

1915(i) Policy

Home and Community-Based Settings (HCBS) 510-08-25

The HCBS Settings Rule establishes requirements for the settings that are eligible for reimbursement for 1915(i) Medicaid Home and Community-Based Services and requires states to ensure the 1915(i) HCBS benefit will be furnished to individuals in their homes and community, not in an institution; and, to ensure all individuals have personal choice and are integrated in and have full access to their communities including opportunities to engage in community life, work, attend school in integrated environments, and control their own personal resources.

Resources and Tools available to accompany this policy include:

- (1) **HCBS Settings Assessment Guide** is located here: [HCBS Settings Assessment Guide](#). This guide contains characteristics which are expected to be present in a HCBS setting and provides suggested questions to use in determining the presence or absence of each requirement in a setting while completing the site review and either the Initial HCBS Setting Review or Heightened Scrutiny Visit forms. The guide contains a "Quick" Reference and an "Expanded" Reference.
- (2) **1915(i) Person-centered Planning Guide** is located here: [Person-centered Planning Guide](#). This guide provides instructions on the self-assessment and how to weave HCBS settings compliance throughout the person-centered planning process.
- (3) **The Council on Quality and Leadership (CQL) Toolkit for States** is located here: [HCBS Settings Rule: Toolkit for States - The Council on Quality and Leadership \(c-q-l.org\)](#). This toolkit provides detailed support using CQL tools and data elements to comply with CMS HCBS Settings Requirements.
- (4) **ND Department of Health and Human Services (NDHHS) HCBS Settings Training** is located here: [HCBS: Settings \(nd.gov\)](#)
- (5) **The 1915(i) HCBS Settings Rule Training** is located here: [Download the PowerPoint#](#)
- (6) **Initial 1915(i) HCBS Settings Review** form is located here: [Initial 1915\(i\) HCBS Settings Review](#)

- (7) **HCBS 1915(i) Heightened Scrutiny Visit Form** located on the ND 1915(i) website: [1915\(i\) Forms | Health and Human Services North Dakota](#)
- (8) **The CMS HCBS Toolkit** is located here: [Home & Community Based Settings Requirements Compliance Toolkit | Medicaid.](#)
- (9) **CMS Training Resources** is located here: [Home & Community Based Services Training Series | Medicaid.](#)
- (10) **Medicaid Living Arrangement Reference** is located here: [Medicaid Living Arrangement Reference Hard Card 510-03-105-10 \(nd.gov\)](#)

NDDHHS Process to Verify Compliance with 42 CFR 441.710(a)(1)-(2)

CMS requires states to ensure compliance with the home and community-based settings criteria for those settings in which the Medicaid beneficiary receives HCBS, and does not require the state to ensure compliance with the settings criteria for the setting in which that individual resides. NDDHHS policy in response to CMS regulations is as follows:

*If an eligible 1915(i) individual is residing in any setting other than the identified institutions and is not receiving any 1915(i) funded services within the residential setting they reside, then the setting itself does not need to be initially verified compliant through the use of the Tier 1 or Tier 2 compliance measures. However, CMS does require correction for at any point settings non-compliance is identified. In addition, NDDHHS requires the Tier 3 compliance measure be completed for all 1915(i) individuals regardless of where they reside or where they receive services. *See Table 1 below which defines each of the compliance measures required for Tiers 1, 2, & 3; also, each of the four categories of settings including a list of institutions.*

NDDHHS will implement the following HCBS Settings Rule Verification process to ensure compliance with the requirements at 42 CFR 441.710(a)(1)-(2).

This table depicts what type of Tier 1, 2, & 3 settings compliance verification is required for each of the 4 residential setting categories if the individual is receiving 1915(i) funded services in the setting. If the individual is not receiving 1915(i) services within their place of residence, then only Tier 3 compliance measures must be completed for all 1915(i) individuals regardless of where they reside or where they receive services. However, CMS does require correction at any point settings non-compliance is identified.

Table 1. HCBS Settings Categories and Compliance Measure

Category	Residential Setting Types	Tier 1 – Setting Compliance Measures 1915(i) Initial HCBS Settings Review Form & Site Visit Required?	Tier 2 – Setting Compliance Measures Heightened Scrutiny Required?	Tier 3 - Individual Compliance Measures Person-Centered Planning Process and Self-Assessment Required?
1	Private Residence: A private home or apartment that the individual lives in, which is rented or owned by the individual or legal guardian. Also, Respite Care Homes fall within this category.	No CMS says the state can presume that these settings are compliant, but if areas of concern are identified, they must be addressed.	Potentially	Yes – Tier 3 Compliance is completed and documented in the POC initially and at least annually thereafter for all 1915(i) individuals regardless of where they reside.
2	Provider Owned or Controlled Residential Setting: A setting where the individual is living with an unrelated caregiver in a provider-owned or controlled residential setting. (Example: Sober Living/Recovery Homes, Group Homes, Foster Homes, Treatment Foster Homes, Transitional Living Homes)	Yes (Requires a lease)	Potentially	Yes – Tier 3 Compliance is completed and documented in the POC initially and at least annually thereafter for all 1915(i) individuals regardless of where they reside.
3	Residential Settings Presumed to have Qualities of an Institution: <ul style="list-style-type: none"> • A setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment. • A setting that is located in a building on the grounds of, or immediately adjacent to, a public institution. • Any other setting that has the effect of isolating individuals from the broader community. 	Yes (Requires a lease)	Yes - Always	Yes – Tier 3 Compliance is completed and documented in the POC initially and at least annually thereafter for all 1915(i) individuals regardless of where they reside.
4	Institutions (i) A nursing facility (ii) An institution for mental diseases (iii) An intermediate care facility for individuals with intellectual disabilities (iv) A hospital *The department has further defined Institutions as: incarceration (jail or prison), Nursing Facility (NF), Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), Institution for Mental Diseases (IMD), Qualified Residential Treatment Program (QRTP), Psychiatric Residential Treatment Facility (PRTF), and	N/A Individuals residing in an institution are not eligible for the 1915(i) and cannot receive 1915(i) services.	N/A Individuals residing in an institution are not eligible for the 1915(i) and cannot receive 1915(i) services.	N/A Individuals residing in an institution are not eligible for the 1915(i) and cannot receive 1915(i) services.

