

The Nitty Gritty of COVID-19 Preparing for Vaccine Administration

Pharmacists will play a major role in bringing the COVID-19 pandemic under control in the U.S., with both the federal and state governments relying on their ability to vaccinate a wide swath of the American population. What does that really mean for pharmacists? We've put together a quick guide to the essentials and will update it as new information becomes available.

Register now. There is a national registration program, industry registration programs, and state-level registration requirements, so allot some time to make sure you've checked all the boxes.

- To participate in the vaccine effort, pharmacies must register with www.vaccinefinder.org. Without registration, you won't be included in the program, so do it right away. The website has been expanded to include the new COVID-19 vaccine and will allow individuals interested in immunization against SARS-CoV-2 to find you and see your projected availability. With restrictions on who can receive the vaccine over the next few months and anticipated shortages until more vaccines are approved, the website will allow you to update your status and save time communicating with each prospective patient.
- Next, verify that your National Council for Prescription Drug Programs ([NCPDP](#)) pharmacy profile shows you offer immunizations.
- Submit your Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program Provider [Agreement](#) to your state department of health. You'll need to register each pharmacy you own separately.
- For most states so far, the CDC agreement will be sufficient. Some states, Texas among them, require additional paperwork for pharmacies to register specifically as a COVID-19. You'll need to provide your NPI number, pharmacy license number, ID number for state vaccination registry, and if applicable, the ID for your childhood vaccination program. While you're checking those requirements, add your pharmacy to the state vaccination registry.
- Registering with your state will also allow you to place an advance order for vaccine to be delivered once they are available for community pharmacies, which will not occur until phase 2 of the immunization program except for rural pharmacies involved in immunizations at long-term care facilities. While CVS and Walgreens have been contracted to provide immunizations at LTC facilities around the country, the large chains generally do not operate in small towns where other plans will be made. For most pharmacies, February is likely the earliest possible date for distribution to pharmacies.

Sign up for payment. Pharmacies will receive COVID-19 vaccines free of charge and cannot charge patients for immunizations but will still be paid for their work. Before you

start vaccinating, make sure you've filed all the paperwork to receive reimbursement in a timely manner.

- The U.S. Centers for Medicare and Medicaid Services (CMS) set Medicare reimbursement rates at \$16.94 for the initial dose of a two-dose vaccine and \$28.39 for the second dose, with some geographic adjustment. A single-dose vaccine, when approved, will be also reimbursed at \$28.39. The U.S. Department of Health and Human Services (HHS) recommends the Medicare rates as guidance for commercial insurers' reimbursement rates and prohibits significant reduction in reimbursement rates for out-of-network providers.
- If you are not already a Part B Medicare Provider with billing privileges, you will need to [enroll](#) to receive payment. If you will be conducting a vaccine program at schools, large employers like meat packing facilities or manufacturers, schools, or community events, you need to register as a [mass immunizer](#) with CMS. As a mass immunizer, you can bill for all the vaccinations in one batch using "roster billing."
- If you don't already have software that automates medical billing and reporting, this would be a good time to consider getting it.

Update staff training. In a move that supersedes state laws, HHS approved administration of pediatric and COVID-19 vaccines by state-licensed pharmacists, qualified state-authorized pharmacy interns, and qualified pharmacy technicians under the supervision of a qualified pharmacist to any person age three or older during the COVID-19 public health emergency. The Public Readiness and Emergency Preparedness (PREP) Act also provided liability protection for all three groups of vaccinators. All vaccinators need to have specific [training](#), however, so double check that you and your staff have completed everything.

- An ACPE-approved practical training program that includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and recognition and treatment of emergency reactions to vaccines is required for all vaccinators. Pharmacists must have at least 20 hours of this training.
- Training on reactions is particularly important given the anaphylactic response of two nurses immunized with the Pfizer/BioNTech vaccine in the first day of the UK's rollout. Both women had known serious allergies and carried epipens.
- All vaccinators must have a current certificate in basic cardiopulmonary resuscitation.
- Pharmacists and technicians must complete at least two hours of ACPE-approved, immunization-related continuing pharmacy education during each state licensing period.

Understand obligations for pharmacists and pharmacy staff under PREP.

In addition to the education requirements above, PREP assigns specific responsibilities to various levels of vaccinators.

- Pharmacists must order the vaccination and must be immediately available during vaccination by any staff member.
- The COVID-19 vaccine must be ordered and administered in accordance with the Advisory Committee on Immunization Practices (ACIP)'s COVID-19 vaccine recommendations.
- Pediatric vaccines must be ordered and administered in accordance with ACIP's standard immunization schedule.
- Prior to ordering the vaccination, the pharmacist must review the vaccine registry or other records to ensure appropriateness. For COVID-19, this includes ensuring that patients receive a second dose of the same vaccine as they received initially.
- Pharmacists are responsible for maintaining records of vaccinations and reporting them to state and local vaccine registries. They must also update the patient's primary care provider, when available.
- When vaccinating children, qualified pharmacy technicians or state-authorized pharmacy interns must tell the patient and adult caregiver about the importance of well-child visits with a pediatrician or other licensed primary care provider and refer patients to a primary care provider as appropriate.

