



COVID-19 Vaccine Toolkit

What Pediatric Providers Need to Know



Updated: July 8, 2022

These materials have been created based on information currently available from the Center for Disease Control ("CDC"), other third-party experts and Children's Healthcare of Atlanta, Inc.'s ("Children's") own experience. Guidance on COVID-19 is changing rapidly. Consequently, Children's is unable to make any representations and/or warranties of any kind, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. While these materials may be updated from time to time based on new information, Children's is not assuming any duty to update the materials or modify them for the specific circumstances of any individual, practice, business or other entity. The recipient should use his or her own professional clinical judgement with respect to patient care and engage his or her own counsel and/or business and finance advisors on matters such as billing and other business practices.

Table of Contents

Introduction.....	Page 2
Vaccine Specifics.....	Page 3
How to Apply to be a Vaccine Site.....	Page 7
Ordering COVID-19 Vaccines.....	Page 9
Storage and Handling.....	Page 11
COVID-19 Vaccine Training.....	Page 13
Coadministration With Other Vaccines & Booster Vaccines.....	Page 15
Vaccine Reporting Requirements.....	Page 17
Coding and Reimbursement.....	Page 21
Practice Implementation & Best Practices.....	Page 28
Important Points to Consider before becoming a COVID-19 Vaccination Site.....	Page 28
Plan Your Work.....	Page 31
Vaccine Storage Requirements and Life Span.....	Page 31
Staffing Considerations.....	Page 32
Training.....	Page 32
Supplies and Vaccine Administration.....	Page 33
Prepare for the Unexpected & Mitigate Risk.....	Page 34
Vaccine Inventory Management.....	Page 36
Establish Your Practice Flow.....	Page 37
Vaccine Clinic vs. Regular Hours.....	Page 39
Recall Lists.....	Page 42
Closing Thoughts From Your Peers.....	Page 43
Appendix(s).....	Page 44

INTRODUCTION

The onset of the COVID-19 pandemic over the past year and a half has changed our daily routines including the way we live, work, care for our families, and practice medicine. The SARS-CoV-2 virus has impacted families and healthcare entities all over the world. To date, statistics from the [American Academy of Pediatrics and CDC](#) show that more than 9.2 million cases of COVID-19 have been reported in the United States. The numbers, and likewise the toll on all of us, is sobering. Pediatric patients in particular are feeling the effects of the virus in their daily lives and the consequences of this disruption in a time of critical development and education.

Fortunately, there is light at the end of the tunnel. The United States has approved Emergency Use Authorization of three COVID-19 vaccines in the effort to stop the pandemic and thereby protect our communities. Throughout the duration of the COVID-19 pandemic we have seen immense grit, perseverance, and creativity from healthcare providers in the fight against the SARS-CoV-2 virus. We cannot thank you enough for your dedication to the communities and families you serve as we continue to work through challenging times.

As a clinically integrated network of pediatric practices, The Children's Care Network is dedicated in joining the fight against the COVID-19 pandemic by providing our community practitioners with the support, education, and resources to prepare and participate in ongoing vaccination efforts. The current COVID-19 vaccine landscape is dynamic and changing every day. There is a plethora of information available, but it can easily become overwhelming. The purpose of this toolkit is twofold. The first intent is to provide healthcare practitioners with data, science, and facts that you need to know about the COVID-19 vaccines. The second intent is to help pediatricians take all the information they have learned and effectively create systems you can implement within your own practice by following a user-friendly framework.

Instructions for Using the Toolkit:

The COVID-19 Toolkit consists of two parts: data and implementation strategies. We encourage you to thoroughly read and digest all the resources provided within this toolkit so that you can be armed with knowledge on how to best help your patients start to transition out of the COVID-19 crisis.

Please note that the information and framework in this toolkit is designed to be fluid in nature and will constantly evolve as new information is learned. We strongly encourage you to adapt the framework to fit your individual practice needs and to stay updated as new developments arise.

VACCINE SPECIFICS



As of May 2021, there are currently three COVID-19 vaccines that have received EUA approval from the FDA in the fight against the SARS-CoV-2 virus. Although all three vaccines have high efficacy rates as proven from clinical trials, we will go through the specifics about each vaccine and how they differ in structure, recommended age groups, and current efficacy studies. **For the latest information on vaccine dosage and other clinical guidance, please refer to the [CDC website](#) and the [AAP Pediatric COVID-19 Vaccine Dosing Quick Reference Guide](#).**

Update – June 18, 2022 – COVID-19 Vaccine Approved for Children 6 months through 5 Years

The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommended two COVID-19 vaccines: a Pfizer-BioNTech vaccine for children ages 6 months through 4 years and a Moderna vaccine for ages 6 months through 5 years. These authorizations will extend the protection of immunization to the last segment of our population awaiting protection.

New Administration Recommendations:

Select the administration code based on the dose. For instance, 0081A represents administration of the first dose, and 0082A represents administration of the second dose. You may use this code for the trisucrose formulation of the Pfizer-BioNTech COVID-19 vaccine. Code 91308 represents the vaccine product. Providers may administer this dosage for pediatric patients ages 6 months to 5 years.

Pfizer-BioNTech

Status:

The Pfizer-BioNTech vaccine was the first of the three COVID-19 vaccines to receive Emergency Use Authorization (EUA) approval from the U.S. Food & Drug Administration (FDA) on December 11, 2020. From clinical data, the Pfizer-BioNTech was proven to be up to 95% effective at preventing transmission of the COVID-19 virus among individuals without prior infection. Further data gathered from [clinical trials](#) observed that the Pfizer vaccine has shown a consistently high efficacy rate (>92%) across age, sex, race and ethnicity categories and among persons with underlying medical conditions.

To date, the Pfizer-BioNTech is currently the only COVID-19 vaccine that has been approved by the FDA for use in both adult and adolescent populations. The vaccine has been fully approved for adolescents aged 16 and older. The FDA has approved the vaccine under the EUA for adolescents ages 12 through 15 years, children ages 5 through 11 years, and as of June 18, 2022, it has been approved for children ages 6 months through 4 years. Please note that the vaccines are dosed and packaged differently for each age group.

Vaccine Structure:

The Pfizer-BioNTech vaccine is a messenger RNA (mRNA) vaccine that is designed to deliver a small piece of genetic code from the SARS CoV-2 virus to host cells in the body so that the cells can then produce spike proteins. These spike proteins subsequently stimulate an immune response that produces antibodies against the virus.

Storage and handling considerations:

The vaccine must be stored in an ultra-cold freezer, thermal shipping container, freezer or refrigerator. Each thermal shipping container holds up for 5 trays, with each tray containing 195 multidose vials. During the shipping process, the Pfizer-BioNTech vaccine requires dry ice to maintain proper temperatures.

For full vaccine information including instruction on vaccine dosage, preparation, administration, and storage and handling requirements, please refer to the CDC's [Pfizer-BioNTech COVID-19 Vaccine site](#).

Additional information on ordering procedures, vaccine reporting, and updated billing codes for the Pfizer-BioNTech COVID-19 vaccine for children will be included and indicated throughout this toolkit.

For additional information, please also refer to the following resources:

- AAP: [Critical Updates on COVID-19](#)
- AAP: [Becoming a COVID-19 Vaccinator Video Series](#)
- AAP: Guidance on [preparing for authorization](#), [practice implementation](#), [getting paid](#) and [frequently asked questions](#)
- The AMA recently released [new CPT codes](#) related to COVID-19 vaccines for 5- to 11-year-olds.

Moderna

Status:

Moderna received EUA approval from the FDA on December 18, 2020. The Moderna vaccine has shown a 94.1% effective rate at preventing transmission of the COVID-19 virus among individuals without prior infection. The Moderna vaccine is recommended for adults 18 years of age and older. As of June 18, 2022, this vaccine has been approved for administration in children ages 6 months through 5 years.

Vaccine Structure:

Similar to the Pfizer vaccine, the Moderna vaccine is a mRNA vaccine that stimulates cells to make a spike protein to stimulate an immune response against the SARS CoV-2 virus.

Storage and handling considerations:

The Moderna vaccine should not be mixed with a diluent. The vaccine must be stored in a freezer or refrigerator. Unlike the Pfizer vaccine, you should not place the vaccine on dry ice. The vaccine can be transported at frozen and refrigerated temperatures using a portable unit or container qualified to maintain appropriate temperatures.

For full vaccine information including dosage guidance, please refer to the [CDC's Moderna COVID-19 Vaccine site](#).

Janssen (Johnson & Johnson)

Status:

The Johnson & Johnson vaccine was granted approval for EUA use by the FDA on February 27, 2021, for adults 18 and older. The Johnson & Johnson vaccine has shown a [72% overall efficacy in the United States](#) and an 86% efficacy against severe forms of the COVID-19 virus in the United States.

Shortly after vaccine rollout, [the CDC and FDA issued a joint recommendation](#) for states to halt the use of the Johnson & Johnson vaccine “out of an abundance of caution” during an investigation into reports of six U.S. cases of a rare, but severe blood clot complications seen in women between the ages of 18 and 48 years old shortly after receiving the vaccine. On Friday, April 23, 2021, the CDC and FDA released an updated [statement](#) recommending that use of the Johnson & Johnson vaccine resume use in the United States following a safety review of the vaccine. However, both the CDC and FDA caution that women younger than 50 years old should be made aware of the rare risk of blood clot complications after receiving the Johnson & Johnson vaccine and that patients should be made aware of alternative vaccines available where this risk has not been observed.

