Centers for Medicare & Medicaid Services
COVID-19 National Stakeholder Call
August 25, 2020
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OPERATOR: This is Conference # 3995779

Alina Czekai: Good afternoon. Thank you for joining our August 25th CMS COVID-19 National Stakeholder call. This is Alina Czekai, senior advisor to Administrator Verma for external affairs. Today, CMS Administrator Seema Verma will discuss sweeping regulatory changes focused on enhancing COVID-19 surveillance and aggressive new testing and reporting requirements.

As part of the announcement, Administrator Verma will also discuss a new unprecedented National Nursing Home training program for frontline nursing home staff and nursing home management. We're also joined today by Admiral Brett Giroir, Assistant Secretary for Health and Rear Admiral John Polowczyk, supply chain stabilization Task Force lead.

They will provide important updates on point-of-care testing, the provider Relief Fund and supply and personal protective equipment updates. First, I'm pleased to turn it over to Administrator Verma.

Seema Verma: Well, thank you and thank you all for joining the call. Today, the Trump administration is issuing the third interim final rule as part of our unprecedented (inaudible) COVID-19. Specifically, we're announcing sweeping regulatory changes that require nursing homes to test staff for COVID-19.

And we're also requiring laboratories and others performing COVID testing, including nursing homes using point-of-care testing devices to report diagnostic test results as required by the CARES Act. The new rules also require hospitals to report COVID related data to HHS.

Improved surveillance achieved through today's rulemaking will help the administration identify communities more deeply affected by the virus,

pinpoint racial and ethnic disparities and better allocate resources to providers on the frontlines.

These new rules represent a dramatic ramp up in our efforts to track and control the spread of COVID-19 especially in nursing homes. CMS is again acting to safeguard nursing home residents by revisiting its long-term care facility infection control regulations to require nursing homes to test their staff regularly.

This action is being taken under our authority through the Social Security Act to adequately protect the health and safety of nursing home residents. And it comes after a series of steps to increase testing in nursing homes.

In March, CMS changed our policies to allow labs to collect specimens inside nursing homes. In April, we increased our payment for certain types of tests to boost testing in facilities and called on states to prioritize and create a plan for testing in nursing homes. Then in May, we recommended a baseline test for residents along with a weekly one for staff.

In July, President Trump issued an alert that nursing homes would soon be required to conduct routine testing of staff. Today's rule now makes that recommendation a requirement for participation in the Medicare and Medicaid programs and allows states and the federal government to impose fines on nursing homes that are not compliant.

This testing is part of an overall effort to identify asymptomatic staff and residents who may be infected and serve as a source of transmission of the virus in the nursing home. While testing alone will not resolve the spread of COVID-19 in nursing homes, it is an important tool for detecting cases early and helps prevent transmission when combined with screening, use of PPE, cohorting isolation and other precautions.

CMS is also establishing a new requirement for long-term care facilities to offer testing to residents in the event of a new case or symptomatic residents. This is a crucial new element of CMS' aggressive efforts to help nursing homes to control the spread of the virus.

State and federal surveyors that inspect nursing homes will hold them accountable for adhering to the new testing requirements. Facilities that do not will be cited for noncompliance and required to implement a plan of correction. They may face enforcement sanctions based on the severity of a noncompliance such as civil monetary penalties in excess of $400 per day or over $8,000 for an instance of noncompliance.

Alternatively, they can also face denial of payment for new admissions. The administration is making the surveillance testing requirement easier and less costly for nursing homes by providing point-of-care testing devices and test kits to each of the Medicare and Medicaid certified nursing homes in the nation that have received a waiver from the Clinical Lab Improvement Amendments, or CLIA, to conduct low complexity testing.

The point-of-care testing devices are appropriate for surveillance purposes. And yesterday, the FDA issued a frequently asked questions that indicates that antigen test can be used for surveillance purposes in congregate care settings like nursing homes. If there is an outbreak or high clinical suspicion of an infection in an individual resident, a negative point-of-care test should be confirmed with a highly sensitive molecular test.

It is not necessary to perform confirmatory high sensitivity molecular tests on individuals with a negative antigen test or other point-of-care test results if they are obtained during routine screening or surveillance. In addition, the Trump administration is helping facilities offset the cost of testing with new funding from the Provider Relief Fund, which President Trump announced on July 22nd.

Specifically, nursing homes will receive $2.5 billion for testing. This is on top of the $5 billion that HHS distributed and should be available later this week. The new regulations we're announcing today will also hold hospitals and critical access hospitals accountable for reporting several important elements to HHS, including the number of confirmed or suspected COVID-19 positive patients, ICU beds occupied, and the availability of essential supplies and equipment such as ventilators and PPE.

This is a requirement that hospitals report daily and is essential for planning, surveillance, monitoring, and resource allocation during the public health emergency to make sure that frontline healthcare workers and patients have the supplies they need. While many hospitals are currently reporting this information, not all hospitals have done so consistently.

So, to ensure compliance as now required in the Conditions of Participation, CMS can terminate or suspend all funding from the Medicare and Medicaid programs for hospitals that fail to meet this requirement.

CMS' new rules further require, in accordance with the CARES Act, that laboratories including hospital labs and nursing homes using point-of-care testing to report COVID-19 test results to state and local health departments, test results including demographic data such as race and ethnicity information.

If a laboratory or testing provider does not report the required information, CMS will impose a civil monetary penalty and labs will have a three week grace period to learn the new reporting system. This change improves accountability and transparency while allowing CMS to take an aggressive enforcement action against laboratories that fail to provide the required data.

