

Centers for Medicare & Medicaid Services
COVID-19 Call: Lessons from the Front Lines
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Alina Czekai: Good afternoon. Thank you very much for joining our call today, CMS Lessons from the Front Lines on COVID-19. I'd like to introduce CMS Administrator Seema Verma. Administrator, turning it over to you.

Seema Verma: Thank you. And thank you, Alina. So thanks for joining our CMS Lessons from the Front Lines. We are joined today by Dr. Birx from the White House Task Force. We also will have an update from FEMA. And we also have the FDA with us here today to answer your questions.

I'm going to go right into turning this over to Dr. Birx. The other thing we'll spend a little bit of time with today is the new guidance and new flexibilities that CMS is offering through our Hospitals Without Walls and our Patients Over Paperwork initiative. Lots of regulations have been slashed to support providers on the frontlines and to help you increase your capacity to deal with the surge.

So with that, I will turn it over to Dr. Birx.

Deborah Birx: Thank you, Administrative Verma. That's really – I really appreciate these calls. Thank you for setting it up because it really helps us to understand how we can best meet the needs of the frontline health providers. And we just really want to thank you every day for what you are doing.

We see it. We hear it. And for those of us who practice on the frontline and through emergencies, we understand it deeply working across the administration to see how we can better get materials to the frontline in a way that does what Administrator Verma has done is cut through bureaucracy and set up new ideas and new ways of doing things.

I think, you know, we have a very decentralized health care provider community. We have a very decentralized way of ordering and delivering supplies. And we know that those traditional methodologies are not holding up in the middle of this crisis and we appreciate you letting us know.

We also appreciate the clinical guidance that's coming in from many of the frontline workers and that's been very important to us, as well as in this call. And I know you're going to be covering this the innovative ways that you have set up hospitals to really provide with these Hospitals Without Walls to give us ideas about how to do that and how to ensure that other cities have the best information as they move forward.

We are tracking of course, each epidemic separately. We've divided them into metro areas, each metro area and cluster is moving at a different pace. We see clearly the impact of California stay home order, the slow, low progress of the virus there due to the really the community responding comprehensively to all of the guidelines. And then we see the consequences of large gatherings and lack of social distancing and the impact that it's having and other communities.

So we know that those guidelines work. Those are the guidelines that came out of the models. And the models have been extraordinarily helpful, not so much for predicting exactly the number of cases and the number of fatalities, but really predicting the impact of these mitigation methodologies. And we want to thank all of the modelers who provide us that information.

But on a day to day basis, we're tracking the cases and the issues that are happening in each of these clusters. So we can find new innovative ways to be able to respond to the frontline health care providers needs and the frontline client needs.

So thank you, thank you for again to Administrative Verma for setting up these calls. But also for the really that you guys taking time out of your schedules to get on this call and ask us things but also provide us insight. So thank you.

Seema Verma: Thank you Dr. Birx. And I think we're also joined by Dr. Redd, who's the Chief Medical Officer at ASPR, which is our emergency response team at HHS. Dr. Redd?

John Redd: Yes. Good afternoon, everybody. This is Dr. John Redd. It's an honor to be here, Ambassador Bix, Administrator Verna, thank you very much for allowing me to speak. I'm the Chief Medical Officer for ASPR, the Assistant Secretary for Preparedness and Response in HHS.

Right now I am assigned with FEMA, under the Unified Coordination Response that was established under the White House Task Force. And my current role is that I'm the lead for the Health Care Resilience Task Force, which is responsible for ensuring resiliency of our healthcare system during this pandemic and trying to ensure that the things go as well as possible for the future.

I wanted to mention just a couple of top line FEMA reports. One in particular that I think may be of interest to this particular audience is the concept of an alternate care sight, which is something that my task force has been working on with the U.S. Army Corps of Engineers. And it's a concept that I think many of you will have heard about before.

As of now, we've established a total of 20,270 hospital beds through this mechanism. The Army Corps of Engineers has set up now a total of 14 alternate care sites, which have about 9,800 total beds at these 14 sites. They've also assessed 594 additional sites. We've also set up through HHS as part of that overall bed total that I gave you, 41 federal medical stations. And the two hospital ships the Mercy and the Comfort which have approximately 2,000 total beds in capacity.

So I'm going to listen carefully, and it will be an honor to hear all the questions. And thank you very much. I'd be happy to take questions myself later. Thank you.

Seema Verma: Thank you. And just to build on what Dr. Redd talked about, I mean, you're hearing about the FEMA efforts to set up alternative care sites. The regulations that CMS put out just this week earlier on Monday, is allowing you to provide services outside of hospital walls. So that's looking at what resources exist on the ground on a local level. And one of the things that we

also did was allowing surgery centers to be reimbursed as hospitals so that they can also be part of the solution here as well.

There are so many flexibilities that we add – that we laid out. I'm just going to highlight a few of them and then we'll open it up for questions to talk about this piece of it as well. I also want to emphasize today that, you know, we're always here to answer questions. But a lot of what we want to do on these calls is to allow you all to talk about what you're doing so that we do foster that collaborative learning, rapid processing of best practices.

So let me just run through a few more of the flexibilities. And then we will open it up for questions for FEMA, Dr. Birx and I as well. So the other point that I wanted to make was that because we're going to have these different sites or hospitals may be providing services outside of their four walls, they can use ambulances to transport to these locations. So it's not just for emergency purposes or between hospitals but these other sites can be used as well.

We've also provided some flexibility around EMTALA so that you can do some of the screening even in a parking lot. You can also use telehealth to provide services from the E.R. The other piece that we've done is we've expanded telehealth services again in Medicare. So we did that a couple weeks ago. But some of the new flexibilities are also allowing phone calls. And as many of you know, there's a lot of barriers or a lot of restrictions inside Medicare around telehealth and requiring face to face visits.

And so we've gone through all of our regulations and gotten rid of those as well. In terms of testing, we're also paying lab companies to go out for to homebound patients, including nursing homes to do testing as well. And also around Stark Laws to help support our workforce. We've given flexibility to hospitals to provide meals and childcare and laundry and other types of services as well.

We're also working on kind of a general approach around workforce trying to get flexibilities so that providers at different levels, nurse practitioners, nurse anesthetists, and a variety of different professionals can operate at the top of

their license in accordance with state laws. So we're going to do some more work on that. There were few flexibilities that were already offered on Monday as well.

Also, remote patient monitoring, we've expanded that as well. And then finally, in our Patients Over Paperwork initiative, a lot more flexibility there from reporting requirements. All of those have been extended or extended or suspended. We're also allowing for verbal orders. And there's a lot of flexibility around discharge orders, just sort of understanding that hospitals and providers are operating in a crisis situation.

Also last week, and I think we announced that our call we are also offering advanced payments to healthcare providers. We also know that many of you aren't able to provide services, you're not able to do elective surgeries, and that's having an impact on revenue. CMS has already put out \$3 billion dollars as of yesterday and we continue to process those requests.

The agency is also focused on the CARES Act implementation which provides \$100 billion to the healthcare system. And so you'll be hearing more from us around how those dollars will be allocated. And so with that, I'd like to open it up to questions on these three portions on the hospital flexibilities, any questions for Dr. Birx or for FEMA?

Operator, please open the line for questions.

Operator: All right, ladies and gentlemen, at this time, I would like to remind everyone, in order to ask a question, simply press star, then the number one on your telephone keypad.

We have a question from an anonymous line. Please state your first and last name, the line is now open. Again, for the person to press star one. Your line is now open.

(Dr. Brzezinski): Hello?

Seema Verma: Hi. Yes, we hear you.

(Dr. Brzezinski): Hi. This is Dr. (Brzezinski) calling from Michigan. I did state my name when I dialed in. But anyway, I guess this would be a question for either FEMA or for Dr. Birx. I'm a little concerned about the lack of education and information disseminated to the Rural Health regions even the people that reside in communities in terms of how they're shopping, bringing their families, bringing their children. And I just wonder, is there going to be a nationwide mandate for a stay at home order because I'm not sure that this information about the high transmissibility of the COVID-19 virus is being communicated effectively in these regions?

Deborah Birx: Yes. Thank you for that question, and I really appreciate it. So yesterday I went to the American College of Physicians and talked to them and their association to really ensure that they have gone to their health commissioners in each and every one of the states to talk about the consequences of not doing a stay at home order.

You know, obviously, we have a lot of state rights. And the governors have to be the ones to really endorse this position because they are the ones that would have to enforce the guidance. Obviously, we're not going to set out the military to enforce stay at home orders.

