

Home and Community-Based Services (HCBS) Settings Procedures

Provider Presentation

October 8, 2024



DEPARTMENT OF
**PUBLIC HEALTH &
HUMAN SERVICES**

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HCBS Settings Rule

In 2014, the Centers for Medicare and Medicaid Services (CMS) announced the Home and Community Based Services (HCBS) Final Rule, or Settings Rule.

The Settings Rule is a set of rules that providers, case managers, and states must follow regarding HCBS settings and the person-centered planning (PCP) process. In Montana, these rules apply to services delivered through the 0208, the Severe Disabling Mental Illness (SDMI), Big Sky Waiver (BSW) waivers and Community First Choice (CFC) services.



HCBS Settings Rule

General Requirements

A setting is defined as any residential or nonresidential site where HCB Services are delivered. The HCBS Settings rule requires that **each** setting:

- Is integrated in and supports access to the greater community
- Provides opportunities to seek employment and work in competitive, integrated settings, engage in community life, and control personal resources
- 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
 - Person-centered service plans document options based on the individual's needs and preferences



HCBS Settings Rule

General Requirements

- Ensures the individual receives services in the community to the same degree of access as individuals not receiving Medicaid HCBS
- Ensures an individual's rights of privacy, dignity, respect, and freedom from coercion and restraint
- Optimizes individual initiative autonomy, and independence in making life choices
- Facilitates individual choice regarding services and supports, and who provides them



HCBS Settings Rule

Additional Requirements for Provider-Owned or Controlled Settings

Each individual has privacy in their sleeping or living unit:

- Units have entrance doors lockable by the individual, with only appropriate staff having keys to doors
- Individuals sharing units have a choice of roommates in that setting.
- Individuals have the freedom to furnish and decorate their sleeping or living units within the lease or other agreement



HCBS Settings Rule

Additional Requirements for Provider-Owned or Controlled Settings

- Individuals have the freedom and support to control their own schedules and activities and have access to food at any time.
- Individuals are able to have visitors of their choosing at any time.
- The setting is physically accessible to the individual.



HCBS Settings Rule

For Additional Information on the HCBS Settings Rule Requirements, please visit: [Home and Community Based Services \(mt.gov\)](https://www.mt.gov/Departments/Health/Community%20Health/Community%20Health%20and%20Human%20Services/HCBS%20Settings%20Rule)



Provider Self-Assessment (PSA)

Purpose & Scope

Purpose:

The purpose of the PSA document is for an HCBS provider to assess their settings for HCBS Settings Rule compliance. The PSA submission is the first step in the HCBS Settings Monitoring Process.

Scope:

The following situations warrant completion of a PSA by a provider for a residential or non-residential setting:

- New provider requesting enrollment of one or more settings
- The addition of a new setting by an existing, enrolled provider*
- Existing provider setting that changes physical location
- Change of ownership (CHOW)
- Existing provider – PSA reevaluation
- Existing Provider (non-compliance issue identified)

*DPHHS has encountered scenarios in which an additional setting has opened, providing Medicaid beneficiaries HCB Services prior to the completion and approval of a Provider Self-Assessment (PSA) and/or an on-site Validation Tool Visit.



Provider Self-Assessment (PSA) Procedure

- **Step 1:** The provider submits the Provider Self-Assessment (PSA) when opening a setting. The Department may also request a PSA at any time.
- **Step 2:** The Department program staff evaluates the PSA against the compliance criteria outlined in the Settings rule. The Department program staff will pursue additional documentation from the provider, if needed, to make a determination of compliance. (Please see Slide #32 for more information on documentation.)
- **Step 3:** The Department establishes if any provider response on the PSA indicates potential non-compliance with the Settings Rule.
- **Step 4:** The Department establishes if any provider response on the PSA indicates presumed or potential Heightened Scrutiny evaluation.



Provider Self-Assessment (PSA)

Procedure (continued)

- **Step 5:** If the providers' responses on the PSA indicates full compliance with the Settings Rule, the Department may use the Settings Evaluation and Tracking System (SETS) to provide approval. Department staff may schedule an on-site validation visit prior to approval.
- **Step 6:** The Department contacts the provider if the responses on the PSA indicate one or more potential non-compliance and/or Heightened Scrutiny issues. The provider will need to decide whether they will or can come into compliance.
- **Step 7:** If the provider confirms they want to pursue compliance, the Department will communicate the necessary actions to resolve the areas of non-compliance.
- **Step 8:** If the provider confirms they will not bring the setting into compliance, the Department denies the PSA on the HCBS Settings portal and proceeds with the Provider Enrollment Denial or Disenrollment Process.



