Jean Moody-Williams: Good afternoon, and thank you for joining today. We are going to go ahead and get started, because we have a really full agenda. I am Jean moody-Williams, and I am the Deputy Director of the Center for Clinical Standards & Quality at CMS. I’m joined by a number of colleagues from the CDC, and many of our team from CMS, who I will introduce shortly. Before we get started, I would like to share a few housekeeping items with you. The webinar is being recorded. It will be posted, as well as a transcript, so you will be able to go back and look through or share with your colleagues. All participants right now are muted, and you will be muted throughout the call, however, I can see that the chat is already alive and well, and we have folks from Connecticut and Texas, everybody greeting each other. Please keep questions to the Q&A box. If you have joined this call before, you know we will answer many of them as we go along and also some at the end, but they are very important, because they help us to form what we still need to communicate down the road. There is close captioning available via the link, and you can see that at the bottom of your screen. If we have members on the call today, you are always welcome. Questions from the media should go to the CMS media inquiries form, and which can be found at CMS.gov/media-inquiry, and you are probably pretty familiar with that.

So, we met not too long ago, but since our last call, we have published staff turnover rate for the first time ever, and weekend staff for nursing homes. That can be found on the medicare.gov website. We know that staffing and nursing homes have a substantial impact on the quality of care and the outcome that the residents experience. So, we hope that having this information helps consumers. Generally, our consumers on this call understand about each nursing home facility's staffing home environment. We never suggest using this one tool, but this will really help consumers. It is another tool to help consumers know what kind of questions to even ask when they are deciding on a nursing home. As a result, the united states supreme court stated preliminary injunction that had prohibited the enforcement of the CMS health care staff presentation rule that was in 24 states and the U.S. District court for the northern district of Texas that granted a motion, and it dismissed a related case in Texas. So as a result, the omnibus health care staff vaccination role is now in effect nationwide, so this will enable us to add another layer of continued protection for the residents that we all have a goal of keeping safe. So on today's call, we are going to provide a number of updates from both CMS and CDC on the covid-19 vaccine and talk about the importance of stress. We do want to bring some clarity where we can, and then we are going to have to have a special treat from the frontlines, from one of our nursing home administrators, and I will talk more about that, as well as a demonstration from our test kits that will be sent from the nursing home facility in the immediate future. With that, we are going to start with Dr. Kara Jacobs Slifka from the CDC.
Dr. Kara Jacobs Slifka: Thank you very much. Since we are anticipating new IPC guidance today or in the very near future, I wanted to provide litigation on a couple of topics some of you have questions. So, the last time I was here, we talked a little bit about two of the CDC guidance documents that came out in late December, one that covers quarantine and isolation and health-care personnel and the other that provides strategies for mitigating staff shortages. Both of these guidance documents provide recommendations based on whether health care personnel are considered to be up-to-date with their vaccinations, which is how CDC refers to a person who has received all recommended covid-19 vaccinations. So, I am going to put the website link into the chat. Ok, I am going to share my screen here, so that you can see the website. I wanted to bring this to your attention, because we had a lot of questions coming in about what up-to-date means and what fully vaccinated means, so I wanted to make sure you are aware of this website. I think this may be a resource that you can use as you are working your way through and figuring out who meets each of these definitions. I think the key thing to point out at the top of this slide is up to date means the person has received all recommended vaccines, including booster doses when they are eligible. If you scroll down this webpage, you will see a table that actually walks through each of the different vaccinations that can be used, and it gives you information on when they are recommended, so for example, for Pfizer, you are expected to be fully vaccinated two weeks after the primary dose in the series, some two weeks after your second vaccination. At that point, you are considered to be up-to-date, because you’re not yet eligible for the booster, but you are fully vaccinated. You then become