Vaccine Structure:

The Johnson & Johnson vaccine is a viral vector vaccine. As a viral vector vaccine, the Johnson & Johnson vaccine uses a modified version of a different virus (the vector) to deliver instructions to cells to produce a harmless piece of the virus that causes COVID-19. From there, the spike protein is recognized by the immune system and begins to trigger the body to produce antibodies against the virus.

Storage and handling considerations:

The Johnson & Johnson vaccine should not be mixed with a diluent. The CDC recommends discarding vials when there is not enough vaccine to obtain a complete dose. The vaccine can be stored in a refrigerator and will be shipped in a qualified shipping container. Each carton contains 10 multidose vials (50 doses). Each multidose vial contains 5 doses of the vaccine.

For full vaccine information including dosage guidance, please refer to the [CDC's Johnson & Johnson COVID-19 Vaccine site](#).

*Note for physicians: [Please also refer to the CDC's COVID-19 Quick Reference Guide for Healthcare Professionals](#) for a table comparing all the features, storage requirements, and vaccine administration information including contraindications and common side effects.

HOW TO APPLY TO BE A VACCINATION SITE

After learning about the specifics and carefully considering the clinical details for each available vaccine, the second step in the process is to enroll as a COVID-19 vaccination provider. According to the [CDC vaccination provider enrollment](#) website, all COVID-19 vaccines in the United States have been purchased by the U.S. government for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program. Only healthcare professionals enrolled as vaccination providers directly through a health practice or organization can legally store, handle, and administer COVID-19 vaccine in the United States.

The CDC has outlined the steps that providers must follow to participate in the COVID-19 vaccination program. They are as follows:

1. Any health professional interested in being a vaccination provider is required to sign the CDC COVID-19 Vaccination Program Provider Agreement. Before signing the agreement, the CDC recommends that all providers consider the following requirements:
 - You must be legally authorized in your jurisdiction to administer vaccines.
 - COVID-19 vaccines are 100% free for the patient. No administration fees, copays, or co-insurance can be charged. However, vaccination providers may seek reimbursement for vaccine administration fees from a patient's health coverage program or plan or through the [Health Resources and Services Administration COVID-19 Uninsured Program](#) for uninsured patients.
 - You must administer COVID-19 vaccines in accordance with all [program requirements and recommendations](#), including those of CDC, the [Advisory Committee on Immunization Practices](#), and the [U.S. Food and Drug Administration](#).
 - You must be able to [store and handle](#) COVID-19 vaccines under proper conditions to maintain the vaccine cold chain.
 - COVID-19 vaccine preparation differs among COVID-19 vaccine products and is different from that of routinely recommended vaccines. Therefore, vaccine preparation training is essential.
2. COVID-19 vaccine training is required for everyone, including providers who have administered a vaccine in the past 12 months and Vaccines for Children providers. The CDC emphasizes that training must be ongoing as developments arise for the COVID-19 vaccines and recommendations evolve as we learn more about the vaccines and how best to improve the vaccination process.
3. As part of the COVID-19 vaccination program, providers are required to report information on vaccine administration, vaccine supply, and vaccine adverse events. To meet these reporting requirements, vaccine providers must enroll in their jurisdiction's immunization information system. Providers are also required to report specific vaccine administration information daily into their organization's medical record system within 24 hours of vaccine administration as well as reporting that information to an immunization information system within 72 hours.

States and jurisdictions are encouraged by the CDC to establish plans to provide the COVID-19 vaccine safely and effectively to residents in their communities. They are also encouraged to expand the pool of qualified people who can participate in the COVID-19 vaccination program and administer vaccines. As such, the Public Readiness and Emergency Preparedness (PREP) act was amended to include both “current and retired traditional and non-traditional” health care professionals and students in health care programs. There are many ways that pediatricians and health care professionals can help in the fight against the COVID-19 pandemic. To find out more, please visit the [U.S. Department of Health and Human Services Public Health Emergency \(PHE\) website](#) or [contact your state or local immunization program](#).

Additional Actions to Take During the Enrollment Process

In conjunction with applying to be a vaccination site through the CDC, there are also several actions that pediatricians can take while they wait for approval. [The American Academy of Pediatrics](#) recommends the following course of action:

- Administer catch-up vaccines to patients who are behind schedule. Due to the pandemic, many parts of the country have seen a significant decrease over the past year in the rates of routine childhood and adolescent immunizations. The AAP encourages practices to actively recall patients to get them back on schedule. Additional resources regarding [messaging](#) and [recall strategies](#) can be found on the AAP website.
- Pediatricians can play a pivotal role in promoting COVID-19 vaccine confidence. There remains a plethora of misinformation about the COVID-19 vaccine, and vaccine hesitancy can threaten the progress towards herd immunity. The AAP also provides [COVID-19 vaccine confidence resources](#) that pediatricians can use to educate their patients.
- If your practice chooses not to become a COVID-19 vaccination site, the AAP advises you to identify and compile a list of known COVID-19 vaccination sites within your community to share with patients.

For practices who want to administer the COVID-19 vaccine, the AAP advises practices to do the following:

- Enroll to administer the COVID-19 vaccine in your state. For Georgia, additional information can be found on the Georgia Department of Public Health website at www.dph.georgia.gov.
- Secondly, you may also consider learning more about providing COVID-19 vaccine to adults, including enrolling in Medicare to provide the vaccine to senior citizens. Some practices may choose to participate in both state and local vaccination efforts, with the ability to vaccinate entire families. For pediatricians to be eligible to be paid to administer the vaccine to seniors, they must be enrolled in [Medicare](#). Provisional enrollment during the public health emergency can be granted over the phone by contacting the [Medicare Administrative Contractor \(MAC\)](#).

ORDERING COVID-19 VACCINES

Please Note: The summary below is for the Pfizer-BioNTech COVID-19 Vaccine Only

Once your practice is approved to be a COVID-19 vaccination provider, vaccine orders and distribution will follow the national protocol for [Pandemic Vaccine Program Distribution, Tracking, and Monitoring](#).



First determine the number of doses you want to receive

- A. The full box of 195 vials, 1170 doses of the Pfizer Vaccine
- B. Smaller shipments of 60 or 120 doses of the Pfizer Vaccine

Order the box of 195 Vials

1. Enroll as a COVID-19 Provider in Georgia ([LINK](#))
 - a. Complete an online enrollment application in GRITS (Georgia Registry of Immunization Transactions & Services)
 - i. Videos
 - ii. Forms
2. You have to be approved
3. Then you will be sent a link to order

Order a smaller shipment of 60 or 120 doses

1. Enroll as a COVID-19 Provider in Georgia ([LINK](#))
 - a. Complete an online enrollment application in GRITS (Georgia Registry of Immunization Transactions & Services)
 - i. Videos
 - ii. Forms
2. You have to be approved
3. Once your application is processed you will receive a confirmation email that includes an online order survey. Complete the Pfizer-BioNTech COVID-19 Vaccine Specialty Order Form online.

**Note: if you are ordering the smaller amount of 60 or 120 doses, you will receive a phone call to confirm both the day you will receive the shipment and the number of doses.*

***Note: After completing the order form online, if your practice is not contacted on either the Friday or Monday following your order placement, please call **DPH at 404-825-0250** for follow up.*



Additional notes from the Georgia Immunization Program on ordering and receiving COVID-19 vaccines:

- Orders should be placed via ReadyOp by 5pm on Tuesdays in order to receive the vaccine shipment the following week
- Orders will be reviewed and confirmed by the end of the same week
- The warehouse will call and confirm POC's and delivery locations
- Vaccines will be delivered via state law enforcement in temperature-controlled coolers, all vaccines are shipped at frozen temperatures (between -15 to -25 Celsius).
- When you receive your order, it will include a *Vaccine for Pediatrics Information Sheet* from the Department of Public Health. (Appendix A).
 - This cover sheet will indicate the appropriate use by date for your vaccines depending on your practice's storage capabilities.
 - A phone number and email address for the warehouse are located on the cover sheet if you need additional assistance with your vaccine delivery.
- Once you receive your vaccine delivery, each provider will be required to sign for their delivery and will need to fill out a *Transfer of Custody Form* (Appendix B).
 - The provider will need to record the receiving time and temperature of the vaccine ○ The provider should take a picture or make a copy of the transfer of custody form for their records. Return the original form to the delivery officer
 - An additional custody form will also be included for adolescent ancillary supplies (for 1" needles only)

STORAGE AND HANDLING PROTOCOLS

No matter which COVID-19 vaccine product your practice chooses to begin the vaccination process with, it is important to note that each vaccine product has specific instructions regarding vaccine preparation, administration, and storage and handling protocols. Storage protocols in particular do not necessarily translate from one product to another. Providers will need to familiarize themselves with the applicable vaccine instructions prior to administration and implementation in their practice.

Included vaccine resources from the CDC are linked as follows:

Pfizer-BioNTech COVID-19 Vaccine

- [Pfizer COVID-19 Vaccine Standing Orders](#)
- [Preparation and Administration Summary](#)
- [Storage and handling CDC guide](#)

Storage Summary for Pfizer Vaccine for Ages 16 and older:

Location	Temperature		Lifespan
Ultra-cold freezer	-90°C to -60°C	-112°F to -76°F	9 months
Freezer	-25°C to -15°C	-13°F to 5°F	Up to 2 weeks
Refrigerator	2°C to 8°C	36°F to 46°F	30 days*
Once mixed	2°C to 25°C	35°F to 77°F	6 hours

*Note: On [May 19, 2021](#), The U.S. Food and Drug Administration is authorizing undiluted, thawed Pfizer-BioNTech COVID-19 Vaccine vials to be stored in the refrigerator at 2°C to 8°C (36°F to 46°F) for up to 1 month. Previously, thawed, undiluted vaccine vials could be stored in the refrigerator for up to 5 days.

