Centers for Medicare & Medicaid Services
COVID-19 Lessons from the Front Lines
Moderator: Alina Czekai
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OPERATOR: This is Conference #: 9146779.

Alina Czekai: Thank you for joining our CMS Lessons from the Front Lines on COVID-19 Call today, May 8. We'd like to begin by thanking all of you for the work you are doing day in and day out to care for patients around the nation amidst COVID-19. This is Alina Czekai leading stakeholder engagement in the office of CMS Administrator Seema Verma. Today's call is part of our ongoing series, Lessons from the Front Lines.

And while members of the press are always welcome to attend these calls, we ask that they please refrain from asking questions. All press and media questions can be submitted using our media inquiries form which can be found online at cms.gov/newsroom. Any non-media COVID-19 related questions for CMS can be directed to COVID-19@cms.hhs.gov.

Here at CMS, we recognize the government's role during COVID-19 is to offer maximum flexibility and regulatory relief to allow you all to do what you do best: care for the patients in your local communities. Around the nation, providers and local communities are innovating in response to COVID-19. And at CMS, we hope to bring together local innovators to share best practices that can be scaled at the national level.

Today's call will focus on these expanded flexibilities and innovations and we will hear from providers who are seizing the opportunity to innovate and transform to support their local systems. We will hear from providers who are in the midst of reopening the healthcare system. We'll have a conversation on patient registries, successful best practices for reaching out to patients during these times, and we'll also hone in on best practices to support post-acute care and transitions to the home and nursing homes.

And we do encourage you to direct your questions to our guest speakers today. Should you have more technical questions on CMS waivers, guidance, or questions on billing and coding, we encourage you to join our CMS office hours which are held every Tuesday and Thursday at 5.00pm Eastern. And I'd first like to begin with a brief update from the agency.

As you are likely aware, CMS unveiled a second final rule last week and additional waivers that institute a further set of regulatory flexibilities under the authority of President Trump's emergency declaration as well as the CARES Act. And there are several components to the new policies which largely run along the same lines as our previous rule and that includes Hospitals Without Walls, maximizing the healthcare workforce, expanding tele-health, putting patients over paperwork, and testing.

And I'll provide some important detail on all five of those elements. First, in regards to testing, as you all know that has been a priority for a long time and over the last few months, CMS has worked hard to quickly implement recently enacted legislation that removed barriers to testing in Medicare, Medicaid and private insurance. In addition, this legislation provides $1 billion to cover testing for the uninsured which we are working to make available to providers.

And from day 1, we have worked to ensure that there was no cost barrier to being tested to coronavirus committing Medicare to covering tests with no cost sharing. And even before the CARES Act required it, CMS also was working with private insurance companies and state Medicaid agencies to cover testing with no cost sharing. In Medicaid, we implemented the Families First Medicaid Optional Eligibility Group and this allows states to cover uninsured citizens testing with no cost sharing.

Additionally, CMS will also separately pay outpatient departments and physician practices to collect lab samples. Medicare will also pay pharmacies that are enrolled as labs to perform tests for beneficiaries. This will encourage these entities to make tests available at parking lot sites and promote widespread access for Medicare beneficiaries. And we're doing something similar in the Medicaid program where we're giving state flexibility to cover

parking lot COVID-19 tests and tests in other community settings such as the home.

And when it comes to supporting our healthcare workforce, CMS is expanding the number of practitioners that can provide important health services to patients that may need to remain home. For example, home health patients can get care planning services from nurse practitioners and more in addition to physicians. And we are further reducing burden by using a variety of measures. One important action is we are waiving the requirement that ambulatory surgery centers periodically reappraise medical staff privileges for the duration of the emergency declaration.

And you may remember that we did something similar with hospitals in the previous rule. This simply aligns ambulatory surgery centers, many of which are now providing hospital services with what we did for hospitals. And we're also further increasing hospital capacity as part of our CMS Hospitals Without Walls initiative. We're helping providers increase their supply of beds to manage a surge due to COVID-19 while still maintaining stable, predictable Medicare payments. And this will allow institutions such as teaching hospitals and freestanding inpatient rehabilitation facilities to alleviate the strain on traditional hospitals while not forfeiting Medicare reimbursement.

And we'll also be paying for hospital outpatient services like wound care and drug administration and behavioral health services that are delivered in temporary expansion sites such as parking lots, tents, converted hotels, and so on. And finally, I'll close my remarks by highlighting even more expansions of Medicare tele-health. As you know, tele-health has been one of the administration's top priorities during the pandemic because it really is a win-win. It gets Americans the care they need and it reduces unnecessary exposure to the virus.

This rule waives all restrictions on which kinds of practitioners can furnish tele-health. Previously, only doctors, nurse practitioners, physician's assistants and certain others could deliver care through tele-health. Now, many others are eligible including physical therapists, occupational therapists,

and so on. We're allowing hospitals to bill for services furnished through tele-health technologies provided by clinical staff of the hospital when Medicare payments are registered as hospital outpatients including when the patient is at home.

In addition, this rule increases our payment for services conducted on the phone to match payments for similar office and outpatient visits. Finally, we are implementing provisions of the CARES Act. That increases tele-health for federally qualified health centers and rural health clinics often located in rural areas. So, in sum, CMS continues to assess what government regulations are doing more harm than good in the context of the pandemic. And we continue to offer as much flexibility where we can.

So, now, I'd like to turn to best practices and peer-to-peer learning. We'd like to hear from the physician leaders around the country about what they're doing in their local communities and strategies that are working for them as we address the pandemic. Our conversation today will start with a focus on patient registry and with that, I'd like to turn it over to my colleague, Dr. Michelle Schreiber. Michelle is the Director of the Quality Measurement and Value-Based Incentives Group at the Center for Clinical Standards and Quality at CMS.

She'll be offering an update on the agency's efforts to ensure data-based decision making as well the agency's quality improvement programs. Dr. Schreiber, over to you.