So I think the associations can really help us, the Physicians Association, the Nursing Association, because in the end, it is those associations that are going to get hit so hard and they're providers by states that have risk or have basically not follow the guidelines.

And I think you raise a critical point. If you I could do something differently or talk to additional people. I'm happy to do that. But I've really called on the American College of Physicians to really help me with this.

(Dr. Brzezinski): May I just add another comment to that? And thank you, Dr. Birx for your leadership during this crisis. I think that, you know, within the State of Michigan, we already have a stay at home executive order. I'm just not sure if there's just a disconnect with what's been communicated before about the serious nature of this pandemic. And I just don't believe it's really resonating with especially the rural regions in Michigan.

Deborah Birx: And what was that last point again?

(Dr. Brzezinski): My point was, is that I'm not sure that despite the executive order in the State of Michigan that Governor Whitmer put into place, I'm not really sure that it's resonating with those that reside in, especially the rural regions of Michigan.

Deborah Birx: Yes, so, and this would be really helpful. And maybe you can contact me separately to really, I'm trying to figure out what or obviously my organizations are like your organizations, I go through the physician and nursing networks. But if you think we should go through other associations that may have more impact, whether it's the Farming Association or the small – I'm willing to send out the messages however you think it would be helpful.

(Inaudible)

John Redd: OK. I'll go. This is Dr. Redd, I can answer that one very quickly if that's OK. Under the FEMA structure, one of our task forces is community mitigation. And we have been reaching out specifically to rural populations and we concur that that's quite an important issue. And I just want to let you know that that we've got that as a specific task and our task force and you'd be welcome to contact us as well. Thank you.

(Alina Czekai): Thank you. Next question, please.

Operator: Your next question comes from the line of Theresa Noe. Your line is now open.

Theresa Noe: Yes. Thank you. This is Theresa Noe with Patient First. We, our organization run 76 urgent care centers across the Mid Atlantic. My question is, can EMTALA be relaxed to enable triage of E.R. patients to urgent care centers? At this time there's significant capacity to be able to treat those patients.

Deborah Birx: Can I just ask you a quick question? This is Debbie Birx again. Do you have and we're believing that you might this new Abbott I.D. now passed in most of your urgent care facilities.

- Theresa Noe: We do not, but we're expecting it in about three weeks. Our supply chain is the Abbott test are going to the hospitals in the next two weeks, and then whatever allocation remains is going to others in the community urgent care centers and others.
- Deborah Birx: And you can do full social distancing and protection of your health personnel as well as the clients.
- Theresa Noe: Yes.
- Seema Verma: So under the CMS regulations. I think that would be permissible. We'll follow up with you to give you some more information on that.
- Theresa Noe: All right, that'd be terrific.
- Seema Verma: Thank you.
- (Alina Czekai): Next question, please.
- Operator: Your next question comes from the line of (Robert Graff). Your line is now open.
- (Robert Graff): I'm also an urgent care provider in the State of Maryland. And we have not received any kind of information, which makes transfer from the emergency room lobby or in triage to urgent care. In fact, the hospitals are terrified that they'll violate a rule. We give comprehensive care and testing. But there's nothing in writing allows us to have a dialogue with the hospital that says this is permissible. They would like to do it. They're just afraid to do it. What can we tell them?
- Seema Verma: Well, that's, that's really helpful. I mean, I think that the idea with hospital without walls is to allow for those types of arrangements so that hospitals can triage and send people to different sites. We can try to go back and try to and make that more clear in the regulations and also try to follow up with you about how we can be more specific about that flexibility.
- (Robert Graff): They're interpreting that hospital without walls to be an organization that's financially related, that they're either property site owner or systems they put

in place. They don't see an unrelated financial institution as being somebody safe to transfer a patient to.

Seema Verma: And we can try to give you some more clarity around that.

(Robert Graff): So helpful and thank you for all the work you're doing on behalf of the medical providers.

Seema Verma: And do we have somebody from the CME team? Do you want to answer that question to give them a little bit more specificity? (Emily), (Ing-Jye), would you like to address that question?

I think we're having some technical difficulties. Let's follow up with you on that issue. I mean, I think the idea here is that there could be a financial arrangement. But I think the other thing we're encouraging communities to do is to develop that system of care. And so that it doesn't necessarily require there to be a formal arrangement.

The other thing that we've done around surgery centers and we'll look a little bit more about how urgent visit centers can be a part of the solution is allowing them to register as hospitals to be – to provide those services. But we'll go back and provide some more specificity about the urgent care centers and about how those relationships can work with hospitals.

(Robert Graff): That would be wonderful. Thank you so much.

Operator: Your next question comes from the line of Leslie Narramore. Your line is now open.

Leslie Narramore: Hi. My name is Leslie. And I am with the American Gastroenterological Association. I was just wondering if this correct forum to ask a question regarding telehealth as it relates to the interim final rule.

Seema Verma: Yes, you can ask questions, please.

Leslie Narramore: Excellent. Thank you. OK. So, you know, as we were going through the whole thing, we noticed that in Section C, which is telehealth modalities and

cost sharing, you know, it says that audio only communications, you know, that his phones are now considered telehealth and that made us very happy.

But then we noticed that Section S further down, says that E&M provided via telephone is now covered by Medicare. However, it is covered using the CPT codes for telephone E&M, which in the rule, CMS is saying they feel like telephone E&M is really more a keen to a virtual check in. So the issue that I'm having is that our physicians are telling us that they're trying to offer telehealth via like a real time audio visual system or an app like FaceTime.

But many seniors like they either lack the bandwidth or the signal strength to conduct the visit over those kinds of platforms or apps, or, which actually seems to be the more common occurrence. They're just not comfortable using the technology and they don't want to use it. So, the physicians, you know, understanding now that, you know, that they must use these, you know, if CPT E&M, telephone co – a telephone E&M codes, which reimburse between \$15 and \$39 nationally, they feel like they're being penalized for factors beyond their control that is, like the patient's ability and willingness to use a real time audio visual platform.

So, you know, it's, you know, we're in a medical crisis, but we're also in a financial crisis for, you know, physicians that that aren't on the front line but still need to see their patients like gastroenterologist. So my question is, you know, what can CMS do enact parity for E&M provided over telephone when it's not the physician's fault, you know, that they have to use the telephone?

Emily Yoder: Hey, this is Emily Yoder. I'm the telehealth subject matter expert. And what I can say is that we definitely have heard this question a lot and we really appreciate your concern. And we're looking into what we can do with whatever sort of additional authority that we have through the CARES Act to see if we can mitigate some of this, some of the hardships because as you as, you know, and as you point to right now, the Medicare telehealth technology restrictions meeting to be two-way audio/video remain in place for Medicare telehealth services while the telephone evaluation management or assessment management codes. They are audio only, but they do reimburse less than Medicare telehealth.

So all I can say is that we really appreciate you bringing this to our attention and we're working on it.

Leslie Narramore: Excellent. Thanks, Emily. I appreciate it.

(Alina Czekai): Thank you next on our agenda, we'd like to move to best practices and some of our peer to peer learning these CMS flexibilities. We'll turn it over to Kim Brandt to introduce our speakers today.

Kim is the Principal Deputy Administrator here at CMS. Kim, over to you.

Kim Brandt: Great. Thanks so much (Alina). We're going to start with Dr. Harold or Hal Paz, who's executive vice president and chancellor for Health Affairs, as well as CEO at the Warner Medical – I'd say the Wexner Medical Center at The Ohio State University. Dr. Paz, over to you.

Harold Paz: Thank you very much Kim. And I appreciate the opportunity to speak with everyone this afternoon. So, we're based here in Columbus, Ohio. The Ohio State University and Columbus has a population of roughly 2.4 million people in the metro area. We have a long standing history of collaboration on behalf of the Central Ohio community with the other major hospital systems in the city, two adult hospitals and then in large Nationwide Children's Hospital.

And through these collaborations over the past several decades, we focused on public health priorities in the community patient safety and quality of care issues, and of course, infectious disease outbreaks. Through this work, we formed the Central Ohio Trauma System, which is a collaboration of these hospitals and is under the leadership of a retired hospital CEO and a retired trauma surgeon who is leading these initiatives in the community.

The organization, Central Ohio Trauma Systems, also known as COTS, serves as a community wide organization to coordinate with EMS and the management of time sensitive disease situations, including trauma, stroke, STEMI, and also works to align disease preparedness and disaster preparedness as well as managing disaster preparedness drills twice a year.

And in addition to that, with the recent events that have occurred in the past month or so, COTS has now expanded these relationships beyond the three adult systems in Columbus and the Children's Hospital to also now bring in 40 hospitals across 36 of Ohio's 88 counties.

