

>> We're going to go ahead and begin the webinar. Thank you for those who have been on the line and waiting. We were trying to sort out some technical difficulties.

>> Hello everyone. And thank you for joining the Home and Community-based Settings Regulation Implementation: Guidance on Heightened Scrutiny training. I am Anthony, and I will be providing technical assistance. You can e-mail me if you have any trouble. You can find a download of the presentation on the right-hand side of the screen. This call has been globally muted to avoid background noise. Please use the chat pod to ask any questions at any time. They will be collected and addressed during the Q&A period. In order to monitor the quality and effectiveness of this training, please take the survey at the end of the presentation. We would also like to note that the call is being recorded for quality assurance purposes. I will hand it off to Ralph, director of the Division of Long-term services and Supports.

>> Hello, folks. We're glad you could all join us on this line for this call. As you know CMS published regulations regarding home and community-based settings in March of 2014 they became effective. Since that time, we've worked with states to get to approval on statewide transition plans. One of the major issues we've discussed were the settings that were presumed to have institutional characteristics and specifically heightened scrutiny. We are here today to talk to you about some information regarding that important concept and as we start the webinar I'm going to turn the webinar over to Mike Nardone who is the director of the disabled and elderly group. And he will be followed by Lance Robertson, and then Linda Joyce.

>> Hello. This is Mike. And as as Ralph said I'm the director of the Disabled and Elderly Health Group at CMS. My team and I are pleased to hold this webinar today to discuss guidance we released last week on the home and community-based settings regulations. They were developed through extensive collaboration with our state partners and key stakeholders including providers and advocates. From the beginning of our effort to issue this new guidance, our goal was to achieve the right balance between the tenants of state flexibility, ensuring that a range of providers and service models were available to meet the different needs of individuals receiving home and community-based services and engagement with stakeholders to facilitate transparency and collaboration both at national and local levels.

As you can imagine, finding that balance was not a quick or easy process and we greatly appreciate hearing from so many of you on what was important to include as part of the heightened scrutiny process moving forward.

I hope everyone can see examples in Friday's guidance where their priorities were incorporated and I am pleased that we have upwards of 1,000 people participating in today's call to learn more about the heightened scrutiny guidance.

So with that, I'm going to turn it over to Lance Robertson, the administrator for the Administration for Community Living and assistant secretary for aging and who has been a partner in this work with CMS. Lance, do you want to take it away?

>> Yes. Thank you, Mike. Thanks to you and Ralph. And I know for the Administration for Community Living, we are grateful for you allowing us to be a partner in the rules implementation and for saying a few words at today's webinar. The Administration for Community Living is committed to its ongoing partnership with the disabled and elderly health -- boy -- one more time. The Disabled And Elderly Health Programs Group, DEHPG, at CMS, providers, and our federally-funded networks, to ensure that the requirements continue to be implemented with integrity. The heightened scrutiny provisions continue to reinforce the key premise behind the HCBS rule that it should be focused on supporting individuals and settings that are truly home and community based. And in its continued commitment, we will continue to provide staff to support review of the plans and packages by states under heightened scrutiny. Additionally, we are committed to delivering more robust technical assistance aging and disability networks, who we recognize play a critical role in helping states system change and provider transformation efforts.

We also want to help continue supporting states in providing high quality HCBS, so older Americans and individuals with disabilities have supported to live, work, participate, and thrive. All of us benefit from the inclusion of older Americans and individuals with disabilities in our daily lives. Finally, we believe the future success state of HCBS system state efforts are largely dependent on the ability of advocates and other stakeholders to be meaningfully engaged in the process. We encourage state leaders to think creatively about how to enhance the participation of self-advocates, providers, and other stakeholders in the implementation of the federal HCBS requirements. Thanks so much. Ralph, turning it back over to you and Mike.

>> With that being said, we want to welcome everybody to the conference and we don't want to take much longer in the introductions. What we would like you to do is on an ongoing basis, as we continue the presentation, if you have questions, if you can put them into the chat line, we'll be prepared to go over them at the end of the call. But rather than wait until the end and try to remember what your issue was, if you can put it in while we're doing the presentation that may be helpful to you. Linda Joyce, are you on the line?

>> Ralph, I'm here.

>> Would you begin the presentation, please?

>> Absolutely. Thank you very much. We will clarify the process for assessing presumptively institutional settings. And review the latest frequently asked questions for guidance that replaces or supplements prior guidance affecting all presumptively institutional settings including the characteristics of a setting that isolates home and community-based beneficiaries from the broader community.

Next slide please.

In addition, we will articulate promising practices on how settings presumed institutional due to isolation of home and community-based services beneficiaries can comply with the regulations and we will review assessment compliance for private homes and residential settings when Medicaid only funds non-residential services. Next slide please.

So what is the impetus for issuing this guidance? As CMS continues to provide technical assistance to states and other stakeholders on ways to ensure compliance with the home and community-based settings criteria, CMS has received several requests to clarify the process by which states should identify and assess presumptively institutional settings.

There is a clear need for implementation guidance that recognizes states' decision making authority, while adhering to the regulatory framework from years of stakeholder engagement. The guidance provides a venue to articulate promising practices to assist states in determining how such settings that can ultimately comply with the regulatory criteria.

Next slide please. In its efforts to gather information, CMS heard from states that states wanted increased state autonomy in determining whether a setting is isolating. They wanted more concise criteria for what an isolating setting looks like so that states have a clearer sense of what to identify as an isolated setting. States wanted the ability to remediate settings to ensure compliance with regulatory criteria during the transition period without necessitating a CMS heightened scrutiny review or elevating the requirement for those settings that must undergo for compliance.

For reviewing the state's process for ensuring setting compliance by the end of the transition period, which is March 2022.

Next slide please.

CMS also worked with advocates to express the following: They wanted to assure that states have a process in place that identifies all presumptively institutional settings, including both residential and non-residential, and ensures that any settings remediation plans are actually implemented. They wanted the development of a meaningful and independent review of both states' processes for identifying presumptively institutional settings and of the individual settings that states submit as overcoming the institutional presumption.

They wanted assurance that the state utilized robust stakeholder engagement in the heightened scrutiny process, including a transparent and well-publicized notice and comment period coupled with

the process for how CMS will approach disagreements between states and stakeholders on settings that are presumed institutional.

Advocates also wanted to stress the importance the community has no single -L definition and a range of models and service options should be available to provide home and community-based services.

And they wanted to require state practices to describe how individuals actually engage and integrate in the broader community.

Next slide please.

In addition to working with states on the heightened scrutiny work group, CMS initiated a heightened scrutiny pilot project with Montana, Nevada, New Hampshire, North Dakota, Ohio, and Oregon. The purpose is to provide feedback on packages with residential settings that are located in a building that is also a publicly or privately operated facility that provides inpatient treatment, or in a building that is on the grounds up or immediately adjacent to a public institution. States received a feedback letter and summary of findings detailing what the state has done and still needs to do to demonstrate that the setting has or will overcome its institutional presumption.

I think we need to point out, too, that a concentrated effort was made in the pilot to ensure that the feedback letter and summary of findings provided enough detail to assist the state in gathering additional information needed to provide the evidence necessary to overcome the presumption. The major purpose was to streamline and understand what communications were most successful between CMS and the states. Next slide please.

