Frequently Asked Questions: Home and Community-Based Settings Regulation Implementation: Guidance on Heightened Scrutiny

Division of Long-Term Services and Supports
Disabled and Elderly Health Programs Group
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Objectives for Today’s Session

• Share the issues on heightened scrutiny from CMS’ collaborative work with states/other stakeholders and the pilot project on heightened scrutiny review.

• Clarify the process for assessing presumptively institutional settings.

• Review the latest Frequently Asked Questions (FAQs) 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 services (HCBS) beneficiaries from the broader community.
Objectives for Today’s Session (con’t.)

• Articulate promising practices for how settings presumed institutional due to isolation of HCBS beneficiaries can comply with the regulations.

• Review assessment compliance for private homes and residential settings when Medicaid only funds non-residential services.
Impetus for Issuing this Guidance

• Technical Assistance requests to clarify the process for states to identify and assess presumptively institutional settings.

• A need for implementation guidance that recognizes states’ decision-making authority while adhering to the regulatory framework.

• A venue to articulate promising practices for how settings can comply with the regulatory criteria.
What CMS Heard from States

- Increased state autonomy in determining whether a setting is isolating.
- 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.
- Ability to remediate settings to ensure compliance during the transition period without a CMS heightened scrutiny review or limiting the requirement to elevate information to CMS only for those settings that must undergo remediation.
- Limit the CMS role in heightened scrutiny to reviewing the state’s process for ensuring setting compliance.
What CMS Heard from Advocates

• Assure a state process that identifies all presumptively institutional settings and ensures that any remediation plans are implemented.

• Develop a meaningful and independent review of states’ processes for identifying presumptively institutional settings and of the individual settings that states submit as overcoming the presumption.

• Assure the use of robust stakeholder engagement: transparency, well-published notice and comment period, resolution of disagreements between states/stakeholders.

• Stress the importance that “community” has no single definition, and a range of models and service options should be available to provide HCBS.

• Evidentiary packages should describe how individuals actually engage and integrate in the broader community.
Heightened Scrutiny Pilot Project

- CMS engaged 6 states in a pilot to review and provide feedback on packages submitted for residential settings that are in a public or private facility that provides inpatient treatment, or on the grounds of, 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.
Heightened Scrutiny guidance issued on March 22, 2019.

The HCBS Heightened Scrutiny Frequently Asked Questions (FAQs) can be found at:

1. Heightened Scrutiny Reviews of Presumptively Institutional Settings

The HCBS settings regulations describe three categories of residential or non-residential settings that are presumed to have the qualities of an institution requiring a heightened scrutiny review:

• Settings that are located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment;

• Settings that are in a building located on the grounds of, or immediately adjacent to, a public institution;

• Any other settings that have the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS.
CMS intends to take the following factors into account in determining whether a setting has the effect of isolating individuals:

- 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 individuals not receiving Medicaid-funded HCBS;
- The setting restricts beneficiary choice to receive services or to 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 a beneficiary’s person-centered plan.
• **Note**: “Opportunities”, as well as identified supports to provide access to and participation in the broader community, should be reflected in both individuals’ person-centered service plans and the policies and practices of the setting.

• 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.
2. Questions Specific to Settings that Isolate HCBS Beneficiaries: Characteristics of the Setting (3 of 3)

Implications of this new criteria:

- No specific examples of settings that isolate.
- All settings will be reviewed individually by the state to determine if they meet any of these factors and require heightened scrutiny.

This response replaces in totality prior guidance on the criteria of an isolating setting. See: https://www.medicaid.gov/medicaid/hcbs/downloads/settings-that-isolate.pdf.
3. Questions Specific to Settings that Isolate HCBS Beneficiaries: Rural Areas

• Settings in rural areas are not automatically presumed to have the qualities of an institution, specifically not considered as automatically isolating.

• States should only submit a specific setting for heightened scrutiny if the setting is 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).

• To determine if a rural setting may be isolating, compare the access that other individuals living in the same geographical area, but who are not receiving Medicaid HCBS, have to engage in the community.

• See Question 2 for the elements of an isolating setting: use with all Medicaid HCBS settings irrespective of geographic location.
3. Questions Specific to Settings that Isolate HCBS Beneficiaries: Rural Areas (con’t)

- State responsibility under *Olmstead*: enable persons with disabilities to be served in the most integrated setting appropriate to their needs. While an important resource, compliance with federal Medicaid will not necessarily permit states to satisfy these responsibilities.

