

**Centers for Medicare & Medicaid Services
National Nursing Home Stakeholder Call**

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Jean Moody- Williams: Good afternoon, everyone. Thank you so much for joining this call today. I'm Jean Moody Williams. As usual I need to do a few housekeeping tips before we get started. Just a reminder, the webinar today is being recorded. I think you heard that when you signed on. It will be posted on a CMS transcript page and on the podcasts page, should you want to listen again or share it with your colleagues. All participants are muted throughout the call but we will be taking your questions through the Q&A section. Close captioning is available via the link in the closed caption window at the bottom of your screen. Members of the press may be on today's call, however for all press inquiries please submit to <https://www.cms.gov/newsroom/media-inquiries>. Any questions about that, let us know. Maybe we can put that in the chat. First let me acknowledge that many of you are still working to resolve the aftermath of hurricanes Ian and Fiona and we will continue to work with you and your state agencies to meet the needs of the residents in your nursing facilities course you know CMS issued many waivers and rod flexibilities at the beginning of the pandemic that will terminate eventually at the end of the PHE. Some have been made permanent but I know there are questions about that that we will address in a Q&A section but as a reminder to minimize disruption including potential coverage loss, etc., Secretary Becerra has committed to giving states a 60-day notice prior to termination. The notice has not yet been given and we will stay tuned to make sure that you know and are aware when it is given. But we are encouraging health providers to be aware for the end of the flexibilities into look forward to not meeting that particular waiver or flexibility so that we can ensure that health standards are in place. Lastly as we approach the cooler seasons in some parts of the country at least, we do encourage everyone, regardless of where you are, to stay up to date with your COVID vaccines and continue to encourage residents to stay up to date. That includes the bivalent booster. It is expected to trigger a better immune response against new subvariants and will lessen the overall severity for those affected. So, speaking of that our next speaker is going to highlight some important information. I am really excited to welcome Dr. Thomas Tsai, currently a senior policy advisor on the COVID-19 response team. Following him we will have our colleagues from CDC and CMS provide some updates and then we will end with a question and answer period.

Dr. Tom Tsai: Thank you so much, Jean. I wanted to thank everyone for being here. I'm also here with Dr. Meg Sullivan, chief medical officer. We will both be sharing a little bit about the strategy to really protect our seniors heading into the winter. We want to make sure we are prepared and people truly have access to all the tools from the updated COVID vaccines as

mentioned earlier, which are incredibly important for preventing infections and severe outcomes all the way through the clinical care spectrum including testing and diagnosis that can lead to safe and effective treatments, such as Paxlovid, ultimately able to protect nursing home residents from, from, from hospitalizations and death. So, we truly have access to a week of treatment and preventive measures and our challenge is to figure out how we can work together collaboratively to deliver on this promise of treatments. I want to share some of the data that is influencing some of our thinking. This is a graphic showing where we are in the pandemic terms of COVID-19 deaths. The last six months have marked the lowest deaths of any six months during pandemic. That's even with the July wave in August where we made remarkable progress in our ability to make sure our older Americans can prevent infections and can be safely treated for they have infections from COVID-19 there has been a shift towards hits -- non-Hispanic whites with multiple comorbidities. Death certificate data shows the demographic trend and distribution of deaths over time and currently where we are in September, actually October now, the, almost 90% of deaths over the age of 65, 70% over the age of 75. Replicating each once again in 2020. With all the nursing home leaders the front line of the pandemic. Have always been and continue to be and we want to make sure that we all work together to be able to provide all the resources and treat it's that are truly widely available at all locations and pharmacies across the country. Not only are the deaths happening more among the older population, it's happening more and more outside the hospital. This data shows the distribution of deaths crossing from settings of care with a decrease happening in the patient setting with an increase happening in nursing home settings and decedents homes. We recognize that you guys are truly on the front lines in not just preventing COVID but all -- ultimately entreating COVID-19 as well. So, as we look ahead to the winter, how can we work together to make sure that we have full access to testing symptomatic patients to make sure that they received timely and effective treatments? in some ways our job is to make access to these treatments no longer extraordinary but part of ordinary high quality care delivered every day in our long-term care facilities and settings and there are a couple of ways to do that. One, increase the test to treat locations and relationships with pharmacies and nursing homes. Making sure that we are treating based off of the risk factors and indications for treatment and not waiting for individuals to get sick who say they need treat or not because part of the reason for using Paxlovid and others is to prevent disease progression to others meeting hospitalizations or severe symptoms. The second part of this is why we are increasing access through the test to treat programs, there are opportunities to make sure that we increase the awareness of our clinical leaders and patients on the availability and the role of these patient -- these treatments and saving lives. The Administration is launching a broader effort across the U.S. government to make sure that we can increase clinical awareness of the latest data on the effectiveness of Paxlovid with updated information on rebound symptoms not leading to severe outcomes but also making sure we have the information so that clinicians can make those adjustments in medications around drugs and drug reactions. A second part of that is working with our patient groups. Our association people- Leading age, AARP, making sure older residents and Americans truly understand we are in a different place this year because of our