Michelle Schreiber: Thank you, Alina, so much. In addition to that title at CMS, I am also a long-time primary care physician from the city of Detroit and have witnessed firsthand what is going on with COVID. We all want to sincerely express our thanks to the providers on this call and to all providers across the country for their dedication and commitment to the highest quality care during this COVID pandemic. We recognize that we must have evidence-based data to make the best decisions in order to quickly learn more about COVID and to inform appropriate clinical and even policy decisions.

So, to this end, CMS is providing incentives to the physicians to engage in scientific activity and report COVID data through participation in clinical trials and using clinical COVID registries. Our presenters today will highlight some best lessons from the front lines about this. You may recall in the first interim final rule with comment, CMS established a new improvement activity in the MIPS program. Recall that MIPS) is comprised of four categories: quality, improvement activities, cost, and promoting interoperability.

In this new improvement activity, providers who (inaudible) to participation in a COVID clinical trial and report data have an opportunity to earn credit in the improvement activity. This is a highly weighted I.A. and it constitutes half of the category. So, providers need only complete one more high weight improvement activity or two moderate activities and they will complete their entire requirement for improvement activity performance in the MIPS) program.

The process is simple in that providers need only attest to this activity. They don't have to report their data to CMS. We know that you're reporting it in the registry or through the clinical trials. But in this way, we hope to engage more providers to contribute to the scientific body of knowledge and help all of us combat the COVID disease. I'd like to thank every speaker today who's going to share their insights in what they have been doing, and I will pass this, with pleasure, to Dr. Helen Burstin who is the Chief Executive Officer of the Council of Medical Specialty Societies.

And they've been doing a lot of work around COVID and COVID registries. Helen, to you.

Helen Burstin: Wonderful. Thank you so much. And thank you to Michelle and CMS for inviting me to join this important conversation. Also, special kudos to CMS for recognizing the importance of supporting engagement in clinical registries and clinical trials related to COVID-19 in CMS programs.

We are very hopeful that clinical registries can be an important part of our national strategy to provide timely data and information to both front line

clinicians and policymakers. It's pretty clear from watching the news and social media that the COVID-19 crisis has really exposed the limitations in our current research and dissemination enterprise. Without having timely evidence-based information about diagnosis and treatment of COVID-19, physicians and other clinicians are relying on social media and clinical anecdote to identify promising diagnostic and treatment strategies.

The current crisis and the likely second wave that will follow likely in the fall, present an important and urgent opportunity to think about how clinical registries can help support our nation's COVID response. We've already begun to see some remarkable examples of specialty societies in partnership with our academic partners stepping up to build COVID-19 information into existing registry platforms as you'll hear from the (inaudible) college of surgeons, and who are rapidly expanding up new registries to support COVID-19 diagnosis and treatment.

We've begun to see impressive collaborations across specialty registries as you'll hear shortly from the Society of Critical Care Medicine and the American College of Radiology and many more to come. We've seen registries focusing on surveillance of some of our patients who are at highest risk for COVID-19 including oncology, hematology and rheumatology who have all stood up new registries in that space – both in the U.S. and in fact the rheumatology registry, for example, is a global registry. Since the pandemic is global, so should our information, data and (inaudible) and review.

And finally, we're also beginning to see registries that are focusing on identifying new symptoms directly from front line clinicians. Many of you have probably seen the news discussions – so, for example, COVID (toes). The American Academy of Dermatology has stood up a new registry to handle – understand what are the dermatologic manifestations, for example, related to COVID?

So, we've recently been fortunate to receive funding from the Gordon and Betty Moore Foundation to launch a webinar series focused on COVID-19 and clinical registries. How do we rapidly develop, deploy registries to answer some of these key questions? Given that the importance of our

academic partners and so much of this work happening at teaching hospitals and academic health centers, we're just going to be launching this new webinar series with the (AAMC) to help address a series of key questions.

We launched this effort last Friday at our virtual CMSS meeting where we had many of the speakers you'll hear today and others talking about what they're beginning to work on. So, I'd love to share with you some of our thinking of what the key questions are as we look forward to get your insights on how we can do this in the best possible ways and minimize burden on already stressed front line clinicians and providers. We're going to need to get your insights and broad insights about what are the really most important clinical data elements that we need within electronic data sources to support COVID-19 treatment, prognosis and treatments.

How do we consider the reliability of some key data that are kind of difficult like COVID-19 diagnostic tests? How do we rapidly use electronic data sources and other innovative methods and standards – to integrate in electronic data sources using passive and automated data upload to decrease burden on you? How do we build capacity to have more integrated registries and multidisciplinary data sharing to get the fullest possible picture of what's happening in the pandemic and best responses?

How do we harmonize and standardize data collection across clinical registries including standardized tools and forms? Considering, obviously, issues around privacy and security are always going to be important, particularly when we're looking at patients who are – for who data are going to be really important to look across registries, how do we work with big data vendors like Google and others who are collecting data outside of our clinical data that could really supplement our understanding of the current pandemic and what may be to come?

And last, but definitely not least, how do we ensure we have the right data to be able to look at critical equity questions given early evidence of COVID-19 clinical disparities? So, just in wrapping up, as we think through these issues, we want to hear from you. We really are committed to thinking through how we can do this in the least burdensome way, but also provide the – rapidly

provide information from clinical registries around diagnosis, prognosis and treatment modalities.

And, you know, we'll be launching these registries. We'll share all this information as broadly as possible as we launch these registries and the webinars to begin answering these questions. And then, finally, echoing Michelle's comment, just a thank you from me personally to all the front-line clinicians and providers on the call. We realize this is just a remarkable time and your efforts deserve our gratitude and thanks.

So, with that, I'll close, Michelle. And thank you and look forward to the discussion.

Alina Czekai: Thank you, Dr. Burstin. Really appreciate your perspective. We'd now like to hear from Dr. Rebecca Laborde. Dr. Laborde is from Oracle and she'll be giving an overview of the Oracle Learning System. She is a health scientist and strategist. Dr. Laborde, over to you.

Rebecca Laborde: Thank you so much. And thank you to CMS for the time today to share some information about a newly developed system called the COVID-19 Therapeutic Learning System. This is a system that has been created through a partnership with the Department of Health and Human Services and donated by Oracle to support the U.S. government's efforts to collect real-time medical data related to COVID-19.

