



Guidance

U.S. Department of Health & Human Services
Office of the Assistant Secretary for Health
Wednesday, April 8, 2020

Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act

On January 31, 2020, the Secretary of Health and Human Services declared that the 2019 novel coronavirus (COVID-19) is a public-health emergency for the United States. 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.

A key component of that response is rapidly expanding COVID-19 testing across America. Within HHS, the Office of the Assistant Secretary for Health leads federal efforts to support that expansion.

Pharmacists, in partnership with other healthcare providers, are well positioned to aid COVID-19 testing expansion. Pharmacists are trusted healthcare professionals with established relationships with their patients. The vast majority of Americans live close to a retail or independent community-based pharmacy. That proximity reduces travel to testing locations, which is an important mitigation measure. Pharmacists also have strong relationships with medical providers and hospitals to appropriately refer patients when necessary.

Therefore, as an Authority Having Jurisdiction under the Secretary's March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), OASH issues this guidance authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) has authorized. *See* 85 Fed. Reg. 15,198, 15,202 (March 17, 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.¹ By doing so, such pharmacists will qualify as "covered persons" under the PREP Act. And they may receive immunity 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 FDA-authorized COVID-19 tests. 42 U.S.C. § 247d-6d(a)(1).

¹ FDA's Emergency Use Authorizations for diagnostic and therapeutic medical devices to diagnose and respond to particular public health emergencies are available [here](#).

² This guidance does not speak to or change reimbursement policy whether a licensed pharmacist may obtain reimbursement from a government or private payer for ordering or administering an FDA-authorized test.