eligible for the booster about five months after your last dose, so at that point, the recommendation is to go ahead and receive a booster. And when you are boosted, you are then considered to be, again, up-to-date, but if you are eligible for a booster and have not yet received it, if you have not been vaccinated or are partially vaccinated, you are not considered to be up-to-date. All right, I will stop sharing that now. I also wanted to share some updates to our guidance. So with the rapid spread that we have seen with omicron, with the large number of individuals we have seen of the infected, and with the strain that we have seen on health care settings, including nursing homes, CDC has updated our infection prevention guidance that applies to nursing homes, so regarding testing, I first want to emphasize that anyone with even mild symptoms of COVID-19, regardless of vaccination status, should receive a viral test as soon as possible. Without, omicron can spread rapidly. It is extremely important to monitor residents closely for any clinical changes. It is also extremely important for health care personnel to monitor themselves for any signs or symptoms. Rapid tests or Antigen tests remain a great way to be tested. Sometimes rapid tests may not pick up that infections early on. CDC continues to recommend that asymptomatic residents, with a close contact exposure, should have a series of two viral test for sars-cov-2 infection. It should be negative again in five to seven days. We have expanded the two-test recognition in the guidance that will be posted shortly to include newly admitted residents as well as residents who left the facility for 24 hours. We have updated the quarantine and isolation information for residents and visitors, and they are similar to the health care providers. There will definitely be more updates in the guidance, but focusing on residents first, one important difference is we recommend a 10-day isolation after symptoms first appeared for residents who are infected with sars-cov-2, who are either asymptomatic or had a mild to moderate illness and are not moderately to severely immunocompromised. If you are health care personnel, we give you the option to shorten the duration of isolation with a negative test, however, this is not a recommended option for residents. The recommendations are to quarantine, however, its similar to those recommendations for health care personnel. For residents who are not up-to-date with all recommended doses and who have had a close contact exposure, they should be in quarantine. Even if their test is negative after exposure and cared
for by personnel using full PPE. Residents can be used from a transmission-based protection, after they do not develop symptoms, but they can be removed after day seven if a viral test is negative for sars-cov-2 within 48 hours and they don't develop any symptoms. For residents who are up-to-date with all recommended COVID-19 vaccinations but have had a close contact exposure, they should also have that series of two tests performed, but those up-to-date residents, as well as those in the prior nine days, should wear source control but do not need to be quarantined. For visitors, even if they have met the community criteria to discontinue isolation or quarantine, CDC is recommending that they should not visit if they have not met those same criteria used to discontinue isolation and quarantine for residents, so about 10 days, as well as that they have had a positive viral test, if they currently have symptoms of covid-19, or if they have close contact with someone with sars-cov-2 infection. And if that visitation cannot be postponed, that visitor might need to be subjected to additional precautions. I wanted to give one additional update. So, CDC does continue to recommend source control for everyone in health-care settings. CDC continues to recommend the use of gown, gloves, eye protection, an N95 or equivalent or higher-level respirator when caring for residents known or suspected to be infected with sars-cov-2. In the updated guidance, however, we have added in counties that have substantial to high community transmission, a NIOSH-approved N95 should be used in certain higher risk situations come and this may include when you're caring for residents who are not up-to-date with covid-19 doses or in an area that is fully inoculated, or if there is transmission occurring in the facility, such as during outbreak. I am going to stop there. This is quite a bit of information that I've shared with you, but you will be able to view it shortly on the website, and I will do my best to answer questions in the chat and any questions that may come in the future. I want to thank you again for your continued adaptability during this pandemic and for continuing to raise questions and any clarifications that you mean. Thank you so much.

**Jean Moody-Williams:** Thank you so much, Kara, and there are questions in the chat that I will take a look at that -- in the chat.