This system was designed to collect this real-time data to augment and supplement traditional clinical trial efforts that are occurring globally. And the system is available for use by all U.S. physicians through a very simple authenticated registration process that you can access by visiting COVID-19.oracle.com. The Therapeutic Learning System is an easy to use platform that's accessible through computer, tablet and cell phone access. It collects the minimal critical data necessary to understand the outcome of treatment plans in place to address COVID-19.

The system collects both inpatient status updates on patient symptoms and treatment which are added by physicians during the hospital stay, and also daily status updates related to symptoms from outpatients and those patients

that have been discharged from hospital care. So, this allows data to be collected for the duration of the disease course including the period of convalescence which is occurring in the patients' home. So, physicians and real patients can provide updates through a very simple to use interface that includes quick logins and easy to use drop down lists.

The TLS system was designed to provide as simple an experience as possible allowing physicians to log in once a day, access all patients in a single dashboard, and provide a quick process for updating status. Outpatients also experience a similar process for entering status which takes only a couple of minutes per day to complete. The vitally important data collected through this Therapeutic Learning System is used to provide real-time views of aggregated data that are made available to critical members of the U.S. government which are supporting agencies including HHS, FDA, (NIH), CDC, and CMS to inform on trends in success of therapies and patient outcomes across the country.

We are pleased to collaborate with CMS in their encouragement of physicians to participate in the Therapeutic Learning System effort earning credit in the MIPS system and contributing scientific and evidence-based data to fight COVID-19. So, again, we encourage all physicians to join the effort by registering today at COVID-19.oracle.com and helping to move this important work forward. So, I thank you for your time today and for all that you are doing to fight this pandemic on the front lines.

Alina Czekai: Thank you so much, Dr. Laborde. I'd now like to turn it over to Amy Sachs. She is senior manager of Program and Registry Operations at the American College of Surgeons, as well as Dr Frank Opelka, medical director at the American College of Surgeons for a perspective from the surgery community.

Amy and Dr. Opelka, over to you.

Amy Sachs: Great. Thank you so much for having us today. I'd also like to let the audience know that Dr. Clifford Ko, director of the ASC's Division of Research and Optimal Patient Care is also on the phone today.

So, the American College of Surgeons has seven registries and various quality domains, and we are present in about 3,000 hospitals over the world. So, these include the National Surgical Quality Improvement Program, or N S Q I P, or NSQIP, both adult and pediatric version, the Metabolic and Bariatric Surgery Registry, a national cancer database, the Trauma Quality Improvement Program Registry, and the Surgeon Specific Registry.

Our newest registry, which just launched a few weeks ago, is our COVID 19 Registry. The ACS COVID 19 Registry was launched in mid April, and already has approximately 55 who are inputting hundreds of cases a day on COVID 19 patients. This covers all COVID patients, both operative and non operative.

The registry is free, it is hospital based, and any hospital can join, whether they are in the U.S. or international. The registry is also (IRD) exempt as a quality improvement initiative. The variables tracked in the registry cover patient demographics, presenting symptoms, comorbidities, treatments and outcomes for patients from admissions through discharge.

The variables present in the registry were created in conjunction with medical experts at COVID impacted hospitals, especially those in New York City. We are able to gather information from these hospitals and the others participating in the program to see what modifications and additions to the registry need to be made over time in order to account for the newest evidence and research and in treatment options.

When looking at surgery and COVID 19, it's very clear that more data are needed, especially as elective surgery is resuming in the United States. We know that published literature from outside the U.S. show higher complications and mortality rates for patients with COVID 19. Worse outcomes are also being reported in the U.S. in emergent, urgent and recently in elective operations. Our hope is that with this COVID 19 Registry, we will be able to get that additional data to better analyze patients and lead to better outcomes and treatments.

At the same time when we launched this new COVID 19 Registry, the ACS Registry has also added COVID 19 variables to many of its registries, specifically NSQIP, NSQIP Pediatric, Trauma and Bariatric to provide data and support guidelines, recommendations and considerations for surgery and surgical patients.

Taking a look at one of these registries, the ACS' NSQIP, this was established in 20 – in 2004, and is a multi specialty registry that looks at surgery across general, orthopedic, neurosurgery, urology, ENT, thoracic, vascular and other specialty areas. NSQIP covers both inpatient and ambulatory procedures, and provides risk adjusted 30 day outcomes on complications and mortality to all participating sites.

NSQIP is present in 49 states in the U.S. and over 13 countries, and thus far, over 2,000 publications have been released using NSQIP data. NSQIP added a pre op and a post op COVID 19 variable for all cases starting in 2020. Our hope is that we will be able to obtain the experience of COVID 19 patients undergoing surgery in different hospital settings, look at their patient reported outcomes, demographics, comorbidities, and then reliably risk adjust this data to provide benchmarking and quality improvement data for all of our sites, including our regional collaborative.

If you'd like more information on the ACS COVID 19 Registry, or any of our quality program registries, please visit our website at facs.org. Thank you very much for your time today.

Alina Czekai: Thank you so much, Amy.

Now, we're like to turn it over to perspectives from the critical care community. Joining us today is Dr. Vishakha Kumar from the Society of Critical Care Medicine, Dr. Allan Walkey from Boston University, and Dr. Rahul Kashyap from Mayo Clinic.

Vishakha Kumar: Great. Hello everyone, I'm Dr. Vishakha Kumar, and I'm the acting director for research at the Society of Critical Care Medicine. On behalf of the society and the Discovery Research Network, along with the virus investigators, we

would really like to thank the organizers and the moderators for this opportunity to discuss this global virus COVID 19 Registry work.

The virus registry really rooted from the urgent need for reliable data to inform clinical decision making. I'll just get a very high level overview, and I'll let Dr. Walkey and Dr. Kashyap speak to the details. So this really has been a true collaborative effort during these difficult and urgent times. And the collaboration came right after the WHO announced COVID 19 as a pandemic on March 11.

This was followed by Dr. Kashyap and (Dr. Giak) at the Mayo Clinic reaching out to SCCM discussing that this was the right fit within the Discovery's existing critical care data registry work. And within a day we saw Dr. Walkey put a tweet out on social media asking if anyone was doing a COVID 19 registry. And then the collaborations just kept moving forward. And now, here we are after eight weeks.

