

Centers for Medicare & Medicaid Services
COVID-19 Call with Nursing Homes
July 15, 2020
5:30 p.m. ET

OPERATOR: This is Conference # 9391146

Seema Verma: Good evening. This is Seema Verma, and welcome to our call with nursing homes. Today, we are also joined by Admiral Brett Giroir, and we just wanted to take a few minutes of your time today to give you an update on yesterday's announcement around the testing.

But before I do that, I wanted to just thank all of you. I really appreciate the partnership that we've had with you over the last few months, especially around the coronavirus. And I particularly want to thank Mark Parkinson who's just been a terrific partner. He's always been available. We've had many conversations and just really appreciate the support of AHCA through all of this.

In our conversations that we've had and many of you have reached out and we've also had some conversations with the board, we've had discussions about a lot of the challenges that nursing homes have faced on the ground. And I think we all share common interest and common concern for the safety and welfare of our – of residents of nursing homes.

And we know that this has been a particularly difficult time for them being restricted from visitors, not being able to see friends and family, and even inside the nursing homes, not being able to have their normal routines has had a significant impact. But it's also had a major impact on nursing home workers and all of you just day to day. It's just been an extraordinary challenge.

And of course, there's always the media that's not always kind to us but I just wanted you to know from the administration standpoint that we really appreciate all of your efforts. And from our standpoint, you know, our view on this is that we've been wanting to just work with you from the very beginning.

And although sometimes CMS has a – obviously has a regulatory function with nursing homes, we also want to be partners with you and move away from an agency that's just sending out fines and finding problems but actually working with you around solutions. And over the last couple of weeks, we had conversations on the state level with many of the state associations and appreciate all of you that have participated in those calls.

Because, that's what gives us insight and tells us about the barriers and issues that you are facing, and we appreciate all of you that brought up the testing issues. We also talked to Genesis who I know has nursing homes across the country and they also gave us a unique perspective about the differences that they were seeing around testing across the country.

So as you know, a little while ago, we were sending supplies and again that was because of the work of Mark Parkinson and letting us know your staffing needs and beds and all of that and we were able to help with supplies. And this new effort is around supporting your efforts with testing. We heard from you that you were facing significant challenges with turnaround times and even being told by labs that they couldn't support the testing or the need for testing every week of your nursing home workers.

So, we know that this has been a difficult time as you have tried to abide by the CMS recommendations. And so based on those calls and Dr. Giroir also participated in those calls and I think he's been working on this and we've had discussions about this issue for some time now. But, we really appreciate the great work that he's done with making these point-of-care tests available to nursing homes and he's going to go through the details with you on this.

But you know, I think just a couple of things to note, we are focusing on the hotspot areas. So obviously, those are some of the nursing homes in Florida and in Texas and in Arizona. We've also been using the data that you all been turning into the CDC and that's really been critical to our efforts. We are able to see how many cases you have in terms of your staff and also patients and residents. Sorry.

And from that, we've been able to put together a list of nursing homes not only in designated hotspots but also those of you that are seeing three or more cases. And so we've come up with the list and we'll be prioritizing those nursing homes here in the next week or so. And again, Dr. Giroir will tell you a little bit more about the distribution, but we'll be working through – with HHS on how we get those point-of-care tests out.

That being said, as you can imagine that's a large logistical operation that needs to be undertaken and I'm sure with Dr. Giroir's leadership, it will go well. That being said, it's going to take a bit of time and so we also just want to encourage you that it is important that we do that testing every week. We know that there are areas of the country that are having significant spread. And when we see significant community spread, the chances of it coming into the nursing home obviously are high.

And screening your healthcare workers and testing your healthcare workers is so critical to ensuring that your nursing home is safe. And so while we are getting to the point where we had those point-of-care tests inside the nursing home, I just encourage you to continue doing what you are doing, so we can all work together to make sure that we're mitigating the spread.

The other question that we've been getting a lot, we've been hearing a lot about is visitation and again we know that's been a particular challenge for everyone involved whether it's the staff having to address some of those psychosocial needs at a different level than is normally expected as well as just the difficulty for friends, families and our residents.

You know with these point-of-care tests, I think that's going to accelerate that reunion of family members with the patients inside of the nursing home. And so, what we're hoping is that when you get these tests and we can see that there's no spread in the nursing home for a couple of weeks and that is also something that you could use those point-of-care tests for. You could use those for visitors that are coming in to the nursing home.

