March 22, 2019

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) is issuing the attached set of guidance responses to Frequently Asked Questions (FAQs) on implementation activities associated with the January 2014 home and community-based settings final rule,\(^1\) based in part on collaboration with states, state associations, and other stakeholders. Promoting community integration for older adults and people with disabilities remains a high priority for CMS. The FAQs discuss settings identified by the regulation as being presumed to have the qualities of an institution, unless CMS determines through a heightened scrutiny review that the settings do not have the qualities of an institution and that the settings do have the qualities of home and community-based settings. The FAQs focus on settings that have “the effect of isolating individuals receiving Medicaid [Home and Community-Based Services] HCBS from the broader community of individuals not receiving Medicaid HCBS.” Where noted, this guidance replaces or supplements prior guidance; content not specifically referenced in the attached as being replaced remains in effect.

CMS is issuing this guidance in keeping with a letter from CMS Administrator Seema Verma to the nation’s Governors on March 14, 2017, indicating the intention to provide additional flexibility to states and to streamline implementation efforts associated with the home and community-based settings regulation. The attached guidance is designed to ensure that implementation decisions balance the need for robust stakeholder engagement with administrative feasibility.

In addition to information clarifying the heightened scrutiny process, the FAQs also clarify two other topics that have often been raised with CMS: whether an individual’s private residence should be assessed for compliance with the settings criteria, and whether an individual should reside in a compliant setting in order to receive Medicaid reimbursement for non-residential HCBS.

If you have any questions regarding the information in this letter or in the attached FAQs, please contact Melissa Harris, in the Disabled and Elderly Health Programs Group, by email at Melissa.harris@cms.hhs.gov.

Sincerely,

Chris Traylor
Deputy Administrator and Director

Enclosure

cc: National Association of Medicaid Directors
National Academy for State Health Policy
National Governors Association
American Public Human Services Association
Association of State Territorial Health Officials
Council of State Governments
Frequently Asked Questions: HCBS Settings Regulation Implementation

Heightened Scrutiny Reviews of Presumptively Institutional Settings

1. **Question:** What types of settings are identified in the home and community-based settings regulation as presumed to have the qualities of an institution to which the heightened scrutiny process applies?

   **Answer:** The regulations describe three categories of residential or non-residential settings that are presumed to have the qualities of an institution:
   - 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; and
   - Any other settings that have the effect of isolating individuals receiving Medicaid home and community-based services (HCBS) from the broader community of individuals not receiving Medicaid HCBS.

**Questions Specific to Settings that Isolate HCBS Beneficiaries**

2. **Question:** What are the characteristics of a setting that isolates HCBS beneficiaries from their broader community?

   **Answer:** 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 to engage in activities outside of the setting; or
   - The setting is physically located separate and apart from the broader community and does not facilitate beneficiary opportunity to access the broader community and participate in community services, consistent with a beneficiary’s person-centered service plan.

* “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 in accordance with 42 CFR 441.301(c)(1)-(3) and (4)(vi)(F), 42 CFR 441.530(a)(1)(vi)(F) and 441.540, and 42 CFR 441.710(a)(1)(vi)(F) and 441.725.

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2 42 C.F.R. 441.301(c)(5)(v); 441.530(a)(2)(v); and 441.710(a)(2)(v).
States may identify additional factors beyond those included above. However, the state needs to clarify any additional characteristics of isolation so that stakeholders have a clear understanding of what the state considers isolating.

The above response replaces in totality prior guidance published on the criteria of an isolating setting under 42 CFR 441.301(c)(5)(v); 441.530(a)(2)(v); and 441.710(a)(2)(v). The criteria of an isolating setting have been revised and examples of settings that may have isolating effects have been removed.

3. Question: Does CMS expect states to submit information specific to settings located in rural areas for a heightened scrutiny review?

Answer: 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 qualities of an institution, and if the state believes that the setting has overcome the presumption. With respect to determining whether a rural setting may be isolating to HCBS 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 2 for the elements of an isolating setting, which states should use to apply to all settings where individuals are receiving Medicaid-funded HCBS, irrespective of geographic location.

