



HCBS Settings Final Rule Site-Specific Assessment and Heightened Scrutiny Process

This document describes the process by which the Department has been assessing settings for compliance with the HCBS Settings Final Rule and for the application of heightened scrutiny. The heightened scrutiny process applies to settings with certain factors—detailed below—that trigger a presumption that they are institutional. Settings with these factors may submit evidence that despite this presumption, they are compliant with the rule and not institutional after all. The Department is putting forward such settings for public comment and, ultimately, for review (“scrutiny”) by our federal partners.

Identification of covered settings

At the outset, the Department determined which providers would be required to demonstrate compliance through Provider Transition Plans (PTPs) and the settings for which PTPs would be required. The Department created a registry of covered providers and settings using various data sources, such as Medicaid billing records, the Colorado Department of Public Health & Environment’s (CDPHE’s) licensing records and Program Approved Service Agency (PASA) list, and requests that certain providers complete a Google form identifying their settings.

The Department excluded (a) settings outside the scope of the rule (those where respite may be provided at institutional settings) and (b) settings presumed compliant during the transition period (e.g., private homes belonging to individuals or their families; locations where Individualized Supported Employment is provided). The Department later excluded from the PTP process settings similar to the originally excluded ones, such as those where the respite-like Youth Day Service is provided. As noted in the [December 2016 Statewide Transition Plan \(STP\)](#), anyone could seek to rebut the presumption of compliance by providing information about a particular setting to the Department. To date, the Department has not received any objections regarding the presumption of compliance at any particular setting where the presumption applies.¹

Over time, the Department added providers and settings, such as those that had been inadvertently overlooked, and deleted or marked as Retired settings that had closed.

¹ In the [December 2016 STP](#), the Department said that it planned to test the presumption of compliance in certain private homes. In a [March 2019 State Medicaid Director Letter](#), CMS said that “states are not responsible for confirming this presumption.” In light of that guidance, the Department decided not to test this presumption. The next version of the STP will detail ongoing monitoring processes to ensure that these settings comply after the end of the transition period.



The Department issued guidance in November 2017 regarding compliance requirements for new providers and new settings. Under this guidance, new providers and new settings have been required to come onboard compliant, outside the PTP process.

Introduction to the PTP

The Department developed PTP templates allowing providers to provisionally identify each affected setting's compliance issues under the HCBS Settings Final Rule; develop remedial action plans for these compliance issues; assess the potential application of heightened scrutiny; and where applicable, assess whether the setting should be put forward to the public and/or CMS for heightened scrutiny. PTPs were subject to state review and verification; provider updates; and finally, state verification of the updates.²

The Department created different versions of the PTP template for each broad setting category (adult residential, children's residential, and nonresidential). The Department enhanced the content and format of the PTP templates over time, as follows:

- The initial PTP template was an Excel workbook (example: [Adult Residential PTP - Excel](#)) with tabs for provider/setting demographic information, compliance issues and corresponding remedial action plans, institutional characteristics potentially triggering heightened scrutiny, state analysis regarding heightened scrutiny (if applicable), notes from the state's review/site visit, and a summary of the setting's status. Completed workbooks were stored in folders with the providers' supporting documents, such as policies and procedures, leases/residential agreements, and more. The Department and its contractor, Telligen, began using the initial PTP template on site visits in April 2016. CDPHE began using this template in July 2016.
- The second PTP template contained similar categories of information, but could be completed online via the SharePoint site (example: [Adult Residential PTP - SharePoint](#)). While the Department's intent was for providers to be able to use this site to complete and update their PTPs, an issue with site securities and permissions prevented a broad roll-out to providers. The Department and CDPHE were able to use the site internally to track information from site visits and other work with providers.
- The third PTP template again contained similar categories of information, but could be securely accessed via the Google Cloud Platform (GCP) by providers. The Department rolled out the adult residential component of this platform to providers in November 2018. It rolled out the children's residential and nonresidential components in June 2020. Here are PDF versions of the GCP templates: [Adult Residential PTP](#); [Nonresidential PTP](#); [Children's Residential PTP](#).