So, I just wanted to highlight those particular issues but again we really appreciate the strong partnership that we had with all of you. We're very

encouraged by this effort from Dr. Giroir and his team to provide these tests. I think this is going to be a turning point in this fight against the coronavirus and keeping our nursing home residents safe.

So again, thank you all for being on the call today and with that, I will turn it over to Dr. Giroir, who can give you some more details about what you might expect over the next few weeks. And before – one other last thing that I did want to mention, as part of this effort with our hotspots, while we are focusing on testing, I did also want to let you know that we are making our QIOs, our Quality Improvement Organization available.

They had been going into the hotspots. They had been doing trainings, anything from a one-hour training which is more general. They're also available to come in to the nursing home to work with you, if you have questions. They could do that over the phone or if you like them to come into your nursing home, they can do that as well. Obviously, there's no cost. This is not a survey.

There are no penalties but it's really something to help support your efforts and interpreting our guidelines and implementing them and helping you to identify best practices. And also what we will be doing over the next few weeks is we'll be announcing sort of a national training for infection control around coronavirus and that will be coming out in early August.

That will be obviously a free program but would encourage all nursing homes to participate in that and we'll be providing more details in the coming days. But, I just want to make sure that in addition to testing which I think is the first major step here in terms of keeping nursing home resident safe and controlling the spread but these other pieces are also an important part of the equation.

So again, thank you for your efforts and with that I'll hand it over to Dr. Giroir.

Brett Giroir: So, thank you all for being on the call and it's really been fantastic working with Administrator Verma. Literally, three or four times a day now we're on the phone talking about how can we support nursing homes, how do we

protect our vulnerable and really everything has been on the table. So in that kind of environment, it's very motivating for all of us to work on the issues and try to do our small part to support you.

It was very clear listening to all of you that there were – among all the problems with testing, there were two primary problems. Number one, being able to get your test done anywhere within a reasonable turnaround time, particularly now with our outbreaks in many parts of the country. We understand and we do follow this, that your turnaround times at the big labs can be many days.

And if you have a turnaround time of many days, it really minimizes the effectiveness of infection control because during those times, people could be inadvertently spreading. Then the second is cost, when you use central labs and I know many of you may have good relationship with universities or small labs but the cost is pretty high. And we hear \$100 to \$150 per test that you're paying for the central laboratory test.

So, we've known for a long time that point-of-care testing, meaning something you could do right there in a CLIA waived environment and Administrator Verma has assured me that the vast majority of nursing homes have a certificate of waiver. That point-of-care testing could really be a solution for nursing homes, that we want to prioritize the nursing homes because of their importance, of the vulnerable population.

So, there are – there are several companies who are in this space but two – that have technologies that we're going to be using. First, Quidel, that's Q-U-I-D-E-L who has a Sofia 2 system. This had received their emergency use authorization in the later part of March but it had very limited numbers of tests available. And BD with the "Veritor" system, that just received their EUA last week.

Both of these are point-of-care antigen tests which means they don't amplify DNA. They're not sophisticated tests but they are widely used. Each of these have very little cost to instrument. They're between 25,000 and 30,000 of each of these throughout the country. They're in most docs' offices and urgent

care. This is how you get your flu diagnosed, this is how you get your strep throat diagnosed.

So, we are in a position right now with both of these having authorized tests to really try to solve your problem. One way it solves the problem is each of these – there's a clear mechanism to do, at least 15 or 20 per hour, if you need to do that many – with the system. It's immediately available to you obviously with that result there within that hour. And secondly, as opposed to \$100 or \$150 a test, you can buy the test that go in the system at under \$25.

I don't know eventually how this is going to work out but it's clearly under \$25 kind of test that you can use. So, we thought this would really kill two birds with one stone by allowing you to have immediate testing capability and lower the cost. And of course, as these tests became more available, and we're still scaling them up now, this is not solved tomorrow, this could be used if you had testing protocols for your visitors as well, should you have concern or should that be the public health recommendation.

So, what we are doing is we have decided collectively and it – Administrator Verma was kind of nice, she let me kind of realized the extent that we need to do this over a couple of days. That we are committed to purchasing one or the other machine for every single nursing home and supplying a number of tests, probably in the neighborhood of 400 or so, to get you started and then, allow you with a special service.