Storage Summary for Pfizer Vaccine for Ages 5 to 12:

Location	Temperature		Lifespan
Ultra-cold freezer	-90°C to -60°C	-112°F to -76°F	6 months
Freezer	-25°C to -15°C	-13°F to 5°F	N/A
Refrigerator	2°C to 8°C	36°F to 46°F	10 weeks
Once mixed	2°C to 25°C	35°F to 77°F	N/A* (information pending CDC recommendation)

Moderna COVID-19 Vaccine

- [Moderna COVID-19 Vaccine Standing Orders](#)
- [Preparation and Administration Summary](#)
- [Storage and handling CDC guide](#)

Storage Summary:

Location	Temperature		Lifespan
Freezer	-50°C to -15°C	-58°F to 5°F	Until the expiration date
Refrigerator	2° to 8°C	36°F to 46°F	30 days
Punctured Vials	2°F to 25°C	36°F to 77°F	12 hours

Janssen COVID-19 Vaccine (Johnson & Johnson)

- [Johnson & Johnson COVID-19 Vaccine Standing Orders](#)
- [Preparation and Administration Summary](#)
- [Storage and handling CDC guide](#)

Storage Summary:

Location	Temperature		Lifespan
Refrigerator	2° to 8°C	36°F to 46°F	Until expiration date
Punctured Vials	2°F to 25°C	36°F to 77°F	6 hours

UPDATES ON HANDLING AND REPORTING VACCINE WASTE

The CDC recently released guidelines outlining how to handle COVID-19 vaccine waste, disposal, and reporting. The CDC states,

“As access to COVID-19 vaccine increases, it is important for providers to not miss any opportunity to vaccinate every eligible person who presents at vaccine clinics. We recognize that as we continue to create more opportunities to vaccinate more people, it may increase the likelihood of leaving unused doses in a vial. While we want to continue to follow best practices to use every dose possible, we do not want that to be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.”

Highlights include:

- Identifying waste
- What to do with compromised vaccines
- Vaccine disposal
- Reporting of wasted COVID-19 vaccines
- Vaccine wastage best practices and tips to reduce vaccine waste

Source: [CDC's Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage](#)

COVID-19 VACCINE TRAINING RESOURCES

Ongoing training is not only a requirement under the COVID-19 vaccine program, but it is also vital to the success of all participating providers. The CDC has several training resources available that cover a wide range of topics related to the COVID-19 vaccine to help you get started.

COVID-19 Vaccine Provider Training Modules:

[COVID-19 Vaccine Training Modules \(cdc.gov\)](#)

- Includes a general overview of immunization best practices for healthcare providers
- Pfizer-BioNTech COVID-19 Vaccine: What Healthcare Professionals Need to Know
- Moderna COVID-19 Vaccine
- Janssen COVID-19 Vaccine (Johnson & Johnson)

[CDC COVID-19 Vaccination Provider Trainings](#)

- How to prepare vaccines
- Vaccine administration
- Vaccine storage and handling
- Vaccine documentation
- Vaccine safety and monitoring
- Preventing vaccine administration errors
- Overview of program requirements

General Vaccine Administration Training and Resources:

Online Training: *You Call the Shots*, [Vaccine Administration module](#)

Resources:

- [CDC's Vaccine Administration web page](#)
- [CDC's Injection Safety website](#)
- [CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases, "Vaccine Administration"](#)

Adverse Events Information: [VAERS website](#)

Vaccine Storage and Handling Training and Resources:

Online Training: *You Call the Shots*, [Vaccine Storage and Handling module](#).

- Updated for 2021 to include:
 - Beyond Use Date (BUD)
 - Routine Maintenance for Vaccine Storage Units
 - New Definition Added to the Glossary
 - COVID-19 Vaccine Information

Resources Regarding CDC's storage and handling recommendations and best practices:

- [CDC's Vaccine Storage and Handling Toolkit](#). Note: A COVID-19 Vaccine Addendum has been added
- [CDC's Identification, Disposal and Reporting of COVID-19 Vaccine Wastage](#)

V-safe After Vaccination Health Checker:

[Online Training and instructions to use V-safe](#), which is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine.

COADMINISTRATION WITH OTHER VACCINES

Previously the CDC recommended a vaccine black out period, but this requirement has since changed. The CDC's Dr. Kate Woodworth said,

"Extensive experience with non-Covid-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone...For these reasons, the clinical considerations regarding coadministration are being updated to state that Covid-19 and other vaccines may now be administered without regard to timing. This includes simultaneous administration of Covid-19 with other vaccines on the same day, as well as coadministration within 14 days."

This change is due in part to the recent decline in routine childhood vaccinations, of which many children are overdue. The AAP has also [endorsed the simultaneous administration of the COVID-19 vaccine with other vaccinations](#). As stated on the AAP site, given the importance of routine vaccination and the need for rapid uptake of COVID-19 vaccines, the AAP supports coadministration of routine childhood and adolescent immunizations with COVID-19 vaccines (or vaccination in the days before or after) for children and adolescents who are behind on or due for immunizations (based on the [CDC/AAP Recommended Child and Adolescent Immunization Schedule](#)).

Source: [CDC Recommends use of Pfizer's Covid-19 Vaccine in 12-15 Year Olds](#)

Source: [CDC Recommends Pediatric COVID-19 Vaccine for Children 5-11 Years](#)

UPDATE ON COVID-19 BOOSTER SHOTS

In a press release dated [September 22, 2021](#), the FDA amended the emergency use authorization for the Pfizer-BioNTech COVID-19 vaccine to allow for a single booster dose to certain populations that can be administered at least six months after the primary series. These eligible populations include:

- individuals 65 years of age and older;
- individuals 18 through 64 years of age at high risk of severe COVID-19; and
- individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.

Additionally, [on October 20, 2021](#) the FDA expanded on its September press release to allow for the use of a single booster dose for both the Moderna and Janssen (Johnson and Johnson) COVID-19 vaccines.

The requirements for the Moderna booster dose include:

- The use of a single booster dose of the Moderna COVID-19 Vaccine that may be administered at least 6 months after completion of the primary series to individuals:
 - 65 years of age and older
 - 18 through 64 years of age at high risk of severe COVID-19
 - 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2

The requirements for the Janssen (Johnson & Johnson) booster dose include a single booster dose that may be administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older.

In the same release, the FDA also stated that individuals in the eligible populations listed above can also use any of the available COVID-19 vaccines as a heterologous (or “mix and match”) booster dose following completion of primary vaccination with a different available COVID-19 vaccine.

*On November 19, 2021, the US Food and Drug Administration authorized the Pfizer/BioNTech Covid-19 vaccine for [all individuals 18 years of age and older](#) after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. Shortly following, on December 9, 2021 the US FDA also authorized the Pfizer/BioNTech Covid-19 vaccine for use as a [booster in people ages 16 and 17](#). FDA authorization for the Pfizer/BioNTech Covid-19 vaccine [booster shots for 12-15 year olds](#) was released on January 3, 2022. The CDC also updated all [COVID-19 vaccine booster shot recommendations](#) on their website to include information for all approved age groups that are currently eligible to receive the COVID-19 vaccine booster shots.

VACCINE REPORTING REQUIREMENTS



All providers participating in the CDC COVID-19 Vaccination Program are required to follow specific reporting guidelines outlined in their signed provider agreement. More information can be found on the [CDC COVID-19 Vaccination Program Requirements and Support](#) page as well as outlined briefly in the following section.

For provider agreements not specifying vaccine administration data to be recorded or reported, the following applies:

After administering a dose of COVID-19 vaccine, record to the extent not already recorded in the vaccine recipient's record all information marked below by an asterisk and report the following required vaccine administration data, or other data elements if revised by CDC, to the appropriate entity noted in the agreement:

- a. Administered at location/facility name/ID
- b. Administered at location type
- c. Administration address (including Company)*
- d. Recipient name and ID*
- e. Recipient date of birth*
- f. Recipient sex*
- g. Recipient race
- h. Recipient ethnicity
- i. Recipient address*
- j. Administration date*
- k. CVX (product)*
- l. NDC (national drug code)
- m. Dose number*

- n. Lot number (Unit of Use [UoU] or Unit of Sale [UoS])*
- o. MVX (manufacturer)*
- p. Sending organization (name of the Agency submitting the report)
- q. Vaccine administering provider's name and suffix*
- r. Administering provider's address, if different than the administration address*
- s. Vaccine administration site (on the body)*
- t. Vaccine expiration date*
- u. Vaccine route of administration*
- v. Vaccine series

Requirements for Reporting to VAERS:

<https://vaers.hhs.gov/reportevent.html>

The Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to detect possible safety problems in vaccines used in the United States. VAERS accepts and analyzes reports of adverse events (AEs) after a person has received a vaccination. Healthcare professionals are required to report certain adverse events and vaccine manufacturers are required to report all adverse events that come to their attention.