**Dr. Jacobs-Slifka:** I will take a look at them.

**Jean Moody-Williams:** Several of them are about testing, and the CDC has been working with the testing and diagnostic working group, and they also organize the shipments that nursing homes have been getting each week. But because of the increased testing needs during the omicron surge, they are planning to send out some additional test in the coming weeks. I know this was a frequent question that I've seen in the chat. Those tests will be the new Celltrion kits, what you are accustomed to seeing. And since this will be new to you all, we have asked some of the folks in the companies to join us to do a five-minute demo that I understand the instructions are pretty clear, but I always like to see something—so we have quick demo for you today. I want to turn now to Tiffany Choi, who is the Director of Strategic Management at Celltrion.
Charlotte Jaeun Kang: This is Charlotte Jaeun Kang. Tiffany is in another meeting so I am presenting. Today, I will be showing the product that we hope you will get soon and give a quick demo on how it can be used. It is very simple and easy to use, so I will try to go slow, but if you have any questions, if you have trouble understanding, then you can pause me anytime. This is the full package that nursing homes will receive going forward. Inside the kit, there are components, in an aluminum package, and 25 nasopharyngeal swabs. Inside the box, there will be 25 individually packaged test devices. And you will also receive positive and negative control swabs that you can used for control for the shipment. And one quick reference instruction that explains how you can conduct the test. This will have 25 buffer caps that you will attach to the individual buffers, so there are two types of products in the market when it comes to rapid antigen tests, like the buffer comes in a big packet, and you have to use a single buffer first 25 tests, that comes inside the kit. But the covid-19 antigen test has 25 individual buffers and 25 individual buffer caps, for ease of the end users. In order to conduct the test, you need four components. Actually five. PPE, according to the CDC guidelines, and for actual test components, you need 4, 1 is the swab, and the test device, solution, and the buffer cap. First, open the test device, which is individually packaged in an aluminum house -- pouch. When you open it, you will see a test like this. You put in a flat surface, and you get ready for the sample collection. You will have a collection swab, and when you peel it, taking a sample is what you are expert on. Something I want to emphasize is our swab is very flexible compared to many other products, so we got great feedback about it. When you do the sampling of your patient, you open the buffer cap, and you put your sample here and swirl about in time, in order to make the samples go directly to the buffers, about 10 times up-and-down, and swirl, and when you are taking out, we recommend to squeeze the swab, so you can get the maximum amount of the sample to the buffer. To do it, discard the sample swab, according to your guidelines, and put the buffer cap on top of the buffer. Think of it as a flat surface, and you put three drops of samples to the test device. And the conjugation pad will go up, and after 15 minutes, you can read the results.

Jean: Thank you for that demo, Charlotte. We will get the questions likely in the chat, and we will get instructions. This recording will be made available, and there are other resources, but Charlotte, could you take a look at the chat and see if there are any questions you can answer?

Charlotte: Yes. I was briefly looking into it, and there were questions about the anterior nasal swab sampling and the minimal time reading the results. As of now, the covid-19 test is intended for a nasopharyngeal swab. We did some implementations which we are pending approval from the FDA. To answer your question at this point, only nasopharyngeal swab sampling is allowed. If you see the two lines, two lines indicates a positive or confirmation of the results should come in 15 minutes, from the drop income of three drops of the sample to the test device.
Jean: I see many others. We are going to move on, but you can feel free answering them in the Q&A, and we will make sure to collect them as well. Or do the testing work room, as far as that kind of thing. So, I want to move on, if you joined our call, the last call we had, we were fortunate to have the CMS Administrator join, and she really illustrated CMS’ intention to leverage the full spectrum of the tools to promote safety. One of the things she emphasized was the sharing of best practices and invited you to send in your best practices, and that invitation remains open. We’ll provide the email address through our partnership back for that purpose. But today, we thought it would be good to hear directly from the front-line, from someone who successfully implemented a plan to ensure vaccination status of residents and staff, and we are fortunate to have the CEO of Forest Hills of Washington, DC. They’ve implemented an award-winning approach, and was actually been featured on CNN and in the New York Times- and she has also testified for the Hill on their approach, so we want to give a few minutes to Tina to talk about that on this call. Tina?

Tina Sandri: Good afternoon, everybody. Can you hear me ok?

Jean: yes, thank you.