Frequently asked questions, HCBS settings, regular implementation, heightened scrutiny guidance was issued on March 22nd of 2019. These FAQs can be found on the link that is noted on this slide.

Next slide please.

Under the heading heightened scrutiny reviews of presumptively institutional settings, question one asks "What types of settings are identified in the home and community based settings regulations as presumed to have the qualities of an institution to which the heightened scrutiny process applies?" The answer is the HCBS settings regulation describe three categories of residential or non-residential settings that are presumed to have the qualities of an institution requiring a heightened scrutiny review.

First, settings that are located in a building that are also a publicly or privately operated facility that provides inpatient treatment.

Settings on the ground up or adjacent to a place that provides treatment.

Next slide please.

Under the heading questions specific to settings that isolate home and community-based services, question two asks what are the characteristics of a setting that isolated home and community-based services beneficiaries from their broader community. CMS intends to take the following factors into account in determining whether a setting may have the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving HCBS.

Due to the design or model of service provision in the setting, individuals have limited, if any, opportunities for interaction in and with the broader community including with individuals not receiving Medicaid-funded HCBS. The setting restricts beneficiary choice to receive services or engage in activities outside of the setting, or the setting is located separate and apart from the broader community without facilitating beneficiary opportunity to access the broader community and participate in community services consistent with the beneficiary's person-centered plan.

Next slide please.

Please note that opportunities as mentioned in the previous slide means opportunities as well as identified supports to provide access to and participation in the broader community should be reflected in those individuals' person-centered service plans and the policies and practices of the setting in accordance with the regulation. States may identify additional factors beyond those included here. However, the state needs to clarify any additional characteristics of isolation so that stakeholders have a clear understanding of what the state considers isolating.

Next slide please.

So what the implications of this new criteria? There are no specific examples of settings that isolate, and all settings will be reviewed individually by the state to determine if they meet any of these factors and will be held under heightened scrutiny. Please note that this response replaces in totality prior guidance published on the criteria of an isolating setting under the relevant portions of the regulations. The criteria of an isolating setting have been revised and examples of settings that may have isolating effects have been removed. Please see the link noted on this slide to be aware of what guidance has been replaced.

Next slide please.

Question number three, under question specific to settings that isolate home and community-based services beneficiaries and does CMS expect states to submission information specific to settings located in rural areas for a heightened scrutiny review? The answer is settings located in rural areas are not automatically presumed to have qualities of an institution. And more specifically, are not considered by CMS as automatically isolating to HCBS beneficiaries. States should only submit a specific setting to CMS for a heightened scrutiny review if the setting has been identified as presumed to have the qualities of an institution and the state believes that the setting has overcome the presumption or will by the end of the transition period.

With respect to determining whether a rural setting may be isolating to home and community-based services beneficiaries, states should compare the access that individuals living in the same geographical area, but who are not receiving Medicaid HCBS have to engage in the community.

See question two that we just went over on slide 10 for the elements of an isolated setting, which states should use to apply for all settings where individuals are receiving Medicaid funding, home and community based services irrespective of geographic location. Next slide please.

CMS reminds states about their responsibility to enable persons with disabilities to be served in the most integrated settings appropriate to their needs. While Medicaid may be an important resource to assist states in satisfying their responsibilities under Olmstead, compliance with Medicaid requirements will not necessarily permit states to satisfy these responsibilities. CMS encourages states to review their operations to ensure they are enabling persons with disabilities to be served in the most integrated settings appropriate to their needs. Please note the above response supplements prior guidance given on this topic.

And you can review this in detail at the website noted on this slide and see specifically question 13 on page 6. Next slide please.

Under the heading questions specific to settings that isolate HCBS beneficiaries can a state bring a setting presumed to isolate into compliance without requiring heightened scrutiny?

Question four asks may states work with settings that are presumed to be isolating to bring them into compliance with regulatory criteria of a home and community-based setting without necessitating a heightened scrutiny review? The answer states the transition period for states to ensure provider compliance with the regulatory settings criteria in which a transition period applies extends to March 17th of 2022. Within that time frame, states should determine when to conduct assessments of settings to identify those that are isolating. If the state initially determines that a setting has the effect of isolating individuals and that setting implements remediation to comply with regulatory criteria to the

state's satisfaction by July 1st of 2020, then there will be no need to submit information on that setting to CMS for a heightened scrutiny review.

The settings, however, should be identified in a state's statewide transition plan for public comment and/or identified in information disseminated separate from the STP for public comment. And we'll talk more about that in question Zen and get some additional information.

So the CMS reserves the right to review any setting that the state has attested as remediating isolating characteristics. If the state receives significant public comment disagreeing with the state's assessment.

Next slide, please.

Now let's take a look at timeframes. As long as a state determines that an isolating setting can implement remediation before the expiration of the transition period, which is March 17th of 2022 and also determines that the isolating setting can achieve compliance with the settings criteria, states may also submit to CMS those isolating setting that have not completed remediation by July 1st, 2022. Those that have not completed remediation by July 1st of 2020 should be submitted to CMS within 20 days.

The transition period runs until March 17th of 2022, during which states may work with all existing HCBS providers to complete their remediation and be validated as fully complying with the setting criteria. Payment for these settings will continue until the end of the transition period.

CMS notes that states have discretion to rely on the July 1st, 2020 date in their work with providers and to submit packages for heightened scrutiny review prior to this timeframe. Next slide please.

Question five asks what are some promising practice to remediate settings that have been identified as being isolating to ensure compliance with the home and community-based setting criteria. CMS is collaborating with federal partners in the administration for community living to develop comprehensive sets of promising practices. In the meantime, CMS offers the following for state and provider consideration.

Increasing technical assistance to assist states to transform the long-term services and support systems to fully implement person-centered thinking, planning, and practices. Increasing engagement with the broader community by developing partnerships and alliances with generic community-based entities that result in inclusion of HCBS beneficiaries in the broader community available to all community members.

And establishing a community-based advisory group to help identify and design new models and strategies for the setting to expand its individualized service offerings and increase greater access to activities in the broader community.

Next slide please.

States and providers can also consider implementing a broad range of services and supports, programming, and multiple daily activities to facilitate access to the broader community that allows for each individual to be able to select from an array of individual and/or group options and control their own schedule. Such activities should promote skill development and facilitate training and educational opportunities among home and community-based services beneficiaries designed to attain and expand opportunities for community-based integration including volunteering, social and recreational activities, and competitive integrated employment.

Expose beneficiaries to community activities and situations comparable to those in which individuals not receiving HCBS routinely engage.

Next slide please.

States and providers can also encourage families and friends to participate regularly in activities with the beneficiary on site as well as in the broader community and/or promote greater home and community-based services beneficiary independence and autonomy.

Another promising practice might be implementing organizational changes that assure the required level of support including appropriate staffing and adequate transportation options to offer both group and individualized options that facilitate optimal community engagement based on individual preferences as articulated in beneficiary centered service plans. And, next slide, decentralize staff structures to promote flexibility and encourage staffing focused on individual's access to and participation in the broader community, rather than centralized, insular staff models focused around a specific facility or site. Or states can consider expanding strategies for increasing beneficiary access to transportation, including through existing public transportation friends and family and volunteer organization to activities in the broader community.