access to treat but we must use those treatments and vaccines effectively to be able to make sure we are preventing and treating. Last part is about making it more accessible, easier, launching accessible virtual care programs. Test to treat from the location to the clinical journey where patients with symptoms get tested and make sure they get the right care at the right time and especially at the right place. I know you guys are up to the challenge. I look forward to this collaboration. Let me turn it over to Dr. Sullivan for more on the work that is being done and how we can continue to provide access to these treatments, test treat, or others. And we are going to stop the slides.

Dr. Sullivan: Thank you so much and good afternoon, everyone. First, I want to echo everything Dr. Tsai just said, we have worked closely on all the key strategies he just mentioned. And we know that the role of ASPR is broad but we want to focus on therapeutics and the role they play in saving lives and in the older population. I want to make two key points in addition to everything that Dr. Tsai said. Our therapeutics that are currently available right now, we do have ample supply. We talk about oral antivirals and again we have adequate supply. We want anyone eligible to receive these there appeared ask based on age and risk factors and CDC criteria, health care providers feeling confident and ready to talk about them with strategies to increase patient awareness. We want to note that the same thing with our ample supply around the FDA information on what's recommended for those with sufficient supply. And finally, even as we transition to the commercial market to make sure you know it's an option when clinically appropriate. The second thing I will say in terms of distribution is we are doing everything we can to make sure treatments are as readily accessible as possible. 40,000 patients nationwide, specifically as referenced, long-term pharmacy programs that we launched several months ago and have seen really good enrollment. We identified 2000 long-term pharmacies nationwide and have enrollment in the program for the significant number that allows them to order from therapeutics. What we have found recently as though we have a large number we only have a small percentage listed as active providers, they do promote -- become inactive if they haven't ordered in the last 30 days or inventory within the last two weeks. For those of you involved in facilities with long-term pharmacies, they are more than happy to work with you to facilitate the ordering and encourage Access to be able to increase distributional and utilization. I will just stop there and thank you for everything you do. I know how hard it has been. I really have admired everyone whose been working in long-term care in those facilities. Thank you.

Jean Moody-Williams: Thank you so much for that information. I see a number of questions coming in regarding infection control practices and how they are implemented or not and how to relax them. I want to let you know that our next two speakers will be talking about infection prevention control changes. I also see a number of questions coming in about antigen testing. To let you know, we will address that. Kara, I want to turn to the CDC and as usual we really appreciate you joining our calls.