Tina Sandri: Thanks for having me here. We are happy to be here and share our practice and maybe help other folks along. To start off, to give you a little bit about where we are in terms of our data, as of today, our fully vaccinated residents, who have also been fully boosted, is at 95.2%. Yeah, 95.2 percent. Of our staff, we are at 99.1% vaccinated, and of those, 45.5% are also boosted, and we are continuing to move that number up, and that is with a non-mandatory booster policy. In terms of our cases, looking at the first full week of data reported in ending 1/9, we had a total of two residents, one resident death from COVID, and 13 employee cases. As was noted, I think come in the chat a lot, obviously a lot of this is due to the omicron spread. We were able to get our folks upto large to a herd immunity rate by Qtr1 last year. To talk a little bit of our program, it started from a place of compassion and respect, looking at workforce fatigue, and we try to balance the need for employee engagement, the human factor, along with the scientific factors of what was going on, and we tried to connect people to a buffet of really good information so that they could make choices, and sort of the overarching theme of our vaccination program was that knowledge is power and that, as an employee, you should get educated, so that you can exercise your power over your personal situation. So, it was not a message of you need to, you must, you should, you could, you have to, it was get educated, and make a decision— and really everyone came around to that, for the most part. To start with, we wanted to listen harder to our employees and hear with their concerns were, with their objections were, without judgment, and that everybody’s concerns were valid. Starting from there, based on what we heard, we went to a nine-week timeframe of themes, digesting common themes that we were hearing from people and helping to get them more awareness about what those things were. And so the overarching themes where we might spend a week on, what is efficacy? Another week on what is in mRNA, what is herd immunity. What is that cultural history attached with experimentation? So, 85% of our workforce here is African American, or African. And about 10% Hispanic, and the rest is everything else. We spent another week on what is immune response good versus bad. How is the vaccination made? What was in it? Another week on what were trials, how big were trials. Why were they running altogether instead of sequentially? Interestingly towards the end, some of the stragglers, we went into you are a community leader. Particularly some of our younger community leader. Particularly some younger people, they are not going to have access to the vaccine like you are. Like it or not you are going to be the leader in your social group, family group because you will have first access. That made some of them pause and think
and kind of have to step up to the plate. So, along with those things, we then decided to message out in what would like. To call eight ways. So, we would put the same message out. If we were focused on what is in mRNA, the same message could go out in different ways. A phone, a text, an email, posters, flyers, videos, huddles, helping people pull up information on their personal cell phone so they can look at it later, town halls for families and residents, video recordings by our medical director. We put posts on Facebook. We found lots of different ways to put the messages out so people could digest the information in a way most convenient for them.

Next, when we were putting together these messages, we layered on some of people's thinking preferences. This goes back to the science in terms of Herman brain science theory. People process information differently. So, folks who are process-oriented, we might have to explain to them for example, the information that we were putting out, some of them wanted to know that the people we were putting out as speakers had no personal financial interest, there was no conflict of financial interest they would be getting. Or we might have to expend the process of how the vaccine was moving quicker to market than other vaccines in the past. People who were analytical, they liked to see our real-time HR internal data on what percent were vaccinated, because they might not want to be front of the market, but as they saw the numbers climbing, they were having more confidence that, hey, my peers are not disappearing from work from a bad experience. Everyone showed up at work the next day. Or they want to the numbers in the trials or the percent with immune response. So, people who were creative, we want to support them as well. We had a frontline employee who organically evolved into a champion with the frontline staff. And we kind of ran with that and gave them the resources to do what he wanted to do. He was in activities and we would give them the resources to take around the building to educate some of his peers and residents and family. Then there were messages for folks who were more relational. Those were the folks who we said, do you have a loved one at home who is immunocompromised, who does not qualify for a vaccine at this time that you are trying to protect, and it made people pause and think. So, once we took their thinking preferences, we then overlaid learning preferences. As you can see, we developed a wide buffet of ways to connect with folks. So, learning preferences might be someone who is a visual learner versus an auditory learner versus a tactile learner. For auditory learners, we had our medical director videotape, audiotape some messages we were able to send around to share with families and staff. We rolled in a 60-inch television screen at the check in sight so when we were doing daily COVID screening checks, we were able to air the message of the week that we want to people to see. And for people who wish to clean more visual, we would have collages after our first vaccine clinic because at that time our buildings were still on lock down. People were not gathering at water coolers, they were not gathering in employee lounges. Folks who wanted to have their pictures taken, and we started building a collage at the front entrance of people who had been vaccinated. So, as people coming in for their shifts could see, oh, my friend on this shift, who works the weekend shift, they got vaccinated and they were happy about it. We had different visuals. Some might be data, some might be humorous. We also had vaccinated stickers that people put on their name badges, just like I got my flu shot. We had selfie-props so people could take pictures that they could be vaccinated and were kicking out COVID. So, people could engage with it at whatever they were comfortable with. Another approach that we had was, as we were developing all this information, we were trying to make it accessible and flattened the information across departments. When we want to rapidly disseminate information, a hierarchal structure is not always the best. The speed to get data across involves flattening it. And so, we gave all of our department heads equal information, equal training. We told employees whomever run into in management can answer your questions so they did
Jean: Thank you so much for sharing that. You said that sums it up. Like, yeah, that is what we did. That was a lot. You did a lot of work but it really paid off for your staff and your residents and the community overall, from what you are saying. And I really like the idea of the champions. We have promoted that idea here as well. Thank you so much for sharing and keep us posted as you work on the booster. So, we’re going to go to some CMS updates and answer a few questions. I am taking a look at the questions. I am going to repeat this because I see some questions in the chat. The omnibus health care staff vaccination rule is now in effect nationwide. I just wanted to be clear on that. From the questions I am seeing in the chat. So, with that, let me turn to Evan Shulman. I know you have some updates for us and you have also been keeping your eye on the questions so hopefully you can address some of those.