From these companies, we've asked them to establish a special concierge service for nursing homes, so that you have a single stop shopping that you can call one number, make one e-mail and really get the gold plated service because you are those who protect the most vulnerable.

Now how we're going to roll this out? The situation is much too urgent to wait a few months, so we can put (inaudible) and let's stay on the program. So, we're going to – we're going to build this plane a little bit while we're flying it. Our goal is to have somewhere between 1,500 and 2,000 nursing homes being shipped their equipment and their first aliquot of tests by the end

of next week. That's a real stretch goal for us but we are working literally 24/7 to have that happen.

We are going to prioritize those just by whatever CMS provides us as their priority given hotspots around the country combined with cases within the nursing home and some other factors like hospital capacity in those areas. We are arranging online as well as video training and again these are not small companies. These are very mature companies who have tens of thousands of instruments and clients around the country, much less around the world to get you started.

We are still working with production schedules. I will tell you that we are investing federal money in production lines to make sure these are up. By October, there will be no issue with supply, probably by September we expect 15 to 20 million of these tests available per month but we're not there yet. So, the shipping of the available instruments will be coming over the next many weeks, probably six to eight weeks will get us most of the nursing homes, not all of them.

But, we're going to go right down the list to make sure that those in priority areas that are prioritized by CMS will get instruments and will be able to start testing. And then after their first aliquot of supply, be able to resupply themselves with concierge service at the companies. We want to hear the issues. We know this is not going to be perfect. Again to get it perfect, we'd have to wait six months and dress it up.

We're going to do this to get it as fast as possible to you with proven technology. And by the way, this also diagnosed – you can diagnose flu and a number of other things with the same instrument. So, we hope that it will reap even more benefits for you at a lower cost moving in the future.

Let me pause here. Administrator Verma, do you want me to go into any more details or is that a good sort of overview to get us started?

Seema Verma: Just one other thing, if you may want to address, is just the issue of the sensitivity and specificity and how they should interpret results and if there's any need to do follow-up testing.

Brett Giroir: Yes – yes, thank you very much and I meant to do, it was on my notes here to do. So, these tests are slightly less sensitive than the laboratory tests. So, we envision the test somewhere in the neighborhood of 85 to 90 percent as opposed to 95 to 98 percent. But you know, there's no such thing as a free lunch. The perfect test would be immediately available in a 100, 100, that's not there.

Let me tell you that once you wait over 48 hours for a laboratory test, the extra sensitivity is beaten 100 times out of 100 by a test that you get a quick turnaround on. So, this is your right solution unless you had a lab giving you those results within one day and you have to afford that. But what it does mean though is if you get a positive, these are essentially 100 percent specific.

If you have a positive, it is positive, you can bet the farm on it. Never 100 percent but literally they are operating at about 99-plus percent specificity. If you get a positive, it's real. If you get a negative and you're in a high-risk environment, in other words if you think that person has symptoms or is the roommate of a person, you need to take it as a presumptive negative and you should repeat that with the – with the laboratory test.

But for normal surveillance screening, this works really, really well and I'll remind you of a – of Administrator Verma's and I – maybe she – I'm going to paraphrase her but she could be specific. If you got positives in your institution, then Medicare will pay for those tests as a diagnostic test. So, you can afford to send those out and that's paid for but again the sensitivity is slightly lower and not much lower.

If you're – if you're really suspicious of a person being positive, don't settle with this, send a confirmatory test. But for routine surveillance, this is a great tool and these are our best tools that we have available.

Seema Verma: And that's exactly it Dr. Giroir. The Medicare program doesn't pay for surveillance test but if a patient had a positive test with one of these point-of-care tests and you wanted to do that follow-up testing, then we would reimburse for that and that can be done at the laboratory and fully reimbursed.

And how about we open it up to questions, does anybody have any questions for Dr. Giroir or myself?

Mark Parkinson: Administrator Verma, this is Mark Parkinson.

Seema Verma: Hi Mark, go ahead please.

Mark Parkinson: Great, great. Well, I just want to start out on behalf of our 10,000-plus skilled nursing facilities that we represent and all of the 50,000 buildings across the country, I want to thank you very, very much for this effort. Dr. Giroir, this is so huge. I appreciate your comments, Administrator, and I think you're absolutely right. We have had a terrific partnership. Your responsiveness has been incredible. There are literally times that I sent you e-mails and you called me within a minute.