Provider Self-Assessment Procedure (continued)

An HCBS Setting must have a PSA completed at least once every three to five years.

An On-Site Validation Visit must occur prior to proceeding with a Provider Corrective Action Plan (PCAP) request, Enrollment Denial or Disenrollment process occurring.

The provider may voluntarily withdraw their enrollment application or choose to disenroll a setting prior to an on-site validation visit or PCAP



Validation Tool

Purpose & Scope

Purpose:

The purpose of the Validation Tool to verify the Setting's compliance with the Settings Rule.

Scope:

The Department **may** complete the Validation Tool in order to:

- validate the Provider Self-Assessment (PSA);
- verify HCBS Settings Rule compliance; and/or
- validate a concern of non-compliance.

The Department **must** complete the Validation Tool in order to:

- determine if a Provider Corrective Action Plan (PCAP) is required; and/or
- determine if a Heightened Scrutiny Evaluation is required.



Validation Tool Procedure

- **Step 1:** Once the HCBS provider submits the PSA for review and/or a potential non-compliance issue is identified, the Department determines if a validation visit is required. At the Department's discretion, a validation visit can be completed for any reason regardless of the Provider Self-Assessment results.
- **Step 2:** The Department program staff will complete the on-site visit using the validation tool, documenting evidence of compliance or non-compliance for each section of the validation tool.
- **Step 3:** After the validation visit is completed, Department program staff will review the validation tool to determine if the setting is compliant.
- **Step 4:** If compliant, the provider is sent communication indicating compliance.



Validation Tool

Procedure (continued)

- **Step 5:** If there are minor areas of noncompliance that can be easily remedied, the Department program staff communicates issues with the provider and the provider agency has 5 calendar days to rectify the issue and provide evidence of compliance (e.g., pictures, policy, etc.). If the noncompliance has been resolved within that timeframe, the Department program staff indicates this in the notes/evidence on the Validation Tool, including the date of accepted compliance. The provider is sent communication indicating compliance (Step 4). If compliance is not met in the specified time, the Department program staff initiates the PCAP process.
- **Step 6:** If the Department program staff determines the setting is not compliant, the provider is sent a Provider Corrective Action Plan request.



Validation Tool

Procedure (continued)

- **Step 7:** If a setting has been identified as a heightened scrutiny setting, meaning it is presumed to have institutional qualities, Department program staff will begin entering evidence gathered during the validation visit into the Heightened Security Packet Template document.
- **Step 8:** At a minimum, the Department program staff must conduct an on-site visit at least once every five years per HCBS setting. At the Department's discretion, a validation visit can be completed for any reason and at any cadence.



Heightened Scrutiny

Purpose & Scope

Purpose:

The purpose of the Heightened Scrutiny On-Site Review is to determine whether each setting identified as meeting Heightened Scrutiny criteria complies with regulatory requirements. Compliance with these requirements means that the service location overcomes the presumption that a setting has the qualities of an institution and instead has the qualities of a Home and Community-Based Setting.

Scope:

If the Department identifies a service location that is presumed to be a setting that has the qualities of an institution, the Department must conduct a Heightened Scrutiny on-site review to gather evidence on whether the location overcomes institutional presumptions. Department Program Staff will perform the on-site review, gather evidence through interviews with staff and members/residents, chart reviews, desk audits, and capture pictures of the facility that demonstrates whether the facility overcomes institutional presumptions. The Heightened Scrutiny evaluation process provides evidence for CMS on how the Setting overcomes institutional qualities or what action the provider must take to bring a Setting into compliance.

Heightened Scrutiny Scope

Settings that are presumed institutional include:

- A Setting that is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment, or
- A Setting in a building on the grounds of, or immediately adjacent to, a public institution.

Settings that are presumed institutional, but need further evaluation include:

- Any other Setting that has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS.