So, I'll now hand it over to Dr. Walkey and Dr. Kashyap to go into the details of this global registry. So, Dr. Walkey, do you want to take it over now?

Allan Walkey: Sure. Thank you so much again for inviting us. I'm Allan Walkey, I'm a pulmonary and critical care doctor from Boston University and Boston Medical Center, and it's really heartening to hear all the innovative approaches that have been presented so far today.

I'm going to talk a little bit about the goals for our registry, so my experience attending in the COVID intensive care unit at Boston Medical Center during these past few weeks. A peak surge can confirm that intensive care units face much of the burdens of care for patients with COVID, as many of them, unfortunately, become critically ill. And that there's also confusion as to best practices regarding management of patients with COVID 19, and I think we've heard that theme already today.

So, the overarching goal for our registry is that we can start to inform these knowledge gaps and guide best practices for the hospital based and ICU care of patients with COVID 19. So, I just want to outline a few of the short medium and long term goals to inform these practices.

In the short term, we'd like to have as much high quality, accurate and complete data from as many diverse hospital sites entered into the registry as possibly, and Dr. Kashyap will in a few moments detail what we've been able to accomplish in the short eight weeks since we were first conceived.

In the medium time – medium term, we'd like to have the data that we've been collecting provide up to date information and research, and we'd like this information research to be used in about three different ways. First, we have this week released a data dashboard that uses the data entered into the registry to inform the current epidemiology and ICU resource utilization of COVID – in patients with COVID 19 that are part of the registry, and also informs potential researchers and investigators what types of data we have in the registry to help them plan research.

So, that informs our second goal, which is to have data available for people to apply and use for their important and novel research questions that are going to inform best practices. Additionally, we're working to develop platforms and validate platforms for rapid data collection via automated EMR electronic health record upload, and near real time analysis and results and methods to allow near real time data analysis and results dissemination.

So, in the long term, we'd like to establish an infrastructure that allows us to rapidly respond to future pandemics and public health emergencies that require such nimble responses. We would like the now established large network of health care centers, that's an international network, to use the infrastructure that we rapidly developed and will continue to develop over the next month, few months, to respond to new crises, and we envision that this network will hopefully be able to be expanded to rapidly roll out things, such as pragmatic randomized control trials, as well as the observational studies that we're currently conducting.

So, I'd now like to pass this over to Dr. Rahul Kashyap from Mayo Clinic to discuss some of the details and the current status of our registry.

Rahul Kashyap: Thank you, Allan. Thank you so much to Dr. Kumar, and you as well, as well as (inaudible), so we are delighted to be here.

To start off with, I just want to underline that the capabilities and availability of having a rapid (inaudible) really broad application with the (inaudible) category having rapid data user regimens, as well as availability of institutional REDCap resources. That was a huge bonus for us to start something like this eight weeks ago.

To give you overview as of today, we have 120 plus sites from eight countries contributing data, and all – more than 2,400 patients, hospitalized patients with COVID 19 positive diagnosis. And another 350 plus (inaudible) the first stage. As Dr. Walkey mentioned, the dashboard is up and running. We are hoping to provide weekly updates. You can visit them on – at sccmcovid19.org.

It works really well on your smart phones, and please be look out for updates every Friday from next week onwards. One thing we'd like to really emphasize that through the first – especially to (inaudible) foundation, others across society collaboration has taken off as well. We are finalizing many of these things, especially the American College of Radiology is going – Dr. Pisano is going to be talking afterwards.

We had a – made a really huge progress with them, and most likely we should start our collaborative efforts early next week. And we already made first contact with American Heart Association, and Infectious Disease Society of America as well.

Lastly, we cannot thank enough our hospitals, and centers, and the volunteer providers, investigators and research colleague – the research fellows who have stepped up during these tiring times. On top of, they were already doing it for clinical care. They've taken on this additional work and then helping out to provide the data and inform the clinical practice (inaudible). And thanks to patients who have allowed to have this access to data, so we can never forget that this work will never be possible without those efforts.

Special thanks to (inaudible) Foundation. I'm not only seeing value in this work with us and a few others on this call today as well supporting the

registry work, and especially providing these network opportunities which are valuable – are being proven valuable during these times.

To end with, I would like to say that those who are listening in today, we would like to invite investigators and hospitals to take part, join registries and share this (inaudible) data, not only for greater good, we will have access to data, all data dashboards, they can see (inaudible) ideas, but really will do – answer many questions as we pullthis data and try to see if we can find some solutions.

That's all from us from Critical Care COVID 19 Registry. We'll be happy to take questions in the end.

Alina Czekai: Great, thank you all.

And for our final speaker in this segment, we'll be hearing from the radiology community. Joining us today is Dr. Etta Pisano. Dr. Pisano is a professor of radiology at Harvard Medical School in residence at Beth Israel Deaconess Medical Center, and she is the chief research officer at the American College of Radiology. Dr. Pisano, over to you.

Etta Pisano: Thank you so much. Thank you for inviting me today, and thanks to all the clinicians on the front lines.

The ACR's COVID 19 Registry is a multidisciplinary effort involving both electronic health record and imaging data. Current partners include multiple radiological societies and, as you just heard, the Society of Clinical Care Medicine, and a group of pulmonary intensivists with a grant from the NHLBI called (Pedal), as well as the CTSA's NCATS Consortium.

We expect to upload data from the 18,000 sites that are currently connected to the American College of Radiology from multiple other registry efforts via a piece of software called TRIAD. This allows the upload of anonymized image data that is – and I think – an important point to emphasize with so many sites, is that it allows us to represent the rural community, as well as non academic health systems pretty completely.

And, of course, will allow us to monitor the pandemic as it spreads from predominantly now urban areas. In addition, I believe, with such a broad representation, it will allow us to make good assessments of the impact on the minority community. In addition, there are multiple purposes for our registry.

Besides the obvious public health surveillance purpose and quality and safety purpose for the Medicare payment, as was described at the beginning of the call, there is also a huge desire for us to learn new knowledge about the disease, which we believe with such a large registry we will be able to do. In addition, we have imaging aims, per se. So, there's a huge interest in developing AI machine learning algorithms and, of course, validating them.

