

# Key Facts on Distribution, Provider Enrollment & Coverage/Payment for COVID-19 Vaccines

The first doses of COVID-19 vaccine may be available by late December for front-line health-care workers (which includes pharmacy staff), first responders and other essential workers. Although vaccine likely will not be available in sufficient supplies for wide distribution before next Spring, CMS has announced important guidelines governing the distribution, coverage and reimbursement for immunizers. Here are some essential facts you need to know for your pharmacy.

## Major Vaccines in Development

There are 49 vaccines in development around the world that are currently in human trials; only 11 of them are in Phase 3 human trials. These are the major vaccines likely to be distributed in the United States.

Manufacturer	Vaccine Type	Age Group	# Doses	Dose Timing	Storage
Moderna	mRNA	18 or older	2	28 days apart	<b>-4°/7 days refrigerated</b>
Pfizer/BioNTech	mRNA	16 or older	2	21 days apart	<b>-94°/1-2 days refrigerated</b>
AZ/Oxford	mRNA	TBD	2	4 weeks apart	TBD
Janssen/J&J	Non-replicating Viral Vector	18 or older	1	NA	Frozen/3 mos. refrigerated
Novavax	Non-replicating Viral Vector	18 or older	2	21 days apart	Refrigerated
Sanofi/GSK	Recombinant Protein Subunit	TBD	2	TBD	Refrigerated

## Vaccine Development Status

Pfizer and partner BioNTech are sure to have the first available COVID-19 vaccine. The Phase 3 clinical trial of Pfizer's BNT162b2 vaccine began July 27 and has administered two doses of vaccine (or a placebo) to 38,955 test subjects as of 11/8. **On Nov. 9, Pfizer announced that for a target group of 94 test subjects, the vaccine produced an efficacy rate of 90%+ for the 64-person study group.** Pfizer says it expects to have sufficient test data to submit to the FDA by Nov. 20 to seek an Emergency Use Authorization. Moderna's submission is more likely in December and the AstraZeneca-University of Oxford group's submission is possible by year-end.

**FDA approval usually takes 2-3 weeks (if there are no complications), so Pfizer could receive FDA authorization by early or mid-December. Pfizer says it could produce as many as 50 million doses of vaccine by year-end, all of which would go to vulnerable Phase 1 populations. Quantities of vaccine from all producers sufficient for the general population are not expected before Spring or Summer.**

## Vaccine Distribution Priorities (CDC)

### Phase 1: Essential Workers:

- Health-care workers (EMS, hospital staff, immunizers, LTC staff; pharmacy staff)

### Phase 1a: Those at High Risk for Severe COVID-19

- People 65 or older
- LTC facility residents (nursing home, rehab, assisted living, other)
- People with underlying, high-risk conditions

### Phase 2: People at Higher Risk of Contracting or Transmitting COVID-19

- Racial & Ethnic Minorities | Tribal Communities
- Corrections Facilities
- Homeless & Shelter Residents
- College/University Students
- Other people living or working in high-density situations

### Phase 3: People with Limited Access to Vaccinations

- Rural Residents
- The Disabled
- The Uninsured & Underinsured

### Phase 4: Healthy Younger Adults & Children

**NOTE:** These are priorities articulated by the Centers for Disease Control and may not match exactly the priorities outlined in individual State Vaccine Playbooks.

## CDC Requirements for COVID-19 Vaccine Providers

To participate as a COVID-19 vaccine immunizer, you must complete the **CDC COVID-19 Vaccination Program Provider Agreement**. The form also may be available on your state health agency's website.

In addition, you:

- Must have an active NPI/TPI number.
- Must follow ACIP requirements & recommendations.
- Must comply with CDC requirements for COVID-19 vaccine management:
  - maintain adequate storage capacities



- maintain integrity of vaccine cold-chain requirements (few pharmacies are equipped to handle vaccines with ultra-cold-storage requirements. The Pfizer vaccine, which could be the first to arrive, must be stored at -94 degrees and has a refrigerated shelf life of 24-48 hours. The Moderna vaccine must be stored at -4 degrees but has a refrigerator life of 7 days; most other vaccines undergoing U.S. trials require only refrigeration and can be stored for months.)
- Must report each vaccination within 24 hours to your designated state or local immunization registry.
- Must report all doses received including those administered, lost, wasted, etc.
- Must report any adverse patient event related to receiving the vaccine.

## State Requirements for COVID-19 Immunizers

Some states – such as Texas – are requiring immunizers to register specifically as COVID-19 vaccinators. The process is different in each state, but you generally will be required to provide your NPI number, pharmacy license number, ID number for your state vaccination registry and perhaps the separate ID for your childhood vaccination program (if your state issues one). Check the Resources section below for links to state-specific registration sites for COVID-19 vaccinations.

