaccines(Moderna & Pfizer) for People who are NOT Moderately or Severely Immunocompromised

Ages 6–11 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses*
Unvaccinated	Moderna ___or___ Pfizer BioNTech	1	0.25 mL/25 ug	Dark blue cap; gray label border	—
		1	0.2 mL/10 ug	Orange	—
1 or more doses monovalent mRNA (no doses bivalent mRNA)	Moderna ___or___ Pfizer BioNTech	1	0.25 mL/25 ug	Dark blue cap; gray label border	At least 8 weeks after last monovalent dose
		1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 or more doses monovalent mRNA and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
Ever received 1 dose bivalent mRNA (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

NDC 80777-282-05

Abbreviation: NA = not authorized

*An 8-week interval between the first and second doses of Moderna and Pfizer-BioNTech COVID-19 vaccines might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

†FDA EUA requires that children who transition from age 4 to 5 years during the Pfizer-BioNTech vaccination series receive the 0.2 mL/3 ug dosage (maroon cap and label with a maroon border) for all doses.

Available at: Clinical Guidance for COVID-19 Vaccination | CDC accessed 4/24/2023

Updated COVID-19 Vaccine Clinical Recommendations

TEXAS
Health and Human Services
Texas Department of State Health Services

- For children 6 months through 5 years of age, multiple doses continue to be recommended and will vary by age, vaccine, and which vaccines were previously received.

Pfizer HCP FS 04182023 (fda.gov)
Pfizer Recipient and Caregiver FS 04182023 (fda.gov)
Moderna Recipients and Caregivers Fact Sheet 6m+ 04182023 (fda.gov)
Moderna HCP Fact Sheet 6m+ 04182023 (fda.gov)

mRNA COVID-19 Vaccines(Moderna & Pfizer) for People who are NOT Moderately or Severely Immunocompromised

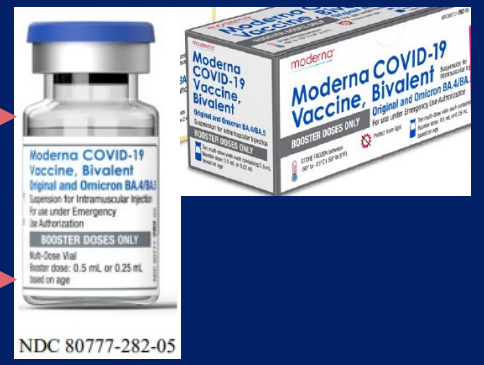
Age 5 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses*
Unvaccinated	Moderna	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
	___or___				
	Pfizer BioNTech	1	0.2 mL/10 ug	Orange	
1 dose monovalent Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; gray label border	4–8 weeks after monovalent dose
	___or___				
	Pfizer BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after monovalent dose
2 doses monovalent Moderna	Moderna	1	0.2 mL/10 ug	Dark pink cap; yellow label border	At least 8 weeks after last monovalent dose
	___or___				
	Pfizer BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent mRNA	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 or more doses monovalent Pfizer-BioNTech	Pfizer-BioNTech	1	0.2 mL/10 ug	Orange	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
Ever received 1 dose bivalent Pfizer-BioNTech (regardless of monovalent vaccine history)	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

Abbreviation: NA = not authorized

*An 8-week interval between the first and second doses of Moderna and Pfizer-BioNTech COVID-19 vaccines might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

†FDA EUA requires that children who transition from age 4 to 5 years during the Pfizer-BioNTech vaccination series receive the 0.2 mL/3 ug dosage (maroon cap and label with a maroon border) for all doses.



NDC 80777-282-05

NDC 80777-283-02

Available at: Clinical Guidance for COVID-19 Vaccination | CDC accessed 4/24/2023

mRNA COVID-19 Vaccines (Moderna & Pfizer) for People who are NOT Moderately or Severely Immunocompromised

Ages 6 months–4 years

COVID-19 vaccination history	Bivalent vaccine	Number of bivalent doses indicated	Dosage (mL/ug)	Vaccine vial cap and label colors	Interval between doses*
Unvaccinated	Moderna ___or___ Pfizer BioNTech†	2	0.25 mL/25 ug	Dark blue cap; gray label border	Dose 1 and Dose 2: 4–8 weeks
		3	0.2 mL/3 ug	Maroon	Dose 1 and Dose 2: 3–8 weeks Dose 2 and dose 3: At least 8 weeks
1 dose monovalent Moderna	Moderna	1	0.25 mL/25 ug	Dark blue cap; gray label border	4-8 weeks after monovalent dose
2 doses monovalent Moderna	Moderna	1	0.2 mL/10 ug	Dark pink cap; yellow label border	At least 8 weeks after last monovalent dose
2 doses monovalent Moderna and 1 dose bivalent Moderna	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA
1 dose monovalent Pfizer-BioNTech	Pfizer BioNTech†	2	0.2 mL/3 ug	Maroon	Dose 1: 3–8 weeks after monovalent dose Dose 1 and Dose 2: At least 8 weeks
2 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
3 doses monovalent Pfizer-BioNTech	Pfizer BioNTech	1	0.2 mL/3 ug	Maroon	At least 8 weeks after last monovalent dose
2 doses monovalent Pfizer-BioNTech and 1 dose bivalent Pfizer-BioNTech	NA; previously received 1 bivalent vaccine dose	NA	NA	NA	NA

NDC 80777-282-05

NDC 80777-283-02

Abbreviation: NA = not authorized

*An 8-week interval between the first and second doses of Moderna and Pfizer-BioNTech COVID-19 vaccines might be optimal for some people ages 6 months–64 years, especially for males ages 12–39 years, as it might reduce the small risk of myocarditis and pericarditis associated with these vaccines.