	hospitals including the ND State Hospital which is an IMD.			
--	--	--	--	--

HCBS Settings Compliance Measures & Verification

Required HCBS settings compliance measures must be completed, and verification of compliance documented in the POC by the care coordinator prior to submission of the POC and approval of service authorizations. Individual Settings Compliance Measures including Person-Centered Planning and Self-Assessment are completed for all individuals. Additional Settings Compliance Measures must be completed for individuals receiving services in their place of residence.

Tier One – The care coordinator completes a site visit and the *1915(i) Initial HCBS Settings Review form*.

Tier Two – The care coordinator completes a site visit and the *1915(i) Heightened Scrutiny Visit form* and process.

Tier Three – As part of the individual’s Person-Centered Planning process, the *POC Attachment 1 - Self-Assessment* is completed initially, and at least on an annual basis to capture the individual’s experiences that incorporate the CMS HCBS Final Rule regulations to ensure on-going compliance with the requirements.

Self-Assessment Requirements

See the *1915(i) Person-Centered Planning & Self-Assessment Guide* and *POC Instruction Guide* for full details on completing the Self-Assessment.

The POC Attachment 1 - Self-Assessment, Items 1 – 12 address the following regulations from Paragraphs (a)(1)(vi)(A) through (D) of the Home and Community-Based Settings Federal Rule at 42 CFR 441.710. If modifications are required to any of the regulations to be in compliance, then the *HCBS Settings Modifications section of the POC* must be completed as part of the required HCBS Settings Rule individual compliance verification measures:

1. People are living and regularly participating in integrated environments (e.g., using and interacting in the same environments by people without disabilities, regularly accessing

- the community, having the ability to come and go from the setting, access to public transportation, etc.).
2. People have opportunities for employment and to work in competitive integrated settings (e.g., choice and opportunity to experience different work and/or day activities, support to look for a job if interested, meaningful non-work activities in the community, etc.).
 3. People have control and access of their money (e.g., able to buy needed items, use own money when choose to, accessibility of money, have their own bank account, etc.).
 4. People have options and choices in where they live, work, and attend day services (including do they continue to be satisfied, choice in their own bedroom, and choice in whom they live with/share bedroom, etc.).
 5. People experience privacy, dignity, and respect (e.g., have time alone, privacy during personal assistance, confidentiality of information, respectful staff interactions, being listened to and heard, ability to close/lock bathroom door, access to phone, etc.). In provider-owned or controlled residential settings, people are provided the right to have lockable bedroom doors.
 6. People have choice and control in daily life decisions, activities, and access to food (e.g., they understand their rights, they practice rights important to them, individual choice/control in schedule and routines, availability of food, choice in when/what/where to have meals, etc.).
 7. People have the freedom to furnish and decorate their room/home (e.g., choose decorations, arrange furniture, hang pictures, change things if want to, décor reflects personal interests and preferences, etc.).
 8. People have access to all areas of the setting (e.g., kitchen, break room, laundry room, community rooms, etc.).
 9. People have visitors of their choice and at any time.
 10. People exercise their right of freedom from coercion and restraint (e.g., give informed consent, know who to talk to if not happy, least restrictive methods utilized first, etc.).
 11. People choose their services and supports (e.g., choice in providers, service options, opportunities for meaningful non-work activities, opportunity to update/change preferences, etc.).
 12. People are involved in their own planning process to the extent desired (choice of meeting location, people to invite, desired level of participation, development of plan, etc.).

Below is the section of the POC where verification of compliance is documented:

Document less intrusive attempts to meet the need that were not successful.
Include a clear description of the condition, i.e., diagnosis or other, that is directly proportionate to the specific assessed need pertaining to the modification.
Indicate how data will be collected and reviewed to measure the ongoing effectiveness of the modification.
Indicate how often the need for continuing the modification will be re-assessed.
Has this modification been made with the informed consent of the individual? <input type="checkbox"/> Yes <input type="checkbox"/> No
Explain how the modification(s) meet expectations for safety, allow the individual to feel safe, and prevent harm to the individual?

Process to follow when a 1915(i) individual is receiving services in a Category 1 Setting:

Individual, privately-owned homes (privately-owned or rented homes and apartments in which the individual receiving Medicaid-funded HCBS lives independently or with family individuals, friends, or roommates) are presumed to be in compliance with the regulatory criteria of a home and community-based setting. CMS has confirmed that states are not responsible for confirming this presumption for purposes of ensuring compliance with the regulation, so NDDHHS does not require the Tier 1 - 1915(i) Initial HCBS Settings Review form or site visit be completed.

However, there may be times where Tier 2 - Heightened Scrutiny must be completed on a Category 1 setting. For example, land owned by the Life Skills Transition Center contains private residences owned by a private landlord. These residences are located in a building on the grounds of a public institution, thus the Heightened Scrutiny process needs to be completed.

CMS does require correction at any point settings non-compliance is identified.

If the particular residential setting is known to be utilized by the department's Developmental Disabilities or Aging Divisions, or another C Waiver Authority, it has likely been previously determined compliant. Upon verification of the settings compliance with either division, the 1915(i) Care Coordinator may

obtain verification of their compliant finding and determine it is not necessary for a second Tier 1 or Tier 2 verification to be completed. It is suggested the 1915(i) Care Coordinator ask the C Waiver Authority whether or not a particular setting has been determined compliant when they contact them to verify non-duplication of services.

