HCBS FINAL REGULATIONS
QUESTIONS AND ANSWERS REGARDING HOME AND COMMUNITY- BASED SETTINGS

Planned Construction of Presumed Institutional Settings

Q1. Can a state's request for heightened scrutiny of a setting under development or new construction be approved before the setting is operational and occupied by beneficiaries receiving Medicaid-funded home and community-based services (HCBS)?

A1. No, a setting presumed to have the qualities of an institution cannot be determined to be compliant with the home and community-based setting regulatory requirements until it is operational and occupied by beneficiaries receiving services there. To comply with the HCBS settings regulations, requirements beyond the physical structure of the setting itself must be met. These requirements ensure that the individuals residing or receiving services in the setting actually experience the setting in a manner that promotes independence and community integration. For example, individuals have the right to privacy, the ability to choose their own schedules for meals and other activities, and have access to the broader community.

It was CMS' expectation that after the publication of the final regulation, stakeholders would not invest in the construction of settings that are presumed to have institutional qualities, but would instead create options that promote full community integration, per the regulatory requirements for the 1915(c) waiver program, the 1915(i) HCBS state plan option, and the 1915(k) Community First Choice state plan option, found in 42 CFR 441.301(c)(4)(i), 441.710(a)(1)(i), and 441.530(a)(1)(ii), respectively. As those regulations establish, Medicaid-funded HCBS must be provided in compliant settings and individuals should have a choice of settings, including non-disability-specific settings. As states, counties, developers and other stakeholders are considering the construction of new settings in which Medicaid-funded HCBS would be provided, CMS notes that these regulatory provisions must be taken into account and adhered to. In recognition that there may be some locations where the ability to construct additional settings in which Medicaid-funded HCBS would be provided may be significantly limited, such as heavily built-up urban areas, states may request a heightened scrutiny review of newly operational settings meeting any of the presumed institutional scenarios described in the regulation. However, CMS strongly encourages states to limit the growth of these settings.

CMS notes that further technical assistance is forthcoming to detail how the home and community-based settings requirements can be implemented for individuals with dementia or Alzheimer's disease. CMS intends to feature promising practices in use by providers or otherwise available for implementation that can facilitate compliance with the regulation as well as provide guidance on implications for new construction.

Q2. What specific settings does the HCBS regulation define as requiring heightened scrutiny?

A2. Settings presumed to have institutional qualities include: 1) settings located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment; or 2) settings located on the grounds of, or immediately adjacent to, a public institution; or 3) settings that have the effect of isolating individuals from the broader community of individuals not receiving HCBS. By way of background, the June 26, 2015 Frequently Asked Questions (FAQ) document on heightened scrutiny (found here) described how a state may submit information to CMS for any setting the state believes overcomes the presumption that it has the qualities of an institution and meets the requirements for a home and community-based setting.

CMS gave examples of settings that may have the effect of isolating beneficiaries in previous guidance found in the HCBS Tooklit. These examples include:

- A setting designed to provide multiple services/activities to people with disabilities all on the same site (e.g., housing, day services, social, recreational activities, medical and behavioral services, etc.);
- A setting using interventions or restrictions deemed unacceptable in Medicaid funded institutional settings (e.g., seclusion);
- A farmstead or disability-specific farm community where individuals have limited access to the broader community outside the farm;
- A gated/secured community for only people with disabilities and the staff working with them, where the majority of their residential, day supports and other services are provided within the perimeters of that community and regular access to the broader community is limited; and
- Other settings where individuals receiving services have limited interaction with the broader community.

For settings presumed to have the qualities of institutions in which Medicaid-funded HCBS services were provided under state plan amendments, waivers or demonstrations approved prior to March 17, 2014, states must submit requests for heightened scrutiny review and must receive approval by CMS before March 17, 2019 to claim federal matching funds. Requests for heightened scrutiny reviews should only be submitted by a state when the state can provide the necessary information and documentation verifying what the setting has done to overcome qualities of an institution and to come into compliance with the requirements of a home and community-based setting. Settings presumed to be institutional in nature added to an HCBS waiver or state plan option on or after March 17, 2014 must be submitted for approval through the heightened scrutiny process prior to being used as part of an existing or new HCBS program. If states do not submit heightened scrutiny requests for settings presumed to be institutional under the regulation (including settings that isolate), the institutional presumption will stand. Beneficiaries will then need to be provided options to receive HCBS in alternative settings that are compliant with the rule, or the state or provider will need to access other funding sources in order to continue to provide services in the existing setting presumed institutional.

The institutional presumption and heightened scrutiny requirements also apply to new construction. Some states and providers have planned or have partially completed construction of new settings that fall into one of the three categories presumed to be institutional in nature. Some of these affected states have asked if CMS can review the physical and programmatic designs of these proposed new settings and pre-approve them under heightened scrutiny to mitigate any downstream financial risk to the state or a developer. Such "pre-approval" is not possible. A heightened scrutiny review cannot rely on program plans and proposed physical design descriptions alone. We encourage states to contact CMS early in the planning stage of proposed development, to discuss any planned construction and related programming and to discuss risks that could trigger concerns that a setting may be unable to meet heightened scrutiny requirements, along with possible mitigation strategies. CMS will not be able, however to provide any final determination that the proposed setting complies with regulatory requirements and that FFP will be available to match the facility's eventual operational costs. For that reason, states, providers or developers assume financial risk regarding new and planned construction.

Q3. Can a new setting that was not providing Medicaid-funded HCBS on March 17, 2014 under an approved state plan, waiver or demonstration, avail itself of the time remaining in the transition period through March 17, 2019 to come into compliance with the settings requirements?