Kara Jacobs Slifka: thank you so much. Our team focuses on infection prevention in long-term care. Myself and my colleague are very appreciative of the opportunity to join today and share information with you all. So as many of you may know, CDC has had a long-awaited update to our COVID-19 infection prevention guidance health care personnel posted recently on September 23. I want to share a couple of important things and then I will get into some details that I hope help clarify details for all. We are continuing to use community transmission have not community levels to could -- for these measures and I know this adds complexity to the different guidance that has been put out but this allows for earlier intervention for there is a strain on the system. To better protect the vulnerable individuals who seek care in health-care settings including nursing homes. Vaccination status. When we talk about people being up to date, it's no longer used to inform things like source control, screening testing or postexposure recommendations like quarantine work restrictions. And we have archived the standalone nursing home guide. Right now, there is one main COVID-19 infection control guidance document that includes nursing homes. There are some settings specific recommendations including sections for nursing homes at the end of the guidance in section three. So, I want to walk through a couple of the more specific updates because we have definitely been getting questions about things like source control. When community transmission is high, source control is recommended for everyone in areas where they could encounter patients or residents. But we have left some flexibility in the guide for health care personnel and staff in nursing homes who could choose not to wear source control even when the community transmission is high when they are in areas that are restricted from patient access. This might mean a conference room or an administrative area of the building as long as the community level is not high. I know I mentioned we are using community transmission here but there is one place where we talk about source control where we have to keep in mind what's happening in the community and why we have given that flexibility for health care personnel when they are not in areas where patients and residents are located to choose not to wear source control, if the community is, if what they are using to guide recommendations is high, the recommendation from CDC is that anyone in any setting would use source control. I want to highlight a couple of situations where source control should be used. Flagging these for you mainly as a reminder. If an individual is expected to have SARS-CoV-2 or another firmed infection that is a situation where source control should be used. If you have had close contact someone during that 10 days, that's another situation where source control is recommended. If you as a patient or resident are living in an area or residing in an area building or working in an area where there is an out going on that's another where we recommend source control and there may be situations where the public health department recommends source control and the last thing I want to recommend since this has added flexibilities is even if you are not wired by the facility or through the recommendations to use source control, it's always up to an individual to choose to use it based on their personal preference. Maybe you have risk factors yourself for them were serious infection or a loved one at home with increased risks, you can always choose to use source control. Regarding universal PPE, we have changed the guidance having a recommendation for universal PPE. Where the guidance previously recommended this,

we have now left it up for consideration. Meaning your facility for example could choose to use or make the decision to use or recommend universal PPE when community transmission is high but we have left this to the facilities to make the determination. This is about the frequency of testing, there are updates. A series of three test is recommended for asymptomatic individuals following exposure. Testing continues to be recommended immediately generally not less than 24 hours after exposure and if it is negative we recommend testing again in 48 hours and if it is negative again 48 hours after that. Typically, this is day one, day three, Day five if you are thinking about exposures on day zero. Testing is generally not recommended for individuals who have recovered within the 30 days and if it does occur for some reason, antigen testing is what's recommended. Real important, I want you to hear this, screening testing of nursing home personnel who have not had recognized exposure is no longer recommended. The testing I'm talking about, we have called it splendid screening, others have called it general screening, that once a week or twice a week testing that all staff had previously been doing, it's no longer a part of the recommendations but I do want to point out that screening testing remains recommended for new admissions. Residents who are newly admitted when community transmission levels are high, including individuals who have left the facility for 24 hours and are coming back in. We have made updates to quarantine for patients and residents as well as work restrictions for health care personnel. These are no longer routinely recommended for a symptom at individual all of it and exposure. It definitely remains important to monitor for symptoms and perform that series of three tests and continue to use source control for 10 days following exposure but quarantine and work restriction are not recommended because the board. We do recommend however and continue to recommend that individuals, whether they are patients, residents, or health care personnel who develop symptoms, they should be isolated if they are residents and work restricted if person and tested for SARS-CoV-2. We want you all to continue quickly identifying individuals with SARS-CoV-2 or other respiratory infection so that we can continue to prevent spread. As with other vaccine preventable diseases we are best protected from serious this and death from COVID-19 when we stay up to date with recommended vaccinations including boosters and I know you have heard others talk about boosters but the updated and newest, we call them bivalent because they protect against the original virus and against the Omicron Variant. The virus that causes COVID-19 has change over time and the new booster helps to provide protection against the new version. We at CDC strongly encourage you to get both and the flu shot because it is that time of year as well. Our guidance updates reflect the availability of vaccines, boosters, therapeutics, the changing virus, pandemic, and your expertise with prevention and your ability to make decisions for your facility and yourself. I will say thank you for that. My colleague Heather Jones and myself will be doing our best to tackle questions in the chat. Please feel free to turn them in.

Jean Moody-Williams: Before you go, there is a question that has come up many times that you have addressed this but to reiterate, if no one has symptoms and there are no outbreaks, can staff go without masks in their daily work, including patient care areas?

Kara Jacobs Slifka: So yes, if where you are located, your facility, if the community transmission and make sure you are looking at the community transmission metrics or measures on the website, if community transmission is not high, you could choose to go without using source control. However, you could also choose to continue to use source control. If anyone winds up being diagnosed or expected of COVID-19 you should in that situation definitely make sure you are using a respirator and the rest of the appropriate PPE.