The above response supplements prior guidance given on this topic.

4. Question: 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?

Answer: The transition period for states to ensure provider compliance with the regulatory settings criteria for settings in which a transition period applies extends to March 17, 2022. Within that timeframe, 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 1, 2020, then there will be no need to submit information on that setting to CMS for a heightened scrutiny review. The settings, however,

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4 CMS reminds states about their responsibility under the Americans with Disabilities Act and the Rehabilitation Act to enable persons with disabilities to be served in the most integrated settings appropriate to their needs. 42 U.S.C. § 12132; 28 C.F.R. § 35.130(d); 29 U.S.C. § 794; 45 C.F.R. § 84.4; Olmstead v. L.C., 527 U.S. 581 (1999). While Medicaid may be an important resource to assist states in satisfying their responsibilities under Olmstead, compliance with federal Medicaid requirements will not necessarily permit states to satisfy this responsibility. Accordingly, we encourage states to regularly review their policies and operations to ensure they are enabling persons with disabilities to be served in the most integrated setting appropriate to their needs.
7 42 CFR 441.301(c)(4);441.530(a)(1); 441.710(a)(1)
should be identified in a state’s statewide transition plan (STP) for public comment and/or identified in information disseminated separate from the STP for public comment (see Question 7). Further, CMS reserves the right to review any setting that the state has attested has remediated isolating characteristics if the state receives significant public comment disagreeing with the state’s assessment.

States may submit to CMS those isolating settings that have not completed remediation by July 1, 2020 if a state determines that an isolating setting can implement remediation before the expiration of the transition period (March 17, 2022), and also determines that the isolating setting can achieve compliance with the settings criteria. Isolating settings that have not completed necessary remediation by July 1, 2020 should be submitted to CMS by the state for a heightened scrutiny review within 120 days (by the end of October 2020).

The transition period for states to come into compliance with the settings rule runs until March 17, 2022, during which states may work with all existing HCBS providers to complete their remediation and be validated as fully complying with the settings criteria. CMS notes that states have discretion to rely on the July 1, 2020 date in their work with providers, and to submit packages for heightened scrutiny review prior to this timeframe.

5. **Question:** What are some promising practices to remediate settings that have been identified as being isolating to ensure compliance with the home and community-based settings criteria?

**Answer:** CMS is collaborating with federal partners in the Administration for Community Living (ACL) to develop a comprehensive set 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 supports (LTSS) 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/or
  - 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.

- 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 his or her own schedule. Such activities should:
  - Promote skills development and facilitate training and educational opportunities among HCBS 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;
- Encourage families and friends to participate regularly in activities with the beneficiary onsite as well as in the broader community; and/or
- Promote greater HCBS beneficiary independence and autonomy.

- 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 person-centered service plans); and/or
  - Decentralize staff structures to promote greater flexibility and encourage staffing focused on individuals’ access to and participation in the broader community rather than centralized insular staff models focused around a specific facility/site.

- Expanding strategies for increasing beneficiary access to transportation, including through existing public transportation, friends/family, and volunteer organizations, to activities in the broader community. This could include providing transportation in a way that promotes ease of access and optimizes individuals’ ability to select their own options and make decisions about their services and supports.

6. **Question:** When soliciting public input on settings the state has determined to overcome the institutional presumption of isolating individuals receiving HCBS, are there HIPAA-related privacy concerns that states should consider?

**Answer:** The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule restricts covered entities, such as state Medicaid agencies and providers that meet the definition of 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. The state should not include any personally identifiable information of beneficiaries in the submission of 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 constitute 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 be used to identify the individual.8 The addresses and locations of settings that are either on the grounds of or adjacent to public

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8 See 45 CFR 160.103, definitions of protected health information and individually identifiable health information.
institutions or in buildings that provide inpatient institutional treatment are typically known to the general public. The same may not be true for settings that 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 HCBS.