This could include providing transportation in a way that promotes ease of access and optimized individuals' ability to select their own options and make decisions about their services and supports.

Next slide please.

The next area of questions specific to settings that isolate HCBS beneficiaries focuses on HIPAA-related privacy concerns when soliciting public input for settings that isolate.

Question six asks when soliciting public input on settings the state has determined to overcome the presumption of isolating individuals receiving HCBS, are there HIPAA-related privacy concerns that states should consider?

The health insurance portability and accountability act, or HIPAA privacy rule restricts covered entities such as state Medicaid providers from publicly disclosing public health information referred to as PHI without the authorization of the individual unless disclosure is expressly permitted under the rule.

Examples of PHI include home and community-based services beneficiary's name and health condition. The state should not include any personally identifiable information of beneficiaries in submission of the STP or in any notifications or information disseminated to the public. Next slide please.

Under some circumstances, information about a particular setting including the name and address may constitute protected health information if it relates to the past, present, or future physical or mental health or condition of an individual, the provision of healthcare or payment or care, and there is a reasonable basis to believe the information can be used to identify the individual.

Next slide please.

The addresses and locations of settings that are either on the grounds of or adjacent to public institutions or in buildings that provide inpatient institutional treatment are typically known to the general public. But the same may not be true for settings that may have been evaluated by the state as overcoming the institutional presumption of isolating individuals receiving HCBS. Although individual circumstances and recognition of each setting will vary. While recognizing the need for public input, states must also adhere to applicable federal and state laws and regulations protecting the privacy of individuals receiving home and community-based services. Next slide please.

Question six also considers CMS guidance for disclosure of information on settings that isolate. CMS recommends adherence to the following guidance for disclosure of information regarding settings identified as overcoming the institutional presumption of isolating individuals. To the extent possible, states are encouraged to disclose generalized descriptions, not including names or addresses of the settings of how a state determines that a presumptively -- should overcome that presumption.

The state should consider whether the information about the setting will be publicly disclosed is protected health information as defined by HIPAA based on the circumstances of each setting and the individual served by that setting.

The outcome of such a determination will be fact specific and will vary across settings. Next slide please.

If the information is determined to be PHI, the state can take one of the following steps to address HIPAA compliance. It can remove all 18 identifiers described in 456FR Section 162 part B2I including address and other geographic subdivisions smaller than a state and show that the state has no

knowledge that the information can be used to identify the individual before publishing the comment solicitation. He referred to the website noted on this slide to read more information about this.

Next slide please.

Another step the state can take if the information is determined to be PHI is to receive an authorization of every resident from the setting granting permission. In circumstances where state, local, or other law requires a state to disclose PHI, such disclosures are permissible under the HIPAA privacy rule. Next slide please.

Now let's take a look at stakeholder's notice and comment on settings that isolate. Question seven asks to what extent may stakeholders receive notice and provide comment about the state's intention regarding a setting determined to overcome an institutional presumption of isolation. The state may notify the individuals living in or receiving non-residential services in the setting in question. And if permitted by applicable law may also notify family members and guardians identified in the individual's person-centered plan in the following. That the state has determine that had the setting overcomes the individual presumption of being isolating. The state's justification for that determine in addition which is outlined below in number eight, and how these individuals may offer comments in response.

Next slide please.

To the extent the information is not protected health information, the state may notify primary aging and disability rights advocacy organizations in the state of the justifications described on the previous slide.

These organizations may include, but are not limited to, protection and advocacy organizations, developmental disabilities councils, university centers of excellence on disabilities, area agencies on aging, aging and disability resource centers, centers for independent living, long-term care ombudsmans, and service coordinators, and advocacy organizations that include HCBS beneficiaries within their membership.

Next slide, please.

To the extent the justification includes protected health information in compliance with HIPAA, the state may provide the justification to external entities when the disclosure of PHI to those entities is required by law or whether the disclosure is to a health oversight agency.

States may disclose this information including the address of a stating to a state designated protection and advocacy organization required by law or to the long-term care ombudsman requesting that information for oversight activities.

Next slide please.

In compliance with applicable laws, any non-personally-identifiable information related to a presumptively institutional setting may be made available to the beneficiary or any other third party upon request.

The statewide transition plan should publicize an e-mail and mailing address for submitting requests of this information. Please note the above response replaces prior guidance given on this topic to account for HIPAA implications. So please see question eight on page 7 of the website noted on this slide for more information.

The implication of HIPAA requirements on soliciting stakeholder information, the first determination to states due to publishing the address of a setting the state believes overcomes the presumption of isolation would include PHI. The state should consult the HIPAA officers to implement a process to implement these provisions and should communicate this to stakeholders.

Next slide please.

Now we're going to talk about questions pertaining to all presumptively institutional settings. The first topic is information for public comment.

Question eight asks what information should a state provide during the public comment on settings that the state has considered for heightened scrutiny review. The following information should be considered for public input during periods of public comment in compliance with the provisions that we just talked about.

Strategies falling into any one of the three categories. That is any setting that is located in a building that is also a publicly or privately operated facility that provides in-patient institutional treatment or in a building on the grounds of or immediately adjacent to a public institution, or any other setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS.

In addition, the state should disseminate the state's approaches to reviewing settings flagged as being presumptively institutional as well as how the state will use public comments to inform its review and how the state has or will determine whether a setting overcomes the presumption that it is an institutional setting. Next slide please.

The state should also disseminate a numbered list of settings identified for each category of settings that the state believes overcomes the presumption that the settings are institutions.

So for example, adult day centers inside a nursing facility or group home on the campus of a public ICF/IQ, or a setting that the state has identified as isolating.

The list should also identify the presumptively institutional category that each setting falls into for heightened scrutiny. And include a summary of how each setting has or will overcome the presumption that it is an institution. And include the state's plan for oversight of remediation to ensure compliance with the settings criteria by the end of the transition period, which is March of 2022.

Next slide please. It should include a list of settings that the state believes should not overcome the presumption during the transition period, and thus may not receive Medicaid funding after the transition period.

A list of settings, if any, that the state previously identified as presumptively institutional due to isolation, but identified compliance by July 1st of 2020, along with a statement that information for remediation of those settings is available upon request, and the process for applying CMS feedback on specific settings to similarly situated settings, which we'll talk about in greater detail in question nine.

Next slide please.

Additionally, CMS requests that when states publish information related to public comment that they send the public links to the CMS statewide transition plan team as soon as the public comment period begins. Please note that the above response on this and previous slides in question eight replaces prior guidance given on presumptively institutional settings as described in the regulations. As states are no longer encouraged to identify the number of individuals receiving services at each setting.

So please refer to the third bullet of question eight, which is referenced on slide 33 and on the website noted on this slide.

Next slide please.

So now let's look at questions pertaining to all presumptively institutional settings with a focus on CMS's review of heightened scrutiny requests. Question nine says how will CMS review state requests for heightened scrutiny of settings that the state believes overcome the presumption of having the quality of institutional settings.

Based on conversations with our state partners, CMS understands that a sizable number of requests for heightened scrutiny reviews could be submitted by states to CMS throughout the remainder of the transition period. In response, the agency is implementing the following review strategy. Choose a numbered list of settings identified for each category of presumptively institutional settings as discussed in a previous slide will be made available to CMS. Excuse me.