Healthcare providers are required to report to VAERS the following adverse events after COVID-19 vaccination, under Emergency Use Authorization (EUA), and other adverse events if later revised by CDC:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Cases of COVID-19 that result in hospitalization or death
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
 1. Death;
 2. A life-threatening AE;
 3. Inpatient hospitalization or prolonged hospitalization;
 4. A persistent or significant incapacity or substantial disruption in the ability to conduct normal life functions;
 5. A congenital anomaly/birth defect;
 6. 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 Multisystem Inflammatory Syndrome

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

Also report any additional select 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 being authorized under an EUA.

Daily Reporting Requirements

All COVID-19 vaccination providers must report COVID-19 vaccine inventory daily into Vaccines.gov.

In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into Vaccines.gov. If you have questions about the process for your jurisdiction, the CDC recommends contacting your jurisdiction's immunization program.

For additional resources regarding Vaccines.gov, please check out:

- [Vaccines.gov: COVID-19 Vaccine Information for Jurisdictions and Healthcare Providers](#)
- [Enrolling in your jurisdiction/state-based IIS system](#)
- [See CDC's Reporting Requirements](#): Technical Standards for Reporting Data
- [Add the COVID-19 vaccine label to your VTrckS profile](#)

Vaccine Administration Documentation

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., IIS) as soon as practicable and no later than 72 hours after administration.

Click [here](#) to see additional information on the Immunization Information Systems (IIS) page.

Please note the following the requirements for documenting records and managing inventory from the Georgia Immunization Program:

- All COVID-19 vaccination records must also be submitted using a specific eligibility code labeled "COVID Specific"
 - COVID specific is coded as V07 for electronic interfaces
- In addition, each facility will need to ensure that the inventory deduction function is turned on for their interface
- All doses are entered and stored as public doses
- Receipt of vaccine shipments must be manually added to inventory
- VaccineFinder reporting is required to document both daily inventory totals and public facing display

Update as of 6/29/21: Georgia Department of Health Rolling Out COVID-19 Vaccine Management System (VMS)

The Georgia Department of Public Health (DPH) is scheduled to start rolling out a new system for COVID-19 vaccine management, referred to as VMS. VMS is as an interactive portal that streamlines the COVID-19 vaccine ordering, inventory, and reporting dose administration. VMS is being rolled out in phased releases to all COVID-19 pandemic providers in Georgia, through the end of June.

A targeted communication from the COVID-19 DPH mailbox (DPH-Covid19vaccine@dph.ga.gov), will be emailed to the primary and secondary contacts, listed in GRITS. When the team is bringing on your practice - the GA DPH team encourages you to set up your account, when you receive access, if you are currently enrolled as a COVID-19 vaccine provider.

You can expect the following changes with VMS:

- The ability to view COVID-19 vaccine data all in one system
- Order COVID-19 vaccines directly in the VMS provider portal
- Receive automatic notifications when COVID-19 vaccine requests are received as well as when vaccines are shipped

If you have additional questions about orders or access to the VMS system, send an email to the inbox listed above or call (888) 920-0165.

Update as of 10/29/2021: Ordering Pediatric Pfizer-BioNTech COVID-19 Vaccine through VMS

According to the Ga DPH, shipments for pediatrics vaccines can begin once the FDA issues emergency use authorization for children ages 5-11 years old. Vaccine administration can begin once the CDC makes their recommendations.

When ordering COVID-19 vaccines for children in VMS please note:

- The vaccine is listed as Pfizer-Ped in VMS
- The minimum order will be 300 doses for initial product launch and 100 doses in subsequent weeks

CODING AND REIMBURSEMENT



As a COVID-19 vaccination program provider, the CDC stipulates certain regulations regarding the proper billing and coding of the COVID-19 vaccine as outlined below:

The COVID-19 Vaccine is Provided at 100% No Cost to Recipients.

All organizations and providers participating in the CDC COVID-19 Vaccination Program:

- **must** administer COVID-19 Vaccine at no out-of-pocket cost to the recipient
- may **not** deny anyone vaccination based on the vaccine recipient's coverage status or network status
- may **not** charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided
- may **not** require additional medical services to receive COVID-19 vaccination
- **may** seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient, such as:
 - vaccine recipient's private insurance company
 - Medicare or Medicaid reimbursement
 - HRSA COVID-19 Uninsured Program for non-insured vaccine recipients
- may **not** seek any reimbursement, including through balance billing, from the vaccine recipient

As more pediatricians anticipate administering vaccines to their adolescent population, the [AAP](#) has also released guidance on how to properly code and get reimbursed for COVID-19 vaccine administration.

Vaccine Product and Administration

Pediatricians who administer COVID-19 vaccines in their practice can get paid for vaccine administration by following the steps outlined below.

The CPT Editorial Panel has developed several new SARS-CoV-2 vaccine product and immunization administration codes. The new CPT codes:

- clinically distinguish each coronavirus vaccine product and the specific dose for better tracking, reporting, and analysis
- allow for unique CPT vaccine administration codes for each vaccine product
 - this includes unique codes for a 1st dose of a single product and a 2nd dose

This level of specificity is a first for vaccine administration codes, and offers the ability to track each vaccine dose, even when the vaccine product is not reported (e.g., when the vaccine may be given to the patient for free). The CPT codes for the administration include:

- practice expense costs of storage and ordering
- counseling provided to patients or caregivers on the date the vaccine is administered
- administering the vaccine
- updating the electronic health record and the vaccine registry

Note: you will not report the immunization administration codes (90460-90461, 90471-90474) when administering a Coronavirus vaccine. Providers are also **not** allowed to bill for the actual vaccine if they are receiving the vaccine from the government. You will need to place a \$0 charge next to the vaccine code. This rule applies to both CPT codes 91300 and 91301.

A provider should only bill for one of the vaccine administrations codes in the following table referenced from the [Centers for Medicare & Medicaid Services](#).

CPT Code	Labeler Name	Vaccine/ Procedure Name	National Payment Allowance Effective for claims with DOS on or after 3/15/2021
91300	Pfizer	Pfizer-BioNTech Covid-19 Vaccine for ages 12+	\$0.010*
0001A	Pfizer	Pfizer-BioNTech Covid-19 Vaccine Administration First Dose	\$40.00**
0002A	Pfizer	Pfizer-BioNTech Covid-19 Vaccine Administration Second Dose	\$40.00**
0003A	Pfizer	Pfizer-BioNTech Covid-19 Vaccine Administration Third Dose	\$40.00**
0004A	Pfizer	Pfizer-BioNTech Covid-19 Vaccine Booster Administration	\$40.00**
91307	Pfizer	Pfizer-BioNTech Covid-19 Vaccine for ages 5-11 years	\$0.010*
0071A	Pfizer	Pfizer-BioNTech Covid-19 Vaccine for ages 5-11 years- First Dose	\$40.00**
0072A	Pfizer	Pfizer-BioNTech Covid-19 Vaccine for ages 5-11 years- Second Dose	\$40.00**
91301	Moderna	Moderna Covid-19 Vaccine	\$0.010*
0011A	Moderna	Moderna Covid-19 Vaccine Administration- First Dose	\$40.00**
0012A	Moderna	Moderna Covid-19 Vaccine Administration- Second Dose	\$40.00**
0013A	Moderna	Moderna Covid-19 Vaccine Administration- Third Dose	\$40.00**
91302	AstraZeneca	AstraZeneca Covid-19 Vaccine	\$0.010*
0021A	AstraZeneca	AstraZeneca Covid-19 Vaccine Administration- First Dose	\$40.00**
0022A	AstraZeneca	AstraZeneca Covid-19 Vaccine Administration- Second Dose	\$40.00**
91303	Janssen	Janssen Covid- 19 Vaccine	\$0.010*
0031A	Janssen	Janssen Covid- 19 Vaccine- Administration	\$40.00**
0034A	Janssen	Janssen Covid- 19 Vaccine- Booster Administration	\$40.00**

* Since we anticipate that providers, initially, will not incur a cost for the product, CMS will update the payment allowance at a later date. Providers should not bill for the product if they received it for free.

** These rates will also be geographically adjusted for many providers. For providers and suppliers with payments that are geographically adjusted by the methodology used by the Medicare Physician Fee Schedule (MPFS), files with the geographically adjusted payment rates for COVID-19 vaccine administration are included in the “Additional Resources” section below. Certain settings utilize other payment methodologies, such as payment based on reasonable costs.

Please note that the above rates are the Medicare CMS Base Rates. They may range based on your contracted rates.

Please note that documentation needs to support billing an E/M code with one of the vaccine administration codes for established patients. Providers will still need to check patient eligibility prior to billing insurance companies.

Update as of June 18, 2022

The American Medical Association (AMA) today announced an editorial update to [Current Procedural Terminology \(CPT®\)](#), the nation's leading medical terminology code set for describing health care procedures and services, that includes new product and administration codes assigned to the Moderna COVID-19 vaccine for children 6 months through 5 years old.

The provisional CPT codes are effective for use on the condition that Moderna's pediatric COVID-19 vaccine candidate is granted an Emergency Use Authorization by the U.S. Food and Drug Administration (FDA). The AMA is publishing the CPT code update now to ensure electronic systems across the U.S. health care system are prepared in advance for the potential FDA authorization.

"Authorization of a vaccine for children aged 5 and younger would be another important milestone in the fight against COVID-19," said AMA President Gerald Harmon, M.D. "Extending COVID-19 vaccination protection to approximately 18 million young children will significantly reduce their risk of COVID-19 infection, hospitalization, and death, and give their parents incredible peace of mind. We strongly urge all parents to get their infants and toddlers vaccinated as soon as they are eligible for a COVID-19 vaccine."