The 1915(i) Care Coordinator will verify individual compliance using Tier 3 - the person-centered planning and self-assessment process. Each of the identified HCBS settings requirements must be addressed in the individual's plan of care.

Process to follow when a 1915(i) individual is receiving services in a Category 2 Setting:

Provider owned or controlled settings may include, but are not limited to, Sober Living Homes, Group Homes, Foster Homes, Treatment Foster Homes, Respite Homes, and Transitional Living Homes. 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 will be evaluated as such.

The 1915(i) Care Coordinator will verify compliance by completing Tier 1 - 1915(i) Initial HCBS Settings Review form and site visit compliance verification measures; and potentially Tier 2 - the Heightened Scrutiny process. The 1915(i) Care Coordinator will verify individual compliance using Tier 3 - the person-centered planning and self-assessment process. Each of the identified HCBS settings requirements must be addressed in the individual's plan of care.

CMS does require correction at any point settings non-compliance is identified.

If the particular residential setting is known to be utilized by the department's Developmental Disabilities or Aging Divisions, or another C Waiver Authority it has likely been previously determined compliant. Upon verification of the settings compliance with either division, the 1915(i) Care Coordinator may obtain verification of their compliant finding, and determine it is not necessary for a second Tier 1 or Tier 2 verification to be completed. It is suggested the 1915(i) Care Coordinator ask the C Waiver Authority whether or not a particular setting has been determined compliant when they contact them to verify non-duplication of services.

The 1915(i) Care Coordinator will verify individual compliance using Tier 3 - the person-centered planning process. Each of the identified HCBS settings requirements must be addressed in the individual's plan of care.

Process to follow when a 1915(i) individual is receiving services in a Category 3 Setting:

The 1915(i) Care Coordinator will verify compliance by completing Tier 1 - 1915(i) Initial HCBS Settings Review form and site visit compliance verification measures, Tier 2 - the Heightened Scrutiny process, and the 1915(i) Care Coordinator will verify individual compliance using Tier 3 - the person-centered planning and self-assessment process with each of the identified HCBS settings requirements addressed in the individual's plan of care.

CMS does require correction at any point settings non-compliance is identified.

If the particular residential setting is known to be utilized by the department's Developmental Disabilities or Aging Divisions, or other C Waiver Authority, it has likely been previously determined compliant. Upon verification of the settings compliance with either division, the 1915(i) Care Coordinator may obtain verification of their compliant finding and determine it is not necessary for a second Tier 1 or Tier 2 verification to be completed. It is suggested the 1915(i) Care Coordinator ask C Waiver Authority whether or not a particular setting has been determined compliant when they contact them to verify non-duplication of services.

The 1915(i) Care Coordinator will verify individual compliance using Tier 3 - the person-centered planning process. Each of the identified HCBS settings requirements must be addressed in the individual's plan of care.

Process to follow when a 1915(i) individual is receiving services in a Category 4 Setting:

These settings are institutions and will never be HCBS compliant. Individuals residing in an institution are not eligible for the 1915(i) and cannot receive 1915(i) services, with the exception of the Community Transition service under certain circumstances. *See the Community Transition policy for details.*

Responsibilities to Ensure Initial & On-Going Compliance

Care Coordinator Responsibilities

1. Implement person-centered service planning practices and develop POCs according to regulations, which includes documentation of settings compliance.

2. Assess and monitor the physical environment of the client's home and settings where 1915(i) services are provided.
3. Anytime the plan is for a 1915(i) individual to begin receiving 1915(i) funded services within their place of residence, then the care coordinator must verify the new setting is compliant with the HCBS Settings Rule using the appropriate compliance verification measures identified in the table above prior to service provision in the residential setting beginning.
4. Monitor service satisfaction and service plan implementation.
5. Conduct heightened scrutiny reviews and onsite visits.
6. Verification of HCBS Settings Compliance must be documented in the plan of care.
7. Remediate non-compliance issues.

In addition to the required initial HCBS Settings Rule verification which takes place immediately following the individual's eligibility determination and prior to service delivery, verification of settings must be continually assessed by the care coordinator through face-to-face visits and the person-centered planning and self-assessment process, and ongoing compliance documented in the plan of care throughout the individual's eligibility. *CMS does require correction at any point settings non-compliance is identified.* Any identified issues will be corrected through the appropriate measures.

Settings Rule Compliance Remediation

Medicaid reimbursement will not occur for 1915(i) services delivered before initial required settings compliance measures are completed. However, if for any reason settings non-compliance is discovered after the initial compliance verification, then the care coordinator will immediately initiate the appropriate settings verification process for that particular setting category.

If remediation of the setting is a possibility, then the care coordinator will initiate the steps outlined in this policy. Any identified issues will be remediated by using the person-centered plan of care process. An advocacy organization or the NDDHHS may be contacted for issues not able to be remediated.

If a decision is made that the setting cannot be remedied, a denial will be issued for that setting. The care coordinator will issue a 30-day advance written notice to the individual informing them they are not able to receive 1915(i) services in that setting and must relocate to a compliant setting within 30 days if they wish to continue to receive 1915(i) services in their place of residence.

The care coordinator will provide the individual assistance with finding other HCBS options in their community that fully comply with the rule. Individuals will be provided choices among alternative settings that meet the individual's needs, preferences, and HCBS setting requirements. The care coordinator and person-centered planning team will develop a transition plan to assist with relocation efforts.

If it is not possible to provide any 1915(i) services in a compliant setting, the individual's 1915(i) eligibility will terminate.