†FDA EUA requires that children who transition from age 4 to 5 years during the Pfizer-BioNTech vaccination series receive the 0.2 mL/3 ug dosage (maroon cap and label with a maroon border) for all doses.

Available at: Clinical Guidance for COVID-19 Vaccination | CDC accessed 4/24/2023

Moderna Bivalent COVID-19 Vaccines
Dear HealthCare Provider Letter

Moderna COVID-19 Vaccine, Bivalent labeled "BOOSTER DOSES ONLY" is authorized for ALL doses for individuals 6 months of age and older

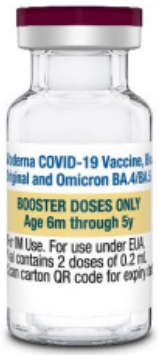
Dear Vaccination Provider:

The purpose of this letter is to inform vaccination providers of the following:

The April 17, 2023, revision to the Emergency Use Authorization of Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) included:

- Use of Moderna COVID-19 Vaccine, Bivalent for **ALL** doses for administration to individuals 6 months of age and older.
- Removal of the authorization for use of the monovalent Moderna COVID-19 Vaccine in the U.S.
- Revision of Dosage and Administration section of the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to no longer refer to "Primary" or "Booster" doses.
- Simplification of the dosing regimen to a single dose for most individuals 6 years of age and older.

There are 2 presentations of Moderna COVID-19 Vaccine, Bivalent (see table). **Even though vials and cartons of both presentations are labeled "BOOSTER DOSES ONLY," doses from these vials are authorized for individuals 6 months of age and older** as conveyed in the Dosage and Administration section of the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers).

Multiple-Dose Vial with Dark Blue Cap and Label with Gray Border[1]	Multiple-Dose Vial with Dark Pink Cap and Label with Yellow Box[1]
 NDC 80777-282-05	 NDC 80777-283-02
For ages 6 months through 5 years, a single dose for Dose 1 and Dose 2 is **0.25 mL** each For ages 6 years through 11 years, a single dose is **0.25 mL** For ages 12 years and older, a single dose is **0.5 mL**	For ages 6 months through 5 years, a single dose for Dose 3 is **0.2 mL**

Available at: Moderna DHCP Letter 6m+ 04182023 (fda.gov) accessed 4/24/2023

en Español

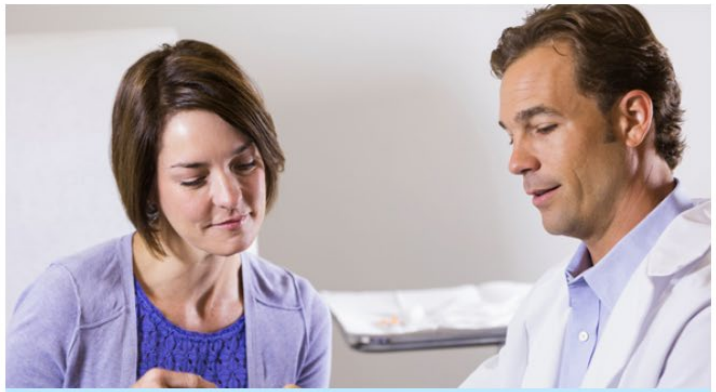
VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

About VAERS | Report an Adverse Event | VAERS Data | Resources | Submit Follow-Up Information

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the downloadable PDF. *New!*

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.



Reporting requirements for healthcare providers administering COVID-19 vaccines

Who can report to VAERS?

VAERS accepts reports from anyone. Patients, parents, caregivers and healthcare providers (HCP) are encouraged to report adverse events after vaccination to VAERS even if it is not clear that the vaccine caused the adverse event. In addition, HCP are required to report certain adverse events after vaccination.

Are all adverse events reported to VAERS caused by vaccines?

No. Some adverse events might be caused by vaccination and others might be coincidental and not related to vaccination. Just because an adverse event happened after a person received a vaccine does not mean the vaccine caused the adverse event.

VAERS accepts reports of adverse events following vaccination without judging the cause or seriousness of the event. VAERS is not designed to determine if a vaccine caused an adverse event, but it is good at detecting unusual or unexpected patterns of reporting that might indicate possible safety problems that need a closer look.

What adverse events must healthcare providers report to VAERS after COVID-19 vaccination?