- States are encouraged to regularly review their policies and operations to ensure they are enabling persons with disabilities to be served in the most integrated settings appropriate to their needs.

4. Questions Specific to Settings that Isolate: May a State Bring a Setting Presumed to Isolate into Compliance Without Requiring Heightened Scrutiny?

• The transition period to ensure provider compliance extends to March 17, 2022.

• If a setting meets the criteria for isolation of HCBS beneficiaries, but implements remediation to comply with the regulation by July 1, 2020, there is no need to submit that setting to CMS for a heightened scrutiny review.

• However, the setting should be identified in the Statewide Transition Plan (STP) for public comment and/or identified in information disseminated separate from the STP for public comment (See Question 7).

• CMS reserves the right to review any setting that the state attests has remediated isolating characteristics if significant public comment disagrees with the state’s assessment.
4. Questions Specific to Settings that Isolate: May a State Bring a Setting Presumed to Isolate into Compliance Without Requiring Heightened Scrutiny?

Timeframes:

- As long as a state determines that an isolating setting can implement remediation prior to March 17, 2022, and can achieve compliance, states may also submit to CMS those isolating settings that have not completed remediation by July 1, 2020.
- States should submit to CMS isolating settings that have not completed necessary remediation by July 1, 2020 for heightened scrutiny within 120 days (by the end of October 2020).
- The entire transition period for compliance is available until March 17, 2022 so providers can complete remediation and be validated as fully compliant.
- States have discretion to rely on July 1, 2020 to work with providers and can submit packages for heightened scrutiny prior to this timeframe.
5. Questions Specific to Settings that Isolate: Promising Practices to Remediate Settings that Isolate to Ensure Compliance (1 of 4)

- CMS is collaborating with federal partners in the Administration for Community Living (ACL) to develop a comprehensive set of promising practices.

- CMS offers the following for state and provider consideration:
  - Increasing technical assistance to assist states to transform the long-term services and supports systems to fully implement person-centered thinking, planning, and practices.
  - Increasing engagement with the broader community by:
    - Developing partnerships with generic, community-based entities, resulting in inclusion in the broader community;
    - Establishing a community-based advisory group.
5. Questions Specific to Settings that Isolate: Promising Practices to Remediate Settings that Isolate to Ensure Compliance (2 of 4)

- Implementing a broad range of services and supports, programming and multiple daily activities to facilitate access to the broader community so individuals can select an array of options and control their own schedule. Such activities should:
  - Promote skills development and facilitate training to attain and expand opportunities for community-based integration;
  - Expose beneficiaries to community activities/situations comparable to those in which individuals not receiving HCBS routinely engage;
5. Questions Specific to Settings that Isolate: Promising Practices to Remediate Settings that Isolate to Ensure Compliance (3 of 4)

- Encourage families/friends to participate regularly with the beneficiary onsite and in the broader community; and/or
- Promote greater HCBS beneficiary independence and autonomy.

• Implementing organizational changes that:
  - Assure required staffing and transportation options to offer both group and individualized options that facilitate community engagement based on individual preferences in the person-centered service plan; and/or
5. Questions Specific to Settings that Isolate: Promising Practices to Remediate Settings that Isolate to Ensure Compliance (4 of 4)

- Decentralize staff structures to promote flexibility and encourage staffing focused on individuals’ access to/participation in the broader community, rather than insular staff models focused around a specific facility/site.

- Expanding strategies for increasing beneficiary access to transportation through existing means; could include providing transportation to promote ease of access and optimize individuals’ ability to select their own options and make decisions about their services and supports.
The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule restricts covered entities from publicly disclosing protected health information (PHI) without the authorization of the individual, unless disclosure is expressly permitted under the Rule.

Examples of PHI include an HCBS beneficiary’s name and health condition.

States should not include any personally identifiable information of beneficiaries in the STP or in any notifications or information disseminated to the public.
Under some circumstances, information about a particular setting, including the name and address, may be PHI if it relates to:

- The past, present or future physical or mental health or condition of an individual;
- The provision of health care or payment for care; and
- There is a reasonable basis to believe the information can identify the individual.
Addresses and locations of settings on the grounds of or adjacent to public institutions or in buildings that provide inpatient institutional treatment are typically known to the general public.

This may not be true for settings that have been evaluated as overcoming the institutional presumption of isolating individuals, although circumstances and recognition of each setting will vary.