1915(i) Other Service Provider Responsibilities

1. Develop and implement agency policies and procedures that are aligned with the HCBS Settings Rule.
2. Provide initial and annual training on the HCBS Settings Rule to their staff who are responsible for service delivery as necessary.
3. Collaborate with the care coordinator during site visits, heightened scrutiny processes, person-centered planning process, and complete required remediation as needed.

NDDHHS Responsibilities

1. Utilize the Quality Improvement Strategy process.
2. Provide policy and educational materials for care coordinators.
3. Participate in the internal HCBS settings committee.
4. Participate in the heightened scrutiny process.

Heightened Scrutiny Process

When a setting requires heightened scrutiny, the care coordinator will utilize the 1915(i) Heightened Scrutiny form to evaluate all regulations and identify any institutional characteristics. The Heightened Scrutiny form is completed onsite for each setting by the care coordinator using provider policy review, observation and discussion with individuals, guardians, and provider staff. The care coordinator will work with the provider to complete the Heightened Scrutiny form and identify any areas of noncompliance, remediation efforts, and timelines for completion.

Examples of settings that may have the effect of isolating beneficiaries are found in the HCBS Toolkit. 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.

Care coordinators will implement remediation efforts for any noncompliance identified. The care coordinator will gather feedback from individuals/legal decision makers to confirm remediation and compliance. The feedback will be gathered from individuals/legal decision makers in person or over the phone. Once this process is complete, the information along with the information submitted in the evidence package will be reviewed by an internal HCBS settings committee. The committee will be comprised of a representative from the State's Aging Services Division, Developmental Disabilities Division, Medical Services Division, and the State Risk Manager. The committee will decide if the setting:

- a) Has successfully refuted the presumptively and now fully complies;
- b) With additional changes will fully comply; or
- c) Does not/cannot meet HCB settings requirements.

If it is determined that the setting has provided enough evidence that they fully comply, the evidence package will be submitted for public comment for 30 days. After the public comment period, it will be submitted to CMS to see if they concur.

If a decision is made that the provider cannot meet the regulations, they will be issued a denial for that setting. The care coordinator will inform the

individual that the setting is not an option for them to reside in and receive 1915(i) services and will offer to assist the individual with locating a setting that complies with the HCBS Settings Rule. If any relocation of clients is needed, the person-centered planning process will be followed.

See the Heightened Scrutiny FAQ section of this policy, or visit the CMS FAQ documents located in the CMS Home and Community Based Settings Toolkit for answers to specific questions relating to heightened scrutiny:

[Home & Community Based Settings Requirements Compliance Toolkit | Medicaid](#)

The Home and Community-Based Settings Federal Rule at 42 CFR 441.710

(a) Home and Community-Based Setting. States must make State plan HCBS available in a home and community-based setting consistent with both paragraphs (a)(1) and (a)(2) of this section.

- (1) Home and community-based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:
 - (i) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.
 - (ii) The setting is selected by the individual from among setting options, including non-disability specific settings and an option for a private unit in a residential setting. The setting options are identified and documented in the person-centered service plan and are based on the individual's needs, preferences, and, for residential settings, resources available for room and board.
 - (iii) Ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.
 - (iv) Optimizes, but does not regiment, individual initiative, autonomy, and independence in making life choices, including but not limited

to, daily activities, physical environment, and with whom to interact.

- (v) Facilitates individual choice regarding services and supports, and who provides them.
- (vi) In a provider-owned or controlled residential setting, in addition to the above qualities at paragraphs (a)(1)(i) through (v) of this section, the following additional conditions must be met:
 - (A) The unit or dwelling is a specific physical place that can be owned, rented, or occupied under a legally enforceable agreement by the individual receiving services, and the individual has, at a minimum, the same responsibilities, and protections from eviction that tenants have under the landlord/tenant law of the state, county, city, or other designated entity. For settings in which landlord tenant laws do not apply, the State must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS individual and that the document provides protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law;
 - (B) Each individual has privacy in their sleeping or living unit:
 - (1) Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors;
 - (2) Individuals sharing units have a choice of roommates in that setting; and
 - (3) Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement.
 - (C) Individuals have the freedom and support to control their own schedules and activities, and have access to food at any time;
 - (D) Individuals are able to have visitors of their choosing at any time;
 - (E) The setting is physically accessible to the individual; and

(F) Any modification of the additional conditions, under paragraphs (a)(1)(vi)(A) through (D) of this section, must be supported by a specific assessed need and justified in the person-centered service plan. The following requirements must be documented in the person-centered service plan:

- (1) Identify a specific and individualized assessed need.
- (2) Document the positive interventions and supports used prior to any modifications to the person-centered service plan.
- (3) Document less intrusive methods of meeting the need that have been tried but did not work.
- (4) Include a clear description of the condition that is directly proportionate to the specific assessed need.
- (5) Include regular collection and review of data to measure the ongoing effectiveness of the modification.
- (6) Include established time limits for periodic reviews to determine if the modification is still necessary or can be terminated.
- (7) Include the informed consent of the individual.
- (8) Include an assurance that interventions and supports will cause no harm to the individual.

(2) Home and community-based settings do not include the following institutions*:

- (i) A nursing facility.
- (ii) An institution for mental diseases.
- (iii) An intermediate care facility for individuals with intellectual disabilities.
- (iv) A hospital

*The department has further defined Institutions as:

incarceration (jail or prison), nursing facility (NF), Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF/IID), Qualified Residential Treatment Program (QRTP), Psychiatric Residential Treatment Facility (PRTF), or Institutions for Mental Disease (IMD, like the State Hospital). Individuals in these settings are receiving 24/7 institutional level services; therefore, 1915(i) services would be considered duplication of services.

