



U.S. Department of Health & Human Services
Office of the Assistant Secretary for Health
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PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures

On January 31, 2020, the Secretary of Health and Human Services (Secretary) declared that the 2019 novel coronavirus disease (COVID-19) is a public health emergency for the United States.¹ The United States Department of Health and Human Services (HHS) is the lead agency for the federal government's response to the COVID-19 pandemic.

Key components of that response are rapidly expanding COVID-19 testing across America, expanding access to childhood vaccinations to help address a decrease in childhood vaccination rates due to the COVID-19 pandemic, and expanding access to COVID-19 vaccines when they become available. Within HHS, the Office of the Assistant Secretary for Health (OASH) serves a leading role for such expansions.

Pharmacies and pharmacists, in partnership with other healthcare providers, are well positioned to aid with efforts to expand access to testing for COVID-19 and to expand access both to routine childhood vaccines for individuals age 3–18 years and to COVID-19 vaccines. Pharmacists are trusted healthcare providers with established relationships with patients in their communities. The vast majority of Americans live close to a retail or independent community-based pharmacy. That proximity reduces travel to COVID-19 testing or vaccination locations. Pharmacists also have strong relationships with medical providers and hospitals to appropriately refer patients when necessary.

On March 10, 2020, the Secretary issued a Declaration under the Public Readiness and Emergency Preparedness (PREP) Act.² With promulgation of the third amendment to the Declaration on August 24, 2020,³ and guidances for pharmacists, pharmacy interns, and pharmacy technicians, certain pharmacists (and pharmacy interns and technicians) are covered persons under the PREP Act when they administer certain covered countermeasures, including certain COVID-19 tests, routine childhood vaccinations, and COVID-19 vaccinations, provided that the conditions described in the Secretary's Declaration have been satisfied.⁴

¹ The Secretary's declaration of a public health emergency was retroactively effective on January 27, 2020.

² See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198 (Mar. 17, 2020); 85 Fed. Reg. 21,012 (Apr. 15, 2020); 85 Fed. Reg. 35,100 (June 8, 2020); 85 Fed. Reg. 52,136 (Aug. 24, 2020); see also Pub. L. No. 109-148, Public Health Service Act § 319F-3, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e.

³ 85 Fed. Reg. 52,136 (Aug. 24, 2020).

⁴ Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act, OASH, (Apr. 8, 2020), <https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf>; Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, (Sept. 3, 2020), <https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>; Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-

In some circumstances, however, a pharmacy may submit claims for reimbursement for testing or vaccine administration carried out by its staff pharmacists, pharmacy interns, and pharmacy technicians acting consistently with the Secretary’s Declaration and OASH guidances. Such claims are not always submitted by the individual staff pharmacist, pharmacy intern, or pharmacy technician. For example, many state Medicaid programs and Children’s Health Insurance Programs (CHIPs) enroll and pay the pharmacy (rather than the individual pharmacist, pharmacy intern, or pharmacy technician) as the furnishing and billing provider for items and services covered by those programs. In addition, pharmacies employing those staff pharmacists, pharmacy interns, and pharmacy technicians purchase, store, and distribute these covered countermeasures.

Therefore, as an Authority Having Jurisdiction under the Secretary’s March 10, 2020 Declaration under the PREP Act, OASH clarifies that pharmacies are also qualified persons under 42 U.S.C. 247d-6d(i)(8)(B) when their staff pharmacists order and administer, or their pharmacy interns and pharmacy technicians administer, these covered countermeasures consistent with the terms and conditions of the Secretary’s Declaration and guidance, as of the date that these staff pharmacists, pharmacy interns, and pharmacy technicians were authorized to order or administer these covered countermeasures. Such pharmacies qualify as “covered persons” under the PREP Act,⁵ subject to other applicable requirements of the PREP Act and the Declaration. Such pharmacies are therefore immune from suit and liability under the PREP Act with respect to all claims for loss caused by, arising out of, relating to, or resulting from, the administration or use of “covered countermeasures” as described in the Secretary’s Declaration and guidance, including the administration or use of COVID-19 tests authorized, approved, or cleared by the FDA and the administration or use of FDA-authorized or FDA-licensed COVID-19 vaccines or ACIP-recommended childhood vaccinations. 42 U.S.C. § 247d-6d(a)(1).⁶

Any state or local law that prohibits or effectively prohibits those pharmacies that satisfy these requirements from distributing or administering COVID-19 vaccines, ACIP-recommended routine childhood vaccines, or COVID-19 tests as set forth above, is preempted. State and local laws that permit additional individuals to order or administer COVID-19 vaccines, ACIP-recommended routine childhood vaccines, or COVID-19 tests to additional persons are not preempted.⁷

Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, (Oct. 20, 2020), <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>.

⁵ See 42 U.S.C. 247d-6d(i)(3), (6), (8)(B).

⁶ Regarding vaccines subject to the National Vaccine Injury Compensation Program, the Third Amendment to the Declaration states: “Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party’s ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa-10 et seq. are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program.” 85 Fed. Reg. at 52,140 (Aug. 24, 2020).

⁷ Nothing herein shall affect federal-law requirements in 42 C.F.R. Part 455, subpart E regarding screening and enrollment of Medicaid and CHIP providers. This guidance does not speak to or change reimbursement policy with respect to whether a pharmacy may obtain reimbursement from a government or private payer for ordering or administering an FDA-authorized test, administering a COVID-19 vaccine, or administering routine childhood immunizations.