And you need a very large dataset to do so. Of note about our registry, besides the image upload, we also have very facile and user friendly methods to upload data from the HR through automatic feeds which do not require this – the – a human being to enter them. We have HL7 feeds and other automatic feeds.

But if sites wish to upload data by typing and hand, we also allow that. Eventually, we expect to convert our – all of our registries. We have over 40 at the American College of Radiology for all different purposes. We expect to convert them to a more federated model, where data is not uploaded to the cloud, but is kept behind the firewall at institutions and on premises.

We believe this is the future of registries and we're moving rapidly to that. So we're replacing TRIAD with a tool called ACR Connect. So, I'd be happy to answer questions when the time comes and welcome others to participate with us if it interests.

Alina Czekai: Terrific, thank you so much. And before we open it up to questions and best practices from our call attendees, I'd like to offer my CMS physician colleagues the opportunity to share any perspectives, or comments, questions for our speakers today.

Michelle Schreiber: So thanks, Alina, this is Michelle again. We are so excited about the rapid, yet extensive scientific collaboration in innovation, and we encourage

all providers to contribute to the scientific evidence of COVID 19. We all want to be making the best decisions for our patients and the public.

I'd also like to remind everybody that there's a great deal of body of clinical trials that are ongoing, and I would refer you to the NIH website that has extensive information on ongoing clinical trials at nih.gov/coronavirus. I would like to ask the presenters today, how many people are you starting to see get engaged, and is this catching on across the country that providers are participating in these registries? Thank you.

Helen Burstin: Hi, this is Helen Burstin, I'm happy to start. Certainly, at our session we had last week, each of the registries, that presented about five of them, presented the data, and it is remarkable to see the level of engagement they're seeing both nationally and internationally. And also, the speed with which these are standing up. I mean, within five days some of these registries are up and running and having hundreds and thousands of patients included.

I think one of the key issues for us all is going to be to make sure that we can do it in a way that is not very burdensome on, you know, already very overworked front line staff, and that's a key aspect of all of our work going forward, is how do we do this in the least burdensome way, but get the right data that we need now.

Rebecca Laborde: And this is Rebecca from (Oracle), and I would echo that same response, and that, you know, over the last week or so, in particular, we're seeing across the country, you know, a really large increase in the number of inquiries and, you know, interest in participating in these types of efforts. It seems that, you know, as this situation evolves outside of just main cities and into rural – you know, more rural areas, we're also seeing smaller hospitals, you know, wanting to participate and looking for options to do so.

Clifford Ko: Good afternoon, this is Clifford Ko. I think that in support of everything that's been said, that as – especially now, as places are, kind of, post peak and resuming their – trying to get to normalcy, figuring out where they are, how they're doing with their COVID patients and with their non COVID patients in the context of a COVID setting.

So, getting more and more data about themselves has been a big ask that we've heard at the American College of Surgeons. And so, for all of these registries, the ability to contribute data to the greater good of science and expertise and experience is one reason, but also another reason that we're hearing from hospitals is for them to know how exactly they're doing, because it might not be so easy if they're taking care of patients every single day to, kind of, take a snapshot of how they're doing day to day to day to day, and to the extent that these registries help hospitals know how they're doing day to day to day, with their own dashboards and so forth, has been very helpful, and we see that increasingly, more hospitals are gaining their own local expertise with the use of the registries in that way.

Rahul Kashyap: This is Rahul Kashyap, from VIRUS COVID-19. I echo the proposed sentiment. As we see the decline, or at least continuing amplifying the issues after hospitalization or post-ICU – defined as post-ICU syndrome, is going to be very important, actually spreading it and carrying it for months and years, so we might have some of this around that time in the next couple of weeks.

We are looking to see if we can gather that data, at least from (inaudible) facilities and so and so forth, but that will be hugely important, as living with a post – what happens to daily activities, of daily living and so on and so forth, after a hospitalization discharge.

Alina Czekai: Thank you. Any other questions or comments from my CMS colleagues before we open up the line? Great, Whitney let's take some questions from the phone.

Operator: If you would like to ask a question, please press "star," then the number "1" on your telephone keypad. We'll pause for just a moment to compile the Q&A roster. Your first question is from the line of (Sheila Rodriguez).

(Sheila Rodriguez): Hello.

Alina Czekai: Hi, Sheila, what is your question?

(Sheila Rodriguez): My question is regarding the telehealth list that Medicare updated last week. For audio only, is modifier 95 still required?

Alina Czekai: Sheila, I don't believe we have our subject matter experts on this phone today to address that question, but I will encourage you to either send an email into our COVID-19 email box, which is covid-19@CMS.hhs.gov, or feel free to join our office hours, which are every Tuesday and Thursday at 5pm Eastern, and on those calls, we have all of our CMS subject matter experts and technical experts on the line to answer those types of questions. So thank you for your question, and we will take our next question, please.

Operator: Your next question is from the line of Robert Phillips. Robert, your line is now open.

Robert Phillips: Thank you, this is Dr. Bob Phillips with the American Board of Family Medicine, and I direct the PRIME Registry. It's a national primary care clinical registry, QTDR, certified by CMS, that has about 12 million visits every year and is disproportionately rural. Clinics in 47 states and patients in 50.

And we have an invited proposal into CDC now with the American College of Emergency Physicians and the (CEDA) registry, which has about 28 million visits a year, a lot of them from smaller hospitals across the landscape, with the goal of contributing data about COVID and influenza-like illness that show up in the outpatient setting, with the goal of also looking at how the care of those patients transitions into hospital care, or doesn't.

Because it's EHR derived data, we also have race and ethnicity for 83 percent of the patients, and socioeconomic data for 92 percent, and hoping that that can contribute to understanding the increase in morbidity and mortality for certain populations. We just published a paper about the PRIME Registry and its capacity to look at influenza-like illness. Hoping to do that on a weekly basis for the next 12 months, and would welcome any opportunity to talk with the folks who presented so well today, to understand how we might collaborate. Thank you.