Other settings like Alternative Care Services (ACS) and hospitals (other than the State hospital) are not automatically deemed institutions. Individuals in these settings may not be receiving 24/7 institutional level services; therefore, if 1915(i) services are needed by an individual while in the setting, a HCBS site visit by the care coordinator is necessary to determine compliance with Paragraphs (a)(1)(vi)(A) through (D) of the Home and Community-Based Settings (HCBS) Federal Rule at 42 CFR 441.710.

(v) Any other locations that have qualities of an institutional setting, as determined by the Secretary. Any setting that is located in a building that is also a publicly or privately operated facility that provides inpatient 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 will be presumed to be a setting that has the qualities of an institution unless the Secretary determines through heightened scrutiny, based on information presented by the State or other parties, that the setting does not have the qualities of an institution and that the setting does have the qualities of home and community-based settings.

HCBS Settings Rule Quality Assurance

The state has a Quality Assurance monitoring process to ensure that all settings meet federal home and community-based settings requirements, initially, and ongoing. *See the 1915(i) Quality Assurance policy for specifics.*

The NDDHHS' quality assurance process involves reviewing a select number of plans of care annually. The NDDHHS will check that all HCBS settings have been verified compliant on each of the plans reviewed.

CMS Question & Answer Section

Heightened Scrutiny Q & A

Question. 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)?

Answer. 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.

Question. What criteria does CMS use to review state requests for heightened scrutiny?

Answer. CMS reviews the information presented by the state as part of its request for "heightened scrutiny," in order to determine that the setting has the qualities of a home and community-based setting and does not have institutional qualities. When a state makes a request to CMS to use the heightened scrutiny process for a particular setting or

settings, CMS reviews all information presented by the state and other parties. CMS may solicit the input of federal partners. CMS, upon consultation with these federal partners, if appropriate, will review the information to determine whether each and every one of the qualities of a home and community based setting outlined in 42 CFR 441.301(c)(4)/441.530(a) are met, whether the state can demonstrate that persons receiving services are not isolated from the greater community of individuals not receiving Medicaid HCBS, and whether CMS concludes that the information indicates that there is strong evidence the setting does not meet the criteria for a setting that has the qualities of an institution. When a state submits documentation for a heightened scrutiny review, CMS will review the information or documentation to ensure that all individuals in that setting are afforded the degree of community integration required by the regulation and desired by the individual. Providing documentation that a percentage or “some” individuals have community access will not be considered sufficient to show that the setting meets the regulations.

Question. What information should states submit in a heightened scrutiny process?

Answer. CMS expects the state to submit several types of information and documentation to support its position that a particular setting has the qualities of home and community-based services and does not have the qualities of an institution. Evidence of how a setting overcomes its presumed institutional qualities should focus on the qualities of the setting and how it is integrated in and supports full access of individuals receiving home and community-based services into the greater community, not on the aspects and/or severity of the disabilities of the individuals served in the setting. For heightened scrutiny requested under 1915(c) or 1915(i), such information should also include the information the state received during the public input process. CMS will also consider information provided by other parties. The exploratory questions available in the Toolkit can also be helpful in determining the type of information that should be included in the documentation.

Some additional examples might include:

- Licensure requirements or other state regulations for the setting that clearly distinguish it from institutional licensure or regulations, to demonstrate how the setting is integrated in and supports full access to the greater community.

- Residential housing or zoning requirements that demonstrate how the setting is integrated in and supports full access to the greater community.
- Description of the proximity to and scope of interactions with community settings used by individuals not receiving Medicaid funded home and community-based services.
- Provider qualifications for staff employed in the setting that indicate training or certification in home and community-based services, and that demonstrate the staff is trained specifically for home and community-based support in a manner consistent with the HCB settings regulations.
- Service definitions that explicitly support the setting requirements. For example, definitions of employment supports that facilitate community-based integrated employment or, for facility-based programs, maximize autonomy and competitive employment opportunities.
- Documentation that the setting complies with the requirements for provider-owned or controlled settings at §441.301(c)(4)(vi)A through D, and if any modifications to these requirements have been made, such modifications are documented in the person-centered plan(s) consistent with the requirements at §441.710((a)(1)(vi)(A)through (D), and at §441.710(a)(1)(vi)(F)
- Procedures in place by the setting that indicate support for activities in the greater community according to the individual's preferences and interests, staff training materials that speak of the need to support individuals' chosen activities, and a discussion of how schedules are varied according to the typical flow of the local community (appropriate for weather, holidays, sports seasons, faith-based observation, cultural celebrations, employment, etc.).
- Documentation that the individuals selected the setting from among setting options, including non-disability-specific settings.
- Description of the proximity to avenues of available public transportation or an explanation of how transportation is provided where public transportation is limited.
- Pictures of the site and other demonstrable evidence (taking in consideration the individual's right to privacy). The information submitted may also include a report from an on-site visit to the setting conducted by the state (which as noted in previous Toolkit documents will facilitate the review), public input on the setting in question, consumer experience surveys that can be linked to the

site for which evidence is being submitted, and any other documentation made available. Supporting information could include individual interviews outside the presence of the provider conducted by an independent entity or state staff with demonstrated expertise and/or training working with the relevant population. If warranted, CMS may conduct an onsite review as well. Please note that, in accordance with provisions of the Health Information Portability and Accountability Act, no personally identifiable or other protected information should be submitted to CMS.

Question. How can a state demonstrate that settings in a publicly or privately-owned facility that provides inpatient treatment meet the home and community-based services (HCBS) characteristics?