The reporting requirements for COVID-19 vaccines are the same for those authorized under emergency use (EUA) or approved under Biologics License Application (BLA). Healthcare providers who administer COVID-19 vaccines are **required** to report the following to VAERS:

- Vaccine administration errors, whether or not associated with an adverse event (AE):
  - If the incorrect mRNA COVID-19 vaccine product was inadvertently administered for a second dose in a 2-dose series, **VAERS reporting is required**.
  - If a different product from the primary series is inadvertently administered for the additional or booster (third dose), **VAERS reporting is required**.
  - **VAERS reporting is not required for the following situations:**
    - If a mixed series is given intentionally (e.g., due to hypersensitivity to a vaccine ingredient)
    - Mixing and matching of booster doses (as of October 21, 2021, mixing and matching of booster doses is allowed)

- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

- Cases of myocarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine, or Janssen COVID-19 vaccine
- Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine, or Janssen COVID-19 vaccine
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure whether vaccination caused the event.

Also, healthcare providers must report any additional selected AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine's Emergency Use Authorization (EUA) or any approved COVID-19 vaccine as outlined in the Fact Sheet for Healthcare Providers.

Available at: Vaccine Adverse Event Reporting System (VAERS) (hhs.gov) accessed on March 17, 2023

V-safe Update

TEXAS Health and Human Services

Texas Department of State Health Services

- **V-safe** is a safety monitoring system that lets you share with CDC how you, or your dependent, feel after getting a COVID-19 vaccine.
- Next Steps for v-safe
  - Timing for final registration and completing surveys will be announced soon
  - Next generation v-safe is under development
    - Plans to collect data on new vaccines
    - Will allow greater flexibility for surveys and use CDC IT infrastructure
    - Designed to permit longer-term support for collecting data rapidly from a large number of vaccine recipients

V-safe After Vaccination Health Checker | CDC

Available at: https://www.cdc.gov/vaccines/acip/meetings/slides-2023-04-19.html, Accessed 4/19/2023

TEXAS
Health and Human Services

Texas Department of State Health Services

Future COVID-19 Vaccines

COVID-19 Vaccines – Fall 2023

TEXAS
Health and Human Services
Texas Department of State Health Services

- The Food and Drug Administration (FDA) advisory committee on Vaccine Related Biologics and Product (VRBPAC) will hold a meeting in June 2023 to discuss the strain composition of the COVID-19 vaccines for fall of 2023.
- Much like the FDA does yearly with the influenza vaccines, the agency will seek input from the committee on which SARS-CoV-2 variants and lineages are most likely to circulate in the upcoming year.
- Once the specific strains are selected for the COVID-19 vaccines, the FDA expects manufacturers to make updated formulations of the vaccines for availability this fall.

Available at: Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines | FDA, Accessed 4/19/2023

DISCLAIMER

The information presented today is based current preliminary data and on CDC's recent guidance. Information is subject to change.

April 25, 2023

TEXAS
Health and Human Services

Texas Department of State Health Services

Thank you!

Live Q&A

VacShipments	COVID19VacShipments@dshs.Texas.gov
VacManagement	COVID19VacMgmt@dshs.Texas.gov
VacEnroll	COVID19VacEnroll@dshs.texas.gov
ImmTrac2	ImmTrac2@dshs.Texas.gov ImmTracMU@dshs.texas.gov (**for data exchange**)
COVID-19 Inventory	COVID19Inventory@dshs.texas.gov

