

The Virgin Islands Consortium

CDC Tells States to Be Ready to Distribute Covid-19 Vaccines by Nov. 1

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Moderna, a Biotechnology company in advance stages of development for its Covid-19 vaccine, stores protocol files for vaccinations at the Research Centers of America in Hollywood, Florida, on August 13, 2020. By. Chandan Khanna | AFP | Getty Images

PROVIDENCE, R.I. (AP) — The federal government has told states to prepare for a coronavirus vaccine to be ready to distribute by Nov. 1.

The timeline raised concern among public health experts about an “October surprise” — a vaccine approval driven by political considerations ahead of a presidential election, rather than science.

In a letter to governors dated Aug. 27, Robert Redfield, director of the U.S. Centers for Disease Control and Prevention, said states “in the near future” will receive permit applications from McKesson Corp., which has contracted with CDC to distribute vaccines to places including state and local health departments and hospitals.

“CDC urgently requests your assistance in expediting applications for these distribution facilities and, if necessary, asks that you consider waiving requirements that would prevent these facilities from becoming fully operational by November 1, 2020,” Redfield wrote.

He wrote that any waivers will not compromise the safety or effectiveness of the vaccine. The Associated Press obtained the letter, which was first reported by McClatchy.

The CDC also sent three planning documents to some health departments that included possible timelines for when vaccines would be available. The documents are to be used to develop plans for early vaccination when the supply might be constrained, according to one of the documents, which outlined a scenario in which a vaccine could be available as soon as the end of October.

“The COVID-19 vaccine landscape is evolving and uncertain, and these scenarios may evolve as more information is available,” the document reads.

Another of the documents says that limited COVID-19 vaccine doses may be available by early November and that supply will increase substantially in 2021.

It also states that initially available vaccines will either be approved by the Food and Drug Administration or authorized by the agency under its emergency powers.

The documents encourage health officials to work out now which groups to prioritize for a vaccine, identify providers who will administer vaccine, and take other steps to prepare. The planning documents were first reported by The New York Times.

Redfield told Yahoo Finance that officials were preparing “for what I anticipate will be reality, is that there’ll be one or more vaccines available for us in November, December.”

James S. Blumenstock, a senior vice president at the Association of State and Territorial Health Officials, said the CDC was offering “an aggressive but necessary timetable” and that public health agencies were mobilizing to prepare detailed plans.

Several public health experts pointed out that final stage trials of experimental vaccines are still recruiting, and are at best halfway through that process. The vaccines are two doses, and each is given a month apart. The experts told the AP they did not understand how there could be adequate data on whether the vaccines work and are safe before Nov. 1.

“Being ready is reasonable. Cutting short phase 3 trials before you get the information you need isn’t,” said Dr. Paul Offit, a Children’s Hospital of Philadelphia immunization expert who sits on the FDA’s vaccine advisory committee.

Peter Hotez, dean of Baylor University’s tropical medicine school, said he was “very concerned” about whether the FDA would use an emergency use authorization to

approve a vaccine before knowing whether it works and is safe.

"It gives the appearance of a stunt rather than an expression of public health concern," Hotez said.

FDA Commissioner Stephen Hahn previously said the agency wouldn't cut corners in evaluating vaccines, though it would aim to expedite its work. He told the Financial Times this week that it might be "appropriate" to approve a vaccine before clinical trials were complete if the benefits outweighed the risks.

Unlike a therapeutic that is given to sick people who may have no alternative, a vaccine is given to healthy people, "so you have a much higher burden of proof," said Ashish Jha, dean of Brown University's public health school.

"I think it's reasonable to be communicating to hospitals and saying — at some point late in the fall or winter," Jha said. "November feels awfully early."

Michael Osterholm, a University of Minnesota infectious disease expert, said he was concerned about an "October surprise" with a vaccine being rushed through ahead of the election.

"The public health community wants a safe and effective vaccine as much as anybody could want it," Osterholm said. "But the data have to be clear and compelling."

He said there was a "credibility gap" between doctors and the FDA about how rigorously products are being evaluated during the pandemic.

Some state officials said Wednesday that they were working on next steps while still awaiting details from CDC, and some sounded a cautious note.

Kris Ehresmann, Minnesota's infectious disease director, told the AP the state would only move forward "once we know it is safe." She said they would take their lead from the CDC's Advisory Committee on Immunization Practices, which she said "will only recommend a vaccine that has met the safety criteria."

The Oregon Board of Pharmacy said it would expedite McKesson's applications but wouldn't waive requirements necessary to maintain public health and safety. Its executive director, Joe Schnabel, said in a statement that the board didn't have enough information on how distribution would work "to speculate about whether it will be fully operational by November 1st."

The office of Pennsylvania Gov. Tom Wolf, a Democrat, said state officials don't know yet what is being asked of them, and will first need to do "an extensive review of the potential benefits or pitfalls of such waivers."

New Mexico Human Service Secretary David Scrase said the state was preparing to administer coronavirus vaccines on a limited basis starting in November to health care workers and residents of long-term care facilities. The broad public vaccine roll-out is slated for January. He said current vaccine provider networks are robust and adequate for the COVID-19 effort.

Regarding the timing of the CDC request to expedite or waive permits for distribution centers to open Nov. 1, Scrase said, "I can't tell you about the political motivations on that."

A spokesman for Tennessee Republican Gov. Bill Lee said the state was reviewing its next steps.

"News of a vaccine is encouraging and a testament to the power of American innovation," said the spokesman, Gillum Ferguson.

And in Florida, Republican Gov. Ron DeSantis said he wasn't aware of the CDC news, but he said people shouldn't think that the virus will be gone in two months once a vaccine is released.

"I would hope that the federal government would kind of take the lead on that," said DeSantis, a Trump ally. "Hopefully they have a plan to do it and will really focus on those vulnerable among us."