Answer. The state must submit strong evidence that the setting presumed institutional has the characteristics of a HCBS setting and not an institutional setting. In addition to the guidance previously provided in the toolkit, at a minimum, states should submit information clarifying that there is a meaningful distinction between the facility and the community-based setting such that the latter is integrated in and supports full access of individuals receiving HCBS. For example, the state can submit, and CMS will consider, documentation showing that the HCBS setting is not operationally interrelated with the facility setting, such as:

- Interconnectedness between the facility and the setting in question, including administrative or financial interconnectedness, does not exist or is minimal.
- To the extent any facility staff are assigned occasionally or on a limited basis to support or back up the HCBS staff, the facility staff are cross-trained to meet the same qualifications as the HCBS staff;
- Individuals in the setting in question do not have to rely primarily on transportation or other services provided by the facility setting, to the exclusion of other options;
- The proposed HCBS setting and facility have separate entrances and signage;
- The setting is integrated in the community to the extent that a person or persons without disabilities in the same community would consider it a part of their community and would not

associate the setting with the provision of services to persons with disabilities:

- The individual participates regularly in typical community life activities outside of the setting to the extent the individual desires. Such activities do not include only those organized by the provider agency specifically for a group of individuals with disabilities and/or involving only paid staff; community activities should foster relationships with community individuals unaffiliated with the setting;
- Services to the individual, and activities in which the individual participates, are engaged with the broader community.

Question. How can a state demonstrate that a building located on the grounds of or immediately adjacent to a public institution meets the home and community-based services (HCBS) characteristics?

Answer. The state must submit strong evidence that the setting presumed institutional has the characteristics of a HCBS setting and not an institutional setting. In addition to the guidance previously provided in the toolkit, the state should, at a minimum, submit information documenting that there is a meaningful distinction between the institution and the community-based setting such that the latter is integrated in and supports full access of individuals receiving HCBS services. For example, the state can submit, and CMS will consider, documentation showing that the HCBS setting is not operationally interrelated with the institutional setting, such as:

- Interconnectedness between the institution and the setting, including administrative or financial interconnectedness, in question does not exist or is minimal;
- To the extent any institutional staff are assigned occasionally or on a limited basis to support or back up the HCBS staff, the institutional staff are cross-trained to meet the same qualifications as the HCBS staff.
- Individuals in the setting in question do not have to rely primarily on transportation or services provided by the institutional setting, to the exclusion of other options.
- The setting is integrated in the community to the extent that a person or persons without disabilities in the same community would consider it a part of their community and would not associate the setting with the provision of services to persons with disabilities.

- The individual participates regularly in typical community life activities outside of the setting to the extent the individual desires. Such activities do not include only those organized by the provider agency specifically for a group of individuals with disabilities and/or involving only paid staff; community activities should foster relationships with community individuals unaffiliated with the setting.
- Services to the individual, and activities in which the individual participates, are engaged with the broader community.

Question. How can a state demonstrate that a setting does not have the effect of isolating individuals receiving home and community-based services (HCBS) from the broader community of individuals not receiving HCBS?

Answer. The state has several options for the type of evidence it can submit to overcome the presumption that a setting is isolating. The evidence should support the following qualities:

- The setting is integrated in the community to the extent that a person or persons without disabilities in the same community would consider it a part of their community and would not associate the setting with the provision of services to persons with disabilities.
- The individual participates regularly in typical community life activities outside of the setting to the extent the individual desires. Such activities do not include only those organized by the provider agency specifically for a group of individuals with disabilities and/or involving only paid staff; community activities should foster relationships with community individuals unaffiliated with the setting.
- Services to the individual, and activities in which the individual participates, are engaged with the broader community.

Question. What tools are available for states to collect documentation and information to be submitted to permit CMS to conduct heightened scrutiny?

Answer. States may consider using the Exploratory Questions for Residential Settings and/or Non-Residential Settings as a framework against which to examine settings. The questions are designed to elicit information through review of documents and/or site visits. States are

free to develop their own tools for collecting and evaluating the information received. In addition, states are expected to solicit public input on settings the state has flagged for heightened scrutiny, as part of a Statewide Transition Plan, a waiver-specific transition plan, or a waiver or state plan amendment filing submitted to CMS. This public reaction will facilitate the state's understanding of how the community at large views the settings in question.

Question. What should states consider when performing a site visit?

Answer. CMS does not have a specific protocol for a site visit, which is highly recommended in order for CMS to evaluate the evidence. A site visit should include a significant amount of time that is observational in nature. The purpose of this type of site visit is to observe the individual's life experience and the presence or absence of the qualities of home and community-based settings. Record reviews and interviews are supplemental, but we believe are important to corroborate adherence to requirements and should align with observations. In order to provide strong evidence, states should consider some of the following activities:

- Gather information from stakeholders with relevant information about the setting, such as the state Protection and Advocacy Organization, or other organizations or individuals that raised concerns in the public comment process;
- Conduct visits with individual(s) who have expertise with the community at large (to facilitate an understanding of local routines and interactions), and have training and/or experience in interviewing relevant populations;
- Review staff logs or other daily records of the setting, including any instances of seclusion and/or restraint; facility policies and procedures on resident/individual rights, person-centered service plans and records of how those plans are met; documentation regarding individuals' selection of the setting from among setting options, including non-disability-specific settings;
- Evaluate individuals' access to the broader community including the availability of transportation and geographic proximity to other community resources, including shopping, entertainment, worship, etc.;
- Look for evidence that settings have institutional characteristics, such as cameras; individual's schedules or other personal information posted; lack of uniqueness in room décor; indicators of seclusion or restraint such as quiet rooms with locks, restraint

chairs, or posters of restraint techniques; regimented mealtimes and other daily activities; and barriers that inhibit community individual involvement, such as fences or gates;

- Conduct interviews that generally:
 - o Include as many individuals as possible selected by the interviewers without influence by the provider or staff;
 - o Include staff, specifically including direct support staff because they implement the program policies and procedures on a day-to-day basis, outside of the presence of the supervisor or administrator;
 - o Have specific questions/goals based on the exploratory questions; and
 - o Avoid leading questions that suggest the preferred answer and instead use questions that are open-ended, yet sufficiently specific to elicit a description of how the setting operates and the individual's experience in it.