² Before implementing the PTP process, the Department asked providers to complete self-assessment surveys. The results are summarized in scorecards available on the Department's [website](#). This initial survey process was informational and helped the Department identify common areas for improvement statewide; it was not a substitute for the PTP process.

With each stage of PTP development, the Department added and clarified PTP template language (*e.g.*, to address additional compliance issues in light of guidance from the Centers for Medicare & Medicaid Services (CMS), prior site visits, Individual/Family/Advocate (IFA) Survey results, and the like) and migrated data and documents from older PTP stages so that information would not be lost.

PTP process

The four-step process—detailed further below—can be visualized as follows:



(1) Provider self-assessment: The Department required providers to complete an initial PTP online, via the GCP, for each covered setting. In completing the PTP for a given setting, the provider conducted a self-assessment of its compliance issues at that setting and identified the remedial action plans it would implement to resolve these issues. The provider also self-assessed whether any of the three conditions triggering heightened scrutiny was present at that setting.

The Department provided a User Manual to help providers complete their PTPs and understand the potential application of heightened scrutiny. For heightened scrutiny, see pp. 17-19 of the [current User Manual](#) (supersedes pp. 17-19 of the [original User Manual](#)). In addition, the Department offered training sessions to providers on completing their PTPs.

The Department required providers to complete PTPs via the GCP even if they already had worked on a PTP in an earlier format. Data and attachments for older PTPs were migrated to the GCP, allowing providers in this position to avoid having to redo work while having the opportunity to address new items (such as new compliance issues) and provide updates on their status in addressing older compliance issues.

Providers were required to attach documents to their initial PTPs before submitting them. Typically, required documents included an assortment of policies and procedures, rights handouts, a recent month's calendar of community activities, and (for residential settings) a lease or residential agreement. The exact set of required documents varied by setting type;

examples are provided in the templates and User Manuals linked above. Providers with multiple settings could upload most of their documents just once, at the provider level, but had to upload the activity calendar at the setting-specific level.

The GCP automatically generated periodic reminders to providers that their initial PTPs were coming due or overdue. CDPHE staff leads also reached out to providers by phone and email to arrange for the completion of overdue PTPs. In addition, the Department sent manually generated emails and hard-copy letters (including, eventually, via certified mail) to providers with overdue initial PTPs. The Department ultimately marked unsubmitted initial PTPs with a compliance status indicating that the settings are not compliant. This determination can be changed if/when an overdue PTP is completed with evidence demonstrating compliance. However, as noted in the latest letter to providers in this position, if they do not submit their PTPs before the Department's codification of the federal rule goes into effect, they will not be given the benefit of the transition period in which they failed to participate.

Substantially all (over 95% of) initial PTPs have been submitted.

(2) Initial verification: The state validated initial PTPs via desk reviews at minimum for all providers and settings, plus site visits for some. The validation process was built into the PTP process: state staff could review providers' attached documents, mark additional compliance issues as needing remediation (with notes explaining their reasoning), and record any additional findings and conclusions from their desk reviews/site visits for the provider to review—all within the relevant PTP. To promote consistent and efficient reviews, each provider was assigned a single state staff lead within CDPHE's Community Settings team for all of its PTPs.

Desk review: The CDPHE staff lead assigned to the provider reviewed all of the provider's provider-level documents (such as policies and procedures) and recorded their findings—in particular, regarding additional compliance issues needing remediation—in the relevant PTP, or if the provider had multiple PTPs, in at least one main PTP. The staff lead also reviewed the provider's setting-specific documents (such as an activity calendar) and recorded their findings in that PTP. In addition to adding additional compliance issues to the provider's radar, state staff could save explanatory comments on the relevant screens within the PTP (for example, the screen relating to community integration), as well as on an additional screen reserved for state staff findings not reflected elsewhere in the PTP.

Randomly selected, in-person site visits: The Department arranged for the completion of a statistically significant number of randomly selected, in-person site visits. To identify the random sample of settings to be visited, the Department created a registry of covered settings. Using this registry, the Department used a probability proportional to size sampling strategy to randomly select settings, stratified by setting type, for site visits. The Department's methodology for this process was detailed in the [December 2016 STP](#) (Action Item 14). CDPHE completed all randomly selected site visits by June 2017. (In addition, Telligen, a contractor of the Department's, had conducted some preliminary visits in the spring-summer of 2016.)