Earlier this week, the governor designated the states in three regions among the three major cities, Cleveland, Columbus, and Cincinnati. We now are in the center of what is now called, Zone Two, in the state of Ohio. And as a result of that, have been working on organizational preparedness in preparation for a surge that we have been modeling over the past month or so with our Ohio State Infectious Disease Institute, which does the analytics and modeling work to anticipate when the surge will hit the inflection point and when we anticipate a peak.

The regional response that we're operating through COTS includes coordination of patient flow across the region that will be managed out of a centralized resource coordinated by transfer centers for the three adult health systems here in Columbus.

This group will communicate capacity and demand in real time across all the hospitals with a single triage officer who will be responsible for the assignment of patients across the entire region, including those community hospitals in rural areas in this central and southeast region of Ohio.

And through the Ohio Hospital Association resource tracker, we're able to track capacity and current utilization of multiple types of hospital beds as well as ventilators and ECMO circuits across this entire zone to region to allow for our preparedness work.

In addition, as we are looking to prepare for level three surge, each hospital has an independent surge plan that includes, first level one surge which is maximally utilized routine patient care spaces within our current facilities to optimize our inpatient capacity. Level two surge maximally utilizing non-routine patient care spaces. So for example PACU, endoscopy, recovery areas, operating rooms, and others to increase inpatient capacity.

And then finally, level three surge, movement outside of the traditional hospital walls or a hospital without walls to other facilities within our community. And we've looked at various resources including hotels, dorms, arenas. In preparation for the impending surge, which we predict to hit sometime in mid-April, health systems have agreed to a coordinated patient referral system to preserve resources across the city by ensuring that one hospital or health system does not have all the sickest patients admitted to their institution.

So the four Columbus-based health systems working in conjunction with COTS will have agreed that if we need to stand up a level three surge outside of our walls, we would co-locate those to surge sites in the same location. The surge site is intended for patients who are too sick to go home, but not sick enough to be in the hospital and they'll be triage via hospital emergency departments and EMS.

Over the past two weeks, an immense amount of effort has been put into designing and designating a planned field hospital within the greater Columbus community. And we've selected the Columbus Convention Center to do that work. This work is being coordinated by COTS with the active participation of the Ohio National Guard.

The Convention Center is designed to accommodate up to 900 COVID positive adult patients in three separate operational field hospitals located in the Convention Center that could be expanded further of nationwide Children's Hospital would need to move up to a level three surge capacity.

The site is staffed by clinical staff from all three adult hospital systems to get economies of scale and the hospitals will partner with the Convention Center on other various infrastructures that they need, including staff meals, oxygen, emergency power, environmental services. But each hospital will operate their own clinical operations independently, so pharmacy, lab, EMR, et cetera.

This will allow for consistent billing and easier transition for providers in between their hospitals and the Convention Center as well as to other sites of care as deemed appropriate based on the condition of the patient. It can also

allow us to train staff on new systems without having to cross train between the various hospitals.

So given the centralized process to oversee patient flow across all three regions, including out into the rural hospitals across these large swaths of Central and Southeast Ohio, we hope to be able to manage the volume of patients using only level one and level two surge sites.

Our goal is to make sure the community hospitals are able and capable to manage the sickest patients they possibly can, within the context of this network, avoiding a situation where many sick patients are being transferred to the three systems within the City of Columbus.

In addition to that, we're working with physicians in practice in the community, who will volunteer time and are interested in volunteering their time to work at the Convention Center or at other surge sites, in that currently, most of their work is in elective cases and the opportunity to participate through a collaborative approach that we're working on developing at the current time.

And finally, we continue to expand out telehealth services across the region as well. At the Ohio State University Wexner Medical Center prior to the pandemic, we had about 46 providers. Yes. 46 providers who were offering a telehealth services to about 627 patients.

By the end of March, we had nearly 1,000 physicians that have done nearly 10,000 telehealth patient visits, and that number continues to grow exponentially. We view telehealth as an important source for us to not only provide direct patient care to those that shouldn't be coming in to an ambulatory care or hospital setting at this time, but also an opportunity to do tele ICU and other services as well as we prepare for the impending surge.

I'll stop there and be happy to answer any questions. Thank you.

Kim Brandt: Great, thank you Dr. Paz. Next, we're going to go on to Dr. Lee Fleisher, who is the chair of the Department of Anesthesiology and Critical Care at the University of Pennsylvania Health System. Dr. Fleisher, off to you.

Lee Fleisher: Thank you very much, Kim. And thank you, Administrator Verma for all the work you've done to allow us to take care of all the patients with all the changes.

I'll get a little more granular and think about critical care, which is part of my department, but shared with pulmonary emergency medicine, surgery, and other departments in thinking about how do we take care of these patients.

And as you think about it, we've certainly, as Dr. Paz just mentioned, look at other floors to take care of ventilated patients, which are the critical needs. And thinking about opening units that are traditionally not available for critical care. Examples being, observation units in the emergency department, units that have critical care capacity.

And finally, as was mentioned about the surge two and three, the idea of the O.R. and post anaesthetic care units and PACU's which increases our capacity to have ventilators since the anesthesia machines are all ventilators, and we have providers who know how to work them.

In order to actually expand behind – beyond this critical care footprint, and we have two major academic medical centers but a total of six centers in our system, we've had to think a lot about the manpower that we would use to take care of this large number of ventilated patients being the average time of ventilation, somewhere around 14 to 16 days based upon experience in China and Italy.

And I recently gave a webinar at NQF that's available on the web. But we've really been using the critical care medicine model of critical care trained individuals being those who actually are sort of the top of the pyramid, traditionally, looking at 12 to 14, maybe 16 patients.

And then the second concept of critical care capable providers, physicians, as well as nurses. And that's really for example for me, my cardiac anesthesiologist, liver anesthesiologist, those who do complex patients in the O.R., who, given the fact that this disease is actually management of ARDS,

the training to get them ready to take care of them over this longer period is not that complex. It's sort of one disease, potentially cardiovascular problems.

So as we look at minimal training, and in fact, we've sent them to the unit and developed a lot of material which we have either on our website, as well as multiple other ones, getting them ready next week, for our case, to actually have them in the operating rooms and opening these new units, as well as front lines. And we can't forget about the staff, including the cleaning staff and the people who support us.

So we're providing – we're thinking through this pyramid with an intensivists at the top who's always available for consultation and the new codes that allow us to do tele ICU and in fact, bill for that. Under that, these critically care capable individuals, under that the individuals on the frontlines.

But in addition to that, you have to think a lot about teams and what kind of teams do you need and we had stood up intubation teams, which traditionally emergency departments and intensive care units may or may not do their intubation. But given the need to dawn and dusk PPE, that the ability to have a separate team is very useful.

We just stood up procedure teams, given the need for central lines and arterial lines directly with our surgical colleagues. Many places are looking at proning teams. And we can't forget that given the large number of patients who will be on ventilators, there's actually a limited number of respiratory therapists who are adequately trained so that we've begun to train in my case CRNAs and anesthesia residents to be respiratory therapists.

So to utilize their additional expertise to provide that care, and that the respiratory therapists then would actually take care of the most complex patients. So it's really this integration of using the hospital without walls and that providing patient care in unique areas, and actually taking lower risk non-COVID patients even out to tents or non-clinical space.

Changing this, looking at HVAC, and flow of air to make sure that we don't cross contaminate, which was one of the biggest problems in Italy. And then

not only assigning new manpower, but training them to be ready to provide best care using protocols that are available on multiple sites.

And I think I'll end there. Thank you.

Kim Brandt: Thanks, Dr. Fleisher. Next, we're going to turn to Greg Feirn who is the CEO and Dr. John Heaton who are both with LCMC Health in New Orleans, Louisiana. Off to you gentlemen.

Greg Feirn: Thank you. This is Greg Feirn, appreciate you all putting the call together.

LCMC Health is situated in New Orleans with that in a little bit of perspective. Right now, Louisiana is reporting just over 10,000 positive cases statewide. Over 60 percent of that is in the Greater New Orleans area. They're reporting 370 deaths at this point in time. A majority of that is in the Greater New Orleans area.

LCMC Health operates a five hospital system which includes freestanding Children's Hospital, three community hospitals, and the University Medical Center which serves LSU in Tulane, which is also big safety net facility.

When we look at our census this morning, we have about 400 either COVID positive inpatients or rule outs PUIs. And the hospital represents about 60 percent of our current inpatient census. Our ICU, we have about 105 either COVID positive or PUIs in our intensive care units, which represents about 82 percent of our total ICU capacity at this time.