Jean Moody Williams: Thank you, you knocked out a lot of the questions in the chat. Heather? Does Heather have anything?

Kara Jacobs Slifka: Nothing additional from Heather but she is actively helping to answer questions in the chat right now and I will join her. Thank you.

Kara Jacobs Slifka: Let's move on over to the CMS colleagues Evan and Celeste who will help us with this as well.

Evan Shulman: thank you and good afternoon, everyone. My name is Evan Shulman. I'm the Director of the Division of Nursing Homes. You have heard a lot today about the strength of vaccines and I want to reiterate that. One of our concerns is that the new, revised guidance, that we are delinking or disassociating some of the testing requirements from a person's vaccination status or quarantine expectations for a person's vaccination status. This may cause people to question if vaccination is still important and the answer is unequivocally and absolutely yes. We heard Jean talking about the strength of the vaccine and Kara as well. To put a finer point on it there was a recent study by the CDC that was put out that found the receipt of the second mRNA booster during the circulation of overcome was seventy four percent effective sixty days after administration against severe outcomes of hospitalization and death, and ninety percent effective against death alone compared to those that just had a sooner. So those are super high numbers. Getting your vaccine is still the strongest tool we have against COVID19. So, it is still absolutely incredibly important.

Along with these changes from the CDC website we have released our memoranda to comport with the CDC guidance, testing memo QSO 20-38- NH Revised and our visitation memo QSO-20-39-NH REVISED. We typically get questions about how this impacts our survey process. Some of the questions have in how the surveyor investigative pathways are conducted primarily around some of the discussion and guidance that advises facilities to do daily screening of COVID symptoms. I want to explain what is meant by this. It is not meant to be a documentation of fever checks of every single person, temperature checks. It is what you all do every day, which is to assess your residents and if there are issues, to take actions based on the findings which is documenting by exception. There is nothing special we are looking for here. This is the normal operations from our respected for a nursing home that should be routinely assessing the health and safety of the residents. Some of the other questions we have been getting are about some removal of guidance related to communal activities or dining. Should they go back to normal? The answer is with the exception of some of the guidance from what CDC explained, the answer

is yes. We do say we should encourage physical distancing and avoiding large crowds. That is still an important thing to do. There is nothing on the CDC website or guidance that prohibits communal dining or activities so this can occur as they used to. Same question about visitation. Visitation should be happening for everyone at this point. We have also received questions about visitors participating in communal dining or activities and if they can. The answer is yes, they can. Again, be cautious. The safest practice is to maintain physical distance and where source control but according to where we are right now and the guidance, this is allowable for our visitors to participate in activities and communal dining. So, I went to circle back on the importance of getting the vaccine and flu shot. We strongly encourage that. Please encourage all of your residents to do it. I'm going to turn the discussion over to Angie Duabert to talk about CLIA. Before I do, I want to thank the nursing home staff and operators, and I want to thank our residents and wish you well during the upcoming holiday season and all of the Ombudsman and resident advocates that help to protect you and keep you safe. Thanks for all of your efforts as well. So, Angie, I will turn it over to you.

Angie Duabert: Thanks, Evan. CMS published a memo and enforcement discretion for SARS-CoV-2 tests on asymptomatic individuals outside of the test instructions for use. Laboratories need to follow the manufacturer's instructions including the intended use. While the manufacturer's instructions can often be found in the test kit box, the manufacturer's website and on the FDA website. The FDA has the website which I will post the link in the chat has the in vitro guide antigen diagnostic test page and it lists all of the antigen test that have received an emergency use authorization from the FDA. There is a search bar where you can type in screen or screening and it will filter for all the tests that have the attribute for serial screening for asymptomatic patients. Why did we take this action? Allowance of labs to use tests beyond their expiration was -- Now there are numerous tests with an FDA approved authorization and have the attribute for serial screening of asymptomatic patients. As the pandemic has evolved and the rates of immunity has increased, a lower sensitivity of antigen test compared to the gold standard has become more evident. Scientific literature shows antigen test have lower sensitivity and take longer during the wars of action detect a positive. Some common questions we have been giving -- we have been getting is can I still use my COVID test today? The answer is yes paired by need to be in a high complexity lab Tory to use the test? No, many tests with the attribute for serial screening may be used in wave laboratory setting. How do I find if my test is approved? Check the FDA website. It has the most up to date information and I will post that in the chat. How long the level course to comply with the memo? The memo contains the information kids CMS is rebooted -- is reviewing the appropriate timeline. I'm joined here today with my colleagues from the FDA and CDC listen to your comments and answer your questions regarding the recent memo. I will pass it back to Celeste.