Store it right. There's been a lot of coverage of the specific challenges of properly transporting and storing the Pfizer/BioNTech COVID-19 vaccine. The vaccine uses messenger RNA (mRNA) technology which is inherently unstable and must be stored at -70° Celsius/-94° Fahrenheit. That's way colder than any average freezer and buying one that can hold that temperature would cost \$10,000 to \$15,000 according to the CDC, well outside the budget of pharmacies outside of major academic center systems. The vaccine can be refrigerated for up to five days, but given that the doses will be shipped in lots of nearly 1000, it really isn't feasible for most pharmacies.

While the Pfizer/BioNTech vaccine is the only one with emergency use authorization (EUA) right now, it's unlikely to remain alone in the battle against COVID-19 for long. The vaccine developed by Moderna with the National Institutes of Health appears nearly certain to gain EUA in December. The AstraZenca/Oxford University vaccine will probably follow early in 2021. The vaccines developed by Johnson & Johnson and Novavax could also gain authorization within the first quarter of next year.

So are you out of the game if you can't afford an ultra-cold freezer? Far from it! Most of the doses of the Pfizer vaccine will go to healthcare workers and the elderly in programs managed by hospitals, CVS, and Walgreens. Moderna's vaccine, which also uses

mRNA technology, remains stable at -20° Celsius/-4° Fahrenheit. That's within the capability of a standard household refrigerator's freezer compartment. The other three vaccines that are approaching readiness for FDA authorization only require refrigeration.

So, forget about the ultra-cold freezer. Take these steps instead:

- If you're administering vaccines already, you probably have the equipment you need. Otherwise, look for a pharmaceutical grade unit designed specifically for refrigeration or freezing. A household refrigerator could work, according to APhA, but some parts of the unit may not stay cold enough and the freezer is not acceptable. Single door-style and bar-style refrigerators are not permitted. The unit must have a temperature monitoring device.
- Ensure proper circulation around the unit, with space above, and on all sides.
- Test that the refrigerator maintains a temperature between 36° F and 46° F and that the freezer holds a temperature between -58° F and 5°F over two to seven days.
- Work out a backup plan with another pharmacy, hospital, or other facility in case you lose power so the vaccine doses do not spoil.

Follow the phases/Know your patients. With limited doses available for several months, immunizations will be limited to priority groups, so you'll need to know your patients' jobs, ages, and medical history.

- ACIP has outlined a phased approach for administering the vaccine. While states may adjust the rollout, the national recommendation allocates the first doses to healthcare workers, including pharmacists and pharmacy staff, and residents of long-term care facilities in phase 1a. Phase 1b offers the vaccine to first responders and essential workers such as individuals in the transportation industry, teachers, grocery store workers, and employees of meat processing plants. Adults with high-risk medical conditions and those over age 65 will be vaccinated in phase 1c.

States may shift the 1c groups to a phase 2, adding individuals in congregate living situations like homeless shelters or group homes, prisons and other detention facilities, and students living in dormitories. Phase 3 includes other young adults and children. Phase 4 permits the vaccine to everyone.

To remain on the right side of your state's rollout, make sure that you know—and document—what group your patients fall under and vaccinate them no sooner than your state says is appropriate.

- In addition, stay on top of the recommended groups for each vaccine. The mRNA vaccines from Pfizer/BioNTech and Moderna have not been tested on children or

pregnant women, for instance. Pregnant or lactating healthcare workers should be told that those vaccines have not been tested in that population and offered the chance to wait for approval of one of the other vaccines. (None of the vaccine manufacturers have included pregnant participants in their trials, but the two other vaccine types have been safely used for other vaccines. COVID-19 is the first use of the mRNA vaccine technology.) The Pfizer/BioNTech vaccine is only authorized for individuals age 16 and older at this point.

- The Pfizer/BioNTech vaccine generated an anaphylactic response in two of the first individuals vaccinated in the UK, leading the CDC to issue guidance on how to approach vaccination of individuals with known allergies. The agency recommended against vaccinating anyone with a known allergy to any of the components of the vaccine and anyone who had a severe allergic reaction to the first dose of the vaccine. Individuals who have experienced severe allergic reactions to another vaccine or injectable therapy may be vaccinated, but with caution and following a risk assessment by their primary care provider. People with common allergies (foods, animals, latex, oral drugs, etc.) and with a family history of anaphylaxis, but no personal episodes, can be vaccinated even if they have had an allergic reaction to another injection as long as they did not experience anaphylaxis.
- You'll also need to help patients enroll in [v-safe](#), a mobile app that monitors side effects of the COVID-19 vaccine and provide them with the EUA fact sheets on the vaccine they receive.