CMS strongly encourages states to submit information on settings located in the state building, as a public or private institution or located on the grounds of or adjacent to a public institution by March of 2019 or as soon as possible.

Of

Information on isolating settings should be submitted no later than October of 2020. Next slide please.

CMS will use the list provided by a state to compile a random sample of settings to the review. The review sample will also include any setting the state requests CMS to review and any setting that generated significant public comment in opposition of the state's assessment. CMS are review also information presented by the state and other parties on settings selected for the review sample, and will either approve the state's assertion that the setting overcomes the presumption that the setting is an institution, or provide the state feedback on missing information, questions for clarity, or reasons why CMS cannot agree that a setting overcomes its institutional presumption.

States will then have the opportunity to provide the additional needed to support their assertion before a final determination is made by CMS.

Next slide please.

Based on the process described in the state's statewide transition plan on how CMS feedback on a particular setting will be applied to similarly-situated settings, the state will use the CMS feedback to remediate settings that have the quality of an institution not included in the CMS review sample.

CMS will make final heightened scrutiny review determinations of each setting in the sample available on the Medicaid.gov HCBS website.

Next slide please.

CMS may request to review additional settings and/or suggest changes to the state's heightened scrutiny review process if the sample review highlights concerns with the state's approach for assessing presumptively institutional settings.

CMS may also request information on any setting for which the state received public comments that the setting was presumptively institutional. Please note that this response supplements prior guidance given on this topic to review the process that will be used to review institutions.

Please see question 10 on the website noted on this slide for further information.

Next slide please.

The next question pertaining to all presumptively institutional settings focuses on evidence selected for the review sample. Question 10 asks this. When submitting a setting for heightened scrutiny review, states should provide evidence for how a state has determined that it has overcome the presumption that it has the qualities of an institution.

Information should focus on the qualities of the setting and how the setting is integrated in and supports access of individuals receiving HCBS into the broader community via the organization's policies and procedures as well as in how the setting supports individuals consistent with their person-centered service plans.

The exploratory questions available in the tool kit found at the link in this slide can also be helpful in determining the type of information that should be included in the documentation. Next slide please.

Some additional examples of information the state might include are a description of the proximity to and scope of interactions in and with the broader community which can be demonstrated by mechanisms such as a description of the state's review of a sample of individuals' daily activities. Person-center plan and/or interviews to determine that there is variation in the scope, frequency, and breadth of individual beneficiary interactions and engagement in and with the broader community.

Please note while there is no number or percentage of individuals that states must sample in this context, states should demonstrate a sample size sufficient to obtain data that is representative of the overall experiences of individuals in the setting.

Next slide please. States could also include a copy of the procedures including, for example, the types of activities, transportation, and staffing that are in place, and services provided by the setting that indicate evidence of access to and demonstrated support for beneficiary integration in community activities in the broader community consistent with individuals' person-centered service plans.

It can include a description of processes in place or actions taken by direct support professionals to support, monitor, improve, and enhance individual beneficiary integration in and with the community over time.

And they can provide a summary of examples of how individuals are varied according to individual beneficiary's preferences and recognition of the need to integrate into the local community at times when the general community attends an activity.

Next slide please.

And you can also include procedures that are in place to routinely monitor individual access to services and activities to the broader community to the extent identified in person-centered service plans. States can include a description of how staff are trained and monitored on their understanding of the settings criteria and the role of person-centered planning consistent with state standards as described in the waiver or state plan amendment or in community training policies and procedures established by the state.

Or the state could include a description of the settings proximity to public transportation or how transportation is facilitated.

States can include attestation that the state has reviewed settings and concluded during observation made during an onset visit or a sample of interviews or a review of person-centered service plan any modifications to the settings criteria or in the person-centered service plan as required by the regulation.

Again, please note while there is no number or percentage of individuals that states must sample in this context, states should demonstrate a sample size sufficient to obtain data that is representative of the overall experiences of individuals. This describes the sample size that the state should attest to.

The state can also include a description of the settings remediation plan by the end of the transition period along with the state's oversight to ensure compliance of actions and a summary of other description of stakeholder comments received in response to the state's solicitation of public feedback.

And other information the state deems helpful to demonstrate that the setting overcomes the institutional presumption such as photos of the setting, but not including beneficiaries or other identifying information, attestation that the setting has been selected by the individual from among settings options including non-disability specific settings.

And please note again that this response replaces prior guidance given on this topic to streamline the suggested content of information submitted for a heightened scrutiny review.

So please see question three at the link shown on this slide for more information.

Next slide please. The next piece of guidance pertaining to all presumptively institutional settings refers to some general considerations.

The person-centered planning process should not be limited to consideration of services and supports covered solely under a particular Medicaid funded HCBS authority, which should also include potential natural supports, external resources, or other funding vehicles available to meet individuals' needs separate and distinct from Medicaid home and community-based services.

However, the agency also acknowledges parameters around the scope of services authorized under each state's HCBS programs that providers of HCBS settings must operate within. So, for example, CMS notes that nothing in the HCBS settings regulation requires a setting in which HCBS are provided to finance recreational activities in the community on behalf of Medicaid beneficiaries.

Next slide please. CMS seeks to strike a balance between supporting individuals in accessing and participating in the broader community with available HCBS resources noting that it is not sufficient for HCBS to solely or primarily bring people from the broader community. Rather it's the expectation that through operational policies and practices HCBS settings are also offering meaningful activities and opportunities for individuals receiving services to interact with a community outside of the setting, supporting individuals consistent with their person-centered plan. Heightened scrutiny under 1915C or 1915I of the Social Security act, such information should also include the information the state received during the applicable public input process.

CMS will also consider information provided by other parties. For 1915K, community first choice programs, information should be submitted as part of the state's request for heightened scrutiny for any such settings included in the CSC state plan amendment. Next slide please.

Another question pertaining to all presumptively institutional settings concerns -- hello?

I have an interruption in power here. Can you hear me now?

>> Yes, Linda, we can. Thank you.

>> Okay. I apologize everyone. Let me start again. And I'm on slide 48. Another question pertaining to all presumptively institutional settings concerns CMS's monitoring of these settings to ensure compliance by October of 2022. Question 11 asks how will CMS monitor settings identified as presumptively institutional to ensure adherence to regulatory criteria by the end of the transition period. CMS intends to utilize different mechanisms to ensure the settings presumed to be institutional are compliant with regulatory home and community-based settings criteria by the end of the transition period.

A key component of a statewide transition plan is a description of the process the state will use to ensure identified remediation is completed for all settings presumed to have qualities of an institution.

The description of this process within the STP should also include an articulation of the steps and associated timelines for bringing providers into compliance with the regulatory criteria. CMS will refer to this process when discussing ongoing monitoring with the state throughout the transition period.

In addition, as mentioned in the response to question nine, states should also include in the information submitted to CMS as part of a heightened scrutiny review of a particular setting, a discussion of how the state will monitor that setting to ensure completion of remediation. The state will identify milestones for the completion of activities to bring the setting into compliance and report to CMS in an agreed upon schedule on the progress toward achieving those milestones.

Next slide please.

Now let's turn our attention to a question pertaining to other topics. The first assessment of compliance for private homes.