With that, I will turn it over to Dr. John Heaton, who is our president of clinical services for the system.

John Heaton: Hello. I too am an anesthesiologist. And I will touch on some of the stuff we've done to maintain the onslaught of patients that we received over the last 25 days in New Orleans. For the last week or so, we are bumping up against what was previously our full capacity in our intensive care units.

As a system, we've added 75 beds. So we do have some buffer there over our previous capacity. But it was nip and tuck. And staffing has been a constant

challenge. So one of the things that we've done at LCMC Health and we have academic partners at Louisiana State University and Tulane School of Medicine, who help staff our critical care units.

We have had to extend their reach, in part by taking nontraditional providers such as trauma surgeons. We have an employed anesthesiology group. We have taking both our anesthesiologists and CRNAs and repurpose them as ICU extenders and critical care docs. And I'll touch on that in a second, as well as pulling staff from our Children's Hospital, which is one of our five hospitals, we're redeploying them in a malpractice.

Kind of the linchpin of all of this has been our ICU or ICUs, I should say, because there's three of them at our University Medical Center, which is a large 450 bed at Academic Health Center that we operate.

Our critical care docs there, which is a team consisting of, you know, an employed director and faculty from both Tulane and LSU Schools of Medicine, staffing those units up to trauma ICU and the medical ICU, as well as our surge ICU.

We have our critical care guys there have developed a progression for these desperately ill patients that have been coming in and rather large volumes at once. Many of them coming in, in extremist in the operating – in the emergency room, excuse me, which is a bit different than some of the experience that we've heard from our friends in Puget Sound where I think to paraphrase them, they felt that their med surge unit was a waiting room for their ICU. Many of our patients are bypassing that.

And one of the things that we've found that has helped us survive this surge of patients, and really hold the line without compensating or having to revert to crisis standards of care was both collaboration within our system and within our other health systems in the metro and New Orleans area. We stay in constant communications and have been able to help some of our peers out in several occasions.

And also within our sister hospitals within the system, we have two 350 bed or so community hospitals as well as a small, 60 bed hospital in New Orleans

East, which has turned out to be really one of the hotspots in this epicenter of COVID-19 in Louisiana.

So, what we found is that aggressively treating these patients with trying to rigidly adhere to evidence based guidelines, mostly ARDSNet protocols, giving these patients attempt to use noninvasive ventilation. Generally, CPAP or BiPAP in a negative pressure room, we've managed to get double digit amount of patients over their acute respiratory distress syndrome without intubating them which is a victory in itself to save some ventilator.

For those that have required positive – continuous positive airway pressure, we've typically use UV-60s with a closed circuit. For those that have required mechanical ventilation, we have used low tidal volume, high frequency similar to the NIH ARDSNet trial in aggressively proneness patients for day one. And we have used our anesthesiology providers as proning teams with these patients.

Additionally, we – those patients have put on – have been put on the high pip ladder, that ARDSNet has out there but stuck – but since most of them had severe hypoxemia, they're starting at a very high FO2 because they're really starting at the top rung of the high pip ladder and working down from there.

We maintain rigid, meticulous, fluid balance limiting fluids for those patients that are thought to be volume overloaded or normal (anemic), and only fluid resuscitate those patients that, you know, have evidence such as metabolic acidosis that for hypokalemia. So we're trying to keep them in a neutral fluid state, aggressively prone them or aggressively ventilate them.

Usually four cycles of proning and then start doing breathing trials. With this technique, we have been able to excavate two positive pressure significant number of patients in less than a week of ventilation time. And without being able to do this, I think that we would need in a – to use the colloquial phrase a world of hurt.

We're still – we will be recording his data as we get some of our testing back and have the time to analyze it. But it is certainly worth looking at those who are at a point where they can either move patients through their ICUs or end

up having to revert to the crisis standard of care, which is something none of us want to do.

I think that this is a departure from what we're hearing around the world in Seattle. But it is a real thing and those patients that are able to excavate early have shown good survivorship. And we have about, I believe, about a dozen of them have actually already been discharged from the hospital.

So, again, the message to those of you that are a little bit behind us in the explosive growth of COVID-19, look at your ICU apparatus. Use your neighbors, similar friends to load balance wherever you can to keep your folks from getting overwhelmed and look towards your nontraditional providers, particularly your anesthesiology department as a source of strength to leverage your critical care assets.

I'll stop there.

Kim Brandt: Great, thank you so much, Mr. Feirn and Dr. Heaton. And now we'll go on to Dr. Ted Long, who's the vice president of Ambulatory Care at New York City Health and Hospitals. Dr. Long over to you.

Ted Long: Thank you very much. And thank you Administrator Verma for having me today.

So in New York City Health and Hospitals, we're an 11 hospital system. More than a million patients each year, more than 40,000 employees in New York City. Our mantra approaching COVID has been to provide patients with the right care at the right place at the right time.

And I'm going to tell you about what we've done so far and what's worked and what hasn't worked. And then I'm going to tell a little bit of our problems that we're facing today. When this started a few weeks ago, we – lesson number one is use telehealth.

One of the first things we did is we stood up a clinician hotline overnight that was staffed by clinicians in our system that would take calls from people across New York City. Now one of the initial problems with COVID was

people were very concerned. They had symptoms, sometimes mild symptoms, sometimes exposures, and they're beginning to present to the emergency department with questions or mild symptoms when the right care for them would be to stay home.

In the context of setting up this COVID hotline, we'd start out with a few clinicians immediately grew based on demand and need to over 750 of our clinicians in our system. And to date, we've done more than 50,000 clinician phone calls with patients. I think that really does speak to the need. And 90 percent of the time, we're telling – we're advising people to call us to stay at home because that's the right thing for them, the right thing for New York City.

But if we didn't do that, those 90 percent of the people might very well show up in the emergency department. So we believe we're hurting tens of thousands of emergency department visits by really getting out there ahead of the curve with telehealth.

The other thing we've done is I want to say thank you to CMS for the telehealth flexibilities that you've given us. That's made a huge difference. I mean, I'll tell you a couple of ways it has been different for us. One is last week alone, we scheduled more than 29,000 total visits that would have otherwise been scheduled visits.

We can only do that because we had to rapidly be able to build out our telehealth platform, but also doing just telephone visits. And the flexibility you gave us enabled us to be successful there, taking care of patients. I'm a primary care doctor, myself. And this afternoon, when I hang up here, I'm going to be doing tele visits with my patients.

The other thing that we've done with the increased flexibility is we've been able to be good city partners. And we're now taking calls from 911 callers that are put through to our telehealth platform, which is something we built out again very, very quickly. But what the problem that that solves is anybody that calls 911 is guaranteed to come to the emergency department unless we're to use telehealth to get through to them ahead of time and to

deliver them the right care in the right place, which many times is at home, and the right time, which is right away when they call 911.

Other things that we've done in New York City, that worked well so far, and I want to say thank you to FEMA for this is we've set up five very large tents where we do assessment and testing for coronavirus. The reason this has worked well as it's given us a clear outlet to do assessment for patients that are concerned or may have mild symptoms.

I use the word assessment because here we're trying to conserve our PPE and our testing materials. So we have standards that are – we are guided by through our city Department of Health, in terms of who we test and the reason we test them.

But one of the key things that this is all for us and setting up these tents, which we now have 18 of them in our system, all of our large community health centers, all of our hospitals, is these tents give us a clear diversion from the emergency department if you were presenting to the E.D. and you have mild symptoms, the right place for you is not inside of the E.D., it's in the tent.

Why? Because if you don't have coronavirus, if you're in the Emergency Department with 1,000 people that are coughing, you may well have it by the time you leave. Or if you do have coronavirus, you don't want to be in a crowded area too where you could potentially be contagious to others.

In the tent, we have rapid assessment. We give you what you need, the right care in the right place and it's immediate the right time, you don't have to wait.

The other thing that we've been doing is and this is something that's been reflected in other speakers too is we've been aggressively seeking to expand our ICU capacity and what we need to be successful in the ICU predominant events and PPE. Another thank you to FEMA for helping us significantly with the PPE, which we're using today.

I'm proud to say in our system, we are expanding our ICU beds by 760 as we speak, which is tripling our overall capacity this month. That's a substantial increase and we're able to do that by being very creative with our hospital

space. PACU is just step one. We really are looking across the board in our hospitals for where we can build out extra ICU capacity. But we will be adding 760 beds that we've started we've made significant progress already.

So those are the things we've done so far. And that's what's worked well so far. Again, got to do telehealth, offering a diversion from the E.D. in the form of tents or things like that has been very helpful to us. And planning ahead for ICUs has been very helpful to us.