And it's really important because the work that the members do in normal times really matters. During this pandemic, it's a matter of life and death and the decisions that CMS makes and that our members make and all the providers make will determine whether thousands of people are living on. The partnership has been working.

One of the things that we're very encouraged by is if you look at NHSN data, the number of new COVID cases in skilled nursing facilities has been cut in half between June 1 and the end of June. And we think we're continuing to make progress but as you indicated, the outbreaks that we've seen across the country have us concerned that we may hit in the other direction, and the principal reason has been because of testing.

As the demand for testing has increased in the general population because of the increases throughout the country, it's – we're now hearing the stories again that they're not just taking two days but four and six days to get tested back. So, the ability to get these units in the buildings is absolutely critical and again I'm just repeating myself, this will save lives.

The questions that I was going to – was going to ask, you've already answered. I just wanted to strongly encouraged you to seek machines not just

for 2000 buildings but for all of them and you've addressed that. You've also addressed the questions on the sensitivity.

But again, on behalf of our members and we got our National Chair, Debbie Meade and our Vice Chair, Phil Fogg on the line as well, we just want to thank you for your efforts and just let us know what we can do to help.

Seema Verma: Thank you, Mark and again, thank you. It's been an incredible partnership and also just a special shout out for Dr. Giroir. You know, I came to him with this issue and he agreed to participate on one of the calls.

And when we first started talking about it, he thought he can have a couple of thousand machines, then he came back with 3,000 and he came back with 4,000 and then he figured out how to work through the federal bureaucracy to get all of the nursing homes tests. I think he's a great example of a tireless public servant and the nation thanks him. I thank him and I know all of you do as well.

Brett Giroir: You're much too kind, Seema. We're all on this together. I'll just make one other comment is that we're going to be sending new machines, so there's – there is – we're going to be taking everything that's produced and that's going to take many weeks to get all of the nursing homes.

But, I do say there are 25 or 30,000 of each of these machines out there in your community and you probably know the doctors' offices or the urgent care, in your local area you might say, hey, do you have a Sofia 2 or a Veritor that you're not using or can spare, and that can supply you guys much earlier. I don't have control over all of those but we know there's a lot of – there's a lot of those machines out there that might be able to be moved around.

And again, these are very low cost machines, it's not a barrier, and they weigh like a pound. So if you have nursing homes in an area, it's even possible to use – until we get all 15,000 out there, you might have it at one nursing home on a Monday, Wednesday to test the staff and then other one on a Tuesday and Thursday. You have my personal commitment that you will get them is absolutely fast as possible using all the authorities we have.

But until we do that, I just wanted to let you know that there might be some other workarounds that you can do. And anything we can help you with, we're really committed to making this happen. It's one of the things I feel best about that we've been able to support in the last few months since the pandemic has started.

Seema Verma: I don't know if there's any other questions, I think we have maybe just a couple of more minutes. Is there any other final questions?

Alina Czekai: Operator, do we have any questions in the queue?

Operator Ryan, do we have any questions from the audience in the queue?
Thank you.

Operator: I'm sorry ma'am. I was on mute. I'm sorry about that. And ladies and gentlemen, we are about to start the question-and-answer session. And to ask your question, you will need to press "star" "1" on your telephone. To withdraw your question, press the pound key. If your line is not transcribed yet, I will identify you with the last four-digits of your phone number.

Your first question comes from the line of Lisa Davis from Bernice Nursing Home. Your line is now open.

Operator: Hello, Ms. Lisa Davis?

Alina Czekai: Operator, we'll take our next question please.

Operator: That is noted. Your next question comes from the line of Kimberly Jamarow from Bomas Health. Your line is now open.

Kimberly Jamarow: Thank you. The state of Michigan is not permitting skilled nursing centers to use antigen testing. So, we're hopeful that maybe another solution will be forthcoming either from the state side or through technology.

Brett Giroir: So, this is Brett Giroir. There will not be another solution by technology that is going to be available. I am happy to speak with anyone in Michigan but it would be – it would be a death blow to nursing home residents to not be able

to use this technology unless Michigan could certainly guarantee you one-hour turnaround on something different.

We think the sensitivity is actually better than this but this is what's sort of published now. So, I'm willing to talk with anyone in Michigan. I don't know who regulates that. Again, I'm not a legal person but I can talk about the public health mandate.