Heightened Scrutiny Procedure

- **Step 1:** Upon receipt of the PSA or if the Department receives information regarding potential Settings Rule non-compliance, the Department program staff will review the information.
- **Step 2:** If it is determined that a Heightened Scrutiny review is needed, the Department program staff will complete the Heightened Scrutiny evaluation using the validation tool, documenting evidence of compliance or noncompliance for each section of the validation tool. In addition to the standard validation tool, the evaluation may include:
 - Pictures of the Setting entrances/exits, home accessibility and living arrangements
 - Copies of activity calendar and menu
 - Copy of resident agreement
 - Confirmation of access to community integration
 - Interviews of at least two members/residents and two staff members
- **Step 3:** If necessary to overcome the presumption that the setting has qualities of an institution, Department program staff will address remediation steps necessary for compliance through the issuance of the Provider Corrective Action Plan (PCAP).
- **Step 4:** If it is evident that the Setting can't or won't overcome the qualities of an institution in the PCAP, the provider will be denied enrollment for the Setting. If the Setting is already enrolled, Department program staff will work through the settings disenrollment process.



Heightened Scrutiny Procedure (continued)

- **Step 5:** If it is evident that the Setting overcomes the presumption of institutional qualities, Department program staff will begin entering evidence into the Heightened Security Evidentiary Packet Template.
- **Step 6:** Department program staff must draft a public notice. A 30-day public comment period must be completed prior to the submission of the Heightened Scrutiny Packet to CMS. Information related to the Heightened Scrutiny setting will be posted on the HCBS website as part of the public comment process.
- **Step 7:** At the end of the public comment period, the Department responds to the public comments as needed, and the Heightened Scrutiny Evidentiary Packet is submitted to CMS.
 - Currently, CMS may respond to the Evidentiary Packet in the following ways:
 - CMS agrees with the state's determination that the setting overcomes any institutional presumption and meets all the HCBS settings criteria;
 - CMS requests additional information to make their determination; or
 - CMS disagrees with the state's determination that the setting overcomes any institutional presumption. Department program staff work with provider on denial or disenrollment process.



Provider Corrective Action Plan (PCAP)

Purpose & Scope

Purpose:

The state is required to conduct initial and ongoing monitoring activities which may include a Provider Self-Assessment, on-site Validation Tool Visit, and/or reviewing complaints from a member, family, or citizen. The HCBS Settings Rule encompasses both the physical aspects of the Setting as well as each individual's experience within the Setting. These initial and ongoing monitoring activities ensure agencies with provider-owned or controlled residential and nonresidential Settings obtain and maintain compliance with the rule.

Scope:

If the state has identified a non-compliant component(s) of the rule during the on-site Validation Tool Visit, Department program staff may issue a Provider Action Plan (PCAP) cover letter and form to the provider agency to address and resolve any areas of non-compliance of the Setting.



Provider Corrective Action Plan (PCAP) Procedure

- **Step 1:** Department program staff conducts an on-site Validation Tool visit and notes all areas of compliance and noncompliance on the tool. If there are areas of noncompliance, the Department program staff communicates those issues with the provider agency. The provider agency then has 5 calendar days of the on-site Validation Visit to provide evidence of compliance (e.g., pictures, policy, etc.). If the noncompliance has been resolved within that timeframe, the Department program staff documents this in the notes/evidence on the Validation Tool, including the date of accepted compliance. The provider is sent communication indicating compliance. If compliance is not met in the specified time, the department program staff initiates the PCAP process.
- **Step 2:** The Department program staff completes and emails the PCAP cover letter and PCAP form to the provider.



Provider Corrective Action Plan (PCAP) Procedure (continued)

- **Step 3:** Within 15 calendar days, the provider agency must email the completed PCAP form with the following action items:
 - How the provider proposes to correct the area of noncompliance for each member affected in the setting;
 - Explanation of data/evidence that the provider has or will provide the Department program staff that shows remediation of the setting has occurred;
 - Date that remediation will be completed; and
 - Contact information (e.g., who at the setting will be coordinating with DPHHS staff on the PCAP follow-up activities).