Recognizing the need for public input, states must adhere to applicable federal and state laws and regulations protecting the privacy of individuals receiving HCBS.
6. Questions Specific to Settings that Isolate: HIPAA Related Privacy Concerns /CMS Guidance for Disclosure of Information on Settings that Isolate (1 of 3)

- To the extent possible, states are encouraged to disclose generalized descriptions (not names or addresses of the settings) of how the state determined that a presumptively institutional setting overcame, or will overcome, that presumption.

- If the state needs to disclose names and addresses of the settings, it should consider whether publicly disclosed information is PHI, based on the circumstances and the individuals served by that setting.

- The outcome of that determination will be fact specific and will vary across settings.
• If the information is determined to be PHI, the state can take one of the following steps to address HIPAA compliance:
  o Remove all 18 identifiers described in 45 CFR § 164.512(b)(2)(i), including address and other geographic subdivisions smaller than a state; show that the state has no knowledge that the information could be used to identify the individual, before publishing the comment solicitation.
  o See https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html
6. Questions Specific to Settings that Isolate: HIPAA Related Privacy Concerns /CMS Guidance for Disclosure of Information on Settings that Isolate (3 of 3)

- Receive an authorization from every resident (or their representative) of the setting granting permission to release the address and any other potentially identifiable information.

- In circumstances where state, local or other law requires a state to disclose PHI, such disclosures are permissible under the HIPAA Privacy Rule, and the state would not need to take further action to make such a disclosure.
States may notify individuals living or receiving non-residential services in the setting in question, and if permitted by applicable law, family members and guardians (identified in the individual’s person-centered plan as involved in their care) of the following:

- The state has determined that the setting overcomes the institutional presumption of being isolating;
- The state’s justification for that determination (outlined in number 8);
- And how these individuals may offer comments in response.
If the information is not PHI, the state may notify primary aging and disability rights and advocacy organizations of the justification described on the previous slide.

These organizations may include, but not be limited to:

- Protection and Advocacy organizations, Developmental Disability Councils, University Centers of Excellence on Disabilities, Area Agencies on Aging, Aging & Disability Resource Centers, Centers for Independent Living, LTC Ombudsmen, organizations representing individuals with mental illness or Traumatic Brain Injury, service coordinators, state licensure and certification entities, and advocacy organizations that include HCBS beneficiaries.
To the extent that the justification includes PHI, 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 where the disclosure is to a health oversight agency.

- **For example:** States may disclose this information, including the address of the setting, to a state-designated Protection and Advocacy organization if required by law or to the LTC Ombudsman requesting that information for oversight activities.
7. Questions Specific to Settings that Isolate: Stakeholders’ Notice and Comment on Settings that Isolate (4 of 5)

- 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 STP should publicize an email and mailing address for submitting requests of this information.
- This above response replaces prior guidance given on this topic, to account for HIPAA implications.

7. Questions Specific to Settings that Isolate: Stakeholders’ Notice and Comment on Settings that Isolate (5 of 5)

• Implications of HIPAA requirements on soliciting stakeholder input on settings presumed institutional due to isolation:
  – Defers determination to states of whether publishing the address of a setting the state believes overcomes its institutional presumption of isolation would include PHI.
  – States should consult their HIPAA officers to develop a process to implement these provisions and are encouraged to communicate this process to stakeholders.
8. Questions Pertaining to All Presumptively Institutional Settings: Information for Public Comment (1 of 4)

States should disseminate the following information for stakeholders’ input during periods of public comment, in compliance with the HIPAA provisions already described:

- State strategies to identify settings in any of the three categories of settings presumed to have qualities of an institution;
- State approaches to reviewing settings flagged as being presumptively institutional, including:
  - How the state will use public comment to inform its review;
  - How the state has/will determine whether a setting overcomes the presumption that it is an institutional setting.
8. Questions Pertaining to All Presumptively Institutional Settings: Information for Public Comment

(2 of 4)

- Numbered list of settings identified for each category of settings that the state believes overcomes the presumption that the settings are institutions.