Evan Shulman: Thanks. Yes, I have been trying to keep my eye on the question. Please post them to the Q&A and not the chat. I will try to hit some in my remarks for some of the questions we have already received. First, I want to talk about some information we posted today related to visitation. As you all know, we have a memo on visitation and we’ve recently added to the frequently asked questions. There are a few things we added. We added best practices for improving air quality and managing airflow. CMS will improve applications from facilities request to use CMP funds to purchase portable devices airflow and air quality such as clean air with HEPA filters. As we’ve mentioned before, there has never been one single practice that reduces transmission of covid-19. It has always been a multitude of practices that help reduce the transmission. And all of these things are the things that you know. It is hand hygiene, physical distancening, masking, and it is also airflow. So, we are just trying to layer on top all of the practices that can help reduce transmission of covid-19. So, we need to keep at them all. The FAQ is posted on the CMS emergencies page. It is also attached to the CMS memo on visitation on the webpage for policy and memos to states and regions. Now I’m just going to go over a couple of questions and answers about visitation and the guidance for surveyors related to the staff vaccination
requirement. First on visitation just a few things. First, a reminder about the visitation. You need to maximize visitation. We all know it is critically important for the overall well-being of residents. And it needs to occur by adhering to the core principles of infection prevention. Avoid large gatherings where physical distancing cannot be maintained. And if there is an outbreak, work with local departments to help manage it. When we talk about visitors and visitation, we are not just talking about families, friends and loved ones, although of course we are. We are also talking about support personnel for people with disabilities. All of those need to be able to access residents. So, some of the questions we have been getting around visitation or around visiting residents when they have a roommate. Can I visit a resident in their room when they have a roommate? Ideally the visit would occur when the roommate is not they are or in another area of the facility. Visitation can occur in a room with a roommate as long as physical distancing can be maintained. That is just fine. We have actually also put this out in an info graphic on the CMS emergencies page. It is titled how to safely conduct visits in nursing homes. You’ll see examples of how these visits can be conducted safely, and also a note about visiting with individuals with a roommate in the room. Another question we have received a lot is from states and facilities about states who are asking facilities to test visitors prior to entry. CMS has communicated to states that they can have facilities test visitors prior to entry. However, they need to be provided by the facility and a need to be the 15-minute rapid test. As long as the facility can provide those tests, we believe it is reasonable for facilities to test visitors prior to entry. However, if the facility does not have those tests, the visit must still occur. And we know this because visits can occur safely. The visitors should be going directly to the visitation area where there is a room or another place. They should be masking. They should be adhering to hand hygiene. Now we hope facilities get further into managing airflow and improving air quality. But the visit must occur. And by the way, this goes for vaccinated and unvaccinated visitors. We know that visits can safely happen regardless of vaccination status. Again, following those core principles. I’m going to turn now to the staff vaccination, the regulation and some questions we have received about this.