On a separate note, CMS is also revising its previous policy that allowed repeated COVID-19 testing for Medicare beneficiaries without physician oversight during the public health emergency. The revised policy provides that after their first test, Medicare will cover further tests with a treating physician or non-physician practitioner order.

This change helps ensure that beneficiaries receive appropriate medical attention if they need multiple tests, and it will also stop fraudsters from performing or billing unnecessary tasks. To help ensure that beneficiaries can get the tests that they need, CMS is also paying for tests when ordered by a pharmacist or other health care professionals permitted by their state to order diagnostic laboratory tests, and this will allow for greater access to testing for Medicare beneficiaries.

In a separate release today, CMS also announced an unprecedented National Nursing Home training program for nursing home staff and management

designed specifically with COVID in mind. The program features a tailored course that incorporates the most recent lessons learned from nursing homes, our strike teams, and the CDC, epidemiological investigations, and teaches frontline staff best practices that they can implement to fight COVID-19.

Available immediately, free of charge to all 15,400 Medicare and Medicaid certified nursing homes, the training focuses on critical topics like infection control and prevention, screening of visitors, emotional health of residents, cohorting, safe admission, and transfer residents and the proper use of PPE.

Finally, earlier this week, CMS released guidance for state Medicaid agencies on the new flexibilities CMS has made available under emergency authorities to increase reimbursements for (inaudible) that implements (inaudible) practices such as designating (inaudible) for COVID-19 patients.

This can be temporary Medicaid (inaudible) tailored to the specific needs of the state. And the guidance help highlights case studies in other states that have already taken advantage of this flexibility. And with that, I'm going to turn it over to Admiral Polowczyk to give us an update on his efforts to make sure nursing home have the supplies that they need.

John Polowczyk: Thank you Administrator Verma. I'll be covering a couple of topics. First one is a N95 mask distribution and deferment from the National Stockpile. Because of the administration's use of the Defense Production Act. Back in March, we've increased domestic production of N95 from approximately 30 million masks a month pre-COVID to now more than 100 million masks a month and rising to 160 million masks a month.

Because of that increased domestic production, we're starting to increase the stockpile of N95 masks in the federal stockpile. Based on NHSN survey data, there are some nursing homes that are reporting shortages or hard to obtain N95 masks. Because of that increased domestic production, we are going to do two things.

One, we're going to ship directly to nursing homes approximately 1.5 million N95 masks. Those shipments will start this Thursday and flow into next week

to those designated nursing homes that said that they had shortages or inability to obtain N95 masks. Those lists have also been giving to governors.

Last week on a governor's call with the vice president, each governor received the list of which nursing homes in their states are going to receive these masks. Additionally, we will defer receipt into the National Stockpile 7 million masks from production in the month of August and then again 7 million masks in the month of September.

These 14 million masks will be used to target in the commercial marketplace, hospitals, nursing homes, dentist office, first responders, and trying to provide additional commercial volume for those facilities to purchase.

This distribution is on top of the previous 14 days of supplies the administration has shipped directly to nursing homes realizing that that previous distribution was significant, 14.6 million masks, 13.8 million gowns, 66.3 million gloves.

We are fundamentally in a different place than we are from back in March or April. Back in March, we had about 16,000 ventilators. Today in the stockpile, there's 120,000 ventilators ready to deploy. Back in early March we had about – we were producing 30 million N095 masks a month and as I previously stated, now we're up to 100, going 160 million, so we're steadily increasing our domestic supply of products.

Additionally, states have 30 to 60 days of stockpiles, along with hospital stockpiles. So, you could see the commercial market supplies increasing to meet demand. We're in a fundamentally different place than we were in the beginning of the pandemic. Pending anything else, that's all I have today. Back to you Administrator Verma.

Seema Verma: Thank you. Dr. Giroir, did you want to give an update on testing in nursing homes?

Brett Giroir: Thank you Administrator Verma. As the administrator already covered, significant FAQs were released by the FDA yesterday that further explains the rationale and the use of point-of-care testing in nursing homes. While nursing

homes have complete flexibility on which types of tests can be used, we wanted to make it as accessible as possible, with as instantaneous of turnaround as possible.

So because of investments by the DoD and HHS, we now have a new generation of point-of-care antigen tests with sufficient supply to supply nursing homes to meet the demands of public health in infection control. As you know, we have committed to supply all nursing homes with a CLIA certificate of waiver with their own point-of-care instrument and sufficient tests to test through their staff at least twice as well as their nursing homes.

Following this, nursing homes would be able to order additional tests on a priority basis. As of today, HHS has shipped instruments to 5,593 nursing homes and well over 2 million tests have been sent to those destinations. We expect this to be completed to all 14,000 plus nursing homes with a CLIA certificate by the end of September. So, I'm happy to take any questions at the end of this briefing, but that's our update. Thank you.

Seema Verma: Thank you. Alina, back to you.

Alina Czekai: Thank you, Administrator, and thank you, everyone for joining our call this afternoon. We hope that you'll join us in just about 10 minutes for our CMS COVID-19 Office Hours. That's at 5:00 p.m. eastern, and on that call we will have all of our CMS subject matter experts on the line ready to answer any technical questions you may have.

Again, thank you for joining our call. Thank you for all that you are doing for patients and their families around the country as we continue to address COVID-19 as a nation. Have a great rest of your day.

Operator: This concludes today's conference call. You may know all disconnect.

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