- The list should also:
  - Identify the presumptively institutional category that each setting falls into for heightened scrutiny;
  - Include a summary of how each setting has or will overcome the presumption that it is an institution;
  - Include the state’s plan for oversight of remediation to ensure compliance by the end of the transition period;
8. Questions Pertaining to All Presumptively Institutional Settings: Information for Public Comment (3 of 4)

- A list of settings the state does not believe can overcome the presumption that the settings are institutions by the end of the transition period, and thus may not receive Medicaid funding for HCBS after the transition period;

- A list of settings, if any, that the state previously identified as presumptively institutional due to isolation, but subsequently demonstrate compliance by July 1, 2020, along with a statement that information supporting remediation for those settings is available on request; and

- Process for applying CMS feedback on specific settings to similarly situated settings (see Question 9).
8. Questions Pertaining to All Presumptively Institutional Settings: Information for Public Comment (4 of 4)

• CMS requests that when states publish information related to heightened scrutiny for public comment, that they send the electronic links to the CMS STP team as soon as the comment period begins.

• The response here replaces prior guidance given on presumptively institutional settings under 42 CFR 441.301(c)(5)(v); 441.530(a)(2)(v); and 441.710(a)(2)(v), as states are no longer encouraged to identify the number of individuals receiving services at each setting.

• See the third bullet at question 8 [referenced on slide 33] at: https://www.medicaid.gov/medicaid/hcbs/downloads/home-and-community-based-setting-requirements.pdf.
9. Questions Pertaining to All Presumptively Institutional Settings: CMS Review of Heightened Scrutiny Requests (1 of 4)

- State partners indicate that a sizable number of heightened scrutiny requests could be submitted throughout the remainder of the transition period. CMS’ review strategy includes:

- The numbered list of settings identified for each category of presumptively institutional setting (as discussed in a previous slide) will be made available to CMS:
  - CMS strongly encourages states to submit information on settings located in the same building as a public or private institution or located on the grounds of, or adjacent to, a public institution by March 2019 (or as soon as possible).
  - Information on isolating settings, should be submitted no later than October 2020.
9. Questions Pertaining to All Presumptively Institutional Settings: CMS Review of Heightened Scrutiny Requests (2 of 4)

• CMS will use the list to compile a random sample of settings to review, including any that the state requests CMS to review and any setting that generated significant public comment in opposition to the state’s assessment.

• CMS will review all information presented by the state and other parties and will either approve the state’s assertion or provide feedback on missing information, questions for clarity or reason(s) why CMS can’t agree that the setting overcomes its institutional presumption.

• States can then provide additional information needed to support their assertion before CMS makes a final determination.
• Based on the process described in the state’s STP 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 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.
9. Questions Pertaining to All Presumptively Institutional Settings: CMS Review of Heightened Scrutiny Requests (4 of 4)

- If the sample highlights concerns with the state’s approach for assessing presumptively institutional settings, CMS may request to review additional settings and/or suggest changes to the state’s heightened scrutiny review process.
- CMS may also ask for information on any setting for which the state received public comments that the setting was presumptively institutional but was not included on the state’s heightened scrutiny list because the state determined it to meet the HCBS settings criteria.
- This response supplements prior guidance, to refine the process by which CMS will review settings presumed to be institutions, including the use of sampling.
10. Questions Pertaining to All Presumptively Institutional Settings: Evidence for Settings Selected for the Review Sample (1 of 6)

- Evidence should focus on the qualities of the setting and how it is integrated in and supports access of individuals into the broader community via the organization’s policies and procedures and how the setting supports individuals consistent with their individual person-centered service plans.

- Exploratory questions in the Toolkit can help determine the type of information to include. See: https://www.medicaid.gov/medicaid/hcbs/guidance/settings/index.html.
10. Questions Pertaining to All Presumptively Institutional Settings: Evidence for Settings Selected for the Review Sample (2 of 6)

- Description of the proximity to and scope of interactions in and with the broader community demonstrated by mechanisms such as:
  - Description of the state’s review of a sample of individuals’ daily activities, person-centered service plans, and/or interviews to see if there is variation in the scope, frequency and breadth of interactions and engagement in and with the broader community;
  - **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.
10. Questions Pertaining to All Presumptively Institutional Settings: Evidence for Settings Selected for the Review Sample (3 of 6)

- A copy of procedures and services provided that indicate evidence of access to and demonstrated support for beneficiary integration in the broader community activities consistent with individuals’ person-centered service plans;
- Descriptions of processes in place or actions taken by direct support professionals to support, monitor, improve, and enhance individual beneficiary integration in and with the broader community over time;
- A summary of examples of how schedules are varied according to individual preferences and the need to integrate into the local community at times when the general community attends an activity;
Procedures to routinely monitor individual access to services and activities of the broader community as identified in the person-centered service plans;

• Description of how staff are trained and monitored in the settings criteria and the role of person-centered planning, consistent with state standards described in the waiver or state plan amendment or in community training policies and procedures established by the state;

• Description of the setting’s proximity to public transportation or how transportation is facilitated;
• Attestation that the state reviewed/concluded through an onsite visit and/or a sample of consumer interviews, or person-centered service plan reviews, that any modifications to the settings criteria in provider-owned or controlled settings are documented in the person-centered services plans.