Question 12 asks what kind of compliance assessment with the home and community-based settings criteria does CMS expect of states for private residences?

Individual, privately owned or rented homes and apartments in which the individual receiving Medicaid-funded HCBS lives independently or with family members, friends, or roommates are presumed to be in compliance with the regulatory criteria of a home and community-based setting.

CMS clarifies that states are not responsible for confirming this presumption for purposes of ensuring compliance with the regulation. States should, however, include private residences as part of their overall quality assurance framework when implementing monitoring processes for ongoing compliance with the federal HCBS requirements.

Next slide please.

States should also include private homes in any oversight provisions articulated in their approved home and community-based services waivers or state plan amendments such as activities to ensure the health and welfare of individuals.

Also, settings where the beneficiary lives in a private residence owned by an unrelated caregiver who is paid for providing HCBS services to the individual are considered provider owned or controlled settings and should be evaluated for compliance with the settings criteria.

The above response supplements prior guidance on this topic. Please see question three on page four on the link noted on this slide. Next slide please.

Another question pertaining to other topics focuses on compliance only required for Medicaid funded HCBS. Question 13 asks should Medicaid beneficiary reside in residential settings that comply with the home and community-based settings criteria even if Medicaid is only funding non-residential services for that individual?

CMS is clarifying that states are responsible for ensuring compliance with the home and community-based settings criteria for those settings in which Medicaid beneficiaries receive HCBS. If Medicaid is only funding non-residential HCBS for an individual, then the state is not responsible for ensuring compliance with the settings criteria in the setting in which the individual resides.

However, a state may decide to require beneficiaries receiving Medicaid funded non-residential HCBS to live in settings that meet the federal home and community-based settings criteria, even if the individual does not receive HCBS in that setting.

So I would now like to refer you to the next three pages of resources that we hope will be helpful to you as you review these FAQs, and then Anthony I think we can open up the chat room for questions and answers from CMS. Thank you all very much.

>> Linda, thank you.

>> You're welcome. I'm sorry for the interruption. I don't know what happened.

>> That's quite fine. Things happen. Anthony, are you on the line?

>> Ralph, this is Christa. Are you ready for us to read the question?

>> Please.

>> What happens to settings that are not selected for CMS review?

>> What CMS is doing is picking a sample and reviewing the state's process to determine if we believe their process for recognizing a setting overcoming any institutional presumption is a good process and holds firm. If it holds firm, then the other settings that the state has submitted as long as it meets the same criteria as the sample we've looked at will be, will have met the requirement of overcoming the institutional presumption.

>> And this is Melissa Harris. I would add onto that, that in the state's statewide transition plan or in an addendum to that document, the state will be describing its process for how it will be accepting CMS's feedback on the settings that we do sample, and then applying our feedback to similarly situated settings. So for example, if we pull as part of our sample a nursing facility or an assisted living facility that is part of a nursing home and we provide feedback to that setting including some additional remediation that setting needs to take, we would then expect the state to apply our feedback to all of the other assisted living wings located in a nursing home, including paying special attention to the remediation that we had asked for. It is part of the process that the state will be describing in the statewide transition plan and part of the application of the specific feedback we have provided to the specific settings we did poll in the sample.

>> Thank you, Kristin.

>> How are new settings applying for waiver participation that require heightened scrutiny to be addressed?

>> Currently, if it is a newly constructed setting, the state will submit a heightened scrutiny application if they believe the setting overcomes the presumption. CMS will be further looking into identify additional information that may be helpful to those of you on the line. In the interim, though, you would submit new construction as a separate application. They do not fall under the transition period. They were not functioning and rendering services to individuals as of March 17th of 2014.

>> And it's important to note that CMS is only going to be reviewing new construction of settings that fall into one of the three categories of being presumptively institutional.

>> Yeah.

>> And it's going to be pretty clear cut if a new setting on the grounds of or adjacent to the institution is being built or a new setting inside a setting is being built. For the third category, that of an isolating setting, we all need to be sure to provide Friday's new criterion of isolation in determining whether it will need to come forward to CMS. I think we'll all be interested to see the practical implications of how the criteria that is how defining an isolating setting is put to use when we're talking about a setting that is being newly constructed. Certainly we would expect buildings and builders and states to be mindful of the settings requirements and the criteria of an isolating setting as new settings are being built, so there is effort taken to avoid the new construction of what would require heightened scrutiny because of isolation. So it's important to kind of pay attention to the guidance that we issued a couple of years ago, which is on our Medicaid.gov website, but view it through the lens of Friday's guidance, which did change the landscape particular of isolating settings.

>> Okay.

>> We would say here that that is a discussion that first should be had between the stakeholders and the state itself. I would not opine on the type of settings that are in Washington. I don't live there. I would expect the state to apply due diligence and for the stakeholders to use the public comment period to comment and discuss with the state any concerns.

>> This is Melissa. The other thing that I think is worth saying is that heightened scrutiny tends to take up an awful lot of attention. But the real goal of all of this is to make sure that all of the settings are compliant with the regulatory criteria of a home and community-based setting. And so it's one exercise to determine if a particular setting falls into any of the three categories of being presumptively institutional. Even if it doesn't, that certainly doesn't exempt that setting of meeting the requirements of the regulation. So regardless of whether heightened scrutiny is in the future of a particular setting, that setting should be assuming it's an existing setting right now, should be taking advantage of the remaining time in the transition period to ensure that it is compliant with the regulatory criteria by the end of the transition period, March 2022. And even some of the settings that are not presumptively institutional might have considerable work to do to become compliant. All providers should be working with their states and their stakeholders to develop a plan to ensure that compliance, whether or not heightened scrutiny is required.

>> What if the changes the state is requesting you to do will increase the possibility for isolation?

>> It's an interesting question. We have not seen that. Practically speaking. Or experienced that in CMS. I assume that the individual asking the question has seen, has some remedial plan with the state. I can tell you that to date the remediation plans that we have approved all move toward ensuring that the setting is fully integrated into the community and offers a home-like environment to the individual. If you have concerns regarding how that is being done, I would suggest that you first review the statewide transition plan to ensure that the remediation that you are being asked for is the type of remediation that is outlined in the state-wide transition plan. That would be my first step, the second step would be a discussion with the state. There is an HCBS mailbox where you can send concerns, but I would urge you to have a discussion and to have a followup discussion with the state and to be fully cognizant of what is in the statewide transition plan before you take that step.

>> How does CMS define institutions when starting on the grounds of an inpatient institution?

>> The regulatory language talks about intermediate facilities for individuals with intellectual and developmental disabilities. It talks about hospitals. It identifies nursing facilities, and it identifies institutions for individuals with mental health disease as institutional settings.

>> Where states have a financial or policy interest in supporting placements that overly isolate, how will deference to state review be subject to review by CMS?

>> Well, I think here the answer is in the fact that the statewide transition plan must go out for a 30-day public comment period. And that is where if the stakeholders truly believe that the state is in fact supporting settings that don't comport with the home and community-based service requirements, and that is both for settings that are in the presumptively institutional and any other settings. It is both your right and responsibility to address that with the state during the public comment period. I can tell you that CMS reviews a summary of the public comments. We also to date have reviewed all public comments on statewide transition plans. So I can tell you that your concerns will be heard both at the state level and a federal level. The one thing I would urge you not to do is to remain silent during the STP process, the statewide transition plan process, and contact CMS after the fact. One of the powers of the regulation is the fact that it requires and endorses stakeholder involvement directly with the states. You folks are the most knowledgeable about what is going on in your state and your states are the most knowledgeable about how they've set up their systems. So we would strongly urge you to use the comment period to your advantage.