CPT codes clinically distinguish each coronavirus vaccine and dosing schedule to allow for data-driven tracking, reporting and analysis that supports planning and allocation during the public health response to the pandemic. To date, 38 CPT codes have been created for reporting COVID-19 vaccines.

To help ensure accurate coding and reporting of COVID-19 vaccines and immunization services, the AMA offers a [vaccine code finder resource](#) to help identify the appropriate CPT code combination for the type and dose of COVID-19 vaccine provided to each patient.

For quick reference, the new product code and administration codes assigned to the Moderna COVID-19 vaccine for children in the age range of 6 months to 5 years are:

Product Code

91311 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use

Administration codes

0111A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage; first dose

0112A Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage; second dose

Short, medium and long descriptors for all the new vaccine-specific CPT codes can be accessed on the [AMA website](#), along with other recent modifications to the CPT code set that have helped streamline the public health response to the SARS-CoV-2 virus and the COVID-19 disease.

Changes to the CPT code set are considered through an open editorial process managed by the CPT Editorial Panel that collects broad input from the health care community and beyond to ensure CPT content reflects the coding demands of digital health, precision medicine, augmented intelligence, and other aspects of a modern health care system. This rigorous editorial process keeps the CPT code set current with contemporary medical science and technology so it can fulfill its vital role as the trusted language of medicine today and the code to its future.

Questions on CPT coding and content should be directed to the [CPT Network](#), the authoritative source for CPT coding answers. Also consult the AMA online library of [COVID-19 CPT coding and guidance](#).

Information on Vaccine Counseling Codes

Vaccine Counseling with No Administration

There may be occasions when a patient or parent presents to their medical home for vaccine counseling, particularly for the COVID-19 vaccine. Increasing vaccine hesitancy surrounding this vaccine may be greater and some older adolescents may seek out information on their own. There are many mechanisms by which you can get information out to your patients, however, for those who opt for in-person (i.e., in office or telehealth) individual counseling there are coding options. You should check with your payers for guidance on the most appropriate way to code as some have limitations on the use of Z codes with office-based E/M services (e.g., 99212). Note, if you provide vaccine counseling on the day you also administer the vaccine to the patient you may not report counseling separately. Coding options include:

ICD-10-CM codes:

Z71.89 Other specified counseling

Z28.21 Immunization not carried out because of patient refusal **Z28.82**

Immunization not carried out because of caregiver refusal

CPT Options:

99201-99215 Office-based E/M service: based on time spent with the patient/caregiver.

99401-99404 Preventive Medicine Counseling: based on time spent counseling (Note this code is not listed as an approved telehealth service). May not be used for group counseling.

99411-99412 Preventive Medicine Group Counseling: Used for group visits when discussing vaccine safety

Coding Tips:

- You will not report a 90460, 90461, 90471-90474 with any COVID-19 vaccine administration code.
- Report only one vaccine administration code per COVID-19 injection.
- If you see the patient for a significant and separately identifiable E/M service in addition to the COVID-19 vaccine, append modifier 25 to the E/M service. For example, you see a patient for a routine preventive medicine service (e.g., 99394) and they decide to get the COVID-19 vaccine, report the 99394 and the appropriate product (as required) and the administration code only. Counseling is captured in the COVID-19 vaccine administration code.
- Your ICD-10-CM code for COVID-19 vaccine administration is Z23.

Patients with Medicare Coverage

Some pediatricians may participate in community COVID-19 vaccination efforts, which may include vaccine administration to Medicare patients. According to the AAP, during the public health emergency, non-Medicare providers can enroll as a mass immunizer, which allows billing for COVID-19 vaccine administration. Medicare billing privileges are being granted on a provisional basis and are temporary. Enrollment can be accomplished over the phone by calling your state's Medicare Administrative Contractor's enrollment [hotline](#). The following information will be needed to enroll: legal business name, National Provider Identifier, Tax Identification Number, Practice Location and state license. Additional enrollment information can also be found at the [Centers for Medicare and Medicaid Services \(CMS\) website](#).

Patients without Coverage

Uninsured children receive COVID-19 vaccine through the CDC's COVID-19 Vaccination Program. Payment for vaccine administration is available directly from HRSA via the [COVID-19 Uninsured Program Portal](#). You will be paid the current Medicare rate for COVID-19 vaccine claims.

Participation in the CDC COVID-19 Vaccination Program requires the following steps:

1. Enrolling as a provider participant (through UnitedHealth Group and Optum ID)
2. Checking patient eligibility
 - a To do so, you must first upload a spreadsheet of patients for whom you would like to submit claims to the HRSA COVID-19 Uninsured website. Download a [template for the spreadsheet](#) Once you have uploaded this spreadsheet to the HRSA COVID-19 website, it takes about 24 hours for the patients to be verified as self-pay and a temporary COVID-19 Uninsured ID will be provided.
3. Submitting patient information
 - a You may use this “Uninsured ID” just like you would a child’s insurance ID
4. Submitting claims
 - a Submit claims electronically to the COVID-19 Fund using your typical claims submission process.
5. Receiving payment via direct deposit.

Providers who participate in the COVID-19 Vaccination Program must confirm that the patient is uninsured and **agree not to balance bill recipients**. Providers should refer to their local public health jurisdiction for information on enrolling in the program.

For more information regarding COVID-19 claims reimbursement for uninsured patients, visit the [HRSA site](#).

Underinsured Patients

Providers who have administered Food and Drug Administration (FDA) authorized COVID-19 vaccines under an Emergency Use Authorization (EUA) or FDA-licensed COVID-19 vaccines under a Biologics License Application (BLA) to underinsured individuals, on or after December 14, 2020 (the first date of vaccine distribution in the United States), may now submit their COVID-19 vaccine administration fee claims for reimbursement consideration to the Coverage Assistance Fund. To be eligible for reimbursement, the provider must have first submitted the claim to the individual’s health plan for payment and had the claim denied or only partially paid.

Please go to the [CAF Portal](#) to register

For more information about the COVID-19 Coverage Assistance Fund visit the [HRSA site](#) for more details.

PRACTICE IMPLEMENTATION AND BEST PRACTICES: HOW TO SUCCESSFULLY START ADMINISTERING THE COVID-19 VACCINE

In the first part of this toolkit, we have discussed the ins and outs of the available COVID-19 vaccine options and the pertinent information for anyone seeking to become a vaccination provider. Now that you know all the facts about the vaccines, the question now becomes how do you successfully implement a COVID-19 vaccine program within your practice? We have got you covered! The second part of this COVID-19 vaccine toolkit is dedicated to laying out a step-by-step strategy that will take you from initial considerations to successfully managing your own COVID-19 vaccine clinic within your practice.

Step 1: Important Points to Consider before becoming a COVID-19 Vaccination Site

As with any new program, there are important questions you must ask yourself to see if becoming a COVID-19 vaccine provider makes sense for your practice. We encourage you to carefully think through the following questions before initiating the provider enrollment process.

- A. What ages and patient populations will I be administering the COVID-19 vaccine to?
 - a. Patients only
 - b. Patients and Families
 - c. Community
- B. If you choose to administer the vaccine to the community, how will you inform potential patients?
 - a. Partnering with local police and fire stations
 - b. Posting on sites like Nextdoor to spread the word in local communities
 - c. Partnering with local schools
 - d. Additional ways to raise interest
- C. Do I have enough storage space to fulfill the storage and handling requirements for the vaccine?
- D. Will I be administering the vaccine in regular office hours or extended office hours?
 - a. If you select extended hours, you may need to plan ahead 3-4 weeks in advance to make sure you have available staff for the second dose.
 - b. Some practices may choose to only administer the vaccine in separate clinics that are blocked during normal office hours, or only available during extended hours.



- c. Some practices may choose to administer the vaccine in the waiting room as normal day to day operations resume.
 - d. Would you consider closing your practice for half a day to run a vaccine clinic? This could entail patients waiting in rooms with open doors following vaccine administration so that staff can walk the halls and monitor patients.
- E. Who can be the COVID-19 vaccine champion for my practice?
 - a. We recommend establishing a COVID-19 Vaccine Champion at your office. Typically, this person is the lead for organizing the operation for your practice. They will be responsible for or lead ordering, temperature checks, scheduling, appropriate set up and clinics.
- F. Who is going to mix and/or administer the vaccine?
 - a. You will need to establish one or more designated vaccine administrators who will need to complete the required training.
 - b. You will need to determine who in your practice will draw the vaccine and be trained
- G. Which vaccine does my practice want to administer?
 - a. Pfizer-BioNTech
 - b. Moderna
 - c. Johnson & Johnson/ Janssen

Step Two: Plan Your Work and Work Your Plan!

Managing a successful vaccine clinic will require strategic planning and preparation. Here are some of our best practice tips to keep your operations running smoothly.

- 1) Be flexible and ready to adapt to incoming changes!**
- 2)** When you are thinking about the best times to administer the COVID-19 vaccine, it may be helpful to inquire if your local schools have an upcoming virtual day on the books and potentially select that day to administer vaccines if it works for your practice's schedule.
- 3)** Ask yourself what is your practice's slowest day? Potentially select this day to minimize practice disruptions on busier days.
- 4)** After you have selected your day to administer the vaccines, be sure that you also have availability for the second dose 3-4 weeks after.