Additional in-person and remote site visits: In addition to the randomly selected site visits, CDPHE has conducted additional site visits throughout the state, including at settings where providers requested a voluntary visit to obtain more direct input and technical assistance; settings not included in the universe from which random selections were made in Fall 2016 (e.g., those operated by new providers or identified later); settings that were already visited and were implementing remedial action plans/follow-up; and additional settings where the departments wanted to provide additional support or had concerns about potential noncompliance (e.g., based on responses to the IFA Survey that were identifiable to a particular provider or setting).

Site visit protocol: Site visits are broadly informed by, and used to fill out and verify, the PTP. As noted above, state staff can record pertinent findings from site visits (or desk reviews) directly into the PTP itself—for example, by marking additional compliance issues as needing remediation. The process of preparing for, conducting, and following up from site visits is as follows:

(1) Preparing for site visits

For the initial mandatory, randomly selected site visits, a member of the CDPHE Community Settings team contacted the provider agency at least two weeks in advance of the visit to let them know which settings were selected for a visit. CDPHE provided an explanation of the HCBS Settings Final Rule and the purpose of the visit during the call. For other, more recent visits, initial outreach may look different (e.g., the provider emails to request a visit).

Following the initial conversation, CDPHE sends a confirmation email to the agency representative with a cover letter explaining the steps provider agencies must complete prior to the visit, a PTP template/link for each selected site, the PTP User Manual, and links to the IFA Survey. The cover letter includes instructions to distribute the IFA Survey to individuals, family members, and guardians so that they have an opportunity to share their views, if they so choose.

CDPHE staff work with the provider agency to set up a visit for a time that works well for the individuals and staff at the setting, as well as a provider agency representative. State staff prepare and share an agenda for the visit based on this basic template:

Task	Action Items
I. Kick-off at provider agency main office or nonresidential setting office	<ul style="list-style-type: none"> • Welcome and introductions • Goals of the site visit(s) • Overview of the HCBS Settings Final Rule • Collect supporting documentation the provider may not have submitted before the site visit • Review policies and procedures, handouts, activity calendars, and overall current practices related to the rule • Review effect of rule on waiver services provided by the agency, including services not selected for a visit • Agency shares promising practices

<p>II. Site visit</p>	<ul style="list-style-type: none"> • State staff provides technical assistance toward compliance • Welcome and introductions • Goals of the site visit with brief overview of the rule • Tour of the setting • Observation at the setting • State staff review of client files and documentation related to services • State staff interview individuals, if they are willing, outside the presence of provider staff • State staff takes notes to review areas of compliance and those of concern based on records, input from agency staff, and interviews • In addition to taking notes, site visit team may take photos at the setting, as appropriate (<i>e.g.</i>, to show access to or isolation from community). Individuals are not photographed.
<p>III. Discussion of PTPs</p>	<ul style="list-style-type: none"> • Detailed review of Rights and Autonomy, Informed Choice, Community Integration, and Institutional Characteristics sections of the PTP: <ul style="list-style-type: none"> ○ Compliance issues ○ Technical assistance ○ Documentation and follow up that will be needed • Review of IFA Survey results relating to these issues, when available (without identifying individual survey respondents) • Discussion of promising practices that the provider can share with other providers relating to these issues
<p>IX. Closing and strategic planning session</p>	<ul style="list-style-type: none"> • In person or by phone, the CDPHE staff review findings from all site visits with the provider agency staff • Additional technical assistance is provided, as needed • Review next steps, including revised documents or other evidence the provider agency will need to submit with updated PTPs and timelines • For settings in full compliance, no additional follow up by the provider agency will be needed

The provider agency completes its initial PTP (self-assessment) and submits it with all required documents via email or the GCP (depending on the platform available at the time). The provider agency also shares the IFA Survey with individuals receiving services, families, and guardians. Respondents may return their survey responses online or by mail. CDPHE staff review the submitted PTP and all attached documents prior to the site visit. In addition, they review information available in state data systems to be aware of previously identified issues for a setting that may be relevant to HCBS Settings Final Rule compliance.