Or call (877) 835-7750

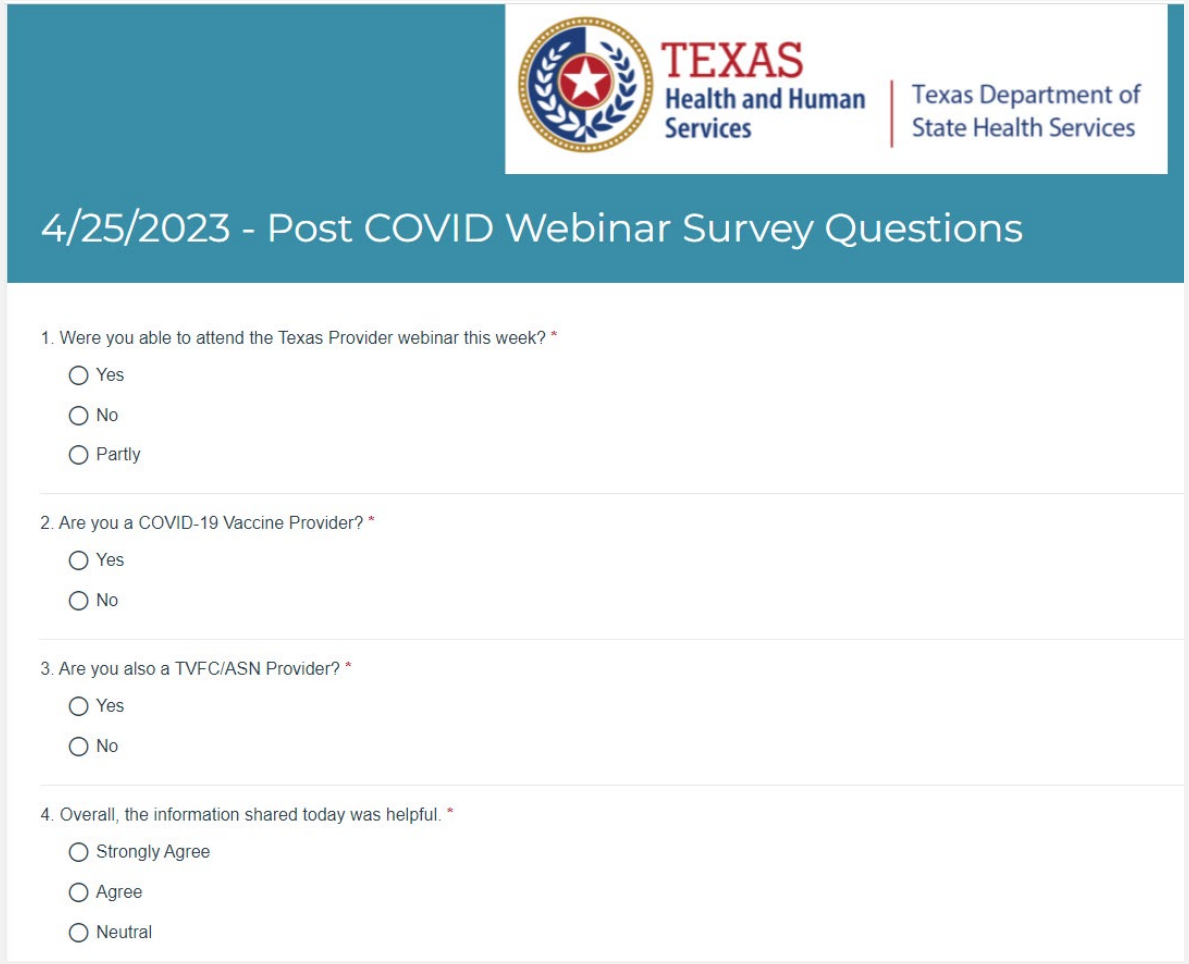
COVID-19 Training & Clinical Reminders

Cheryl Garcia, RN, BSN CCM
COVID-19 Program Nurse

Texas Vaccine Provider Webinar Survey

We want to hear from you in our Texas Vaccine Providers **Webinar Survey**! This quick survey helps us create content that is relevant and helpful for our Texas providers week over week.

Complete our post webinar survey for the date Texas Vaccine Providers Webinar by Thursday, April 27th at 5:00pm CST.



TEXAS Health and Human Services | Texas Department of State Health Services

4/25/2023 - Post COVID Webinar Survey Questions

1. Were you able to attend the Texas Provider webinar this week? *
   - ○ Yes
   - ○ No
   - ○ Partly

2. Are you a COVID-19 Vaccine Provider? *
   - ○ Yes
   - ○ No

3. Are you also a TVFC/ASN Provider? *
   - ○ Yes
   - ○ No

4. Overall, the information shared today was helpful. *
   - ○ Strongly Agree
   - ○ Agree
   - ○ Neutral

COVID-19 Vaccine Fact Sheets

COVID-19 Vaccines Authorized for Emergency Use or FDA-Approved

- **Pfizer-BioNTech COVID-19 Vaccine, Bivalent**
- **Moderna COVID-19 Vaccine, Bivalent**
- **Janssen COVID-19 Vaccine**
- **Novavax COVID-19 Vaccine, Adjuvanted**

Fact sheets for health care providers and patients included
Report vaccine side effects toll-free at 1-800-822-7967 or online

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

TEXAS Health and Human Services
Texas Department of State Health Services

COVID-19 Vaccine Product Ordering Updates

Oscar Paz

Program Specialist V/ Immunization Section

Existing Monovalent Pfizer and Moderna COVID-19 Vaccine Inventory

- Many providers still have monovalent Moderna and Pfizer products on their shelves. Since these are no longer authorized for use, providers should report these as waste in VAOS
- For instructions on reporting waste, review the waste job aid:

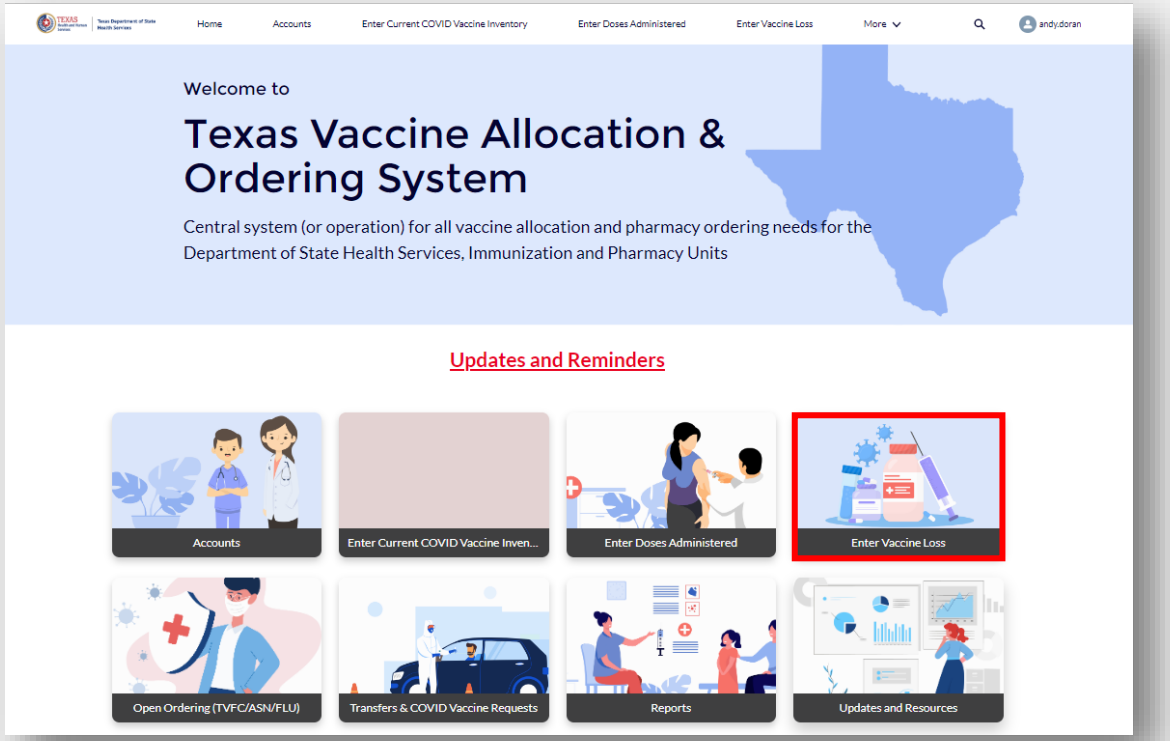
  https://www.dshs.texas.gov/sites/default/files/immunize/covid19/Waste-in-VAOS.pdf
- For disposal guidance, review waste guidelines:

  https://www.dshs.texas.gov/sites/default/files/immunize/covid19/COVID19-Vaccine-Disposal-Guidelines.pdf

Navigate to Vaccine Loss

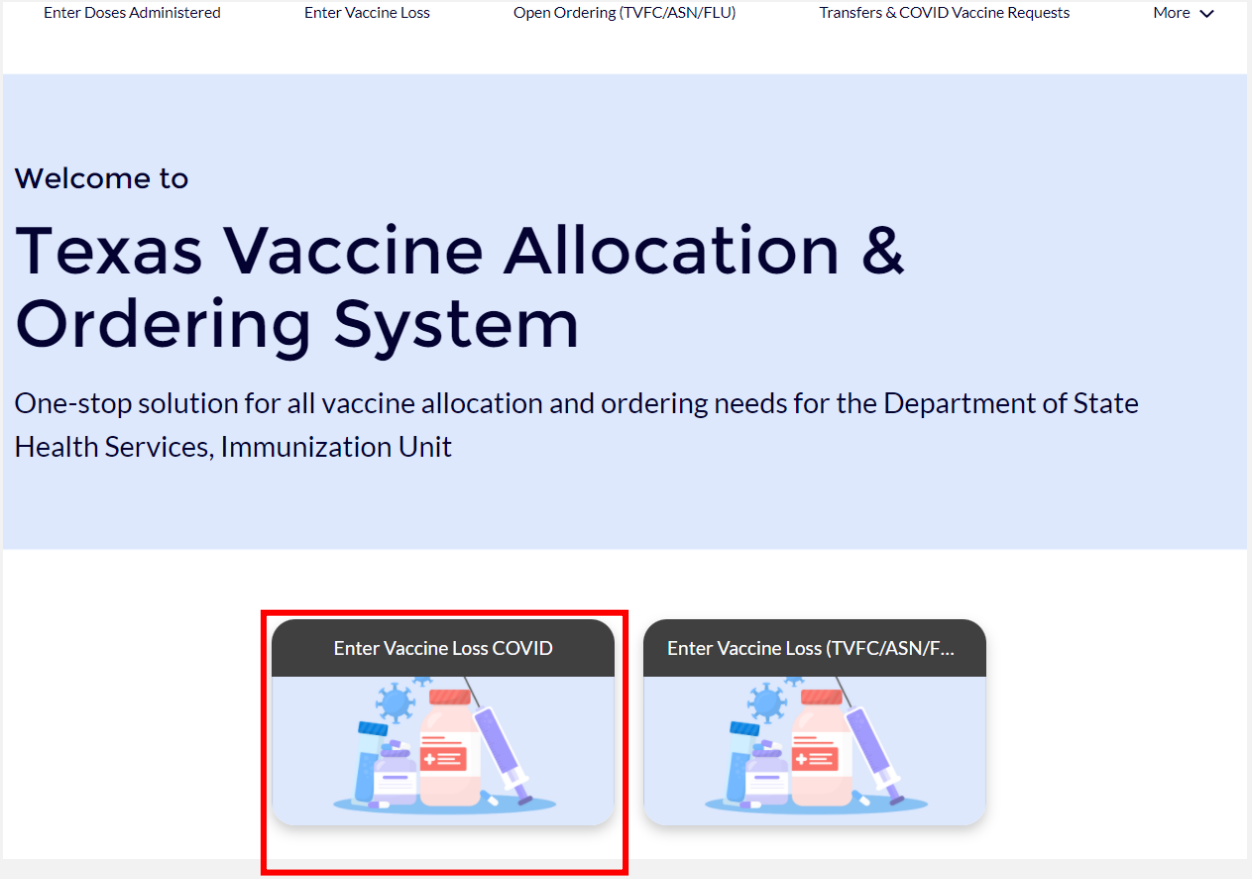
1. Log into VAOS at https://texasvaccines.dshs.texas.gov/.