- a) If you select a Saturday, consider that you may have to pay overtime. Likewise, you will also likely need to do another Saturday 3 weeks later if you have decided to administer the Pfizer vaccine.
- 5) Feedback from practices that have run a vaccine clinic before suggests that one of the hardest parts of running the vaccine clinic is loading patients to the system and filing their insurance – this takes extra staff time.
 - a) You may want to consider setting up an extra registration table in the waiting room to keep the process efficient.
- 6) Pre-establish a plan on what to do if a patient does not show up. Keep in mind that if you pull the vaccine from the vial, you will need to have 6 patients to administer the vaccine to within a 6-hour timeframe.
- 7) Consider having a stand-by list of patients to call for their vaccine if a patient does not show up for their schedule appointment.
- 8) If your practice orders the 195-vial shipment with 1,170 doses, you will need to determine where you can get dry ice for storage.
 - a) Likewise, you will also need to properly train staff on how to handle dry ice.
- 9) Set up the GRITS Interface and reporting.
 - a) Any practices administering the COVID-19 vaccine are required to enter data into GRITS **within 24 hours**. If you have the GRITS interface configured correctly, it will subtract the vaccines administered from inventory and the lot number should be visible.
 - b) Please note that if data was entered manually into the GRITS interface, or if the data was entered as not being “Covid Specific”, GRITS will update the interface with the appropriate date the vaccine was given, but the lot number will often be left blank. This can also be the case when patients receive their first COVID-19 vaccine outside of your practice.
 - c) **Tips on searching for patient data in GRITS:** Sometimes, finding patient information requires additional troubleshooting caused by errors. This may include a reversal of first and last names, duplicate accounts, or misspellings. It is recommended that all practices perform the patient search in different ways to ensure accurate patient data is being displayed.
- 10) Plan for an instant rush of patients in the beginning of your clinic hours, and then expect it to taper off near the end of the day. Perhaps have extra staff ready when you first open the vaccine clinic.
- 11) How will you advertise that you are a COVID-19 vaccine provider?

- a) Will you list it on your webpage?
 - b) Do you want to post on social media?
 - c) Will you list your practice as a participating vaccination site on your county's department of health website?
 - d) Will you place posters in the office for patients to see?
 - e) Do you plan to train staff to ask patients who come in to see if they are interested in coming to the vaccine clinic?
 - f) Will you ask patients when calling to remind them to schedule a COVID-19 vaccine appointment?
 - g) Will you ask parents when they are in the office to schedule their COVID-19 vaccine appointment?
- 12)** It is strongly recommended that you conduct a dry run of the vaccine clinic before the actual day to ensure your operations can run smoothly and work out any kinks. For example, you may need to adjust your layout to increase efficiency.
- 13)** Meet with your team frequently to get feedback and adapt and adjust.
- 14)** Determine if you have enough parking space available to patients if you were to run a vaccine clinic.
- 15)** Train your staff on how to properly administer the vaccine. Refer to the [CDC website for clinical training and resources](#).

Step Three: Familiarize Yourself with Vaccine Storage Requirements and Life Span of the Vaccine

Each vaccine will have specialized storage and handling requirements. Refer to the storage and handling protocols in part one of this toolkit for additional information.

Please Note: The summary below is for the Pfizer-BioNTech COVID-19 Vaccine Only

- Lifespan for Pfizer Vaccine for adolescents and adults
 - Stable at ultra-cold temperatures for 9 months
 - 14 days in the freezer
 - 30 days in the refrigerator- not to exceed 45 days once removed from ultra-cold storage
 - 6 hours once drawn (at room temperature)
- Lifespan for Pfizer Vaccine for children ages 5 to 11 years
 - Stable at ultra-cold temperatures for 6 months
 - 10 weeks in the refrigerator
 - Once drawn (*information pending CDC recommendations*)

Best Practice Tip: Due to the fragility of the vaccine, take care to calculate the anticipated number of appointments on a given day to account for the tight timeline associated with spoilage and to minimize waste.

- For example, if you expect roughly 180 appointments over the course of the next 4-5 days, only move 30 vials from the freezer to the refrigerator.

Dry Ice Safety: <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/dry-ice-safety-hcp.pdf>

Step Four: Staffing Considerations

Regular Day:

- Suggested number of staff to dedicate to vaccine: 3
 - 1 to draw up vaccine, 1 for computer work/documentation, 1 to administer dose.
- Set aside 2-3 exam rooms to accommodate vaccine appointments, depending on how many are scheduled.
- Block a certain amount of time for vaccine appointments – maybe 1 group in the morning, 1 in the afternoon (whichever works best for your office); not doing one-off vaccines throughout the day increases efficiency.
- **NOTE:** Nailing down this workflow will be essential once the initial “waves” of demand begin to subside and fewer patients need/want the vaccine.

Step Five: Training

Ensure staff is appropriately trained to complete their designated responsibilities. The CDC includes a list of [which healthcare professionals need to be trained and training recommendations](#). There is also a list of available trainings from the CDC [here](#) that cover a wide range of topics include vaccine prep, administration and reporting.

Step Six: Gather Supplies Needed and Drawing the Vaccine

Please Note: The summary below and vaccine administration instructions is for the Pfizer-BioNTech COVID-19 Vaccine Only for adolescents 12+ and adults

What's Included in a Full Box (Pfizer)

- 195 vaccine vials
- Syringes
 - 1000 zero-dead space syringes
 - 120 larger syringes (with dead space)
 - Syringes for drawing diluent
- Diluent (saline solution)
- CDC vaccine cards
- Alcohol wipes
- PPE
 - Face shields
 - Face masks

****Gloves, bandages, trash bags and sharps containers are NOT included****

Drawing out the Vaccine (Pfizer)

1. Invert Pfizer vial 10 times – do not shake.
2. Draw out entire vial Diluent (saline) into one of the larger syringes. Push syringe to 1.8 mL of Diluent.
3. Push entire contents of Diluent syringe into the Pfizer vial.
4. Invert Pfizer vial 10 more times.
5. Draw out 6 doses of vaccine from Pfizer vial (0.3 mL each). Wipe vial with alcohol pad between draws.

If you are running an offsite vaccination clinic, check out a suggested supply list [here](#).

*CDC COVID-19 Vaccine Dosage and Administration for Children and Teens can be found [here](#). The following is a short summary of the CDC recommendations for this age group:

- Unlike many medications, COVID-19 vaccine dosage does not vary by patient weight but by age on the day of vaccination.
- Adolescents ages 12 years and older receive the same dose of [Pfizer-BioNTech COVID-19 vaccine](#) as adults.

- Children ages 5 through 11 years receive an age-appropriate dose of the [Pfizer-BioNTech COVID-19 vaccine](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/pfizer-bioNTech-children-adolescents.html).
 - The [Pfizer-BioNTech COVID-19 vaccine](https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/pfizer-bioNTech-children-adolescents.html) for children ages 5 through 11 years has the same active ingredients as the vaccine given to adults and adolescents. However, the Pfizer-BioNTech vaccine for adults and adolescents **cannot** be used for children ages 5 through 11 years.
- Your child will need a second shot of the Pfizer-BioNTech vaccine three weeks after their first shot.
 - If a child turns from 11 to 12 years of age in between their first and second dose, the second dose should be the Pfizer-BioNTech vaccine for people 12 years and older. However, if the child receives the Pfizer-BioNTech COVID-19 vaccine for children ages 5 through 11 for their second dose, they do not need to repeat the dose.

For information on an additional primary dose for children ages 5 and older who are immunocompromised visit [COVID-19 Vaccines for Moderately or Severely Immunocompromised People](#).

Step Seven: Prepare for the Unexpected & Mitigate Risk

Adolescents who are at least 16 do not need special consent to receive a COVID-19 vaccine, but pediatricians should inform them about the FDA's EUA, the potential risks and benefits, their option to accept or refuse and any available alternatives. Health officials are continuing to study the efficacy of vaccines on circulating variants and whether people who are vaccinated can transmit the virus to others. Patients should be counseled to continue taking precautions like wearing a well-fitting face mask and physical distancing even after they have been vaccinated.

Be prepared and trained for Anaphylaxis Reactions:

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported rarely following COVID-19 vaccination. These interim considerations provide recommendations on assessment and management of anaphylaxis following COVID-19 vaccination. Detailed information on CDC recommendations for vaccination, including [contraindications and precautions](#) to vaccination, can be found in the [Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States](#). Patients should be screened prior to receipt of each vaccine dose, and those with a contraindication should not be vaccinated. A COVID-19 [pre-vaccination questionnaire](#) is available to assist with screening patients.

For more information, visit the [CDC's Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](#).

Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

The following emergency equipment should be immediately available for the assessment and management of anaphylaxis.

Should be available at all locations	If Feasible, include at the location, but not required
Epinephrine (e.g., prefilled syringe, autoinjector)*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine, cetirizine)†	Oxygen
Blood pressure monitor‡	Bronchodilator (e.g., albuterol)
Timing device to assess pulse	H2 antihistamine (e.g., famotidine, cimetidine)
	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation [CPR] mask)

*COVID-19 vaccination locations should have at least 3 doses of epinephrine available at all times, and the ability to quickly obtain additional doses to replace supplies after epinephrine is administered to a patient. People with a history of anaphylaxis who carry an epinephrine autoinjector could be reminded to bring it to their vaccination appointment. Detailed information on storage, handling, administration, and dosage considerations is available in the package inserts for [epinephrine](#) (e.g., EpiPen®). Expired epinephrine that appears to be in unacceptable condition (per the manufacturer's package inserts) should be replaced.

†Antihistamines may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to people with impending airway obstruction.

Watch out for Side Effects from the Vaccine and Advise Patient Accordingly.