(2) Conducting site visits

Site visits generally follow the agenda set out above. However, each site visit has its own flow depending on the provider agency's particular compliance questions, concerns, and issues; its overall compliance status; and the potential application of heightened scrutiny.

For most visits, CDPHE staff first meet in-person with the provider agency management at the agency office. During this initial meeting, CDPHE provides an overview of the HCBS Settings Final Rule. The agency policies and procedures, rights handout, and other materials previously provided are collectively reviewed. CDPHE staff provide feedback and recommendations for any changes needed to comply with the rule. Staff review how the rule affects all waiver services the agency provides, including those not selected for a site visit. CDPHE staff answer questions and offers technical assistance for how to transition services to be person-centered, to provide informed choice, and include greater integration in the community.

CDPHE staff next complete in-person visits to the particular settings chosen for a visit, accompanied by a provider agency manager or managers. Staff again review the HCBS Settings Final Rule as needed; tour the facility; review client records; ask questions; and interview individuals receiving services, to the degree they are interested and willing to be interviewed, to gather information about their lived experiences at the setting.

During the COVID-19 pandemic, CDPHE has been conducting site visits remotely as needed for waiver participant, provider staff, and state staff safety. The agenda for remote site visits is largely as set out above, except that instead of visiting sites and interviewing individuals in person, alternative virtual methods are used (e.g., videoconferencing).

(3) Following up from site visits

Once the site visit is complete, the site visit staff finish documenting any changes needed to demonstrate compliance, complete the Site Visit Report tab of the PTP with details from the visit (if needed to capture details not already recorded elsewhere in the PTP), and provide an assessment of the provider's compliance status in the Provider Status Summary tab of the PTP. The site visit staff send the updated PTPs to the provider agency with instructions for further review and provision of documentation demonstrating compliance.

Initial verification of factors triggering heightened scrutiny. In conducting desk reviews and (if applicable) site visits, CDPHE applies the heightened scrutiny standards and guidance set out in pp. 17-19 of the [current User Manual](#) (supersedes pp. 17-19 of the [original User Manual](#)).

To determine whether a setting (i) is located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment or (ii) is in a building located on the grounds of, or immediately adjacent to, a public institution, CDPHE drew on information from the following sources:

- The PTP, including the provider's self-assessment of these factors;

- If a site visit was completed, observation of the location and its surroundings, including whether it was in the same building as a hospital, nursing facility, intermediate care facility for individuals with intellectual or developmental disabilities, or other type of inpatient institution, or near a public facility in these categories;
- Fellow staff within CDPHE, who advised the Community Settings Team of settings that appeared to meet the location-based factors; and
- Internet map applications, which revealed the setting's proximity to inpatient institutions.

To determine whether a setting (iii) has the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving HCBS, CDPHE drew on information from the following sources:

- The PTP, including the provider's self-assessment of this factor and the compliance issues on the Community Integration screen;
- The documents attached to the PTP, including the required setting-specific, recent month's calendar of community activities (or a calendar from shortly before the pandemic, if applicable)—or, for larger nonresidential settings, multiple calendars (to ensure all individuals have the opportunity to interact with others in the community, based on their preferences and interests);
- If a site visit was completed, observation of whether individuals were coming and going; observation of what information about community activities and transportation options was posted for individuals to consider; review of available records relating to community activities and transportation options; asking about community activity opportunities and transportation options during private interviews with individuals; and asking staff about community activities offered, their support for helping individuals be aware of and participate in such activities, and transportation options offered; and
- Fellow staff within CDPHE, who advised the Community Settings Team of settings that appeared to be isolating.

Members of the Community Settings Team worked together to review their observations, calendars, and other documentation to ensure consistency in determining the potential application of heightened scrutiny. In turn, this topic was discussed frequently between CDPHE and the Department. The state's determinations, including comments for the provider's review, were documented in the setting's PTP.

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Throughout the transition period, CDPHE and the Department have met weekly to discuss site-specific verification matters, including the development of the PTP itself and the overall site visit protocol, as well as questions and concerns arising from individual providers/settings and their documents/other evidence. Through these meetings and frequent email communications,

the two departments have ensured that they share a common understanding of the requirements of the HCBS Settings Final Rule and its application to particular cases.