The problems we currently have are threefold. Number one, we – our hospitals as we're expanding their ICU capacity, we're essentially turning our hospitals into large ICUs. That means that we need to have a place for all the other people – patients in the hospital to go. What we're doing for that is working closely with FEMA and the army. We have the hospital ship, the Comfort, which we talked about earlier in this call, which is landed in New York City. And we've begun to transfer patients over to.

We also have other army run facilities. We have something called the Javits Center here in New York City. So there will be more than 2,500 bed facility that we could transfer patients to as well. But every patient we transfer out of one of our hospitals is an ICU bed that's opened up, potentially.

Number two is I want to say thank you again to CMS for expanding the flexibilities for surgery centers. So we're looking to train surgery center beds into hospital beds, and that's, I think, a clear opportunity that wouldn't be afforded to us in the same way if it wasn't for CMS, enhancing the flexibilities there. So thank you.

Number three is the make or break for us with coronavirus and this is where I started with talking about telehealth to keep people at home if they don't need to be in the E.D. And where I talked about our tents as an E.D. diversion tactic. We need to do everything we can to only have truly sick patients come into our emergency department.

But if you're moderately ill we run into this problem, well then what do we do, if we discharge you home and you decompensate that's not a great situation. But if we admit you then we've taken the bed from somebody that is truly sick

of which we have many people in New York City now. So we're creating a new model. But we're also leveraging tents outside of the hospital to be able to run.

We're calling it an Emergency Department Extended Observation Model, where if you have oxygen – increase oxygen requirements, increased labored breathing, you can go and sit in one of these beds, and we monitor through pulse oximetry, and through a clinician that monitor several patients at a time. And then that way, what we're doing is we're decompressing our emergency department.

And if you get better there, you don't need to be admitted. Therefore, that's preventing hospital admissions and saving some of our ICU capacity because every bed that's not used could be an ICU bed in our mind. That's why we're tripling the size of our ICUs.

With that, I just want to say again, thank you very much. I'm happy to answer any questions and I appreciate to be included on today's call. Thank you.

Kim Brandt: Great, thank you so much, Dr. Long. In the interest of time, we are going to move ahead to talk on the surge capacity topic and I'm going to turn it over to Dr. Brendan Carr, who is the chair of Emergency Medicine at the Icahn School of Medicine at Mount Sinai and also with the Mount Sinai Health System. Dr. Carr, it's yours.

Brendan Carr: Thanks very much. Hi, everybody. It's nice to hear friend's voices on the phone. Thank you for everything CMS has been doing for us to make it easier to take care of patients and save lives.

I wanted to highlight but, you know, I don't want to be terribly redundant and you – some of the things that you've heard already amazing clinical insights and amazing operational insights. You will find that part of a story that should be told is that much of what is happening in New York City is happening across multiple sites. And there are a lot of similarities because there's an ongoing dialogue across the health systems inclusive of TED's Health System. And so I will try not to be redundant.

But I wanted to touch on a few things primarily related to surge capacity. But I wanted to just say that the telemedicine piece was – is enormous for us and it can't be disentangled from the surge capacity. We have myriad telehealth use cases that have really expanded our ability to take care of patients. And, like others have said thousands and thousands of visits that would have otherwise happened in real life, are happening both in the scheduled side, in the ambulatory care side, keeping those providers able to work, and then also on the on the acute side.

The surge capacity piece that I wanted to focus on a couple different domains. The first is the freedom to use nonhospital buildings and spaces to care for folks. We, you know, Dr. Fleisher I think mentioned how long this hospital courses. And, you know, the sudden onset coupled with the long hospital course is really why we have such a terrible capacity problem.

And so as a result, we have looked at lots of settings to on the front end, send folks and some of this has been empowered by the new regulations. An example would be seeing sorting people the front desk and maintaining an open orthopedics clinic or an OBGYN clinic or cardiology clinic and sending them internal to the hospital or internal to the campus to have their medical screenings in there and have their care delivered there.

But also, as most people have noted, partnerships with NGOs to set up field hospitals to build additional capacity. We have leased entire hotels so that on the back end when we're trying to move people out as they're convalescing, we have a place to put them. And we have ongoing conversations with multiple other sites, in addition to the state and federal assets that are being created to help to provide space for folks to continue to convalesce.

There is of course, as you heard, Dr. Long mentioned lots of construction inside of our hospitals. We're also working really hard to markedly magnify our critical care capacity and overall bed capacity, including new construction in all the hallways and the open amphitheaters and access points to our hospital to create rooms but also in converting lots of rooms as again, Dr. Fleisher talked about into mega pressure rooms into ICU capable rooms.

Another piece, so in addition to the new – the nonhospital buildings and space, the alternative destinations piece has not been touched on yet or at least if it was, I missed it. And, you know, when New York City is ready to go live with the ET3 program through CMMI and the new – and there have been meetings, conversations across the city over the last several – over the last month really about whether or not to go live early. The guidance that sort of allows for alternative destinations is enormous for us and we're grateful for that.

And then, you know, specifically within the emergency department, the use of telehealth has allowed us to, as I said, sort people early so that we can make sure that we're not exposing our staff unnecessarily. And then beyond just sorting people to supervise, there's new guidance that allows supervision of medical providers. This allows us to use some of our workforce that are pregnant, immunocompromised or older, so those at higher risk, who can supervise remotely, it allows us to decrease our PPE burn rate. And it's just been enormous for us to leverage the workforce that we have.

And then maybe the last piece that I'll talk on, is workforce, which is just a sort of foot stomp the description that was given previously about the critical care guidance for tiered structures so that you can have hospitalists and even outpatient docs and, you know, and surgical specialists who are otherwise not – otherwise not engaged to partner up with multidisciplinary teams and be supervised by somebody with formal critical care training as we continue to sort of see the he numbers grow inside of our health system.

Maybe the last piece is there was some conversation about the respiratory therapist and we've created almost a tiered structure for respiratory therapists with lots of virtual consultations. So a one stop shop for when you are wondering sort of what next moves are for ventilator as people's lungs are evolving.

And I would even say, you know, something that has not been discussed a whole lot is, you know, we are familiar with vents that we have. And when we – now that we have lots of vents that we have not seen, it is very, very helpful to have a couple experts in all of these ventilators immediately

available by video chat so that you can get a consult if you will on a ventilator that is good, it's not entirely comfortable for you.

So just to sort of just – because I neglected to say on the front end, not only health system is an eight hospital system, seven of them have emergency departments, and we've got about 1,500 COVID patients and 250 ICU patients across our system as it stands right now.

Thank you for inviting us to the call.

Kim Brandt: Thank you so much, Dr. Carr. And I really want to thank all members of the panel that just spoke. I think now we're going to go in take a couple of questions. So (Lina), back to you to organize that.

(Alina Czekai): Thanks. Can operator please open the lines for questions? Thank you.

Operator: All right, ladies and gentlemen, at this time, I would like to remind everyone in order to ask a question, simply press star, then the number one on your telephone keypad. Your first question comes from the line of (Myrna Sanchez). Your line is now open.

(Myrna Sanchez): Yes, hello. I am an Upstate New York physician and chair of the ethics. And we've been doing a lot of preparedness and public health experts. So I think we're prepared. The question that I had is the allocation of beds and hospitals.

It appears by listening to all the other speakers that there has not been in the surge yet. And you have not had to allocate beds and hospitals. You hear it from the television, that there isn't enough beds or ventilators. So we had heard the CNN about having everyone become a DNR or having, you know, their DNR status rescinded. And I just wanted to ask if anybody has come across that situation yet.

(Ted): Hi, this is (Ted). I can get started as I know New York City has been in the news a little bit recently. So first off, good to be in touch with fellow New Yorker. I hope all is well with you Upstate. For us in New York City to be clear, every patient that needs a ventilator has one and we actually currently

have more than we need and we're aggressively getting more because we know the surge will continue to hit.

The surge has begun in New York City. It began at Elmhurst Hospital. But every staff member that needs PPE has PPE. And that's thanks to FEMA. And every patient that needs a vent currently has one. So we have not done any rationing or any allocation of hospital beds.

And I think that's in large part because we've been able to work with our federal colleagues. Again, FEMA has been extremely helpful. And I think it's also because we've been very aggressively expanding, you know, mobilizing your hospital to triple the size of your ICUs, no small task. But in doing that, we've been able to just to create the capacity we need to be successful to take care of all patients. The surge is happening, though, but so far, so good for us in New York City.