Celeste Saunders: Good afternoon, everyone. I'm a branch manager in the division of nursing homes LP sharing two important dates. The first is the release of revised long-term survey or

guidance which supports the implementation of the revised long-term care facilities requirements for participation which were published in 2016. Advanced copies of these revisions were posted in June and clarifies specific phase two and three regulatory requirements and provides information on how compliance will be assessed. If he could changes in this guidance include changes to abuse and neglect, admission transfer and discharge, mental health and substance use disorder, nurse staffing and payroll based journal data, arbitration and infection prevention to name a few. This guidance strengthens the management of complaints and facility reported incidents. These revisions will be in court rated into the long-term care survey and begin to be surveyed for on over 24th 2022. CMS released training in the quality, safety and educational portal for surveyors and educational portal for surveyors in nursing home stakeholders to explain the updates and changes to regulations and interpretive guidance. Also happening this month, CMS informed providers the six-month increase of quality measure rating thresholds will occur on October 26. Should have received notification in your five-star provider review and the five-star technical users guide will be updated with the new Rush Holt soon. I will turn it back to you for the Q&A portion of the call.

Evan Shulman: Great information from everyone. We have been receiving a few questions. There are a few we will start off with. Amy, do you want to hit a few questions?

Eimee Casal: Good afternoon, everyone. So, you have heard Evan and Kara speak of vaccinations and testing and everything required. In August, we received a lot of questions and received and chose the top three. The CMS regulation requires staff to be up-to-date with their vaccination. The answer is no. The staff vaccination relation requires staff to be fully vaccinated. It is not requiring staff to obtain booster doses. We do encourage everyone to please obtain all recommended vaccine doses including their booster doses. Another question we have received is due nursing home still need to test unvaccinated staff as part of additional precaution. Routine screening testing is no longer recommended for asymptomatic staff regardless of vaccination status. Implementation of additional precautions for staff who are not fully vaccinated is required. A facility may use the discretion to perform screening testing as part of its additional precautions for staff who are not fully vaccinated but it is not required. The last question is do new admissions need to be tested for COVID-19? In general admission should be tested upon admission. Tested is recommended in if negative, 48 hours after the first negative test. If negative again 48 hours the second negative test so it would be day 1, 3 and five. They should be advised to wear source control for 10 days following admission. Admission testing at lower levels of community transmission is at the discretion of the facility. Vaccination status does not factor into the new admissions testing.

Evan Shulman: Thanks. Thanks for answering those questions. I see another question here about can you verify our normal assessment processes will suffice or if we need to screen for COVID symptoms and document that? This is any relation to the quick loan pathway surveyors used. The answer is your normal assessment does suffice. We expect facilities to be assessing their residence daily or more than daily for any changes in condition. We are not expecting you

to document something every time, if they don't have symptoms. I also see a number of questions here about is CMS going to change a regulation or expectation or issue a new regulation and just hit all of these questions at once, we can't comment on any pending changes or potential changes, regulations or sub regulatory changes. We will do that through either the normal regulatory process or through CMS memoranda. I wanted to cover a lot of those. I think most of the questions have then hit unless you sell any. A lot of the same questions around the tests.

Jean Moody-Williams: Right. I think we have answered most of the questions. We will keep all the questions and we can go through them and see where we need to doubt any additional information. Angie has already noted additional information about testing is forthcoming. We will keep everybody abreast of that. With that, I think we will close out and we will stay in touch. I see a that there are a couple questions floating in right now. Go ahead and put your questions in the chat. We are going to end the call but will give you another minute for questions. The last-minute rush. Thanks, everyone. Goodbye.

Lee Fleisher: In response to the one question you had, people at this point do not need to throw out their cards. We encourage them to continue using their cards at this time. Thank you.

Jean Moody-Williams: Thank you. Thanks, everyone.