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 the state determined that a presumptively institutional setting overcame, or will overcome, that presumption.

- Should a state determine it is necessary to disclose the name or address of the setting, the state should consider whether the information about the setting that will be publicly disclosed is PHI as defined by HIPAA, based on the circumstances of each setting and the individuals served by that setting. The outcome of such a 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:
  - Remove all 18 identifiers described in 45 CFR § 164.512(b)(2)(i), including address and other geographic subdivisions smaller than a state, and show that the state has no knowledge that the information could be used to identify the individual, before publishing the comment solicitation.
  - 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.

7. **Question:** 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?

**Answer:** 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 service plan as involved in their care) of the following: that the state has determined that the setting overcomes the institutional presumption of being isolating, the state’s justification for that determination (outlined below in number 8), and how these individuals may offer comments in response.

To the extent the information is not PHI, the state may notify primary aging and disability rights and advocacy organizations in the state of the justification described above. These organizations may include, but are not 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 and Traumatic Brain Injury, service coordinators, state licensure and certification entities, and advocacy organizations that include HCBS beneficiaries within their membership.

- To the extent the justification includes PHI, the state may provide the justification to external entities when the disclosure of PHI to those entities is permissible under HIPAA, such as when 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.

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.

The above response replaces prior guidance\(^{12}\) given on this topic, to account for HIPAA implications.

**Questions Pertaining to All Presumptively Institutional Settings**

8. **Question:** What information should a state provide during the public comment on settings that the state has considered for heightened scrutiny review?

**Answer:** The following information should be disseminated by states for stakeholder input during periods of public comment, in compliance with the HIPAA provisions described above:

- State strategies to identify settings falling into any of the three categories of settings presumed to have qualities of an institution;
- State 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/will determine whether a setting overcomes the presumption that it is an institutional setting;

- A numbered list of settings identified for each category of settings that the state believes overcomes the presumption that the settings are institutions (e.g., adult day center inside of a nursing facility, or group home on the campus of a public ICF/IID, or a setting that the states 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 as well as the state’s plan for oversight of remediation to ensure compliance with the settings criteria by the end of the transition period;

- A list of settings that 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 with the settings criteria by July 1, 2020, along with a statement that information supporting remediation for those settings is available upon request; and

- Process for applying CMS feedback on specific settings to similarly situated settings (described in greater detail below in Question 9).

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

The above response both provides new guidance and 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.

9. **Question**: How will CMS review state requests for heightened scrutiny of settings that the state believes overcome the presumption of having the qualities of institutional settings?

**Answer**: 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:

- The numbered list of settings identified for each category of presumptively institutional setting (reflected in the previous question) will be made available to CMS. (CMS seeks to provide states with useful feedback prior to the close of the transition period. Therefore, 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. Information on isolating settings should be submitted no later than October 2020.)

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CMS will use the list provided by a state to compile a random sample of settings to 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 will review all 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 reason(s) why CMS cannot agree that a setting is able to overcome the presumption that it is an institution. States will then have the opportunity to provide the additional information needed to support their assertion before final determination is made by CMS.

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 that have the qualities 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.

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 in determining whether a setting overcomes the presumption that it is an institution.

CMS may also request 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.

The above response supplements prior guidance14 given on this topic, to refine the process by which CMS will review settings presumed to be institutions, including through the use of sampling.

10. Question: What information should states submit to CMS for a heightened scrutiny review of a setting selected for the review sample?

Answer: When submitting a setting for heightened scrutiny review, states should provide evidence of how the state has determined that a setting overcomes 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 practices as well as in how the setting supports individuals consistent with their person-centered service plans.