Female: Thank you so much for sharing that with us.

Operator: At this time, there are no further questions.

Alina Czekai: Great, thank you. Thank you to all of our speakers for sharing their expert perspectives and the research and work that they're doing in regards to patient registries, as we address COVID-19. Now, we'll pivot our conversation. We know that patient outreach and communication during this time is really critical, and there's a tremendous opportunity to not only leverage data from registries, utilize technology and discover other creative and evidence-based ways to conduct productive patient outreach.

And joining us today to share best practices on this topic is Mark Mantei. Mark is the Chief Executive Officer at Vancouver Clinic. Mark, over to you.

Mark Mantei: Thank you for having me today. Just a quick background on Vancouver Clinic. We're a 350 clinician organization that's a multi-specialty group practice, so we concentrate on ambulatory care. We are located in Southwest Washington, right across the river from Portland, Oregon, and we serve about 200,000 patients in Southwest Washington. We also are heavily involved in the Medicare Advantage Program, and take care of about 14,000 patients through a risk contract with various payers.

In mid-March, as COVID emerged in our area, visits dropped about 70 percent. We immediately instituted video visit capabilities for both our COVID and non-COVID patients, and today, these visits comprise about 20 percent of our total visit volume. As of this week, we've been able to restore overall physician visits to the clinic to about 60 percent of our previous level.

We became very concerned about our non-COVID patients delaying necessary care, so we began a series of outreach, besides the video visit capability, and in caring for our Medicare Advantage population, we have always used registries for tracking preventive medicine and chronic care management. We, in all our primary care areas, assign a personnel. It's usually – I call them a super MA, medical assistant, and what they do is, for the clinicians in that area, track the patients through our Epic Healthy Planet registry, and make sure that they're getting their necessary care.

Post-COVID, or during this time, it's been really challenging to do that with patients, but more than ever, this kind of outreach has proven to be very

important. I can report that the outreach to patients in terms of making sure that we get them on a screening schedule and manage their diabetes or congestive heart failure, et cetera, has been going very well.

We also offer our patients the annual comprehensive visit, and most patients prefer not to do that by video, we are discovering, although it could be done that way, and we try to encourage that, so we're waiting. A lot of those are getting postponed until social distancing and other things become a little more feasible.

So that's kind of our progress report at this point, and I look forward to any questions that people might have.

Alina Czekai: Thank you so much, Mark. Any questions or comments from our CMS physician leaders?

Michelle Schreiber: Hi, Alina, it's Michelle again. Thank you for your presentation. I'm curious, what are your patients saying as you open up? Are they feeling comfortable coming back in? What do you think it's going to take for patients to feel comfortable?

Mark Mantei: That's a great question. I would say, yes, they are feeling – the majority are feeling quite appreciative and comfortable. We have pretty – our facilities, we control the access very carefully. We're asking them not to bring a visitor. Everyone is masked as they enter, and then, we segregate our waiting rooms. And our COVID has really flattened out somewhat in this area, which we are very thankful for, so we have two dedicated areas throughout our clinic for that patient population, and we make that known.

We've done some blast email work to educate folks about the safety precautions that we're taking, and it's from our Chief Medical Officer, and I think that's been very effective, so we're getting a good response from people that need to be seen in the clinic, and they're feeling pretty safe about doing that. Other folks, where we can do a video visit, we are encouraging that.

Alina Czekai: Thank you. Any other questions or comments from my CMS colleagues before we open up the line?

Michael Lipp: Sure, this is Michael Lipp. First, I want to applaud you for that approach, and patient-centric proactive approach identifying both the COVID and non-COVID patients, so very much appreciated. I'm curious, you mentioned the outreach to patients and the communication strategy. I was wondering if you have any additional advice around the types of messages that patients and providers – that seem to resonate to allow those patients to be seen where they otherwise may have been hesitant.

Mark Mantei: Yes, I would say that nothing substitutes – nothing is better than a call from your own physician, so as we experience this 70 percent decline, we were able to keep our physicians relatively whole in terms of compensation, and encouraged them to reach out to their panel of patients and reassure them that they would be taken care of, and we would be back to them about rescheduling their appointments, and I think that that was the most effective. There's been other methods, in terms of, like, as I said, a blast email, et cetera, but there's no substitute for that personal outreach.

Michael Lipp: That's great, thank you.

Alina Czekai: Thank you. Whitney, let's open up the line for questions from the phone. Thank you.

Operator: Again, to ask a question, please press "star," then the number "1" on your telephone keypad. We'll pause for just a moment to compile the Q&A roster. At this time, there are no questions.

Alina Czekai: Terrific, thank you. Thanks again, Mark, for sharing everything that you're doing at Vancouver Clinic. Our final topic for today is taking a look at post-acute care for patients, specifically facilitating successful transitions of care during COVID-19. Our speakers today will offer perspectives from both the clinical and operational side, of best practices and strategies.

Our first speaker is Dr. Dave Thimons. Dr. Thimons is President and CEO of Personal Care Medical Associates, and he's also the Medical Director at Concordia at Villa St. Joseph and Brighton Rehabilitation and Wellness from the Greater Pittsburgh area. Dr. Thimons, over to you.

Dave Thimons: Thanks so much. I appreciate all of you at CMS for making the changes such as telemedicine, amongst other things, that are allowing us to better care for patients and facilities, and for the geriatric population in a safer manner. I was just going to walk through and share a few of the things that we're seeing and doing in our clinical practice.

We are specifically a geriatric and palliative post-acute practice that takes care of patients in 40 or 50 facilities, as well as in hospitals and some home-based care, just to give a little background. We've seen about 300 patients in nursing homes with COVID, and are taking care of a couple of homes with pretty large outbreaks.

And a couple of things that I wanted to talk about that I think are really meaningful are, number one, palliative medicine. When this happened, we devoted a full palliative medicine team into these homes, with the goal of seeing all patients diagnosed with COVID-19 to have meaningful advanced care planning conversations, to enhance communication with patients and families, and I think this has been meaningful in a variety of ways.