But, we feel very strongly that given where technology is and the fact that there will not be – there will not be new technology point of care that is any better than this for the foreseeable future. I would certainly urge that we can change that but again you can follow up through the call and send me the contacts and I'd be happy to do what I can.

Kimberly Jamarow: Thank you very much.

Operator: Your next question comes from the line of a participant with the last four-digit of 9815. Please state your first and last name and your organization. Your line is now open.

For a participant with the last four-digit of 9815, your line is now open.

Operator: Your next question comes from the line of a participant with the last four-digit of 6812. Please state your first and last name, your organization. Your line is now open.

Bronze Peterson: Bronze Peterson with Fundamental. I just want to thank you again for your leadership on this. One question we have is with regards to the number of tests that would be provided which I believe you mentioned was around 400 and depending on how often we have to test and how many, obviously those will run out relatively quickly. And even at \$25 a test, it does put a lot of pressure on each facility.

Is there any – is there any thought that decision might be revisited and with this additional testing available that would be provided to the facilities through CMS as opposed to the facilities paying for those?

Seema Verma: Well, one of the things that we're also trying to work on with states is that as you know states had been given – I think it's – about \$14 billion in testing funding. And so that's one of the things that we've encouraged the governors to do is to work with you around some of these additional costs. So again, I would encourage you to work with the state on that because some of the funding for testing has come through the state and that's something that can be worked out on the state level.

There are some states that have already stepped in to do nursing home testing on an ongoing basis. So, this is going to augment those efforts. If your state is not doing that, I would encourage you to have conversations with them on that.

Bronze Peterson: OK, perfect. Thank you.

Brett Giroir: So let me – Brett Giroir here again. These are the lowest cost tests that are available now. There may be a new generation of antigen tests towards the end of the year that will be less costly than this but this is sort of the most cost effective tests that we have available right now. I do want to say that it – there are other ways to go about this that we can orchestrate sort of on a national level.

We do believe that pooling 5 or maybe even up to 10 tests, if you have a very low prevalence as possible and you may wish to – for surveillance purposes, try to get an arrangement with some of your typical testers to maybe pool 5 or 10, so you can reduce that cost. If you pool 5 which is a very reasonable pool and the one that the FDA says the first goal, if you pool 5 into 1, that \$100 test sort of turns into \$25 or \$20 or maybe even less.

So, there's another way but I'm just saying I'm looking for the most cost effective way. These are the best, most cost effective test on the market that we have now pending new technology which may be available sort of in the October, November timeframe but you can't bet on it.

Bronze Peterson: Got it. Thank you very much.

Operator: Your next question comes from the line of Kerry Pitcher from Kula Hospital. Your line is now open.

Kerry Pitcher: Hi, we're wondering if a hood is required for these point-of-care testing kits or machines. Our local diagnostic labs has told us that a hood is required for these.

Brett Giroir: No hood is – no hood is required for these. Again, I can't tell you what any local public health but there is no hood required for these. These are tabletop, no hood. And let me – when we talk about 400 tests, let me tell you the first goal until testing is very widely available, that's sort of an average number but we have sort of very small nursing homes that 400 is like multiple-month supplies.

If you have a very small nursing home, what we're going to do is calculate your number of residents, testing your workers every week and kind of give you kind of time fixed to that to get you sort of through the first six weeks of this until we know what the supply lines are going to be.

So, I don't want everybody to literally say 400. If you have a mega nursing home that has 200-staff, it's our intention to give you sort of – to the degree that we can with the supplies coming out, sort of six weeks' worth of testing capability to kind of get you up and running and the supply chains moving. So, we kind of used that as an average number but it's – it will only apply to a few of you.

And again, the supplies will be ramping up very rapidly for this technology but we don't have all that we want this month or next. By September, we're going to be in awesome shape but just work with us. We want to get you what you need and then in September, October, you can get what you want.

Alina Czekai: Great. Thank you everyone for joining our call today. We really appreciate everything that you are doing for nursing home residents and their families around the country as we address COVID-19 as a nation. As always, you are welcome to e-mail us at our COVID-19 e-mail address with any questions that you might have and again that e-mail is covid-19@cms.hhs.gov.

And we do encourage you to join our biweekly CMS COVID-19 call with nursing homes. Our next call will take place next Wednesday, July 22nd at 4:30 Eastern. Again, this concludes today's call. Have a great rest of your evening.

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