Lee Fleisher: And this Lee Fleisher. And I think the way to think about this is less about rationing on the front end. Since it was mentioned, we have the capacity. But decision making, potentially at the end of life on the back end and having those discussions and understanding how long somebody would want to be on a ventilator, what measures would be achieved, and potentially, as you say, you're an Ethics Committee standing up a group outside, who can help have discussions with families, so that when those decisions are made, the providers on the front line actually have someone more distant thinking through those issues. So again, it's more of that back end in a prolonged critical care environment.

Brendan Carr: And this is Brendan Carr from Mount Sinai. I would just add one last thing is that so that – I would agree with all of that with the surge has definitely happened and we're only keeping up because of the aggressive moves that have been made. Make those moves early so that you are ready because at the moment you are caught up, you are behind.

And the other thing that I would say is that, you know, there's a lot of – there are very, very interesting engineering feats that are happening. There's all kinds of press around converting BiPAP to ventilators as a temporizing

measure. There's all kinds of people working out the algorithms, should they ever be needed to split ventilators.

And obviously, you know, Dr. Fleisher, when he spoke – talked about taking anesthesia machines and moving them into PACUs so that you can use something in the interim. We're no – we are not – we've not allocating ventilators by any stretch. But we are thinking about all the different ways that we would make sure that never happens.

(Myrna Sanchez): Thank you. Well, we are a very small hospital. We have three ventilator beds. Our nearest hospital is about 40 miles away, and they have 28 ventilator beds. And we have a large prison system here with 5,000 inmates and correctional officers. And we're concerned that if the surge does happen, we get a rapid influx.

We don't have a field hospital tent and it would be good, how do we get communicated with FEMA and so forth to actually have something work rapidly? We're trying to expand. But again, we're a small community hospital surrounded by three prison systems that have a big amount of inmates.

(Alina Czekai): Thank you for your question. We'll take our next question, please operator. And then we'll move to our next topic of telehealth. Next question, please.

Operator: Your next question comes from the line of (Roberto Dela Cruz). Your line is now open.

(Alina Czekai): Hi, what is your question, please?

(Roberto Dela Cruz): I'm going to pass I had a question for the first presenters, but I'm going to pass now. Thank you.

(Alina Czekai): Thank you. Next question, please.

Operator: Your next question comes from the line of Michelle Durst. Your line is now open.

Michelle Durst: Hi. My question was also previously just about clarifying the telephone codes. Well, I'm with American Psychiatric Association and we'd like to fill

out the telephone to also be used for psychotherapy. But thank you so much for all the work and the speakers today. You guys are all doing amazing work.

Alina Czekai: Thank you. And as the administrator mentioned, we continue to work on telehealth and we'd be glad to take that as a follow up item. Kim, I'll turn it back over to you to introduce our next speakers. Thank you.

Kim Brandt: Great, thanks. We have two excellent speakers on telehealth. The first one is Dr. Andrew Watson, who's with the Department of Surgery in the Division of Colorectal Surgery and vice president International Division of Insurance Services and Health Services Division at the UPMC in the past president of the American Telemedicine Association. Dr. Watson over to you.

Andrew Watson: Thank you very much. And then a very grateful thank you to the administrator. Also Dr. Schreiber and Dr. Rosen for having me speak today. And I'm an actively practicing surgeon and I focus on crown surgery in inflammatory bowel disease. And most of my patients now immune suppressed at home and I practice almost all my clinics using telemedicine.

And one interesting area that's come up is that telemedicine is rapidly evolving, as we know. And we are so grateful for all of the support from CMS and what they've been able to do to help us enable healthcare of the future that's going on right now. And telemedicine had two big changes that we need to recognize, one in 2015 with the rise of video visits, which have now almost become the currency of healthcare, and also the rapid emergence of remote patient monitoring, which is still emerging right now. But there's a lot of potential moving forward.

And what we're seeing right now at UPMC, there's a tremendous amount of pressure to adapt and go virtual with the COVID tragedy that's really affecting all of us. UPMC so we're based in Western Pennsylvania, our providers cover about 6 million patients. Our insurance side covers 3.7 million members. We have 90,000 employees. And we're the third or fourth largest GME or graduate medical program in the United States.

And so across our 42 hospitals, we have a lot that we have to manage in terms of a payer, provider, and our employees. And so telemedicine has really become a critical force. In terms of surge planning right now, where we are in terms of best practices and also trying to be innovative.

One of the real challenges we've had is that we're a fixed asset business in many ways with our hospitals and physicians. And we've had to convert a large number of our traditional outpatient visits to telemedicine. We have our Chief Medical Information Officer Dr. Rob Barge, and one of our other leaders, Dr. (Rick Waddis). We've done a tremendous amount of work about converting our outpatient visits to our telemedicine modalities.

And that's been very successful. We were doing even a couple hundred and early March a day. And now we're up to 5,000 a day right now. Our typical outpatient volume is about 25,000 outpatient visits a day. And so we have a ways to go, but we're very quickly transitioning our providers onto the tele strategies.

And quite frankly, I've done personally done 500 consults myself and my patients love it and they actually prefer tele in many situations. And now as we're hearing the patients really have bought into this because they don't want to leave home because of the advisories and feel it's safer to get care at home.

There's a lot of learning on both the patient side and on the provider side for this as well. But you can tell there's a tremendous rise of telemedicine here on the outpatient side. We're also seeing it in our direct to consumer urgent care with our patient portals also with our cancer centers. So across the board, we're converting into the tele space.

And I'll tell you, personally, all my clinics are going to tele right now. We also have a real challenge with our employees. We currently have about 150 quarantine providers, physicians right now. We're trying to prevent exposure for them and for all of them. But we can also use them to practice tele when they're quarantined at home, as long as they're well and able to practice medicine safely.

And so a large part of our telepractice is using call centers and also telemedicine to try to prevent exposure to these critical employees, as you've heard, the other panelists talk about because they are the doctors and nurses the critical assets that really keep our patients and our insurance members healthy and well.

A third area that's rapidly rising right now is remote patient monitoring. This is a relatively new form of telemedicine, that's really has tremendous ability to scale and grow. Because it's a synchronous, you can be one to many. We're planning on using it for health plan, our home health, likely emergency medical services, and a lot of work in the post-acute care space. And that's growing very quickly here at UPMC.

And of course, we're working in our long term acute care, our skilled nursing facilities, our cancer centers. So really what you're hearing is across the board for us, it's a tremendous and rapid conversion to the tele space. So we are so grateful for CMS in its support of this rapid transition for us.

There are many implications about safety and quality here with COVID. But as we know that tele has a long history of being a very effective way to provide health care. And so if you look at our hospitals and physicians and our payers and our researchers and our educators, there's a constant theme about moving into virtual and really enabling these really valuable people that we employ and work with and our colleagues to work with the patients when and where they want to be seen, which right now is at home.

And so a lot of the surge capacity and what how we're handling this in the hospital, on the inpatient side and outpatient side is really based on telemedicine. And I should also say that there's a lot of work with inpatient consults been done virtual with the ICU work on how do we actually take providers that might be in one location to help staff, intensive care units to do inpatient consults in a remote location.

And a lot of a challenge there can actually be scheduling. And in terms of the innovation moving forward in the final minute here is that there's a real need, I think, to bring the video visits and remote monitoring together into a unified

platform, because there's a tremendous ability for those two platforms to interact in the pop health manner.

But we are just incredibly grateful here at UPMC to the administrator and all at CMS. It was nice to hear Emily Yoder also speak up for their support of advancing really the practice of medicine into the telemedicine space. And I'm sorry, we don't have a lot of time today. But again, I'm on Twitter, you can follow me on Twitter. We're doing a lot of work on Twitter trying to get the message out.

And I think it's a very exciting time and a very tragic time that we can take this incredible change in healthcare and really try to help our patients with the telemedicine space. And thank you very much for your time and attention.

Kim Brandt: Great, thank you so much, Dr. Watson. And our last presenter on telehealth is Dr. Zeke Silva was a practicing radiologist in San Antonio, Texas, and he's also the co-chair of the American Medical Association's Digital Medicine Payment Advisory Group. Dr. Silva?

Zeke Silva: Yes, thank you. And thank you Administrator Verma for including me in the presentation today.

So one of the nice things about being the last speaker is I can hear the other content, hear the other expertise and start to bring together if I may, sort of some things that I'm hearing collectively. And what I'd like to do is I'm going to walk through some of the things, I'm going to reference some of the speakers that made them and kind of how we're seeing the telehealth space and the innovation they're in, contribute to general healthcare, but particularly the crisis before us.