At the conclusion of the initial desk review and (if applicable) the site visit process for a given setting, the state has verified that the PTP identifies all compliance issues that the provider must resolve and sets out a suitable remedial action plan for doing so. The state has also confirmed the potential application of heightened scrutiny to the setting. CDPHE sends the verified PTP back to the provider (via the GCP), along with any explanatory notes within the PTP or phone calls/emails needed to get the provider on track for its next steps.

Substantially all (over 95% of) initial PTPs have been initially verified.

(3) Provider updates: As soon as providers submitted their PTPs, they were required to begin implementing their remedial action plans and submitting updates (including evidence of changes made) every three months. The Department asked providers to submit updates regardless of whether they had heard back from CDPHE yet in connection with the initial verification process. Providers submit updates via the GCP (or, before the availability of the GCP, via email). Virtually all settings had compliance issues requiring remediation and therefore have been part of the update process.

Provider updates to show that all required changes have been made generally consist, at minimum, of uploading/emailing revised versions of the policies and procedures, rights handouts, and other documents required as part of the initial PTP. Where the pre-pandemic activity calendar did not demonstrate sufficient community integration or support for individual choice of activities, CDPHE requires the provider to upload a plan for post-pandemic compliance on these fronts. Required updates for a setting might also include photographs, such as photos of receipts from purchasing bedroom door locks as well as photos showing that the locks have been installed.

The GCP automatically generates periodic reminders to providers that their PTP updates are coming due or overdue. CDPHE staff leads also reach out to providers by phone and email to arrange for the submission of overdue updates. In addition, the Department sent manually generated emails to providers with overdue updates relevant to heightened scrutiny determinations. (Additional outreach will be conducted for settings outside of the heightened scrutiny process, as needed, for settings in a noncompliant status.)

A provider could submit a single update demonstrating that all required changes had been made; however, several rounds of updates were required for most providers and settings. For example, CDPHE might observe that the provider had made some but not all of the required changes for a given policy or procedure, or it might note that the provider had represented that bedroom door locks were installed without providing evidence of that change. The Department created a comment mechanism within the PTP platform for CDPHE to explain what was still needed and for providers to ask questions or provide further updates/explanations. (CDPHE and providers could also use other communication methods like phone and email.) The provider update/CDPHE verification process generally iterated for several months and is still ongoing in many cases.

Heightened scrutiny determinations have been made based on updates received by May 25, 2021. More broadly, providers continue to submit PTP updates for CDPHE verification. The Department expects all remaining updates to be submitted this summer, allowing final verification of each setting's compliance status by December 31, 2021.

(4) Final verification: The state is validating updated PTPs via desk reviews at minimum for all providers and settings, plus site visits for some. The validation process is built into the PTP process and works along the same lines as the initial verification process described above, except that at this stage, the state's goal is to confirm not just that all compliance issues have been identified, but that they have actually been resolved.

As noted above and as indicated by the back-arrows in the diagram on page 3, the process of provider updates and CDPHE verification is generally iterative, with back and forth exchanges between the provider (making updates, asking questions) and CDPHE (reviewing updates, asking for additional changes to be made or evidence to be provided, providing technical assistance). Some of these exchanges may be reflected in the comments within the PTP itself; others may take place via email or phone.

Approximately 33% of settings have been verified as fully compliant so far.

Heightened scrutiny determinations

The Department has determined that 52 settings have a factor triggering the presumption that they are institutional and, despite that factor, are in fact home- or community-based (or have a state-accepted plan for getting there). The Department determined that a setting overcame the institutional presumption by verifying that it met (or had an accepted plan for meeting) each requirement of the HCBS Settings Final Rule, as set forth in the PTP. The Department is publishing a list of these settings. To summarize this list:

- There are 16 settings subject to heightened scrutiny based on their location (i) in a building where inpatient institutional treatment is provided or (ii) in a building located on the grounds of, or immediately adjacent to, a public institution. These settings have been assigned numbers HS-001 through HS-015 and HS-017.
- There are 36 settings subject to heightened scrutiny based on (iii) their potential effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving HCBS. These settings have been assigned numbers HS-016 and HS-018 through HS-052.