Provider Corrective Action Plan (PCAP) Procedure (continued)

- **Step 4:** If the provider chooses not to come into compliance, they must indicate their intention on the PCAP form:
 - Enrollment of the provider and/or setting is denied; or
 - The Department program staff begins the member transition and setting disenrollment process.
 - Department program staff will work with the provider on the disenrollment process
- **Step 5:** If the provider chooses to come into compliance, the Department program staff reviews the completed PCAP, and the following may occur:
 - Verifies remediation has been completed either through evidence from the provider or verified with another onsite visit and, if so, accepts and closes the PCAP
 - Requires time for remediation to be completed in which the Department program staff verifies as above
 - Requires further assessment and re-issues the PCAP for further review.



Provider Corrective Action Plan (PCAP)

Procedure (continued)

- **Step 6:** If a member has a justified health and safety modification, it must be documented according to the HCBS Settings rule in the person's plan of care. This may require revisions to the plan of care during the initial, mid-year/re-evaluation, annual, or a review/revision meeting. The health and safety modification must be agreed upon and signed by the plan of care team, including the member and/or guardian if applicable.



Provider Corrective Action Plan (PCAP) Cover Letter & Form

Subject: Home and Community-Based Services Settings Provider Corrective Action Plan (PCAP) Request

Dear: [Click or tap here to enter text.](#)

Settings in which Medicaid-funded Home and Community Based Services (HCBS) are delivered are required to be compliant with Federal HCBS Settings Regulation 42 C.F.R § 441.301(c). The Department of Public Health and Human Services (DPHHS) is required to conduct initial and/or ongoing monitoring activities which may include a Provider Self-Assessment and/or an on-site validation visit to ensure compliance with the HCBS Settings Regulations. The HCBS Settings Regulations encompasses both the physical aspects of the setting as well as each individual's experience within the setting. DPHHS has identified an area of non-compliance at the following setting: [Click or tap here to enter text.](#)

DPHHS requests that you complete and return the attached PCAP within 15 calendar days from the date of this notification. The PCAP requests information such as:

- 1) How the setting proposes to correct the area of noncompliance for each member affected in the [setting](#);
- 2) Explanation of data/evidence that the setting is or will provide DPHHS that shows remediation has [occurred](#);
- 3) Date that remediation will be completed; and
- 4) Contact information (e.g., who at the setting will be coordinating with DPHHS staff on the PCAP; or

If you choose not to come into compliance, you must indicate your intention on the PCAP form. Once received, the DPHHS will contact you regarding next steps.

The PCAP and related documents must be submitted to the email address below.

Sincerely,

Provider: Click here to enter text.		PCAP No. Click here to enter text.	
Provider ID: Click here to enter text.		Program Type(s):	
Physical Address: Click here to enter text.		<input type="checkbox"/> Big Sky Waiver (BSW) PT28	
Setting Name: Click here to enter text.		<input type="checkbox"/> Severe Disabling Mental Illness (SDMI) Waiver PT88	
Recipient: Click here to enter text.		<input type="checkbox"/> Developmental Disabilities (DD) Waiver PT82	
Reviewer: Click here to enter text.			
Date Issued: Click here to enter a date.			
State	<p>OBSERVATION (What): It appears that (agency name) failed to meet the following:</p> <ul style="list-style-type: none"> •Choose an item. <p>CRITERION (Reference ARM, Contract, MCA, Waiver, etc.): •42 Code of Federal Regulations (CFR) §441.301(c)</p> <p>Additional Direction if Applicable: Click here to enter a date. Date Response Due: Click here to enter a date.</p>		
Provider	<p>ACTION (Summarize remediation and what action will be taken to address agency wide): Click here to enter text. Completion Date: Click here to enter a date. How will Remediation be Verified: Click here to enter text.</p> <p><input type="checkbox"/> I am choosing to not bring the setting into compliance for the following reason(s):</p> <p>Name of Respondent: Click here to enter text. Response Date: Click here to enter a date.</p>		
State Response	<input type="checkbox"/> REQUESTING FURTHER REVIEW Click here to enter text. Date Due: Click here to enter a date.		Date Reissued: Click here to enter a date.
	<input type="checkbox"/> ACCEPTED – when provider actions have been completed and verified. Click here to enter text.		Date Accepted: Click here to enter a date.
	Has a Health and Safety Modification Form been approved that addresses the identified deficiency? Click here to enter text.		Verification Method: Click here to enter text.