Earlier in the talk, one of the callers was Dr. (Brzezinski) and she and Ambassador Dr. Birx discussed awareness. And that was in the context largely of the shelter in place orders. But one of the challenges that we're seeing from the telehealth space is raising awareness regarding what can be done with a telehealth platform.

And this has largely it's probably with physicians, but it's largely with patients. So what we're doing here locally and I'm in San Antonio, Texas with the Methodist Healthcare System. But what we're doing is really taking an aggressive approach to informing patients that these options are available.

The practice is to have contact information or e-mailing and texting patients. We're making sure that our call centers when inpatients call in are aware that this is an option. And I just have to admit I was relatively struck by Dr. Long's example of 911 being triage to sort of telehealth interface to inform those discussions.

Number two is the technology. And I forget the caller's name, but I thought Emily's response from CMS was spot on regarding how the technology is being used in the community. The requirements in general for telehealth do require a two-way audio visual interface. But what we're finding is, and this is actually across all age groups, that not everyone is as familiar with those types of interfaces, even the more common ones like Skype and those as they are – they're nice mirror – those interfaces.

But what they are familiar with is the telephone. And so we found that that's kind of the least common denominator as far as what we can achieve with from a communication perspective. And I do applaud CMS for allowing those telephonic codes to be paid. To the point that was made earlier, you know, those are the true evaluation and management codes. That is an update the we could consider.

But for my coding folks on the call, there are actual CPT codes 9944133, but that represent the telephonic services. The other important change and the flexibility that CMS has provided is allowing telehealth to be used in other settings. So initially it was essentially with the office based services. But now, we're seeing it in critical care. We're seeing it neonatology. We're seeing in other venues where we haven't typically seen telehealth applied.

And why that's important is it's driving innovation. I mean, we're seeing and I thought Dr. Watson nicely stated it. We're seeing this momentum for telehealth that we've seen over the last few months to years, really

accelerating in the second year of this crisis. So we're seeing really novel actions being made in settings like the tele ICU and the neonatal ICU as I mentioned.

I think Dr. Carr's point earlier about just the sheer volumes that we're seeing in patients, particularly from a telehealth perspective, are particularly relevant. So as we see the need for repurposing of professionals, perhaps are in a profession as a physician or as a support staff where they're not as in demand in the current environment, as we repurpose them to other services. And the example provided earlier was the ICU.

But imagine we take those individuals and we repurpose them to the telehealth purpose. Well, they're you're asking individuals to walk into a space that they're maybe not as familiar as someone like Dr. Watson. And I think CMS to their credit, allowing some laxity in some accommodation regarding HIPAA requirements and security requirements and consents and things of that sort.

I think it's really important for physicians walking into that space, so they don't feel threatened by potential secondary consequences and they're given the chance to do what they want to do to contribute where they're able.

And then I'll just close with one last thought is, you know, the CMS' credit, they look to physicians, they look to providers and they say, we're going to lessen the regulatory burden and we're going to lessen Patients Over Paperwork. And a large part of what they're saying is they're going to rely on we as professionals to undertake and respect and continue to contribute to the quality that's expected of us.

They're not going to look over their shoulders, they're going to expect us to do it. So the messaging we're putting out locally, our physicians and nationally is, you know, really work towards learning these technologies, learning to contribute in the highest quality manner. Ensure that your documentation, the medical records is as adequate as possible, because one, that's important for billing purposes, but later is going to be important for individual local

epidemiology research, health policy wrote their scientific research. And those types of platforms need to be as robust as possible.

With that, I'll close and I want to again, thank you Administrator Verma for the opportunity to contribute. Thank you.

Kim Brandt: Thank you so much. We really appreciate it. And now, we're going to go ahead and skip ahead to the FDA portion of the program just in the interest of time. But just so you know, we will have many more opportunities for you all to ask question. And to call in on various stakeholder calls next week.

So we really encourage you to do that. And we will have some short Q&A at the end of this program as well, where you can ask some additional questions. But if you do have questions, you can send them to COVID-19@cms.hhs.gov. And now with that, I'm going to hand it over to Dr. Anand Shah, who is the Deputy Commissioner for Medical and Scientific Affairs at FDA and an honorary CMS'er. Anand, over to you.

Anand Shah: Thanks very much, Kim. I really appreciate you and the administrator inviting FDA to join this call. And thanks to everyone for dialing in from the frontlines. Most importantly, thank you for your hard work, your creativity, and commitment during this challenging time.

Your input, expertise, and leadership on the challenges we are facing is critical in our efforts to find solutions. Crisis of this unprecedented magnitude really requires all of us working together to marshal resources and ideas in our work to combat the crisis.

It's essential that we bring forward the best ideas and innovation so that we can get new and effective treatments to desperately sick patients as quickly as possible. And on this call, we wanted to focus as an agency on diagnostics. I have our subject matter expert, Dr. Tim Stenzel, who runs the In Vitro Diagnostics Program at FDA. He's going to provide an update on our testing, both on the diagnostic side as well as serology, and we'll be available to answer questions.

And with that, I want to open it up to Dr. Stenzel.

Tim Stenzel: OK. Thank you so much. I really welcome the opportunity to be able to address this group. Thank you to everyone. Most importantly, thank you for all that you're doing.

I do want to give a brief update on overall on diagnostics as our Center, CRH continues to work extremely hard to authorize additional new tests and address certain access issues to reagents and supplies. We do this by examining the literature data and providing known substitutes on their Frequently Asked Questions page.

We have a streamlined approach to EUA Authorizations, Emergency Use Authorizations. And to date, we have authorized 28 different tests including several point of care tests, and also most recently the first serology test for the determination of IgM and IgG. And we'll get back to serology in just a minute.

I wanted to add to this and that is today, just under 40 million, that's 4-0 million tests have been produced by authorized test manufacturers and made available to the U.S. market. We do realize that there may be some distribution challenges as well as implementation challenge as we stand ready to help, as best we can and look forward to adding to this number as fast as we can.

With our March 16th policy update, in order to speed availability of additional tests, we did allow validated serology tests. These are usually rapid point of care type tests can enter the U.S. market without FDA authorization, solely when they are used to determine the status of IgM and IgG. And not for the sole diagnosis of SARS-CoV-2.

We are aware that there have been reports of potential false claims and potentially fraudulent activity. We're going to hear more steps soon about how we can provide greater visibility to actual performance capability of at least some of these serology tests to aid in the selection of what tests may work best for you.

It's important to point out in these serology test with IgG, IgM, serology tests that there are limitations, especially those that have only notified us and not come in for EUA authorization. So to build in that category, the manufacturer must state that this test has not been reviewed by the FDA. They must state them negatively results do not rule out SARS-CoV-2 infection.

It must state that results from antibody testing should not be used as the sole basis for diagnosis or to exclude infection or to inform infection status. And that positive results may be due to past or present infections with non-SARS, non-coronavirus.

And also this policy does not apply to home testing. Home testing applications will require an EUA authorization. And we hope that the first home test collections will be authorized in the near future.

And with that, that sort of summarizes what I wanted to say. Anand, Thank you.

(Alina Czekai): Thank you Dr. Stenzel. This is Alina Czekai. I am at CMS. We're also joined by Dr. Tim Uyeki, the Chief Medical Officer for the Influenza Division at the National Center for Immunization and Respiratory Diseases at the CDC. And I'd like to turn it over to him to share some perspectives and updates from the CDC. Thank you.

Tim Uyeki: Yes. Hi, greetings. Thanks so much for the opportunity to speak. Just to say that what you heard from Dr. Stenzel, about serologic testing, CDC does not currently have any recommendations on the use of serological testing for the diagnosis of COVID-19.

The emphasis is really on virologic testing of respiratory specimens. And so at this time, there's really two ways for clinicians to get COVID-19 testing, and that is really to coordinate with their local and state health department through the public health laboratory system. And the other is, as you've heard from Dr. Stenzel, and now a large number of assays have been authorized by FDA for the diagnosis of SARS-CoV-2 infection or COVID-19 disease.

And so these are available through a number of avenues, either through large commercial laboratories, or on site diagnostics. And the time to test results ranged from less than 15 minutes to 45 minutes to a few hours. And so basically, there's a wide variety of tests, diagnostic tests or molecular assays that are available.

And so, if there are unlimited resources then, obviously everyone could be tested. But that's going to depend upon sort of the hospital setting, the clinic setting, the local availability of testing, testing reagents, swabs, and so forth. So CDC has prioritized certain groups and the first priority is really to focus on patients who are being hospitalized.

And with the goal of really trying to provide the optimal care for hospitalized patients, identify those who are infected to hopefully implement proper infection prevention control measures to reduce the risk of nosocomial spread.