The Department is withholding the address of some settings in the list to protect the personal health information (PHI) of individuals receiving services at these settings. These settings are all subject to heightened scrutiny based on their potential to isolate and are mostly group homes, the nature of which is presumably not known to the public.

For each listed setting, a packet of information for stakeholder review is available as follows:

- Summary sheet: the summary sheet describes the setting, the reason it is subject to heightened scrutiny, and the evidence as of May 25, 2021 supporting the Department's determination that the setting complies with each component of the HCBS Settings Final Rule—or, if the setting is not fully compliant yet, the evidence that is still required and the state's plan for ensuring that the evidence is submitted and verified. Each summary sheet is available on the Department's [website](#) under the header "Heightened Scrutiny."
- Additional evidence: additional evidence for each setting includes its PTP and the documents and photos attached to the PTP as of May 25, 2021. (In some cases where the provider had multiple settings, the most recent attachments may be stored with a different PTP belonging to that provider.) Each packet of additional evidence is available on request, as specified in the public notice.

The Department has determined that some settings that have a factor triggering the institutional presumption are planning to close or stop serving Medicaid HCBS participants, or are not on track to demonstrate full compliance with the HCBS Settings Final Rule. As with other settings not on track to comply with the rule, these settings will be included in a process allowing for informal reconsideration if requested and ultimately, if needed, (a) support for individuals to transition to other settings or funding sources before the end of the transition period and (b) termination of Medicaid reimbursement for HCBS at that site as of March 17, 2023.

Public comment

The Department has a multipronged approach to soliciting stakeholder input regarding settings being put forward for heightened scrutiny:

1. Today, the Department issued formal public notice identifying the affected settings and posted online summaries of the information informing its determinations. Stakeholders may respond with comments via the methods identified in the public notice, including by emailing the Department at hcpf_STP.PublicComment@state.co.us.
2. As stated in the notice, the Department will host three town hall meetings to allow interested parties the opportunity to comment on the affected settings.
3. The Department is sharing the notice with stakeholders who participated in prior work relating to HCBS Settings Final Rule implementation (the Rights Modification Stakeholder Workgroup and the Open Meeting Series for developing the state regulatory codification of the federal rule). These stakeholders include waiver participants and their family members and friends, advocates affiliated with various organizations or no organization, representatives of provider agencies and case management agencies (CMAs), and state staff affiliated with CDPHE and HCPF.

4. The Department is instructing CMAs that work with these settings to inform individuals receiving services at these settings of the opportunity to comment at the town hall meetings or via email/other means.
5. The Department is instructing providers that own or operate these settings to inform individuals receiving services at these settings of the opportunity to comment at the town hall meetings or via email/other means.

The Department will consider input received by July 10, 2021 as it finalizes heightened scrutiny information for submission to CMS. Public input will inform the Department's final decisions but will not necessarily change any determinations, given the availability of other evidence to be taken into account. The Department expects to summarize any input received, along with the Department's response to the input, in the relevant heightened scrutiny packet's revised summary sheet. Provider updates received after May 25, 2021 may also be incorporated into revised summary sheets.

CMS review

The Department will submit to CMS updated summary sheets, prepared as described above, along with a list of affected settings, updated if changes were made based on public input or provider updates. (The Department understands that CMS does not plan to review settings in category (iii)—those with the effect of isolating individuals receiving Medicaid HCBS—determined compliant as of July 1, 2021. All Colorado settings in category (iii) are still coming into compliance as of June 10, 2021, so this exception unlikely to apply here.)

The Department understands that CMS will select particular settings for further review, and that CMS will request the additional evidence available for each selected setting (the PTP and the documents and photos attached to the PTP). The Department will provide the additional information as requested. To the extent that CMS provides feedback on particular settings, the Department will apply that feedback to similarly situated settings. For example, if CMS indicates that an additional document/source of evidence must be consulted for settings in a given category (such as alternative care facilities in category (i), or group homes in category (iii)), the Department would obtain that information for all settings in that category and review it according to the standard CMS provides.