>> Where can we find if we're on the list of presumptively institutional settings? Will agencies be notified if due to this guidance the provider is no longer considered institutional?

>> I'm a little unclear about the question. So I'll answer what I think the question is asking. The settings will be identified in either the statewide transition plan or the addendum that addresses heightened

scrutiny. The settings that are on the grounds of or adjacent to a public institution as well as settings in the same building as a private institution will be clearly identified. Addresses will most likely be in those descriptions. The settings that fall under settings that isolate must comport with the HIPAA requirements. If you have any concerns about whether you have been identified or not, I would be contacting the state itself to ask if I were included in that list. If the state doesn't have a practice of notifying you up front.

>> Theoretically, I mean if you're a provider that falls under either of the first two categories as presumptively institutional based on the location of the setting, you'll know that you automatically require heightened scrutiny based on your location and relation to an institution.

With the release of Friday's guidance, whether or not you are a setting that would require heightened scrutiny for isolation is worth another conversation with the state. You may have had prior conversations with your state in the past and maybe the state has flagged that you would require heightened scrutiny due to isolation. It's worth now that the states are digesting the FAQ, it's worth a conversation with them to say what's your strategy going forward and so everyone is on the same page whether heightened scrutiny will be required. Again, regardless of whether a setting needs heightened scrutiny, a setting should always be working towards compliance with the regulatory requirements.

>> The only other thing I would say is CMS is more than prepared to have a discussion with the state if they want to amend or change information that they have previously given on settings that isolate, particularly those settings that they believe are already remediated and no longer isolate and meet the regulatory requirements.

>> Is it CMS's intention that settings that also provide residential services for children and are licensed to provide those services are automatically considered institutional?

>> I think that we can clearly state that we have set a criteria for home and community-based services. Children certainly have been funded in residential settings that don't meet the definition of institution included here or the definition of settings presumed to be institutional and therefore could clearly fall under the category of home and community-based services. That is a state decision. But CMS certainly did not limit home and community-based services to services only for adults.

>> So there would need to be an assessment of a particular setting to determine whether it falls into any of the three categories of being presumptively institutional. It certainly could fall into one of those three categories. Just because it serves children doesn't mean it can't be presumptively institutional. It also doesn't presumably fall into one of those categories, so it really is a setting by setting assessment that the states will need to do.

>> In Florida, the state identified settings as presumptively institutional based on previous information. Based on this new guidance, many of those settings are no longer presumptively institutional. If by the new standards these campuses are no longer presumptively institutional may providers be allowed to build new settings on these campuses?

>> That's a discussion that is best had with the state. Clearly, since 1981 when President Reagan signed Section 1915C into the Social Security Act, the providers in the settings where services were rendered were under the discretion of the state. So that would be a state decision if the state determines that the settings do not fall under the presumption. A conversation certainly can be had with CMS. But I think that is, that I would not presume to take away that decision from Florida without the discussion with the state and the stakeholders happening first.

>> Given the new milestones for heightened scrutiny submission listed in the guidance, should states revise any milestones previously submitted on their heightened scrutiny steps?

>> I would say that's a state by state discussion and it depends on what is in the milestones. In some cases the answer will probably be yes and in other cases it may be that it didn't move the dial a little.

>> I would assume the issue most likely to come up would be whether or not a state would want to take advantage of the July 1, 2020 to potentially remediate settings into compliance if they were flagged as being isolating in an attempt to avoid heightened scrutiny. That process would not have been built into the state's planning prior to the release of this the guidance. So I think it's fair to say that states are making those decisions now about how to move forward even with an approved statewide transition plan that might have outlined a particular process with particular timeframes.

So any state that does want to make an amendment or make a change to something that was already in a statewide transition plan, whether it's received final approval or not, can certainly come talk to us (coughing) excuse me, we're not looking to make the process of updating a policy onerous at all and it would not impact the final approval of those states that have final approval of a statewide transition plan, but it's fair to say that a state may want to take that into account. But we're open to business to have those conversations with states in that regard.

>> And the only other thing is we would be remiss not to remind everyone on the call that because the state doesn't have to submit settings that isolate until the 2020 date does not mean the state cannot get final approval of their statewide transition plan this year or at any time before then. That is a process that they would include in their statewide transition plan, but final analysis does not have to be there in order for us to approve the plan. That is important for states who want to keep moving in their work.

>> What financial support is available to providers to enable them to provide enhanced training and financial transportation options?

>> I think that question is a question that needs to be answered at the state level.

>> Is the guidance in question six and seven stating that public notice and comment for a particular setting should be targeted to those people who live in the settings and/or use the setting during the day?

>> I have to tell you, the answer is yes. It can be either or both. If it is a residential setting and it falls under the assumption that people are living there. If it is a day living facility, where individuals attend, but they don't live, then they would be included in this. So the answer is we didn't exclude either from the discussion when we wrote six and seven.

>> Those are the questions that detailed the HIPAA requirements and it's also important to understand that HIPAA has some particular implications with regard to settings that isolate. As we indicated in the FAQ, settings that are on the grounds of a public institution or in the same building as a public or private institution are typically already known to the community as a place where individuals are receiving long-term services and supports. And so there is not the same concern about privacy violations for those types of presumptively institutional settings.

So we're really talking about settings that isolate when we list out all of the HIPAA requirements and we certainly recognize that that is new information and we will all be looking to the state HIPAA compliance officers to issue their operational strategy for implementing or how this guidance will be taken into account moving forward.

>> If the state offers multiple waiver-day service options, would there be a presumption of isolation if the provider mixes those services to offer integrated community opportunities such as shopping, attending classes, or recreational events on two or three days per week, then providing site-based services on the alternate days?

>> CMS is not opined at that level. That is a state decision.

So I would be working with my state to clarify that if that is indeed a question internal to your state.

>> Will states need to check these settings going forward for heightened scrutiny even if programmatic operational compliance is achieved during the transition period?

>> Read that again, please?

>> Will states need to track these settings going forward for heightened scrutiny even if programmatic/operational compliance is achieved during the transition period? So March 2022.

>> Yeah, what I will say to you is this. One of the important pieces of all of the statewide transition plans is the state's monitoring activity to ensure that settings remain in compliance and don't fall out of compliance. So I would say that a proactive state and a reasonable state would have a process for tracking all settings on an ongoing basis to ensure they remain in compliance.

>> And one of the things that we articulate in the FAQs, and again we're talking about isolating settings. So for such a setting, at some point in the transition period met one of those criteria of isolation has remediated in the compliance by the July 1, 2020 date. And such that they don't have to come to us for heightened scrutiny, the state is expected to still be maintaining like a list of those settings not only to ensure that they are a part of the state's ongoing monitoring options, but we did indicate that they should be having some kind of conversation with their stakeholders through their statewide transition plan, through some external documents and again looking at that through the lens of the HIPAA provisions, there needs to be some kind of discussion with their stakeholders about how the state has made those decisions and on particular settings. It is a two-pronged answer. Even if the setting does not have to come to CMS for heightened scrutiny, it needs to comply with the reg and the state needs to make sure it complies with the reg in the transition and ongoing and have a process to communicate how they will do that with their stakeholders.