The exploratory questions available in the Toolkit found at www.medicaid.gov/medicaid/hcbs/guidance/settings/index.html can also be helpful in determining the type of information that should be included in the documentation. Some additional examples of information the state might include are:

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• Description of the proximity to and scope of interactions in and with the broader community, which can be demonstrated through mechanisms such as:
  o Description of the state’s review of a reasonable sample\textsuperscript{15} of individuals’ daily activities, person-centered service plans, 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;
  o 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;
  o 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;
  o A summary of examples of how schedules are varied according to individual beneficiaries’ preferences and in recognition of the need to integrate into the local community at times when the general community attends an activity; and
  o Procedures in place to routinely monitor individual access to services and activities of the broader community to the extent identified in person centered service plans;
• 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;
• Description of the setting’s proximity to public transportation or how transportation is facilitated;
• Attestation that the state has reviewed provider-owned or controlled settings and concluded through observation made during an onsite visit and/or through a reasonable sample\textsuperscript{16} of consumer interviews, or through a review of person-centered service plans that any modifications to the settings criteria are documented in person-centered service plans as required by the regulation;\textsuperscript{17}
• Description of the setting’s remediation plan to achieve compliance by the end of the transition period, along with the state’s oversight to ensure completion of actions;
• 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 that the setting overcomes its institutional presumption, e.g., photos of the setting, but not of beneficiaries or other identifying information, or an attestation that the setting has been selected by the individual from among settings options, including non-disability-specific settings.

\textsuperscript{15} 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.

\textsuperscript{16} Ibid.\textsuperscript{17} See 42 CFR 441.301(c)(4)(vi)(F), 42 CFR 441.530(a)(1)(vi)(F), and 42 CFR 441.710(a)(1)(vi)(F).

\textsuperscript{17} See 42 CFR 441.301(c)(4)(vi)(F), 42 CFR 441.530(a)(1)(vi)(F), and 42 CFR 441.710(a)(1)(vi)(F).
The above response replaces prior guidance given on this topic, to streamline the suggested content of information submitted for a heightened scrutiny review.

CMS recognizes the role of person-centered planning to identify necessary services and supports to realize each beneficiary’s goals regarding access to and participation in the broader community. The person-centered planning process should not be limited to consideration of services and supports covered solely under a particular Medicaid-funded HCBS authority, but should also include potential natural supports, external resources, or other funding vehicles available to meet those needs, separate and distinct from Medicaid HCBS). 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. 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.

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 settings to solely or primarily bring people from the broader community into the setting. Rather, it is the expectation that through operational policies and practices, HCBS settings are also offering meaningful opportunity for individuals receiving services to interact with the community outside of the setting, supporting individuals consistent with their person-centered plans.

CMS also notes that for heightened scrutiny requested under section 1915(c) or section 1915(i) 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 section 1915(k) Community First Choice (CFC) programs, information should be submitted as part of a state’s request for heightened scrutiny for any such settings included in the CFC State Plan Amendment (SPA).

11. Question: How will CMS monitor settings identified as presumptively institutional to ensure adherence to regulatory criteria by the end of the transition period?

Answer: CMS intends to utilize different mechanisms to ensure that settings presumed to be institutional are compliant with regulatory home and community-based setting criteria by the end of the transition period. A key component of a state’s STP 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 provider into compliance with the regulatory criteria. CMS will refer to this process in our ongoing conversations with the state through the transition period.

In addition, as mentioned in the response to Question 9, 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(s) into compliance and report to CMS in an agreed upon schedule on the progress toward achieving those milestones.

**Questions Pertaining to Other Topics**

**12. Question:** What kind of compliance assessment with the home and community-based settings criteria does CMS expect of states for private residences?

**Answer:** Individual, privately-owned homes (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 is clarifying 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, as well as any oversight provisions articulated in their approved HCBS 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 as such.

The above response supplements prior guidance on this topic.

**13. Question:** Should Medicaid beneficiaries 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?

**Answer:** 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 for the setting in which that 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 the setting.

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19 42 CFR 441.301(c)(4); 441.530(a)(1); and 441.710(a)(1).
21 42 CFR 441.301(c)(5)(v); 441.530(a)(2)(v); and 441.710(a)(2)(v).