Question. How will CMS respond to the state's submission of information for heightened scrutiny of a setting?

Answer. CMS will respond in writing as part of our review of the action pending – whether in response to a Statewide Transition Plan, new waiver, or SPA. If the CMS review determines that all regulatory requirements are met by the setting in question, and the information submitted to CMS -- which could include information collected in response to CMS exploratory questions -- is sufficient to overcome the presumption of institutional or isolating qualities, the setting will be determined to be home and community based. If the CMS review determines that not all regulatory requirements are met, and the setting is included in the state's Statewide Transition Plan, the state can use the remaining transition period to bring the setting into compliance with all requirements, transition individuals from that setting to a compliant setting, transition the coverage authority to one not requiring provision in a home or community-based setting, or transition to non-Medicaid reimbursement. If CMS has further questions, CMS may conduct a site visit. If the CMS review determines that not all regulatory requirements are met, and the setting is included in a new 1915(c) waiver, new 1915(i) state plan amendment, or new 1915(k) CFC SPA, Federal reimbursement for services provided to individuals in that setting will not be available unless or until the setting achieves compliance with all requirements. Once compliant with home and community-based

services criteria, the setting can be added to the new program and Federal reimbursement for services provided to individuals in that setting can be claimed. Approval of any heightened scrutiny request only pertains to the individual settings subject to the request. CMS and the state will collaborate through the Statewide Transition Plan and the review of waiver and SPA actions to ensure implementation of a plan for ongoing monitoring and oversight to ensure continued compliance. In the approval of those documents, CMS will communicate the settings and the scope under which they are adjudicated to be home and community-based services, and indicate that any material changes to the settings approved through heightened scrutiny such as an increase in licensing capacity, the establishment of additional disability-oriented settings in close proximity (e.g., next door), or changes in the ways in which community integration is realized, will require the state to update CMS and may result in a reevaluation of the setting.

Restrictions & Modifications to the HCB Settings Requirements Q & A

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

Answer. 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 individuals 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.

Question. Does the right to freedom from restraint prohibit locked doors or doors with alarms for individuals who are incapable of protecting themselves unsupervised in the community and/or who have documented histories of wandering?

Answer. In a provider-owned or controlled residential setting, states must ensure that any necessary modification of the requirements specifying the rights of individuals receiving services is based on individually assessed need and justified and documented in the person-centered plan as described in § 42 CFR section 441.301(c)(4)(vi)(F). In other settings, the individual must be afforded the rights of privacy, dignity and respect, and freedom from coercion and restraint. The person-centered service plan must reflect risk factors and measures in place to minimize them, including individualized back-up plans and strategies.

Question. What, if any, restrictions on an individual's choice of roommates, visitors or with whom to interact (e.g., when there is documented history of abuse or exploitation by another individual) are permissible?

Answer. An individual's rights, including but not limited to roommates, visitors, or with whom to interact, must be addressed as part of the person-centered planning process and documented in the person-centered plan. Any restrictions on individual choice must be focused on the health and welfare of the individual and the consideration of risk mitigation strategies. The restriction, if it is determined necessary and appropriate in accordance with the specifications in the rule, must be documented in the person-centered plan, and the individual must provide informed consent for the restriction.

Question. During the person-centered process, what is the measure of whether a past intervention or method has or has not worked to meet an individual's assessed needs? Must strategies have been tried over a certain period of time? Must there be a certain number of incidents to demonstrate that the intervention or method did not meet the individual's assessed need?

Answer. CMS has not established a uniform federal standard for measuring the effectiveness of past interventions. Each individual is unique, so considerations for each individual's person-centered plan will be different, including the appropriate use of interventions. The person-centered planning team must consider what is a reasonable amount of time (e.g., week, month) to evaluate the effectiveness of an intervention, based on the individual circumstances, as well as weigh the risk, success and amount of time given for a response. Data related to the utilization of positive interventions and supports, as well as less intrusive methods of addressing the need, must be collected, and documented prior to making or amending any modification. The person-centered planning team may need assistance from specific experts, such as a behaviorist or behavior specialist, to aid in the person-centered planning process (e.g., behavior analysis, crisis intervention plan). These considerations should be documented in the person-centered plan to support the determination of an intervention's effectiveness. A modification must be reviewed on a regular basis and should never become a "standing order" without time limitations. In addition, the person-centered plan must be finalized and agreed to in writing, based on the informed consent of the individual. It is therefore vital to include the individual in this process, solicit the individual's view of the benefits

or success of an intervention and consider together an appropriate course of action.

Question. During the person-centered planning process, may the effectiveness of prior positive interventions and less intrusive methods for meeting assessed needs be considered from previous settings in order to develop the individual's service plan, or must the methods have been tried and have failed in the current setting?

Answer. Clear documentation of past interventions and positive reinforcement may be used initially at the time of an individual's transition from one setting to another. The new setting itself might make a significant difference as to whether restriction that might have been in place in a prior setting are necessary. If a person moves between settings (e.g., from a large residential setting into a small apartment or group home), the individual's response to the modification currently being used or even the new setting without the modification may or may not be comparable. The person-centered planning team must convene to amend the individual's plan, considering the context of the new setting, and not assume that modifications made in a prior setting necessarily apply but rather evaluate to see if they do. These types of considerations facilitate discussion on what is reasonable for an individual and must be reflected and agreed to in writing by the individual, in the person-centered plan.