2. Navigate to the **Enter Vaccine Loss** tab. You will be redirected to the **Vaccine Uses** view.



Navigate to Vaccine Loss

3. Select **Enter Vaccine Loss COVID** to report COVID-19 vaccine waste.

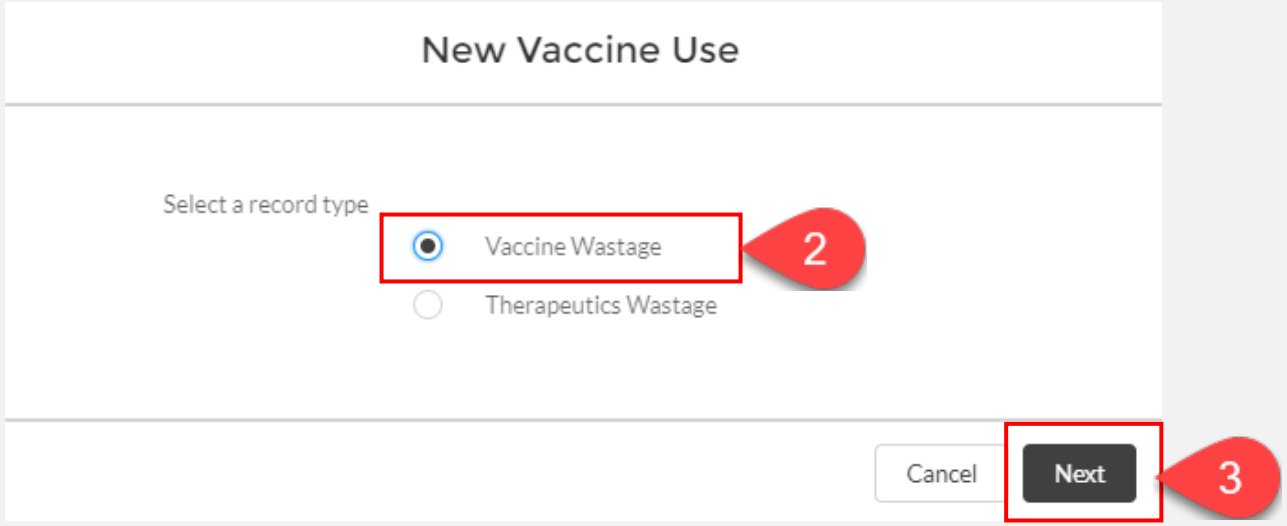


Report New Waste

1. On the Vaccine Uses View, select **New** to report new waste.

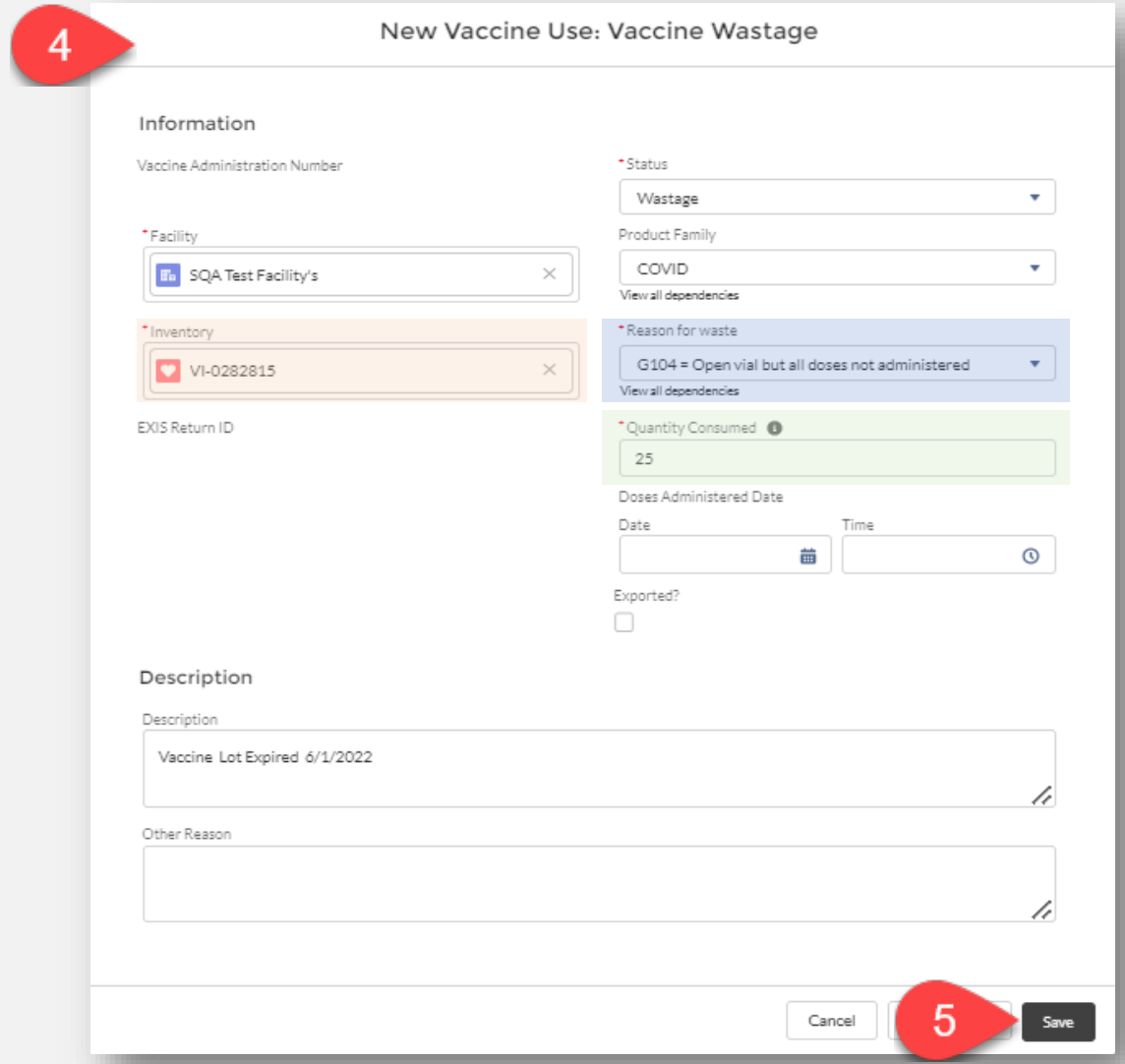
2. From the New Vaccine Use pop up box, select **Vaccine Wastage.**

