

States Slowly Ease Barriers to Pharmacist-Provided COVID-19 Testing

By Fred Gebhart

In early April, the US Department of Health & Human Services authorized licensed pharmacists to order and use coronavirus disease 2019 (COVID-19) tests approved by the FDA. By mid-May, about two-thirds of states had adjusted regulations for pharmacist-provided testing, but just a handful of pharmacies had managed to navigate the maze of federal, state, and supply chain practicalities.

In California, pharmacy, medical, and consumer groups lobbied Gov Gavin Newsom and regulators for nearly 6 weeks before the state's Department of Consumer Affairs eased restrictions that prevented most pharmacies from testing.

"This waiver will allow pharmacists to order COVID-19 tests for their patients and collect specimens to send to a laboratory for processing," said Richard Dang, PharmD, APh, BCACP, COVID-19 Task Force chair and speaker for the California Pharmacists Association. "I am not currently aware of a pharmacy testing site that is set up, but I am hopeful that will change."

Andrew Cuomo, governor of New York, issued his own executive order clearing the way for pharmacists to order and administer COVID-19 tests in late April.

"We got the privilege of testing from the governor, and we're finding out that pharmacies need a laboratory certificate from the state before we can

offer testing," said Christopher Daly, PharmD, MBA, BCACP, a board member of the Pharmacists Society of the State of New York. "Beyond that, there are questions about [personal protective equipment], where will we procure the tests, billing, and more. Pharmacy is going to be a big part of the testing capabilities, especially when the second wave hits. But you can't just start testing tomorrow."

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A key problem involves meeting both state scope of practice and state laboratory requirements. At deadline, the FDA had issued emergency use authorizations for 4 point-of-care COVID-19 tests. The tests require a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver, typically issued by the state health department.

The first step to pharmacy-based COVID-19 testing is the certificate of waiver, said Allie Jo Shipman, PharmD, MBA, director of state policy for the

National Alliance of State Pharmacy Associations. Next comes navigating the scope of practice regulations, which can be a frustrating exercise.

A recent poll by National Community Pharmacists Association (NCPA) found that most of its members want to test for COVID-19. "As an association, we have had to temper expectations a bit," said Hannah Fish, PharmD, CPHA, NCPA's associate director of strategic initiatives. "Testing is coming, but getting there is a step-by-step process, and you need to work out the logistics."

Reimbursement remains uncertain. Federal regulators require insurers to cover COVID-19 testing at no cost to patients, but there are no requirements to reimburse test providers. Commercial insurers have mechanisms to cover medical costs but not pharmacy costs.

"Centers for Medicare & Medicaid Services is trying to take advantage of access to pharmacies as providers, but they are hemmed in by existing statutes," said Tom Kraus, JD, vice president of government relations for the American Society of Health-System Pharmacists. "They are creating work-arounds like having pharmacies register as labs to get paid, and there are mechanisms like incident-to payments for pharmacists in health systems or in medical practices. But there are no mechanisms that work for most community pharmacies. That's something we need legislation to fix." ■