Most importantly, we are respecting patients' goals and values. We've been able to minimize a lot of unnecessary transfers to the hospital. We've been able to review med list and limit a lot of medication, which is really important, because staffing the nursing homes with a COVID outbreak is a real problem, and so, eliminating unnecessary medications and testing is really important in this setting.

So I think that the role for palliative medicine going forward in the COVID outbreak, especially as we look into the future to plan for the fall, as I think that, as a country, we are getting a hold of this, but I worry that the nursing homes are going to see spikes and suffer from this illness for quite some time. I think there needs to be an expanded role for palliative medicine in nursing homes.

I think that telemedicine has been critical. Our program has both clinicians in the homes, as well as telemedicine, and so I'm really appreciate and thankful for you all for allowing us to do that. A couple of thoughts I have are that one

of the barriers to telemedicine in nursing homes is, it takes a support staff from the nursing home to be on the other end of the phone and to provide telemedicine, and I would encourage CMS to consider some type of support to the nursing facilities to help enhance that.

From a practitioner standpoint, again, we're able to do it. We're able to do that. We're able to build the codes to allow it to be sustainable, but the nursing homes may need more support as telemedicine – the need for it increases in homes.

I also think that going forward, as we look at transitions of care and we look at a lot of patients, A, either wanting to leave homes when there's a COVID outbreak in the home, or B, the push to take care of patients in the home in the future. I think that telemedicine and palliative medicine will have a critical role in that area.

The next quick thing I wanted to talk about is, prior to the FDA coming out and issuing guidance on hydroxychloroquine use, to be only used in hospitals or in a clinical trial, you know, our outbreak in one of our largest 500 bed facilities occurred months ago, and after reviewing the literature and looking at studies that were being started by the NIH and the University of Minnesota, we did some post-exposure prophylactic treatment with hydroxychloroquine.

We're tracking our results, and these results will be ready to share in the next week or two, and it looks very good at this point in time in terms of minimizing patients' chances of contracting COVID-19, as well as decreasing mortality, so I look forward to finalizing some of our results and sharing this.

The last thing I wanted to really talk about is, another one of the things that we're doing is, an outpatient COVID-19 telemedicine and testing center for the community, because when we're discharging a lot of patients home from nursing homes, what immediately happens is, the families of these patients are calling, and they're concerned, and they don't know if they should be tested, and they're asking about antibody tests and what does that mean, and the RNA tests and what does that mean, so we've opened up a telemedicine program with rapid drive-through testing in our region.

I think there's a lot of confusion around this, and I think, as a country and as a leadership team, we probably need to do better and offer more guidance, in terms of, what do the results of an RNA test mean, what do the results of antibody tests mean? If someone comes home and they've been exposed to COVID in a nursing home, what does that mean in terms of me going to work?

And, so, I just think that it's great that we have a lot of testing out there, and I know that CMS has guidelines on what to do if you've been exposed, and so on and so forth, but I think clarifying what the test means for the public is really important going forward.

I think that, as we open up our country, what I'm hearing as we're doing this is tons of questions about businesses reopening, and work, and who has had exposure and who should get tested, and what does the testing mean, so, in closing, I really appreciate the opportunity to be here. I'm incredibly appreciative of all that you all are doing to make our lives easier on the frontline, and most importantly, to allow us to give our geriatric patients the care that they deserve.

I think palliative medicine and telemedicine is critical. I think throwing all the resources we can at the nursing home population is so important going forward, and once again, I'm very thankful to be part of this.

Alina Czekai: Thank you so much, Dr. Thimons. And our final speaker in this segment is Brent Korte. Mr. Korte is the Chief Home Care Officer at EvergreenHealth Home Care in Kirkland, Washington. Mr. Korte, over to you.

Brent Korte: Hi, everybody, from the sunny Seattle area. We don't get a lot of sun out here, so we are certainly enjoying an ability to get outside a little bit after being shut in. Great comments from Dr. Thimons. I'm coming from the perspective of home care. A quick recap on who EvergreenHealth is. I was able to join a call about a month ago. EvergreenHealth is a smaller system in western Washington State, and we experienced either the first, or one of the first deaths, from COVID in the United States, which really set forth a sequence of events in our area that caused us to surge very early, and really forced us to

understand what was happening. Really, on February 29, I think, was really day one.

We have had 52 home health patients out of a census of about 1,400, and maybe just right under 50 patients on the hospice sites, 37 deaths, so 7 percent of our entire hospice census has, in the last just over two months, have died from COVID. So that's a significant percentage of our hospice. So today I just wanted to briefly talk about home health and hospice's unique role, and throw out some considerations for everyone when it comes to access to care.

Home health and hospice and the homecare industry really are straddling the provision of health care and promotion of public health, given that we're in the community and we all know that healing happens in the community. Pandemics may be worldwide but health care is very local. We provide over a quarter million visits a year in the community, and that number has decreased significantly, and we do have some related to access to care because of that. And we're finding the trick, the very, very difficult question is, finding that fine line between the promotion of public health and decrease of transmission, and keeping people safely at home.

More specifically, what does it – what does it look like for us to continue to go into folks' homes, which may represent an infection vector, while knowing that if we don't go into folks' – into our patients' homes, then they're going to continue to decondition, and then therefore go into the hospital and possibly get an infection in the hospital, et cetera. So a very difficult question, and it's not endemic just to home health hospice and home care, but we're all having to deal that – deal with that nationally.

Our patients go into hospitals, obviously for important treatment, but generally I would imagine most folks on the call would agree that we want our patients at home recovering, and that's really the role of home health and of hospice. And for us, the persistent question from an industry perspective, from me leading EvergreenHealth, is really, what's the right cadence of visits to keep people from needing to go in the hospital but not be a vector of transmission like I mentioned – like I mentioned early – earlier. So home care

and hospice providers are really poised right now and ready to be able to provide more care.

We've seen visit decreases nationally, which really translate to more availability for us to be able to admit new patients. Now, those of you who are on the call from New York, Connecticut, New Jersey, are places that have been hit extremely hard. Our hearts certainly go out to you, and we're rooting – we're all rooting for you nationally. I know that a lot of providers have had trouble securing PPE, and hopefully people are getting caught up, so I just wanted to translate that we have an increased ability to be able to help folks and provide care in the home.