Once you have registered as a COVID-19 immunizer, your state may allow you to “pre-book” vaccine or submit a request to receive vaccine when it is available. **NOTE: Distribution of vaccine to any pharmacies likely will not take place until Phase 2 of the distribution plan, when vaccines will be available for more general distribution that do not require ultra-cold-storage equipment that few pharmacies have.**

## Vaccine Will be Provided Free to ALL Americans

CMS released an Interim Final Rule on Oct. 28 establishing coverage of any FDA-authorized vaccine at no cost to Americans throughout the public health emergency. **All authorized providers who give COVID-19 immunizations will be provided vaccine free of charge. As a condition of receiving free COVID-19 vaccines from the federal government, providers cannot charge patients for the vaccine.**

**Medicare:** Enrollees will pay nothing for COVID-19 vaccines. Copay/coinsurance & deductible are waived.

**Medicare Advantage:** MA patients also will pay nothing, and their copay/coinsurance and deductible are waived. MA plans will not be responsible for reimbursing providers to administer the vaccine.

**Medicaid:** State Medicaid and CHIP agencies must provide vaccine administration with no cost sharing for most beneficiaries during the public health emergency (PHE). Following the PHE, depending on the population, states may have to evaluate cost-sharing policies and submit state plan amendments to CMS if updates are needed.

**Commercial Plans:** CMS and the Departments of Labor and Treasury are requiring most private health plans to cover a recommended COVID-19 vaccine and its administration, both in-network and out-of-network, with no cost sharing. The rule recommends CMS’s reimbursement rates as a potential guideline for insurance companies and prohibits out-of-network reimbursement rates from being unreasonably low.



**Uninsured:** Individuals who are uninsured will not have to pay for the vaccine. **Providers can be paid for administering the COVID-19 vaccine to uninsured individuals through the Provider Relief Fund administered by the Health Resources and Services Administration.** \$2 billion has been set aside in the fund for reimbursing providers for COVID-19 testing, treatment and vaccinations for the uninsured

### Medicare Reimbursement Rate

**Medicare will pay providers \$28.39 to administer single-dose vaccines. Providers administering vaccines requiring two doses will receive a payment of \$16.94 for the initial dose and \$28.39 for the second dose.** These rates will be geographically adjusted and recognize the costs of administering the vaccine and any additional work involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering questions.

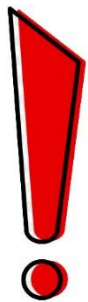
### Distribution Strategy

Operation Warp Speed is developing a cooperative plan for centralized vaccine distribution to be executed in phases by the federal government with the cooperation of all 50 states, territories, tribes, industry partners, and other entities.

Partnerships involving the federal government and state/local jurisdictions will allocate and distribute vaccines along with direct distribution to commercial partners. McKesson Drug Corp. will act as central distributor during Phase 1 with potential back-up distributors enlisted as needed to meet storage and handling requirements. CVS and Walgreens have been announced as retail partners for Phase 1 distribution that targets LTC facilities. Pfizer also has announced that it will directly ship vaccine in freezer containers to mass vaccination sites such as hospitals and LTC facilities.



*UPS is building a "Freezer Farm" at its Louisville, KY, terminal to store COVID-19 vaccine at sub-zero temperatures.*



**The CDC just announced that Good Neighbor Pharmacy and Elevate Provider Network members are joining the Federal Pharmacy Partnership Strategy for COVID-19 Vaccination in Phase II. GNP/Elevate will serve as a network administrator and will place orders with the CDC for vaccine on behalf of its eligible participating pharmacies. ABC will receive a direct allocation of COVID-19 vaccine for its independent pharmacy customers once there is adequate supply to support broader vaccination efforts beyond the initial critical populations targeted in Phase I.**

**ABC will allow any eligible GNP or Elevate member to participate in its vaccine network. You must complete a survey of your qualifications and capabilities before you can participate. The survey has been sent out to all GNP/Elevate members. If you have not received it, [contact GNP](#).**

### State Distribution Plans

Partner jurisdictions are developing, with CDC guidance, a State Vaccination Playbook to establish vaccination sites, address logistical needs and onboard each vaccination site into the online tracking system. Jurisdictions also are responsible for enrolling physicians, pharmacies, hospitals and other eligible entities as vaccine providers. Procedures for enrolling as a vaccine provider vary considerably by state. **Some states have a clearly defined survey and enrollment process; others do not. Some states allow any eligible provider to enroll, but some states – such as California – do not and instead are identifying and inviting providers to participate. It is important that you understand your state's process and take all needed steps to enroll by any stated deadline. Please refer to the Resources section for state-specific information.**

Vaccine site options will vary depending on the nature of the vaccine and the phase of the vaccination program. During Phase 1, administration sites will be limited to settings that can optimize reaching a prioritized population of health-care workers, first responders and other designated essential workers while meeting the early requirements for cold storage and handling of vaccine product. During Phase 2, the expanded administration network will include adult and pediatric health-care providers and pharmacies.