3. Select **Next**.



Report New Waste

4. Enter the required information in the **New Vaccine Use** pop-up window.
   - In the **Inventory Field**, type in the ***VI number*** to search
   - **Quantity Consumed** is the number of ***doses*** wasted
     - For extra guidance on reporting Moderna waste, visit the Moderna Wastage Table.
   - For more information of **Reason for Waste** and waste codes, see the next slides.
5. Select **Save** to complete the process.



Verify expiry dates through the manufacturer.

Ordering Updates and Reminders

- Since they are no longer authorized, Monovalent Moderna and Pfizer vaccines are no longer available for ordering
- Novavax is still available for ordering in VAOS
- Bivalent COVID-19 Vaccines continue to be available for ordering in VAOS
- Providers may see delays with orders of Pfizer Bivalent Maroon Cap (6 months to 4 years) as the state continues to receive more allocations of this vaccine type
- Pack size orders can take 5-7 business days to receive; Small orders can take 7-10 business days to receive

COVID-19 Vaccine Product Availability

When you enter the "quantity requested," remember that each COVID-19 vaccine type ships in different pack sizes. Use the table below to determine how many doses to request:

Novavax (12+ yrs)	
<100 Doses	>100 Doses
Place orders in **multiples of 5 doses (1 vial)** up to a **maximum of 55 doses**	Place orders in **multiples of 100 doses**

Moderna Bivalent Dark Blue cap, Grey border Label	
<100 Doses	>100 Doses
Place orders in **multiples of 5 doses (1 vial)** up to a **maximum of 60 doses**	Place orders in **multiples of 100 doses**

Pfizer Bivalent (12+ yrs)	
<180 Doses	>180 Doses
Place orders in **multiples of 6 doses (1 vial)** up to a **maximum of 96 doses**	Place orders in **multiples of 180 doses**

Pfizer Bivalent Pediatric (5-11 yrs)	
<100 Doses	>100 Doses
Place orders in **multiples of 10 doses (1 vial)** up to a **maximum of 60 doses**	Place orders in **multiples of 100 doses**

Moderna Bivalent (6 months – 5 yrs) Dark Pink Cap, Yellow border Label	
<20 Doses	>20 Doses
Place orders in **multiples of 2 doses (1 vial)** up to a **maximum of 12 doses**	Place orders in **multiples of 20 doses**

Pfizer Bivalent SDV (12+ yrs)
Minimum 50 – Maximum 150
Only available in 50, 100, 150 dose shipments

Pfizer Bivalent (6 months – 4 years)	
<100 Doses	>100 Doses
Place orders in **multiples of 10 doses (1 vial)** up to a **maximum of 60 doses**	Place orders in **multiples of 100 doses**

Last Updated: 04/21/2023

Ancillary Kit

Available Ancillary Kit Options

Providers can opt-out of receiving ancillary supplies for most COVID vaccines.

Vaccines requiring diluent automatically ship with kits.

Use this chart to designate what your ancillary kit options are based on your vaccine presentation.

Presentation	Ancillary Kit Options
Novavax	Adult Kit Pediatric kit No Ancillary Kit
Pfizer (Bivalent)	Adult Kit Pediatric Kit No Ancillary Kit
Moderna (Bivalent)	Adult Kit No Ancillary Kit
Pfizer Bivalent Pediatric (5-11 yrs)	Pediatric Ancillary Kit
Pfizer Bivalent SDV (12+ yrs)	No Ancillary
Pfizer 100 Bivalent (6 months – 4 years)	Pediatric Kit
Moderna 100 Bivalent (6 months – 5 years)	Pediatric Kit No Ancillary Kit

New Self-Reporting Inventory Timeframe

- Starting in May, providers will have until the 7th of the month to self-report inventory, instead of the 5th
  - Providers will now have from the 1st to the 7th of the month to complete self-reporting
- Providers will receive a reminder on the 1st day of the month to complete reporting
- Providers with VAOS accounts that miss the deadline will receive an email notification of non-compliance
  - In this situation, providers should self-report inventory for the month to become compliant
  - Non-compliance will prevent processing of orders

COVID-19 Vaccine ImmTrac2 Updates

Lisa Marie Pawelczak

IIS Program Specialist V/ Immunization Section

Monovalent Vaccines

- As of April 18th, monovalent vaccines are no longer authorized in United States.
- No new monovalent vaccines should be reported to the Immunization Information System (IIS).
- Historical vaccines given before April 18th can still be reported.
- Once the CDC releases new guidelines, the schedules will be updated in the IIS accordingly.