  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.

• Description of the setting’s remediation plan to achieve compliance by March 2022, including the state’s oversight to ensure completion of actions;
10. Questions Pertaining to All Presumptively Institutional Settings: Evidence for Settings Selected for the Review Sample (6 of 6)

- Summary or 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 the setting overcomes the institutional presumption, such as:
  - Photos of the setting, 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.
- This response replaces prior guidance on this topic, to streamline the suggested content of information for a HS review. See question 3 at: https://www.medicaid.gov/medicaid/hcbs/downloads/home-and-community-based-setting-requirements.pdf.
Guidance Pertaining to All Presumptively Institutional Settings: General Considerations

- The person-centered planning process should not be limited to services/supports covered solely under a particular Medicaid-funded authority but should include natural supports, external resources or other funding vehicles available to meet individuals’ needs.
- CMS acknowledges parameters around the scope of services authorized under a state’s HCBS programs that providers must operate within.
- Nothing in the regulations requires an HCBS setting to finance recreational activities on behalf of beneficiaries.
Guidance Pertaining to All Presumptively Institutional Settings: General Considerations (con’t)

- It is not sufficient for HCBS settings to solely or primarily bring people from the broader community into the setting.
- It is the expectation that HCBS settings offer meaningful opportunity for interactions with the community outside of the setting, consistent with person-centered plans.
- For heightened scrutiny requested for settings operating under section 1915(c) or section 1915(i), submissions should also include information the state received during the applicable public input process.
  - CMS will also consider information provided by other parties.
- For 1915(k) Community First Choice (CFC) programs, information should be submitted as part of the state’s request for heightened scrutiny for any such settings included in the CFC State Plan Amendment (SPA).
11. Questions Pertaining to All Presumptively Institutional Settings: CMS Monitoring of These Settings to Ensure Compliance by March 2022

Use of Different Monitoring Mechanisms by CMS:

- Throughout the transition period, CMS will reference the state’s *process* to ensure identified remediation is completed, including the steps and timelines as described in the STP to bring providers into compliance, when discussing ongoing monitoring with states.
- Information submitted to CMS for heightened scrutiny review of a *particular setting* includes:
  - how the state will monitor to ensure that setting’s completion of remediation;
  - the identification of milestones for the completion of activities to bring that setting into compliance; and
  - agreed upon scheduled reporting to CMS on the progress toward achieving milestones.
12. Questions Pertaining to Other Topics: Assessment of Compliance for Private Homes

- **Definition:** Individual, privately-owned homes are privately-owned or rented homes and apartments in which the individual receiving Medicaid-funded HCBS lives independently or with family members, friends or roommates.

- Individual, privately-owned homes are presumed to be in compliance.

- States are not responsible for confirming this presumption.

- States should include private residences as part of the overall quality assurance framework when implementing monitoring processes for ongoing compliance.
12. Questions Pertaining to Other Topics: Assessment of Compliance for Private Homes (con’t)

- States should also include private homes in any oversight provisions articulated in their approved HCBS waivers or state plan amendments.
- Settings where individuals live in a private residence owned by an unrelated, paid caregiver are considered provider-owned or controlled settings and should be evaluated for compliance with the settings criteria as such.

This response supplements prior guidance on this topic:
States are responsible for ensuring compliance with the HCBS regulations only for those settings in which Medicaid beneficiaries receive HCBS.

If Medicaid is only funding non-residential HCBS for an individual, the state is not responsible for ensuring compliance for the setting in which that individual resides.

But states may require beneficiaries receiving Medicaid-funded non-residential HCBS to live in settings that comply with the rule, even if the individual does not receive HCBS in the setting.


Resources (3 of 3)

Feedback

Please complete a brief survey to help CMS monitor the quality and effectiveness of our presentations.

Please use the survey links

https://www.surveymonkey.com/r/HeightenedScrutiny

WE WELCOME YOUR FEEDBACK!