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CORONAVIRUS (COVID-19)

UPDATES

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Covid Vaccine Freezers in Place for Rollout Once FDA Gives OK

- Rehearsals under way for state distribution
- Cold storage is a concern

By Riley Griffin and Jeannie Baumann | November 18, 2020 5:01PM ET

Freezers required to store Covid-19 vaccines are in place at health systems that are preparing to administer the initial doses once the two leading candidates for shots receive a green light from regulators, U.S. health officials said Wednesday.

The federal government will have 40 million doses—enough to vaccinate 20 million—ready to distribute by the end of December should vaccines developed by Pfizer Inc. and its partner BioNTech SE, and Moderna Inc. receive emergency-use authorizations, said Moncef Slaoui, chief scientific adviser of the joint-effort led by the Department of Health and Human Services and Defense Department to expedite the development and distribution of coronavirus vaccines, dubbed Operation Warp Speed.

Pfizer and Moderna are both on the verge of submitting applications to the Food and Drug Administration. The shots will be distributed within 24 hours of an emergency-use authorization.

Operation Warp Speed has identified hospitals, pharmacy chains and universities that have cold storage capacity, and the first-available vaccine doses will initially go to these administration sites.

How to store and transport the vaccine is a matter of concern for states, specifically for Pfizer and BioNTech's vaccine, which must be stored at ultra cold temperatures of negative 70 degrees, thus requiring special freezers. In regular refrigerators, it can only be kept for up to five days. The companies are seeking to create a second-generation version of their two-dose regimen that can withstand warmer temperatures.

Moderna's vaccine, on the other hand, can be stored at regular refrigerated temperatures for up to a month, and be kept in ordinary freezers for long-term use. That means it's a more viable option for health-care facilities in the U.S. and beyond that lack cold-chain infrastructure.

"The states have been working with this," said Gen. Gustave F. Perna, chief operating officer of Operation Warp Speed, said during a media briefing. All vaccine doses will initially go to hospitals, universities, and pharmacies that have cold-chain storage abilities, to "make sure no vaccine is wasted."

“That’s only a constraint because of what we have to do to maintain it at the right temperature for stability,” Perna said. “They can go into normal refrigeration and then execute them in five days.”

He also has stressed to the various jurisdictions running distribution at the local level, “don’t be afraid of the constraints because of the vaccine and the temperature requirements.”

Distribution Preparation

The U.S. federal government has supported states and local jurisdictions, including conducting distribution rehearsals, for the moment U.S. regulators grant an emergency-use authorization to front runners in the race to develop a coronavirus vaccine. Perna said the task force has offered to buy more specialized refrigeration for sites that need it, and has taught health-care facilities how to extend the longevity of the products through dry ice and other means.

States and local jurisdictions also know how to support distribution with dry ice. “The capability exists,” Perna said. “I don’t see any place that the vaccine is delivered that it won’t go to an ultra cold storage refrigerator.”

Pfizer and its partner BioNTech, as well as Moderna, have recently demonstrated a [95% efficacy rate](#) in preventing symptomatic cases of Covid-19 in late-stage trials of their candidates, offering encouraging news amid a global surge in cases.

Pharmacy chains like Walgreens Boots Alliance Inc. know how to break down their distributions into small quantities, so that not all of the supply is removed from temperature-sensitive storage at once, Perna said.

The government has identified 64 jurisdictions in the U.S.—cities, rural counties, states—that will lead vaccine distribution for their areas. One of the preparatory steps for each area is anticipating and resolving distribution hurdles that could cause vaccine shots to be wasted, including cold-chain storage logistics.

Smooth Transition

Vaccine distribution will start with the people most vulnerable to contracting the novel coronavirus and will roll into the next administration to the broader population.

Health and Human Services Secretary Alex M. Azar said he doesn’t expect there to be any bumps “in the event of a transition” because career government staff are handling Operation Warp Speed, not political appointees.

It was a tacit nod to one of the most pressing problems for the transition team of President-elect Joe Biden, which is largely in the dark about the Trump administration’s vaccine rollout plans. The Warp Speed officials offered one of the most detailed descriptions to date of their operation in Wednesday’s briefing.

Other vaccine candidates are still in the pipeline, which means people will be needed to test those shots’ efficacy. Slaoui implored Americans to enroll in future clinical trials.

Beyond shots developed by Pfizer and BioNTech and Moderna, two other candidates that have entered into final-stage studies have only enrolled 11,000 and 8,000 volunteers, respectively, and are still recruiting. He didn't name those companies, but Johnson & Johnson confirmed it has more than 10,000 participants in its phase three trial, and AstraZeneca PLC recently resumed its phase three trial in the U.S.

"Without their participating it's impossible to know whether more vaccines can be demonstrated to be effective and safe," Slaoui said, referring to the clinical trial participants.

Participation in a clinical trial also could provide an avenue for faster access to a vaccine.

It could take a few months for people who aren't the most vulnerable to Covid-19 to get a vaccine after FDA authorization, Slaoui said. There's a 50% chance those people would have access to a vaccine immediately by enrolling in a study, he said.

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