>> And when you think about that logically folks, states will be addressing licensing certification requirements, how case management actually makes observations on site. So there are a lot of regular contacts that the state already has with these settings that could easily be used to ensure that this monitoring is incurring on an ongoing basis.

>> Will CMS offer greater weight to resident feedback or those served by the setting over the public comment of those who ideologically disagree with the program type or provider?

>> You know, it's an interesting question. On the one hand stakeholder feedback is stakeholder feedback and we try not to, you know, parse out what type of stakeholder we're hearing from. Certainly, though, you know, we want to hear from individuals that are receiving services at a particular facility. And again, looking at the settings that isolate, it could be that individuals who are receiving services there have a better opportunity to opine to the state on their experiences because again of those HIPAA provisions. They certainly impact the amount of specific and identifying information that a state can send out for broader stakeholder comments. It's kind of a yes or no response. We don't want to necessarily be saying someone's voice counts more than someone else's voice. But certainly to the extent we're talking about a particular beneficiary who is receiving services at a setting that is being identified as presumptively institutional it's critical to hear from you on whether your experiences support the assertion that the setting overcomes its institutional presumption, or whether your

experience does not support the assertion that the setting overcomes its institutional presumption. To say that we want to hear from you is an understatement.

>> I would also say simply by process inside the state in order to assess the setting to determine if the individual's life experience supports the determination that home and community-based characteristics are being met. That is probably the first touch point the state will have with regard to the settings that are presumed to be institutional. So obviously the input of the individuals who are in this setting will have weight.

>> It is unclear whether the state is expected to submit evidence for each heightened scrutiny setting or only those in the random sample selected. Or do we have to collect evidence for every setting subject to heightened scrutiny and have it available upon request?

>> States should have assessed their settings and then given us a list that follows the process that we've given. We will pick from that a sample and the state will send in those, the evidence they have from the sample. We wouldn't be expecting a state to give us a list, us to give them the sample we selected and then to begin the process of assessing. The states should already know if they're sending it in for heightened scrutiny that they believe the setting has overcome the institutional presumption.

>> Right. And to do that, we'll have required the state to do an assessment. There are various ways the state can do that. It doesn't all have to be done using the same mechanism. But the state's description to us of how that setting overcomes its institutional presumption is the crux of what CMS will be reviewing.

>> Will the physical location of the facility, example, adjacent to a nursing home, will it have an impact on the compliance with the federal rule?

>> Only in this manner. If it meets all of those characteristics and on top of it has layered institutional characteristics there will be an issue in the state. That shouldn't be happening if it meets all of the requirements of the setting.

So I would say practically speaking the answer would be that if it meets all the requirements the fact that it is co-located simply means that it was a setting that fell under the presumption and that the information and evidence that it meets all the requirements should be submitted is part of the heightened scrutiny package.

>> And if it really meets the reg, the state won't have a problem describing that in the package and CMS shouldn't have a problem adjudicating it to confirm that it does overcome its institutional presumption.

>> Okay, what is the size of the random sample?

>> That's going to depend. The sample that CMS will be pulling anyway will be based on the universe of setting that a particular state has. This plays out operationally. We have asked states to send us first settings that fall into the first two categories of presumptively institutional settings.

We will have a universe of those settings from which we will select our sample and as we indicated in the FAQs, the state can ask us to take a look at some of those settings and we will. We will select as part of the sample those settings that had some particular stakeholder input that took issue with the state's assessment. And then among the remaining services or, sorry, the remaining settings from that state, we would select a sample of what's left. And so there's no standard number, because the number of settings that comprises the universe will be different across the board. So our goal is to make sure that we have selected enough settings for the sample, that we have confidence that we've got a good understanding of the state's process for assessing presumptively institutional settings such that the settings that we don't review in the sample will have been assessed by the state in the same way, and to the extent we've got feedback for the state on ways to improve their process or additional remediations that the settings in the sample needed to make, we have confidence in the state's process for applying that feedback to the rest of their settings that we didn't sample. So it's not a hard and fast standard. It will be very state specific.

>> Nor could it be when you think about it. You may have a state that has heightened setting that fall under the presumption that are only residential in nature and only of a specific type. You may have another state with four or five different types of settings, both residential and non-residential, that fall under the presumption. So what we would pull as a sample from those two would be by the nature of what is given to us be a different type of sample.

>> What are the appeal rights for providers that are not part of the random sample but have remediation requirements assessed based on being a similarly situated setting?

>> Again, I think that that is a state-specific question. As I've said before, the states have always had the ability to select the providers. And the settings that will participate in the program. So this is an area where strong relationships between the stakeholders and in this case the providers, but all stakeholders in the state will be paramount to determining this answer.

>> Some usage of EVV creates isolating settings. Is there guidance as to how EVV should be used and not be used to prevent isolating situations?

>> Well, that's a fascinating question.

>> Yeah.

>> And it invokes several things that luckily this group of people is working on. So electronic visit verification is a congressional requirement to implement such an electronic visit verification system for Medicare-funded personal care visits starting in January of 2020. It is a frequently provided home and community-based service that would be provided for in the rule.

There is a statement that nothing about EVV usage should implement how services are being provided. Certainly we know that personal care services are provided in many different ways across Medicaid and across the HCBS authorities, which are under the settings regulation, including agency-directed programs, self-directed programs, and so part of the responsibility for all of us implementing EVV is to make sure the systems do what the statute requires it to do, but also is nimble enough to still facilitate beneficiary autonomy and respecting all the differences across all the different personal care services models.

So certainly we don't anticipate any kind of real inability of the settings rule to be met or the settings criteria requirement to be met for personal care services requiring electronic visit verification. It's a good reminder that CMS as we're issuing guidance on EVV should be mindful of the settings requirements expectations that individuals are able to engage in their community as they see fit. Certainly our expectation with EVV is nothing around EVV implementation should be jeopardizing that kind of community integration.

>> And we would also note that even in this basic discussion, it would only if you felt there was an impact in your state, should be of residential settings. There is also a strong requirement for stakeholder involvement with regard to EVV. So I think when you couple the two together, you should certainly have enough of a venue to communicate any concerns to your state.

>> What is CMS's time line to begin conducting reviews once evidentiary packages are selected? When will they start the review and communicate their findings?

>> We started with a pilot and we'll be contacting the states where we conducted the pilot. From that, we will begin to move to other settings that have to give time for the states to determine if they want to withdraw or make adjustments to what they have submitted. But our intent is to begin to look at as Melissa said earlier several times the settings that fall under the first two categories. Settings in the same building as or adjacent to or on the grounds of as quickly as possible.

>> We recognize that the guidance says we would appreciate states sending those in on the first two categories by March 2019 and we released the guidance in late March of 2019. That is under the it is what it is category. But we certainly recognize the reality of where we are. And we'll be working with states to try to facilitate submissions to us as quickly as possible. But obviously we understand that that

will take some time. And so our commitment is to start employing the processes that we laid out in these FAQs as quickly as possible. And our goal is also to be as transparent as possible. So we will be using the [Medicaid.gov/HCBS](https://www.Medicaid.gov/HCBS) website as the location of all of our communications on individual settings and we encourage you to check back there as time passes to see the various status of our communicate with dates.