Question. What is the consequence if an individual receiving residential HCBS does not consent to a necessary modification of the conditions related to home and community-based settings required in a provider-owned and controlled setting (§ 42 CFR section 441.301(4)(v)(A-F) such as restrictions to privacy in a sleeping or living unit or access to food? Can the individual be permitted to remain in the residential setting without the modification?

Answer. An individual must provide informed consent prior to a necessary modification of conditions related to home and community-based settings being implemented, and providers cannot modify these conditions without such consent. Any modification must be based on an individual's assessed need and directly proportional to that specific assessed need. The state and provider must use the person-centered planning process, and alternative strategies that allow the individual the fullest self-determination and independence. If an individual continues to reside in the setting without the necessary modification in place, the state is still responsible for assuring the individual's health and welfare and implementation of services consistent with the person-centered

plan. The state would therefore need to determine if it could assure the health and welfare of the individual if he or she continues to reside in the setting without the modification. Additionally, there may be state laws that apply to the individual's rights under landlord/tenancy laws or residency agreements.

Provider Owned or Controlled Settings Q&A

Tenancy Q & A

In a provider owned or controlled setting, the state must ensure that a lease, residency agreement or other form of legally enforceable, written agreement will be in place for each individual; the document must provide protections that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord/ tenant laws.

Question. If a provider is furnishing home and community-based services (HCBS) to all individuals in a setting in a property owned and leased by a third party, is this setting considered provider owned and controlled?

Answer. If the individual leases directly from the third party that has no direct or indirect financial relationship with the provider, the property is not considered provider-owned or controlled.

If the HCBS provider leases from a third party or owns the property, this would be considered provider owned or controlled.

If the provider does not lease or own the property but has a direct or indirect financial relationship with the property owner, we would presume that the setting was provider controlled unless the property owner or provider establishes that the nature of the relationship did not affect either the care provided or the financial conditions applicable to tenants.

Question. Can a residential agreement between the individual and the entity that owns or controls the property have the same protections as a lease?

Answer. Yes, however the state must ensure that a lease, residency agreement or other form of written agreement will be in place for each HCBS individual, and the document provides enforceable protections

that address eviction processes and appeals comparable to those provided under the jurisdiction's landlord tenant law.

Visitors Q & A

Question. How will the regulation's requirement that an individual in a provider owned or controlled setting have access to visitors at any time be balanced against the rights and desires of others living in that setting?

Answer. The regulation requires that individuals in a provider owned or controlled setting experience the community in the same manner as individuals not receiving Medicaid funded home and community-based services. While no restrictions on the ability to have visitors should be imposed for convenience purposes, the regulation does not supersede orders of protection or other parameters governing the movement or actions of individuals visiting the setting that may arise under landlord/tenant or other laws or the terms of the lease or rental agreement.

Privacy & Access Q & A

Question. What is the meaning of a "private unit in a residential setting?" Does this mean that an individual must be afforded the option of a private bedroom regardless of the individual's financial resources to pay for room and board? Answer: The state offering HCBS in residential settings under 1915(c), (i) and (k) must make available the option to receive services in a private unit in a residential setting; however, it may be in the individual's own or family home. The regulatory requirement acknowledges that an individual may need to share a room due to the financial means available to pay for room and board or may choose to share a room for other reasons. However, when a room is shared, the individual should have a choice in arranging for a roommate. 8. Question: Are there circumstances under which staff or caregivers may or may not enter an individual's bedroom when the door is locked and the individual is in the bedroom?

Answer. Individuals should be afforded the same respect and dignity as a person not receiving home and community-based services. In an urgent or emergency situation, it may be appropriate for someone providing services to enter an individual's locked room. The person-

centered planning process and plan should address the circumstances in which this might happen.

Question. Must the individual be given a key to his or her bedroom door and be permitted to carry it outside the residence? What types of staff or caregivers would not be considered appropriate to have keys to an individual's bedroom?

Answer. Individuals should have access to their homes at all times unless appropriate limitations have been determined and justified in the person-centered plan consistent with § 42 CFR section 442.301(c)(4) and 441.530 (a)(1)(vi)(F) that outlines the process for modifying any of the condition's required for the individual's assessed need. The staff person(s) allowed to have keys to an individual's room should be determined by the provider and individual and should be documented in the person-centered plan. The provision of keys to anyone other than the residents of the setting should be limited to those individuals and circumstances identified and for the purposes described in the person-centered planning process.

Question. Does the term "living unit" mean that the individual should have a key to the residence as well as his or her bedroom?

Answer. Yes. It is expected that individuals would have keys to the residences in which they live. If there are circumstances that would prevent an individual from having a key to the residence, these should be discussed during the person-centered planning process and described and documented in the person-centered plan. If, as indicated in the person-centered plan, an individual will not have a key to the residence, the individual should still have full access to the residence and methods to make this possible should be included in the plan. 4. Question: How would an individual's choice of roommate be documented? Answer: The individual's choice of roommate must be documented in the person-centered plan. The person-centered plan documents how choice was provided to and exercised by the individual. Conflicts should be addressed if they occur and mediation strategies should be available to address concerns. 5. Question: Do the Home and Community-Based (HCB) setting requirements address the number of individuals living in a residential HCB setting? Answer: No. While size may impact the ability or likelihood of a setting to meet the HCB settings requirements, the regulation does not specify size. Even a very small residential setting may have policies that restrict individual access to things such as food and telephone use that would not be consistent with HCB requirements, while facilities that serve a larger number of

individuals may have structured their system in a manner that comports with the qualities required. The HCBS rule defines the minimum qualities for a HCB setting as experienced by the individual; states may set a higher threshold for HCB settings than required by the regulation, including the option to establish size restrictions and limitations.