A3. No. As indicated in the HCBS final regulations, any setting in which services were not being provided under an approved state plan, waiver or demonstration as of March 17, 2014 must be in compliance with the regulations for HCBS settings by the effective date of the program (the time the state submits a claim for Federal HCBS reimbursement).

For further information on previously-issued guidance on heightened scrutiny, including examples of settings that could have the effect of isolating individuals receiving HCBS, please see the following website: www.medicaid.gov/hcbs

Person-Centered Service Planning Provisions and Modifications to HCBS Settings Criteria

Q1: In the provision of Medicaid-funded home and community-based services, do states and providers have the transition period leading up to March 2019 to comply with all aspects of the person-centered service planning regulatory provisions?

A1: The HCBS regulation requires that Medicaid beneficiaries receiving HCBS services through 1915(c) waivers, 1915 (i) or (k) state plans, must have a person-centered service plan, and outlines specific requirements of the plan document and planning process. These requirements took effect on March 17, 2014 for the 1915(c) waivers and 1915(i) HCBS state plan options, and on July 6, 2012 for the 1915(k) Community First Choice programs. The March 2019 transition period for states and providers applies to only the home and community-based settings requirements for HCBS programs in existence on March 17, 2014.

Q2. Do states and providers have the transition period leading up to March 2019 to comply with the section of the HCBS rule that allows certain settings requirements to be modified in a provider-owned or controlled residential setting through the person-centered service planning process?

A2. Yes, there is a section of the settings provisions in the regulation at 42 CFR 441.301(c)(2)(xiii), 42 CFR 441.710(a)(1)(vi)(F), and 42CFR 441.530(a)(1)(vi)(F) for the 1915(c), 1915(i) and 1915(k) authorities that allows for limitations to be implemented on the qualities of a home and community-based setting that is provider owned or controlled, for health and safety issues of residents. These modifications must meet the criteria set forth in the regulation and be documented in the Person-Centered Service Plan. Due to the fact that this is a modification to the required qualities in home and community-based settings states have the transition period to address the modification requirements in provider-owned or controlled settings. The remainder of the person-centered planning requirements were effective with the effective dates of the regulations.

(For convenience, CMS will provide regulatory cites for the 1915(c) HCBS waivers throughout the remainder of this document. Similar person-centered service planning requirements apply to services authorized under 1915(i) and (k) programs.)

Practically, this means that during the transition timeframe, the state may include in its Statewide Transition Plan a process for adding these specific requirements into the person-centered service plan for individuals experiencing modifications to required characteristics in a provider owned or controlled setting.

Q3: How can modifications to the home and community-based settings requirements be appropriately used in the person-centered service planning process?

A3: The modifications section of the rule is a tool allowing providers to serve individuals with the most complex needs in integrated community settings to ensure that the setting supports the health and well-being of the individual beneficiary and those of people around them. For example, providers in many states serve individuals with severe pica behavior (compulsive eating of non-food items), for whom the physical environment may need to be tightly controlled to prevent the occurrence of individual behavior that can cause severe injury or death. In addition, some community providers support individuals with a history of sexual predation where line-of-sight supervision and limits on interaction with certain members of the community may need to be imposed. Other community providers serve individuals with dementia for whom measures must be taken to account for safety needs in a person-centered manner, including concerns related to wandering. With the HCBS rule's emphasis on full community integration and control of personal resources and activities, the restrictions needed to provide individuals with these kinds of behaviors or other complex needs, alternatives to institutional placement could otherwise violate the HCBS requirements.

However, CMS emphasizes that it is essential that the modifications process be used with strict adherence to its very specific requirements. The modifications process must:

- be highly individualized
- document that positive interventions had been used prior to the modifications
- document that less-intrusive methods did not successfully meet the individual's assessed needs.
- describe how the modification is directly proportionate to the specific assessed need
- include regular data collection

- have established time limits for periodic reviews
- include informed consent, and
- be assured to not cause harm.

Controls on personal freedoms and access to the community cannot be imposed on a class or group of individuals. Restrictions or modifications that would not be permitted under the HCBS settings regulations cannot be implemented as "house rules" in any setting, regardless of the population served and must not be used for the convenience of staff. In the case of individuals for whom modifications are included in the person-centered plan in accordance with the requirements described above, it is equally important to ensure robustness in the person- centered planning process by honoring other preferences the individual has outside of the specific risk targeted by the modification, and to review such restrictions frequently to ensure they are administered consistent with current health and safety needs and are still necessary.

Q4: How can states assure that modifications to home and community-based settings criteria meet the requirements of the rule?

A4: States can use a variety of strategies to assure the efficacy of the modifications process, such as:

- Require providers to ensure that their own policy documents comply with the modifications provisions of federal Medicaid HCBS regulations
- Establish a frequency for providers' periodic reviews of modifications to determine whether or not the modification continues to be necessary or whether it can be removed or an alternative modification that is less restrictive can be created
- Use the state's quality assurance process (e.g. licensing reviews, case management visits, etc.) to sample individual person-centered service plans that include modifications and check them against the criteria in the federal rule
- Create a statewide training system for case managers and provider representatives who are involved in writing plans that include modifications (especially targeting providers who serve larger numbers of individuals with the kinds of behaviors that may require modifications)
- Set a policy of external human rights review of plans or samples of plans that contain modifications, and
- Establish data collection protocols to ensure ongoing monitoring and awareness related to modifications and periodic review of modifications.