>> I would also like to thank and say those states that participated in the pilot really have assisted us in determining what the best methods and best types of communications are for states with regard to settings that fall under the heightened scrutiny rubric. And we will be employing that learning going forward.

To facilitate the reviews.

>> What oversight will CMS be conducting on settings that states deem not publicly institutional if CMS suggests this decision was made in error?

>> We will certainly have a conversation in the state. We said in the FAQs that we reserve the right to follow up with a state if they did not submit a particular setting to us and the stakeholder input said that it should have been flagged as being presumptively institutional.

Of course we would be particularly interested in having conversations with the state in instances where the stakeholder input was clear that a setting was presumptively institutional for specific reasons. We have now in these FAQ documents three different criteria of isolation and then for the other two categories of presumptively institutional settings it's fairly cut and dry based on location. So we do want to hear if stakeholders disagree with the state's decision to not identify something to put forward. Given the flexibility now in the July 1, 2020 for isolating settings, it could be that a setting that a state had planned to submit to us will no longer be required to do so if the setting remediates into compliance. That should be taken into account. But we should ask that stakeholders be specific about why they think a particular setting has not been flagged as presumptively institutional really is, and then CMS will act accordingly. We would start with a conversation with the state to say that we are aware of stakeholder comments about a particular setting and then see where those conversations take us. I don't want to box the agency in to, you know, taking a particular action or one action over another. But, you know, certainly we've left the door open for us to take actions as necessary if that should occur.

>> And the only thing I would underscore here is that we would ask if the discussions had been had and we should be talking to the state first.

>> How does this affect free-standing adult day care centers that are strictly focused dementia care centers? These centers are secure locked for safety. Is this addressed?

>> CMS did, and I would urge you to go back to our tool kit, we worked with ACL on a fairly comprehensive slide deck specifically on how to address wandering behavior techniques, the appropriate use of the person-centered service plan. And I would urge you to take a look at what we already have online as usable tools to help guide you in that, in those considerations and those discussions.

>> Right. We would certainly expect a setting like that, even though it's providing service to people who might have some fairly significant needs and have differing needs among the group of individuals receiving services there. Such a setting should be in compliance, has to be in compliance with the regulations by the end of the transition period. The guidance Ralph was talking about provided some best practices for how a setting like that can achieve compliance. And it's again, it all comes down to the person-centered plan of the individuals residing there. You know, there is the ability in the regulation for a person-centered service plan to document modifications of the settings criteria. If, for example, they would need supports to be able to go out into the community or if there is a need for them to have any kind of other parameter put on them that's not impossible under this reg. The reg doesn't do anything to circumvent an individual's safety, but there are expectations that any kind of modification of the setting criteria is spelled out in a person-centered plan.

So for a setting that is dealing exclusively with individuals with Alzheimer's, dementia, et cetera, we would still expect there to be differences across the person-centered plans and the individuals receiving services there, because there are differences across individuals even with the same diagnosis. So whether or not heightened scrutiny is involved for that particular setting, whether it or not it meets any of the criteria for a presumptively institutional setting, it does need to meet the regulation and we've gotten some good feedback in response to the wandering guidance that we put out. If you've not taken a look at that, it's worth reading.

>> Given the emphasis on an individual's person-centered plan and a person's informed choice, what kind of documentation will CMS be expecting to ensure that the informed choice is an experientially-based choice rather than based on limited opportunities in the past and an inability to truly make an informed choice.

>> I think what I would be saying, what I would say here is the first person who will be examining this issue will be the state and they should be examining it in the framework of person-centered planning. And that should include both the individual's choice and the individual's experience in making that choice. So at a state level you've invoked a couple things here. One is settings. The other is person-centered service planning. Both of which were carried heavy real estate in this regulation and require state involvement and oversight.

>> Can you clarify what the plan is for heightened scrutiny submittals that states have already approved and sent to CMS and were on hold until this guidance was completed?

>> Sure. We're opening the door for states to withdraw when they feel that for instance settings that they submitted to us were in the isolating vane and the state believes has overcome that presumption of isolation. And they have until 2020 to remediate. If they've already remediated, states can withdraw those applications. And we'll move forward reviewing the others as the states notify us which they anticipate remain, and that they would like our review of, and which ones they would like to withdraw.

>> That's a really great question because we know states have submitted packages to us, and we greatly appreciate the patience of those states as we work to finalize this guidance and get it on the street. And now we implement it going forward. The biggest changes that we can see, as Ralph said, would be to submissions that states have previously sent us for settings that isolate.

Settings in the other two categories, to the extent that the states weren't part of the six-state pilot, we can start reviewing those at any time. It would probably make sense to us to circle back with each state to say we're about to put our foot on the gas to start looking at these settings, do you have any questions or is there anything you want us to be aware of before we start. That would be a state-specific conversation. But one of the advantages to having this guidance on the streets is we can start adjudicating the packages that have been pent up. And to our state partners, I would look for us to be circling back with you as we start to engage on those packages. Some of them have been with us for quite some time. So we do want to give you a chance to let you know that we're actively looking at them. But, you know, look forward to kind of clearing the decks a little bit particularly in the first two categories.

>> Will CMS be maintaining its existing policy including not ruling on planned construction prior to it becoming operational?

>> Well, we've already indicated that we are looking and taking a deeper dive into this issue. But the new construction, the bottom line is you have to evaluate the individual's experience as they are in the setting. So it is a regulatory requirement. And we're looking to see where there is, if any, relief or possibility for some other options or clarifications.

>> Particularly given the new FAQ's criteria of an isolating setting, that should be taken into account in determining whether a new setting should come to us for heightened scrutiny. Our goal all along is to facilitate the investment of new resources into settings that were fully integrate into the community. And whether or not you take that as any kind of frowning upon of the construction of new settings or not, the fact remains that heightened scrutiny remains ongoing past the transition period. However, the settings criteria is certainly in effect for new settings. So care should be taken for the construction of new settings, particularly on the grounds of public institutions and inside public or private institutions to make sure that they won't have any trouble in a heightened scrutiny review.

And so as states gain experience, as we and the states gain experience in adjudicating heightened scrutiny packages, it will be that much easier for states and providers and funders to make sure they are

constructing settings in those first two categories of presumptively institutional settings that won't have any problems.

As it relates to isolation, there are opportunities for states to make sure that new settings are built that don't run afoul of those criteria for isolation. We will all get our legs under us in operationalizing the new isolation criteria as it relate to the new construction of presumptively institutional settings. But do take a look if you're a little rusty on the provisions of 2016 guidance around new construction. Take a look at those. We know that this is top of mind for a lot of you. Whether or not we will be revising that guidance. And as we continue to have those conversations internally, you know, we do want to make sure that we are again balancing the availability of a range of settings to meet the needs of different people receiving HCBS and also facilitating the ability of the settings to adhere to the regulatory requirements.

>> We're aware of the timeline that we set for this presentation and that we're coming very close to the end of the presentation. We would like to remind states that they have as a resource HCBS@CMS.HHS.gov for any questions that went unanswered or where you have further