And then another is, maintain the integrity of the health care system. And so that also includes not just hospitalized patients, but also symptomatic health care workers. So not – those not necessarily needing hospitalization but who are health care workers.

And then the second priority group are those focused really on who's at the highest risk of complications and particularly severe complications from what we know today. And, you know, it's true that our understanding of all the risk factors is a bit limited. But we have interim sort of high risk groups.

And by far, before I even discuss those, the highest priority in this group is that individuals residing in long term care facilities who are symptomatic, and that might even be mild symptoms. And we've certainly heard a lot and also read in recent publications about the great impact of COVID-19 in skilled nursing and long term care facilities with fairly devastating impact.

And so, the other would be people who are 65 years and older who are symptomatic and those with certain underlying conditions and those conditions are those with chronic lung disease, chronic cardiovascular disease, particularly heart failure, coronary artery disease, persons with immunocompromised and conditions, people with severe obesity, BMI 40 or

greater, diabetics, those who have chronic kidney disease, persons with liver disease.

And within this priority group to also includes people who are considered first responders. So a first responders, people that respond to emergencies, accidents, natural disasters, terrorism events. So these are emergency medical technicians, paramedics, firefighters, police officers. So those are the first two priority groups.

And third priority group for testing, again, as resources allow, are those in critical infrastructure workers. And it's a wide range of individuals who are symptomatic. And people who don't meet any of the above categories that have symptoms. And then people who have very mild disease in communities experiencing high, high numbers of hospitalizations for COVID-19 patients.

And then just to say that a group that have no priority, so we don't recommend testing unless there were unlimited resources, are people who are completely asymptomatic. So, I would refer to you for more details on the CDC web pages, its interim guidance. Right now, we've backed away from the initial to respiratory – upper respiratory tract specimens, which were a nasal pharyngeal swab and a throat swab to now just a single nasal pharyngeal swab.

But the only other point I would make is that in hospitalized patients, particularly those with lower respiratory tract disease, some people may have a productive coughing. If the diagnosis is not made by testing an NP swab, one could test sputum, but we do not recommend sputum induction because it's an aerosol generating procedure.

The other would be that ventilated patients with the diagnosis has not been made by testing a nasal pharyngeal swab, and COVID-19 is still in the differential or highly suspected. Then, and the tracheal aspirate specimen could be tested. And I think I'll just stop there. Thank you.

(Alina Czekai): Thanks. Thank you so much for this overview. We'd like to open up the lines now, to take a couple of questions as it relates to diagnostics. I know we're a little over time but wanted to give everyone the opportunity to answer some questions. So operator, if you could please open the line.

Operator: Yes, ma'am. At this time, we have a question from (Andrea Quill). Your line is now open.

(Andrea Quill): Yes, hi there. This is Dr. (Quill). So, again, thank you for all this wisdom, it is phenomenal. I'm president of our County Medical Society and one thing that was very concerning to me was that the guidelines for the physicians in our area, we're actually doing the testing themselves.

And in the beginning, obviously, they were not following external guidelines to do it outside. Many of them are doing them outside, but I just don't think that is highly recommended. In my anxiety, I don't want our first responders being physicians that are testing the patients and then they end up becoming infected and then potentially shut down and now we have a caregiver who is, you know, potentially not caring for 2,500 people.

The other thing that I would like to ask is their work being done on viral load. I know that you first have to have a diagnostic test positive but I look at how we look at HIV and how we look at Hepatitis C and we look at viral loads. What's the status of that? And thank you again for your time in this wonderful question and answer panel educational session.

Tim Stenzel: Tim, do you want to go first?

Tim Uyeki: Sure. Tim Uyeki from CDC. So for with respect to the question about the duration of viral shedding, so you're completely right that all these assays out, detect viral RNA, so they don't. A positive test is a qualitative result. It doesn't actually tell you if that represents detection of infectious viable virus.

So, one of the challenges is and as you at least suggest, you know, the correlation of the cycle threshold value for the real time RT-PCR assay with viral culture. One of the challenges is that this virus is not easy to grow coronaviruses are not easy to grow and culture. Nevertheless, some of that testing has been done at CDC and is underway in other institutions.

And so when we've looked at the available published data, we've looked at some of the unpublished CDC data. That's what we have done to come up with some of these, some of the guidance on duration of isolation at home and one could withdraw. So roughly, it appears that and there are exceptions for sure.

But that the great majority of individuals, whether they have severe disease or they have mild disease, appear to have viable virus detection, very high levels in the nasal pharynx in the nasal cavities, very early on in the illness, after illness onset. And this decreases over time.

And after about a period of about seven or eight days, it really drops off in terms of the cycle threshold values really start going up. And so the way to interpret that is it's actually the inverse. So the higher the C.T. values, the lower the amount of virus.

And so it appears that after about a week through eight days, somewhere around there, most people don't have viable virus that's detected. Now, there are outliers. And so different countries have used different duration of like, how long you should stay in isolation, and so forth.

So we're all learning every day from this. And as more and more data become available in our published that'll help inform. And the other is that patients with more severe disease, people who are hospitalized, persons who are critically ill in the ICU, tend to shed or to have viral RNA detection much longer, including in the lower respiratory tract.

And we can't – there's not really good information to really define the period of infectiousness in those with critical illness or more severe illness. But certainly in those with mild illness, people who have recovered from their disease has been discharged from hospital, who have differ vast and most of their symptoms have improved. They're stable. They can go at home. Most of them will not be shedding virus for much longer than that.

But there's a period of uncertainty. And I think we should all acknowledge that we're trying to learn and I think that information will come out over time. Thanks.

Tim Stenzel: I think there was also a question about the frontline clinicians doing the testing. I don't know if this is a point of care or collection. And we agree, and it's why we've already allowed self-collections from anterior nares and also from a mid-turbinate swab in the setting of a clinical health environment that patients can pick up these kits on the way, you know, drive in, perform the sub collection and handed back to minimize the exposure to health care providers.

And we do anticipate authorizing the first home collection EUA, which will of course system in distancing this collection from the healthcare environment.

(Alina Czekai): Thank you. We'll take one final question, please, operator.

Operator: Your next question comes from the line of (John Martin). Your line is now open.

(John Martin): Well, thank you. My question was answered earlier. So I'm all set. Thank you.

(Alina Czekai): Thank you. One final question please, operator.

Operator: Your next question comes from the line of Rohit Malhotra. Your line is now open.

Rohit Malhotra: I had a question regarding telehealth I'm not sure whether I should bring that up now. But I'm at the University of Virginia Medical Center, I'm the Medical Director of the Cardiology Clinic. Many of the patients getting care at trainee clinics that are high resource utilizers and have limited access to technology. But billing visits for these patients is being reserved for both audio and video interactions. And those are difficult for many of the patients in training environments. And we're trying to keep these patients away from the hospital, away from clinics.

The reimbursement for those visits seems to the sort of – it doesn't seem to be existing at all because there's the mandatory requirements seems to be both audio and video capabilities rather than telephone encounters only. I'm not sure whether there's space to liberalize that a little bit.

Zeke Silva: Yes. This is Zeke Silva. It's an important question. We sort of touched on it. Maybe, Emily, she's on a call for some comments from CMS. But yes, the interim final rule last week did allow coverage for the telephonic code, the audio only use code.

Now those are different than E&M codes and to your point the evaluation those is lower but those are available. Now, from the audio visual side as we discussed brought this in alike, yes, those codes can be billed at the – in the same manner as face to face codes and they're paid with payment clarity the same amount, if you will. Thank you.

Rohit Malhotra: And that can be used in a training environment with residents and fellows?

Emily Yoder: I believe, this is Emily Yoder, that is correct. And I just want to echo what I said earlier, that we are definitely hearing about this issue and we're considering it.

Rohit Malhotra: OK. Thank you very much.

(Alina Czekai): Thank you for your question. Thank you.

Again, I'd like to thank everyone for joining our call this afternoon. I'm sure there are questions that might have gone unanswered. And I'd like to give you all the e-mail address, again to direct your questions to CMS, and we'll route them to the appropriate agencies or the appropriate CMS subject matter expert. And that e-mail address is COVID-19@cms.hhs.gov.

And as the administrator noted, we'll continue to have these forums on a weekly basis, in addition to the other stakeholder calls that we're hosting, where we primarily review CMS guidance and update of the like. And really appreciate everything that you all are doing day in and day out to care for patients and their families as we face these unprecedented times.

I hope you all have a restful and healthy weekend. Thank you.

Operator: This concludes today's conference call. You may now disconnect. Thank you for your participation.

End