I want to also mention that skilled nursing facilities, assisted living facilities, and any congregate living centers, that we're noticing a significant trend of not having admittance and not being allowed to be able to provide care, and rationally, we understand why there would be more than just hesitation to allow clinicians to come in, or some interpretation of what may be deemed as essential or non-essential.

But unfortunately, we're seeing a significant negative impact on patients by virtue of not being admitted, and we're seeing I would – what I would say at its most extreme, a prohibition of admittance to assisted living facilities in particular, where assisted living facility administrators certainly want to be able to protect their other patients, and we have empathy and understanding for that. In the same right, patients are deconditioning, and this is their home.

We have – we have readmission and just general assessment data that strongly suggests that overall patient outcomes are worsening by virtue of not having access to home-based care. And while limiting person to person contact, we have to continue to make sure there is access to folks' homes. A peripheral impact of COVID is really occurring not only in COVID-positive patients but in patients who need – who needed care prior to the outbreak and continue to have needs during the pandemic. So if I can sum that up with a couple of statements, just that home care from an industry perspective is certainly already out there and helping in a big way, but we as an industry, hospice in particular, home health in particular, are ready to – and structurally ready to

be able to provide more visits, because we have had some limitations on visits.

The second one is, for all physicians, all the great physicians on this call, I strongly recommend and hope that you can consider clearly communicating expectations through discharge-planning mechanisms and referral mechanisms to any congregate living facilities that you encourage access to care, and that folks – the skilled professionals that provide home health and hospice and home care are allowed to provide that care in person. And again, the risk being that if they aren't able to receive care, then they would perhaps go into hospital.

I'll provide two quick examples. One, we had a spiritual care – one of our chaplains, our excellent spiritual care rabbis, that wasn't allowed to enter a – an assisted living, and it was right after the start of things. We empathize and understand the fear. She actually grabbed a folding chair from her car, went to the edge of the – of the structure, the house, and had the patient prop a window up. It was their dying wish to be visited by clergy, by – excuse me – by a rabbi, and she sang a song through the window, and the patient ended up passing away during the visit. So it sort of speaks to the extremes that people are going.

The other one is probably perhaps a bit less uplifting in my comment, is that we had had not been able to visit a patient for a period of four weeks, after trying with multiple disciplines, and the patient was a hospice patient, and had no wounds, and by the time we actually were able to get in, the patient had a stage 4 tunneling decubitus ulcer. And so it just – it just speaks to the idea that we need to ensure that we have access. And otherwise just a big thank you to all the – all the frontline folks out there, and thanks for the opportunity to talk today.

Alina Czekai: Thank you so much, you both, for sharing your perspectives. It's always interesting to have speakers from opposite sides of the country, but to draw themes on just the creativity and ingenuity that we're seeing throughout the healthcare system. Any questions or comments for my team of colleagues before we open it up to the phone?

Paul McGann: Hi, Alina. This is Paul McGann, and good afternoon, everyone, thank you for joining us. I'm the chief medical officer for quality improvement at CMS, and I'm a geriatrician, so I just wanted to say that I particularly enjoyed this segment, and the geriatric long-term care and home care perspectives. I think both the presenters really had deeply thoughtful comments about their firsthand experience at the frontline. So I want to thank them for that, and thank the entire geriatric medicine community.

I did want to zero in on one particular slot from Dr. Thimons, Alina, and also ask if you could put me in touch with him. He had four very well thought-out suggestions, and I took notes on them. The first one, though, really intrigues me in my role in quality improvement and Medicare, because it's something that I've observed in other situations, and I think it really applies here. He was talking about the implementation of telemedicine within the skilled nursing facility environment.

And he noted, correctly in my opinion, that there are lot of, sort of, technical and structural barriers within nursing facilities to make telemedicine really work smoothly, and that in order to facilitate that, which is in everyone's interests, including the patients' and the staff, it would be really good to have what he called support staff that are trained and dedicated to this. And I've always thought of this as the infrastructure for quality improvement, and I think this is a really excellent example where having adequate infrastructure to do that would be good.

So I want Dr. Thimons and everybody else to know that we're going to be taking that back to the quality improvement group and seeing if we can work something out from that suggestion. Thank Dr. Thimons for his terrific job and thoughtful presentation. And, Alina, I don't know if it's possible for you to put me in touch with Dr. Thimons, but I'd like to get more information from him as well. Thank you.

Alina Czekai: Absolutely. Thank you, Dr. McGann. I'd be happy to put you in touch with him over email. Dr. Thimons also happens to be a former colleague of mine,

so glad to be reconnecting in this forum. Any other questions from my CMS colleagues before we go to the phone?

Shari Ling: Hi, this is Shari Lang, acting chief medical officer here at CMS, and I really don't have a question but just want to add my personal thanks to all of the speakers for being with us today. Clearly, you know, you are all from – each of your perspectives focused on providing the best possible care, despite the circumstances, to each and every one of your patients who's our beneficiaries, whether or not they have COVID-19. So really, really want to express my thanks. And what I hear is that, you know, despite and against all odds, we need to really make it possible for care to proceed in a way that's consistent with each and every beneficiaries' goals of care. So thank you, thank you, thank you. Back to you, Alina.

Alina Czekai: Thanks so much, Dr. Ling. Whitney, let's open up the phone for questions from the audience. Thank you.

Operator: To ask a question, please press "star" and the number "1" on your telephone keypad. We'll pause for just a moment to compile the Q&A roster. At this time there are no questions.

Alina Czekai: Great, thank you. Well, that concludes today's program. I'd just like to thank all of our guest speakers today. I think we all can agree that we learned a bunch on this call. It's always really invigorating to hear just what's happening outside of Washington, and to bring together providers from around the country to learn from each other and to share best practices and tips.

Again, just want to thank you all for joining our call today. And in the meantime, you can continue to direct any questions or comments to our COVID-19 email box, which is covid-19@cms.hhs.gov. As always, we look forward to continuing our partnership, and appreciate all that you're doing for patients and their families around the country as we address COVID-19 as a nation. Have a nice rest of your day. This concludes today's call.

End