**NOTE:** You are eligible to work separately with both a state COVID jurisdiction and a federal network administrator such as GNP/Elevate to receive vaccine distributions. **However, you can work with only one federal network administrator.**

## Enrolling as a Medicare Vaccine Provider

If you are registered as a Medicare Provider with billing privileges under Part B, you already are authorized to submit claims to Medicare for administering an authorized COVID-19 vaccine to a Medicare enrollee. If not, you can [ENROLL HERE](#). If you wish to give multiple vaccinations at an LTC facility, local employer or a vaccination event and bill for administering those vaccinations in a bloc, **you must register with CMS as a Mass Immunizer** so you can use “roster billing” to submit multiple claims in a single batch. (You must complete the [Medicare Enrollment Application for Physicians and Non-Physician Providers](#) to do roster billing.)

## What You Should Do to Prepare

- **Complete and submit to your state health authority the CDC COVID-19 Vaccination Program Provider Agreement.** If you own multiple pharmacies where COVID vaccinations will be administered, you must complete a separate form for each location.
- **Make sure you know your state’s requirements for being a COVID-19 vaccinator.** So far, only a handful of states have published their requirements, which can range from registration to completing a survey to providing other information. If a state has published requirements and/or registration forms for COVID-19 vaccinations, you will find links to them in the Resources section below. **NOTE:** You will not be eligible to receive vaccine through a state distribution plan if you do not meet state requirements.
- **Make sure you are enrolled in your state vaccination registry.** You should also check with your state health agency to see if you also must report COVID-19 vaccinations to a state or local health authority.
- **Determine your vaccine storage capacity and cold-storage temperature capabilities.**
- **Make sure you have the software needed to do medical billing and automated reporting of COVID-19 vaccinations to your state registry.** These tools can reduce your workload considerably.
- **Enroll as provider with CMS so you can bill under Medicare Part B for the vaccine administration fee.** <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf>
- **Start stockpiling the PPE, swabs, syringes, band-aids and other supplies you will need.**
- **Register Your Pharmacy with Vaccine Finder.** This free service helps patients find the closest immunizing pharmacy. Just go to [vaccinefinder.org](http://vaccinefinder.org), scroll down to the “Participate” section and register.
- **Prepare to Address Patient Fears & Questions.** Many patients will have questions about the safety or effectiveness of COVID vaccines, why two doses may be needed or how strong and long-lasting their immunity will be. For help and resources, go to CDC’s [Talking to Patients About COVID-19 Vaccines](#).





## Resources

### Federal | National

[CDC's Phase 1 Vaccine Allocation Plan](#)

[CDC's COVID-19 Vaccine Program Interim Playbook](#)

CDC's COVID-19 Vaccination Program Provider Agreement: [Requirements](#)

CDC's [Talking to Patients About COVID-19 Vaccines](#)

[CMS COVID Vaccine Partner Toolkit](#)

[GNP Vaccine Resources Page](#)

### State Resources & Provider Enrollment Links

AZ: [Pandemic Vaccine Provider Enrollment Form](#)

CA: [COVID-19 Vaccination Plan](#) (see p. 25)

CT: [COVID-19 Vaccinator Preregistration & Survey](#)

FL: [Provider Information for COVID-19 Vaccine](#)

GA: [COVID-19 Vaccine Pre-Enrollment Questionnaire](#)

IN: [COVID-19 Vaccine Allocation Plan](#) (see pgs. 23-24) | [Enrollment FAQs](#)

KS: [COVID-19 Vaccination Plan](#) (see p. 20)

KY: [COVID-19 Vaccination Plan](#) (see pgs. 12-13)

LA: [General Info](#) | [COVID-19 Vaccination Program Provider Agreement](#)

**NOTE: Louisiana has set a Nov. 25 deadline for completion of all enrollment surveys & forms**

MN: [General Info](#) | [COVID-19 Vaccination Pre-Registration Survey](#)

ND: [General Info](#) | [COVID-19 Vaccination Program Provider Agreement](#)

NM: [Preliminary COVID-19 Vaccination Plan](#) (see p. 27)

NY: [COVID-19 Healthcare Provider Update](#) (City of New York; no info available from NY state)

OK: [General Info](#) | [COVID-19 Vaccination Program Provider Enrollment](#)

OH: [COVID-19 Vaccination Program Enrollment](#)

SC: [COVID-19 Vaccination Program Enrollment](#) | [Vaccine Provider FAQs](#)

TN: [COVID-19 Vaccination Plan](#) (see p. 14)

TX: [Texas Vaccinator Registration](#) | [Texas FAQs](#)

VA: [COVID-19 Vaccine Provider Intent Form](#)

WV: [COVID-19 Vaccination Plan](#) (see p. 16)