Live Q&A

VacShipments	COVID19VacShipments@dshs.Texas.gov
VacManagement	COVID19VacMgmt@dshs.Texas.gov
VacEnroll	COVID19VacEnroll@dshs.texas.gov
ImmTrac2	ImmTrac2@dshs.Texas.gov ImmTracMU@dshs.texas.gov (**for data exchange**)
COVID-19 Inventory	COVID19Inventory@dshs.texas.gov

Or call (877) 835-7750

Resources

COVID-19 Vaccine Training/Office Hours

- Moderna
- Pfizer
- Novavax
- Johnson & Johnson/Janssen

TEXAS
Health and Human Services

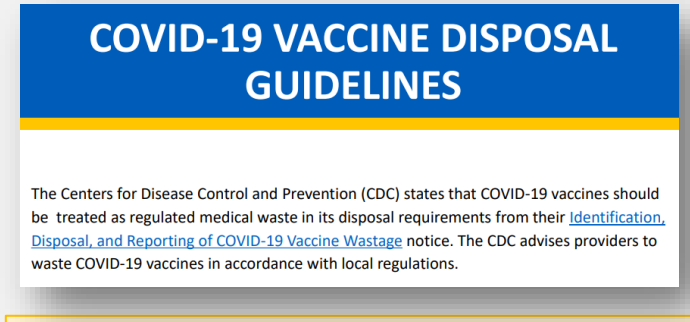
Texas Department of State Health Services

COVID-19 Vaccine Waste Guidance

Waste Disposal and Reporting Resources

While it is important to try to use every dose of vaccine possible, that should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.

Visit the DSHS COVID-19 Vaccine Disposal Guidelines for details on disposing waste: https://dshs.texas.gov/immunize/covid19/COVID19-Vaccine-Disposal-Guidelines.pdf



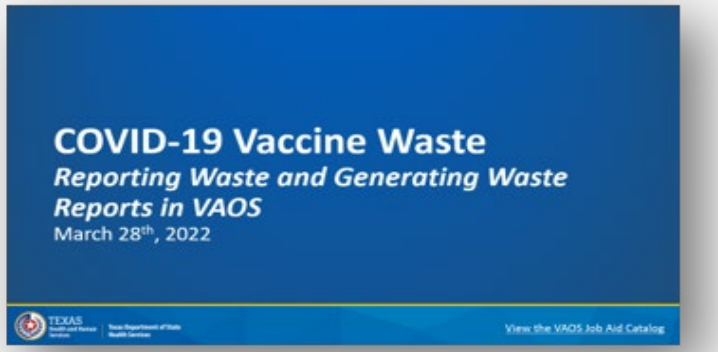
COVID-19 VACCINE DISPOSAL GUIDELINES

The Centers for Disease Control and Prevention (CDC) states that COVID-19 vaccines should be treated as regulated medical waste in its disposal requirements from their Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage notice. The CDC advises providers to waste COVID-19 vaccines in accordance with local regulations.

For guidance on reporting Moderna doses wasted, see the following guide: https://www.dshs.texas.gov/immunize/covid19/Moderna-Wastage-Table-Texas.pdf

Moderna 10/14 COVID-19 Vaccine Wastage Guidance

For guidance on reporting waste in VAOS, see the following guide: https://www.dshs.texas.gov/immunize/covid19/Waste-in-VAOS.pdf



COVID-19 Vaccine Waste

Reporting Waste and Generating Waste Reports in VAOS

March 28th, 2022

TEXAS

View the VAOS Job Aid Catalog

For questions about reporting waste, call (833) 832-7068 (Option 2) or email COVID19VacShipments@dshs.Texas.gov.

Vaccine Manufacturer Resources

Pfizer	moderna	janssen	novavax
Medical Information Phone: 800-438-1985 Email: PfizerMedicalInformation@pfizer.com Website: www.PfizerMedInfo.com	**Medical Information** Phone: 866-663-3762 Email: MedInfo@modernatx.com **Temperature excursion related questions:** Email: excursions@modernatx.com	**Medical Information** Phone: 800-565-4008 **Temperature excursion related questions:** Email: JSCCOVIDTEMPEXCURSION@its.jnj.com	**Medical Information** Phone: 855-239-9174 Novavax.com/contact Website: www.NovavaxCovidVaccine.com

McKESSON

Temperature excursion related questions:
Phone: 833-272-6635
Email: COVIDVaccineSupport@McKesson.com

Updated 7/26/22

DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

April 25, 2023

Thank you!

COVID-19 Vaccine Provider Webinar

April 25, 2023