In terms of management of adverse effects, administration of acetaminophen or ibuprofen after vaccination to manage symptoms is reasonable. Almost all adverse effects occur within 24-48 hours after vaccination.

If community pediatricians are going to provide vaccinations, they may want to consider having clinics on Fridays, especially for 2nd doses in COVID-naïve children and on Fridays for first dose, previously positive children.

Practice Tip: Patients have fainted after the vaccine administration. If possible, try to set up a room where patients can lay down.

What to do if a practitioner in your practice tests positive for COVID-19:

The CDC updated their interim guidance for managing healthcare personnel with COVID-19 infection (or exposure to COVID) in September of 2021. The updated guidance can be found online [here](#). In consultation with a risk management advisor from MAGMutual®, the following recommendations are suggested:

- Notify patients seen by the provider in the 2 days preceding the positive test result (or date in which the provider became symptomatic).
- Recommend patient monitor for symptoms unless their interaction with the provider was something other than a low-risk exposure (e.g., aerosolized procedure, etc.). If considered a high-risk exposure and the patient is unvaccinated, you may wish to recommend testing for the patient.

Step Eight: Think About Vaccine Inventory Management

[Learn more about COVID-19 Vaccine Inventory Management Best Practices.](#)

A review of recent vaccine administration data across all jurisdictions shows that, as of January 30, 2021, of those persons completing their second dose series, 96% received their second dose on or within four days of the recommended 3-4-week time interval. Within the 42-day period from receipt of first dose to second dose, a small percentage of persons do not receive their second dose of vaccine. If it is not feasible to adhere to the recommended interval, the second dose may be scheduled for administration up to 6 weeks (42 days) after the first dose.

- As vaccine first doses are administered, providers should be able to estimate the number of patients that will require a second dose each week.
- Patients requiring second doses should be prioritized. Schedulers may be used to help identify those seeking a second dose and manage apportionment of appointments for second doses based on projections.
 - Note that the optimal time between the first and second doses is 19-23 days. The maximum days between the first and second dose is 42 days.
- On a weekly basis, providers should review missed appointments or other reasons for scheduled second doses not being used, and remaining doses should be repurposed for use as first doses.
 - Second doses should not be held or saved for patients who have not returned after 42 days following their first dose; these should be used as first doses.

Step Nine: Establish Your Registration Process, Clinic Set Up, Process and Flow

Guidance from the CDC for on Vaccine Administration Clinics for HealthCare Professionals and Providers can be found [here](#).

*Refer to Appendix C for a sample process flow you can adapt to your practice needs.

Registration Process

1. **Preregister**
 - a. Consider using online options for pre-appointment paperwork
 - b. Collect Insurance information
 - c. Register the patient in your system if they are not already a patient

Some helpful hints:

- If parent – create the parent under the patient if EMR allows you to do so
- If loading parents/ non typical patients, think about creating a code to put by their name to make it easier once you want to inactivate them at a later date (i.e., Smith, Ann (CV))
 - Having a code name will also help you find the adults easily when you run reports
- Screen for contraindications and precautions
 - Text or email vaccine information statements and emergency use authorizations to patients
 - Register patient to GRITS

Best Practices Tip - Email an appointment reminder with the following information and requests:

This is your confirmation that Patient Susie has an appointment on Date at Time for the Pfizer COVID-19 vaccine at Practice Name

Before you arrive:

Read the [Fact Sheet for Recipients and Caregivers EUA for Pfizer-BioNTech Covid-19 Vaccine, UPDATED MAY 10.](#)

[Learn about the CDC's V-safe program and register to monitor any side effects](#)

Appointment:

- List what time the patient should arrive.
- Tell the patient where to wait (i.e., in car, etc.).
- After the vaccine you will be observed for 15 or 30 minutes in a socially distanced area.
- If this is your FIRST vaccine you will be given a record of your vaccination and an appointment to return in 3 weeks.
- A mask must be worn.
- Bring your insurance card or a copy. There is no charge for the vaccine or any cost share to you, however if you have insurance, we will file for an administration fee.
- Everyone under age 18 years must be accompanied by a parent or adult over 21 who is authorized to give consent or be available by phone.

Suggested screening questions for patients as they arrive for their appointment:

- Are you sick today?
- Have you had a COVID-19 vaccine before?
- Have you ever had an allergic reaction to a vaccine or anything else that required an EPI?
 - If yes, ask additional questions
- Are you immunocompromised?
- Does the parent give consent?
 - Document parent name in records
- Explain possible side effects and what to watch out for

Cancel/Reschedule:

- If you need to cancel or move your appointment, please send an email to (list person)
- Consider if this could be a viable option- if a patient needs a different time, trade times with another family.

Closing:

- We look forward to vaccinating your kids!

See you tomorrow,
Practice Name

Vaccine Clinic vs. Working in Vaccine Appointments During Regular Schedules

VACCINE CLINIC:

- Drawing Station:
 - Set aside a station just to draw up vaccine.
 - ✦ Will likely require multiple staff members, especially if you are scheduled to administer a high number of doses during the clinic.
 - This step is relatively labor intensive and cannot be rushed.
 - **TIP:** Have the staff begin drawing up vaccine doses 1-2 hours prior to the first appointment so that you don't lag behind.
- Card Station:
 - Have admin/front desk staff begin filling out vaccine cards with known fields...
 - ✦ Date
 - ✦ Location
 - ✦ Vaccine manufacturer
 - ✦ Lot #
- Note: If administering a high number of doses, you may consider omitting lot # until patient is in the exam room.
 - **Time Saver:** While patient is in the exam room and the MD/staff is entering data on the computer, have the patient complete their Name & DOB themselves.
- Exam Rooms:
 - Set aside each exam room (as many as needed to accommodate number of appointments).
 - Have a staff member stationed in each room to document and administer.
 - Once room is free, next patient will be called in.
- Monitoring area:
 - Honor system works well, especially if patient is accompanied by the parent.

- Have a staff member floating to check up on patients.

Best Practice Tips:

- Be careful not to draw up more doses than are scheduled. You may consider drawing up less in anticipation of no-shows.
- Develop ways to distinguish between regular patients and vaccine-only patients in EHR system.
 - ✦ Either create a separate “clinic” or...
 - ✦ Add vaccine-only patients with an identifier attached to their name (Ex: Doe, Jane (CV)) so that they may be easily identified when running reports.
- Consider setting aside 1 exam room for severe reactions.

- **FYI:**

- Remember to consider patients with a history of severe reactions/allergic reactions to vaccines.
 - ✦ These patients require 30 minutes of monitoring.
 - ✦ Have EpiPens/auvi-Q on-hand in case of emergency.
- Workflow for 2nd dose is more efficient – less administrative work.
 - ✦ Patient is already in the system, already have their vaccine card, already know what to expect, were scheduled 2nd dose at the time of 1st dose.

REGULAR DAY:

- Please refer to *Step 4: Staffing Considerations* on page 28 for best practice tips on how to staff for appropriately for giving COVID-19 vaccines during regular clinic hours.

Best Practice Tips:

- A practice can review the age of the patient on the schedule and pre-call to see if they are interested in receiving the COVID-19 vaccine. If a practice has more than 6 patients interested, they can mix a vial and have a 6-hour window of time to administer the vaccine to 6 patients.
- A practice can consider scheduling their patients that are 12 years and older in designated blocks of time to ensure use of the vaccination in the 6-hour time frame.
- Determine the maximum number of patients that can be scheduled in that location with social distancing.
 - You may need to rearrange furniture to accommodate
- Determine where the patients will wait for post-vaccination observation.
- Consider getting a non-clinical staff member to act as a time manager where patients could potentially wear a name tag with the time that they can leave or ask patients to set the timers on their phones.
- Consider creating signs and direction arrows for patients to follow in one direction that allows for social distancing in these high-traffic areas.
 - Registration
 - Education
 - Vaccination
 - Observation
 - Check-out
- Determine where in the process you want to schedule the patient's second dose – at check-in or in observation.
- It is strongly encouraged that practices complete a test run of the process before the actual day to ensure efficiency and optimal flow.
- Determine an area to hold the EUA Fact Sheets and Consent Forms.
- Ensure the following supplies are accessible throughout the designated area.
 - Hand sanitizer
 - Wastebaskets
 - Tissues
- Given the extra amount of patient flow consider adding extra time for sanitation and cleaning.

Step Ten: Work Your Recall Lists

To help in your recall efforts, we have provided recall list criteria to help you pull your own patient list from your population health management system.

Recall Lists:

Pfizer Patient Recall Lists (ages 12-21)

For first dose of Pfizer: From your EMR pull patients born between 5/10/2000-5/10/2009 who you have not billed 0001A in the past year (5/10/2020-5/10/2021).

For second dose of Pfizer: From your EMR pull patients born between 5/10/2000-5/10/2009 who you have billed 0001A but not 0002A in the past year (5/10/2020-5/10/2021).

Moderna Patient Recall Lists (ages 18-21)

For first dose of Moderna: From your EMR pull patients born between 5/10/2000-5/10/2003 who you have not billed 0011A in the past year (5/10/2020-5/10/2021).

For second dose of Moderna: From your EMR pull patients born between 5/10/2000-5/10/2003 who you have billed 0011A but not 0012A in the past year (5/10/2020-5/10/2021).

Recall List Best Practice Tip:

It is recommended to schedule patients for their second dose at the end of the first dose appointment. Then, keep that list of patients for recall if they no show to their scheduled appointment.