Shared Settings

DPHHS programs will coordinate HCBS Settings compliance activities for the HCBS Settings Rule when a setting is enrolled in two or more programs: Senior and Long Term Care (SLTC) Division's Big Sky Waiver (BSW), Behavioral Health and Developmental Disabilities (BHDD) Division's Severe and Disabling Mental Illness (SDMI) Waiver, BHDD Division's Developmental Disabilities (DD) Waiver, and/or SLTC Division's Community First Choice (CFC) program.

A Shared Setting occurs when:

- A new provider enrolls in two or more HCBS programs;
- An existing provider adds an additional program to an existing setting; or
- An existing provider opens a new setting and enrolls that setting in more than one program.

The Department program staff will determine and communicate with the provider which program will take the lead in contacting the provider, initiating the PSA, and conduct the on-site Validation Tool Visit to ensure initial and ongoing compliance is completed and not duplicated.

Provider Disenrollment/Provider Enrollment Denial

If it has been determined that a provider/setting is not compliant and is not willing or able to become compliant with the HCBS Settings criteria, Department program staff will formally notify the provider in writing that the setting will be disenrolled as a Medicaid HCBS setting. The disenrollment notification will include the reason for disenrollment, the effective date of disenrollment and fair hearing information. The Department will also notify the member of the disenrollment.

Following the effective date of the provider/setting disenrollment, the provider will no longer be reimbursed by Medicaid for any services delivered to Medicaid HCBS members at the disenrolled setting. Providers must assist with discharge and transition planning for members who will transition providers and/or settings. For members who choose to remain at the disenrolled setting, providers must arrange for alternate reimbursement methods.

When a new provider/setting is enrolling as an HCBS Medicaid provider, and it has been determined that the setting is not willing or able to become compliant, Department program staff will formally notify the provider in writing that the enrollment is denied and therefore Medicaid HCBS services will not be reimbursable.



Citizen Complaint

Citizens can submit complaints or concerns related to HCBS settings and services being delivered in those settings. The Department program staff will review to determine if the complaint is appropriate to be addressed by the Department.

The Department program staff will assess and take the following steps:

- Determine the complaint to not be within scope of the Department's authority,
- Refer complaint to another Department agency,
- Follow up and require further action such:
 - Provider Self-Assessment (PSA)
 - Validation on-site visit; or
 - Other action

Citizen complaints will be responded to, tracked and documented by Department program staff.



Settings Evaluation and Tracking System (SETS) Coming Soon!



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Settings Evaluation and Tracking System (SETS) Provider Portal

- Manage provider information and access
- Manage settings
- Submit Provider Self-Assessment (PSA) for settings
- Respond to inquiries about PSA



Settings Evaluation and Tracking System (SETS) Provider Portal

- Upload Corresponding Documents
 - Residential (assisted living facilities, group homes, foster homes, and supported living)
 - Residential Agreement/Lease
 - Activity Calendar
 - Meals/menu calendar
 - Policies and procedures/processes to include, (if not included in the residential agreement)
 - Grievance
 - Transportation policy and procedures
 - Health and Safety Modifications
 - Member handbook
 - Supported Employment
 - Policies and procedures/processes related to service delivery, such as member handbook.
 - Day Supports (Adult Day Health, Adult Day Care, Vocational/Work Day Services)
 - Policies and procedures/processes related to service delivery, such as member handbook



Settings Evaluation and Tracking System (SETS) Administrative Portal

- Department state staff reviews Provider Self-Assessments (PSA) submitted in the Provider portal
- Department state staff completes Validation Tool from an onsite validation visit
- Uploads related documents, including a Provider Corrective Action Plan (PCAP), if applicable
- Submits comments/questions to providers



Settings Evaluation and Tracking System (SETS) Citizen Portal

- Public facing link for members, families, friends, citizens
- Submit complaints or concerns
- Submit positive feedback or neutral comments



HCBS Settings Rule Resources

- DPHHS HCBS Settings
 - [Home and Community Based Services \(mt.gov\)](https://www.mt.gov)
- 42 CFR §441.301(c)
 - [SUBPART - Home and Community-Based Services: Waiver Requirements \(govregs.com\)](https://www.govregs.com)
- Federal Medicaid HCBS Settings
 - [Home & Community Based Services Final Regulation | Medicaid](https://www.medicare.gov)
 - [DEPARTMENT OF HEALTH & HUMAN SERVICES \(medicaid.gov\)](https://www.medicare.gov)



Questions?