The first question I will go over is, where do facilities need to store the vaccine documentation of both the direct employees, but also those that are contractors? Do they need to store this information on site? And the answer is no. Facilities do not need to store this information on site. Facilities do need to know the status of all the staff that are subject to this rule, they need to know their vaccination status. But documentation and evidence of that status can be stored someplace else. However, when surveyors request it, it needs to be produced. What facilities do not need to store this on-site. Another question that we received is, are N95 masks required at all times for unvaccinated staff? The answer is no. The CDC website is very specific on directions on when it N95 masks should be used, and it does not say N95 masks must be used at all-time. So unvaccinated staff, is not required for them to use in N95 mask at all times. That said, if unvaccinated staff do use N95 mask all the time, that would be considered an additional precaution, which is also in our regulation, where we expect facilities to implement additional precautions to reduce the risk of transmission from covid-19. That would be an example of an additional precaution. Talking about staff who are subject to the rule, we have gotten a lot of questions about this type of staff or that person, the chaplain or a consultant, a vendor. And CMS could simply not list out every single type of individual whose title may be subject to this rule are not. We also would not be able to say yes or no just because of a title, because the title matters less. What matters more is what are they doing. So, if you are wondering if someone is subject to the rule, please go to the actual regulatory
language itself, which says that the people who are subject to this rule are individuals who provide care, treatment, or other services for the facility, and/or its residents under contract or other arrangement. So, if the person you are considering does those things or some of those things, the first answer is yes, they are subject to the rule. There are other parts of the regulation that also need to be considered, such as, does this person work exclusively remote or telework? If they do, they are not subject to the rule. Also, does the individual very infrequently provide ad hoc services to the facility? An example would be an elevator repair man in the preamble of the rule. If they are ad hoc, infrequent, then they would not be subject. So, look at these areas of the rule and these questions to answer the question for yourself if this person is subject to the rule. Another question we have been getting is, do we have to implement all of the actions listed in the memo just as precautions in order to be compliant with the requirements? And the answer is no, you don't have to implement all of the additional precautions in the memo. We do expect facilities to implement as many as they can't to committee -- they can to mitigate transmission. There has never been one single thing that mitigates transition. It has always been a series of layering on different practices and all of those things together help to mitigate transmission. And the last thing I will mention, is that I saw some questions in the Q&A and the chat about NHSN and what is being reported and what surveyors will be looking on-site.

Surveyors will be looking at two types of data from facilities. One, we do not want the NHSN data to just live in a silo by itself. We want surveyors to check that the data is reasonably accurate. It does not have to be exact, and there are reasons it would not be exact such as exemptions, but we are looking to see using the same formula we use for NHSN and what -- the second thing surveyors are going to be looking for is the list of residents and doing a formula based on the requirements in the rule which extracts and removes those individuals who are exempted, and that facilities are meeting requirements of the rule to track the vaccination status of all the staff correctly. So, we are not going to be comparing NHSN to a separate formula for calculated and the percent vaccinated in the facility. With that, thank you so much for all of your hard work. Thank you also to the consumers and advocates, and all the facility staff who have worked so hard throughout this challenging time. Jean, I’m going to turn it back to you.

Jean: thanks, evan. I think that was a good place to end, thanking everyone for all that they do. And thank you and the team. It takes a lot to think through these questions. You all ask very good questions, and we oftentimes have to run them by several people to make sure we are giving you the most accurate information. So, appreciate all the time that has gone into that. With that, we will again have this posted and take the questions that are remaining and look through them and communicate the answers to you in one way or another and we look forward to our next stakeholder call. We will keep you posted on when that will happen. Thank you, and have a good rest of the day.