Closing thoughts from two of our TCCN Practices about their experience joining the COVID-19 vaccine effort:

“This is the hardest thing I have ever done in my career but also the most rewarding thing I have ever done in my career. I believe our whole office, doctors, and staff feel the same way. It has been an amazing experience to be able to offer hope after such a dark year!”

– Jane Wilkov, MD, Dekalb Pediatric Center *

“One of the most important things I’ve personally and professionally done through the pandemic was get COVID-19 vaccines set up for my partners, staff, our families and our patients. As pediatricians, we know that the only way to finally reach herd immunity and win this battle is through vaccination. Seeing our parents, grandparents and families of special needs kids tear up with a sigh of relief once vaccinated was both humbling and gave me the same feeling of hope they felt. “

– Amy Hardin, MD, Northside Pediatrics

***TCCN would like to gratefully acknowledge the assistance from Dr. Jane Wilkov, with DeKalb Pediatric Center for her help in sharing her best practices for administering the vaccine in her practice.**

These materials have been created based on information currently available from the Center for Disease Control (“CDC”), other third-party experts and Children’s Healthcare of Atlanta, Inc.’s (“Children’s”) own experience. Guidance on COVID-19 is changing rapidly. Consequently, Children’s is unable to make any representations and/or warranties of any kind, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. While these materials may be updated from time to time based on new information, Children’s is not assuming any duty to update the materials or modify them for the specific circumstances of any individual, practice, business or other entity. The recipient should use his or her own professional clinical judgement with respect to patient care and engage his or her own counsel and/or business and finance advisors on matters such as billing and other business practices.

Appendix & Additional Resources:

Pfizer-BioNTech COVID-19 Vaccine Recommended Training:

- Information on the [Pfizer-BioNTech COVID-19 Vaccine](#) from manufacturer
- [Preparation and Administration Video](#) from manufacturer

CDC Resources:

- COVID-19 Vaccination: <https://www.cdc.gov/vaccines/covid-19/index.html>
- For Healthcare Professionals: <https://www.cdc.gov/vaccines/covid-19/hcp/index.html>
- [COVID-19 Quick Reference Guide for Healthcare Professionals](#)

For Clinicians:

- [CDC COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals](#)
- [Pre-Vaccination Checklist for COVID-19 Vaccines](#)
- [Summary Document for Interim Clinical Considerations for use of COVID-19 Vaccines](#)
- [Interim Considerations: Preparing for Potential Management of Anaphylaxis at COVID-19 Vaccination Sites](#)

CDC COVID-19 FAQs:

- [Pfizer-BioNTech COVID-19 Vaccine Questions](#)
- [Moderna COVID-19 Vaccine Questions](#)
- [Johnson & Johnson COVID-19 Vaccine Questions](#)

CDC Vaccination Toolkits

- [COVID-19 Vaccination Toolkits Summary Page](#)
- [Vaccine Storage and Handling Toolkit](#)
- [CDC Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage](#)
- [Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit](#)
- [Engaging in Effective COVID-19 Vaccine Conversations](#)
- [Communication Resources for COVID-19 Vaccines](#)

Georgia Department of Public Health <https://dph.georgia.gov/immunization-section/health-care-professionals>

American Academy of Pediatrics: [COVID-19 Updates and Resources](#)

Centers for Medicare & Medicaid Services Toolkit on COVID-19 Vaccine: Health Insurance Issuers and Medicare Advantage Plans <https://www.cms.gov/files/document/covid-19-toolkit-issuers-ma-plans.pdf-0>



Kathleen E. Toomey, M.D., M.P.H., Commissioner

Brian Kemp, Governor

2 Peachtree Street, NW, 15th Floor
Atlanta, Georgia 30303-3142

dph.ga.gov

Vaccine for **Pediatrics** Information Sheet

Thank you for all that you are doing in COVID-19 vaccine campaign to get Georgians vaccinated.

We value your efforts to work collaboratively and interdependently with professionals dedicated to eliminating the spread of COVID-19.

You have been allocated Pfizer COVID-19 vaccine to vaccinate as a COVID-19 Vaccine Provider. Currently, Pfizer is the only approved COVID-19 vaccine at this time for children ages 16 and up (this is subject to change).

If you are storing at **Frozen temperatures (-25°C to -15°C / -13°F to -5°F)**, this vaccine allocation will expire on:

Date: _____ **and Time:** _____ **AM/PM.**

If you are storing at **Refrigerated temperatures (2°C to 8°C / 36°F to 46°F)**, this vaccine allocation will expire on:

Date: _____ **and Time:** _____ **AM/PM.**

If you have any questions or concerns, please call **404-852-0250** or email **dph-rss-operations@dph.ga.gov**.

Below are the items you have received:



PUBLIC HEALTH VACCINE TRANSFER OF CUSTODY

Vaccine Name	RR#		Date		County	
Delivery POC Name					Delivery POC Phone	
Alt Delivery POC Name					Alt Delivery POC Phone	
Delivery Address						
City			State		Zip Code	
Receiving Agency						
NDC Number				Molecular Name		
Medication				Vials		Refrig/Frozen
Lot Number		Expiration Date			Number of Vials	
Lot Number		Expiration Date			Number of Vials	
Lot Number		Expiration Date			Number of Vials	
Lot Number		Expiration Date			Number of Vials	
All parties transporting or receiving material MUST complete information below						
Courier Name				Signature		
Courier Agency						
Phone				Date	Time	
Match Serial Number When Recording Receiving Temp/Time						
Pack-Out Data Logger Serial Number				Pack-Out Temp	Pack-Out Time	Receiving Temp
Pack-Out Data Logger Serial Number				Pack-Out Temp	Pack-Out Time	Receiving Temp
Pack-Out Name				Pack-Out Signature		
Receiving Name				Receiving Signature		
Receiving Agency					GRITS Site ID	
Email					Phone	
Upon final delivery please scan and send to: DPH-RSS-OPERATIONS@DPH.GA.GOV						



Kathleen E. Botnick, M.D., M.P.H., Commissioner

Brian Kemp, Governor

2 Peachtree Street, NW, 15th Floor
Atlanta, Georgia 30303-3142

dph.ga.gov

October 15, 2021

Dear Immunization Partner:

An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech vaccine for children 5-11 years old has been submitted to the U.S. Food and Drug Administration (FDA). While authorization and details about the Pfizer-BioNTech product and the pediatric COVID-19 vaccination program are still pending, the Georgia Department of Public Health (DPH) is providing you with information that will assist you in planning for vaccine administration to this age group.

Facts

- There are approximately 28 million children between the ages of 5-11 years old in the United States, including 987,133 children in Georgia. The U.S. government has procured enough vaccine to support vaccination of this entire population.
- The Pfizer-BioNTech vaccine for 5–11-year-olds will be a new product configuration with new packaging, new preparation, and a new national drug code (NDC). The current product for adults and adolescents should not be used in children.
- The packaging configuration will be 10-dose vials in cartons of 10 vials each with a minimum order of 300 doses during the initial launch and 100 doses later in the program.
- The product will be delivered in updated product shippers at -80°C. It can be stored at the provider site for up to 10 weeks at 2 to 8°C and 6 months at ultracold temperatures of -90 to -60°C.
- Based on information as of October 15, 2021, once a vial is opened, doses must be used within 6 hours.
- COVID-19 pediatric vaccines will require diluent. The diluent will be provided with ancillary supplies which are configured specifically for use in children. NOTE – reconstitution of the product for use in children uses a different volume of diluent than the adult formulation.
- The months of November and December have multiple holidays. This should be considered in vaccine ordering and administration planning

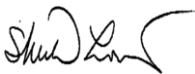
Pediatric vaccines will ship once FDA issues the EUA (tentatively Oct. 26 or 27), and vaccine administration can begin when the CDC Director makes a recommendation (tentatively Nov. 2 or 3).

- Pre-orders will occur in three waves beginning October 20, 2021. (Dates are subject to change.)
 - Providers must have their requests submitted through VMS by 5:00 pm on Tuesday, October 19, 2021, to be included in the initial pre-order. *Reminder: 300 dose order increments.*
 - Orders placed after the deadline, will be included in either wave 2 (Oct. 22) or wave 3 (Oct. 24).
 - Orders received after Oct. 24 will be accepted, reviewed, and approved following normal ordering cadence.
- DPH is requesting that all Vaccines for Children (VFC) providers enroll as COVID-19 vaccination providers to ensure equitable access for the pediatric population in Georgia. <https://dph.georgia.gov/covid-vaccine-information-providers>
- The U.S. government and the manufacturer will be providing additional training to prepare providers to administer vaccine to younger children; providers and locations will all need to be trained.
- To support increased logistics to push out large numbers of pediatric doses during the first week of the pediatric product launch, no shipments of Pfizer adult will be distributed.

DPH will provide additional information as it becomes available about the Pfizer-BioNTech vaccine for children, and as additional products from other manufacturers are authorized.

Thank you for all you are doing to help prevent the spread of COVID-19 in Georgia. Sincerely,

Sincerely,



Sheila Lovett
Immunization Program Director

cc: Kathleen E. Toomey, M.D., M.P.H., Commissioner & State Health Officer
R. Chris Rustin, Dr.P.H., M.S., R.E.H.S., Acting Deputy Commissioner/Incident Manager-COVID-19 Response
Alexander Millman, M.D., Chief Medical Officer
Ben Sloat, Immunization Deputy Director, and Vaccine Manager
Brandyn Taylor, Pandemic Vaccine Program Supervisor