**CQ NEWS** 

Mar. 5, 2020

## Virus testing questions remain after HHS briefs House

March 5, 2020 - 3:16 p.m. By Andrew Siddons, Emily Kopp and Mary Ellen McIntire, CQ

Trump administration health officials Thursday briefed House members on how they plan to ramp up testing to keep up with the rapidly spreading COVID-19 outbreak, but lawmakers are frustrated with the pace of testing availability and were emerging from frequent briefings with more questions than answers.

The administration has been unable to answer questions about how the uninsured would be covered for the testing and treatment they might need, according to House members who attended Thursday's briefing with Health and Human Services officials.

Federal officials have been briefing members on a near-daily basis, and as the number of COVID-19 cases in the United States continues to grow, "the level of concern at each successive hearing I've been to has grown," said Rep. Katie Porter, D-Calif.

Among Democrats, the level of frustration has also grown as some say the administration doesn't have good answers on testing capacity and is laying blame elsewhere for shortcomings in the COVID-19 response. HHS Secretary Alex Azar recently blamed an Obama-era Food and Drug Administration regulation on diagnostic tests for slowing the private lab industry's response to the outbreak, an assertion Trump repeated Wednesday, but the Obama administration never finalized a broad proposed FDA regulation on lab tests.

While the FDA does not oversee lab-developed tests and didn't at the time, the agency says that the last administration did require test developers to go through FDA review during an emergency, but that the Trump administration eased this requirement in the past week.

Lawmakers also say President Donald Trump's messaging has been inconsistent at times with that of his health officials. On the television channel Fox, Trump called the disease mild. He suggested that some infected people will go to work, which would contradict public health agencies' advice.

Federal officials took pains Thursday to explain why Trump challenged World Health Organization figures about the COVID-19 death rate. The WHO says the death rate is approximately 3.5 percent based on the number of known cases, but U.S. officials estimate it is lower based on its modeling of the number of true COVID-19 cases.

"The biggest problem is, for reasons that are obvious, we are concerned that we can't trust what the administration is saying," said Rep. **Dan Kildee**, D-Mich.

While federal officials maintain the risk to most of the American public is still low, they said there is a higher risk in areas like Seattle, where an outbreak in a nursing home resulted in 10 of the 11 known U.S. deaths. The elderly and those with underlying health conditions are at the greatest risk of severe disease and death.

## Few tests conducted

After weeks of faulty tests, there are fears that the number of publicly reported cases in the U.S. is artificially low. While the Centers for Disease Control and Prevention says there are 148 total cases, Johns Hopkins University counted 177 cases as of Thursday.

Azar told reporters after he briefed House members that currently only state-run public health laboratories are able to conduct a diagnostic test developed by the CDC, but that a private company is producing more of those tests and will be distributing more to hospitals within the next week. Private lab companies are also in the process of developing their own diagnostic tests, and some larger labs are expected to be ready for testing by next week.

Azar said he acknowledged to lawmakers that "right now, it is a challenge. If you are a doctor wanting to get somebody tested, you do need to reach to your public health lab and see if they have a test."

But he defended the administration's decision to rely on a CDC-developed test rather than one developed by the WHO that other countries have used. He argued that the U.S. capacity is comparable with other countries facing a similar amount of COVID-19 cases.

By the end of this week, Azar said that public health labs will have the capacity to test up to 75,000 people. Once the hospitals have tests, that capacity could grow to 400,000 or even 1.5. million by next week, Azar said. However, once the labs receive the test kits, it can take days for the tests to undergo quality control tests and be validated, according to the FDA.

Scott Becker, executive director of the Association of Public Health Laboratories, said that 67 public health labs in 45 states are offering tests — compared to eight a week ago — and four more would be running tests by the weekend.

And federal officials are working with Integrated DNA Technologies Inc., to supply tests to hospitals and commercial labs in another 190 locations this week.

LabCorp, one of the largest private testing companies in the U.S., said Thursday that its test was ready for use. Its main rival, Quest Diagnostics, will start offering its own test Monday.

## 'Nobody can tell them where to go'

State and local officials have criticized the Trump administration for the delay in accurate testing. Public health labs for weeks could not validate CDC-supplied tests. Health experts also raised alarm that the CDC's criteria when deciding whether a patient should be eligible for a test were too strict.

The CDC changed the criteria as of Wednesday, so that now any doctor who is concerned that a patient might be infected can order a test, though there are still concerns about how quickly public health labs can return the results.

Sen. Patty Murray, D-Wash., said her constituents at the heart of the U.S. outbreak don't know what to do.

"I'm hearing from people who want to get tested and believe they have been exposed — but nobody can tell them where to go," she said in a letter to Vice President Mike Pence, who oversees the administration's response.

Murray and others also question how many people will have access to tests, and whether they will be able to afford them. Federal and state funding has so far covered the cost of tests, which have all been done through public health labs, but commercial labs are preparing to start analyzing more tests, which could subject patients to out-of-pocket costs.

HHS Assistant Secretary for Preparedness and Response Robert Kadlec told a Senate panel Thursday the agency could also invoke emergency authority to pay hospitals and provide paid leave and food stamps to workers who stay home to avoid infecting others.

"HHS and Secretary Azar are considering all options, honestly, to ensure those

who need care can receive it, and assuming funding potentially through a supplemental, HHS does have authorities not only to reimburse hospitals but to do these other things," Kadlec said.

But Kadlec gave no firm answer on whether the administration would take that route, frustrating senators. Earlier this week, Kadlec said the administration could use emergency authority under the Federal Emergency Management Agency to reimburse care for the uninsured, but the emergency supplemental (HR 6074) the House passed Wednesday does not include extra funding for that purpose.

CMS Administrator Seema Verma told reporters after briefing House members that right now, tests are free to patients since they are conducted by public labs. While Medicare, Medicaid and individual exchange plans will also cover the tests, she acknowledged that other private insurers might have different criteria. While she expected that most insurers would cover the test as they cover flu or strep tests, "people should check with their insurance company," she said.

The board of directors for America's Health Insurance Plans released a statement Thursday, saying private insurance plans would cover diagnostic testing when ordered by a physician.

"We will take action to ease network, referral, and prior authorization requirements and/or waive patient cost sharing," the AHIP board wrote. "We will also take action so that patients will have continuous access to their regular prescription medications while at the same time avoiding potential problems such as drug shortages."

Porter noted the supplemental appropriations bill the House passed Wednesday did not mandate coverage of the tests. She said she expected private insurers would cover the tests.

"It's more an issue of what we do with regard to making sure that there's no gap with how quickly private insurers process this, code it, get it into the system and

cover it," she said. "We don't want anyone to delay calling their physician, seeking testing, because of concerns about costs."

Oregon Rep. **Greg Walden**, the top Republican on the Energy and Commerce Committee, said he plans to meet on Monday with AHIP officials.

"You're seeing this scale up dramatically and exponentially," he said. "We want to make sure that these tests are covered. I would assume that the insurance industry would want to also make sure that they do not become the villain in this story."

Tagged: Coronavirus, Health Care, Outbreaks

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