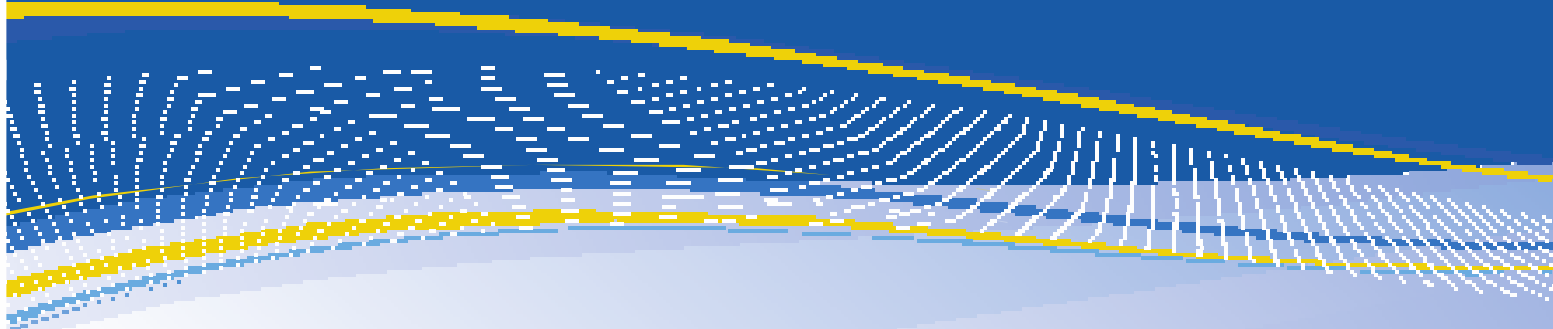
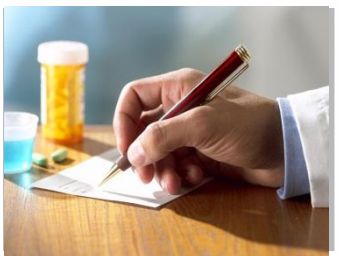




The Home and Community-Based Services (HCBS) Settings Regulation: Where Are We Now and Where Are We Going? – Part II

Division of Long-Term Services and Supports
Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services



Objectives for Today's Session

- Provide a synopsis of CMS' session entitled "The Home and Community-Based Services (HCBS) Settings Regulation: Where Are We Now and Where Are We Going? – Part I;
- Review the key elements necessary to come into compliance with the home and community-based services settings regulation by March 17, 2023;
- Describe how the heightened scrutiny process works;
- Highlight trends in feedback to states on CMS' review of heightened scrutiny evidentiary packages, and review available resources to assist states in determining if settings are in compliance with the HCBS settings requirements;
- Describe actions states should be taking to achieve compliance by the expiration of the transition AND beyond the transition period.

Recap: The Home and Community-Based Services (HCBS) Settings Regulation: Where Are We Now and Where Are We Going? – Part I

- Provided a brief refresher on the HCBS settings criteria, including how the COVID-19 pandemic disrupted implementation of specific criteria;
- Discussed the barriers and challenges resulting from the constraints imposed by the COVID-19 Public Health Emergency (PHE) as states balanced participants' health and safety with the delivery of HCBS, furthering compliance with the settings regulation and ensuring community integration;
- Reviewed the status of the Statewide Transition Plan (STP) implementation timeline;
- Shared the experiences of two states that maintained progress on reaching compliance with HCBS settings compliance during the pandemic.

Review of the Key Components for Successful Implementation of the STP: Initial Approval

Elements needed for Initial Approval:

- ✓ Completion of state's systemic assessment of oversight and enforcement mechanisms against regulatory criteria;
- ✓ Inclusion of outcomes of this assessment in the STP;
- ✓ Inclusion of outline of remediation strategies to rectify issues that the systemic assessment uncovered; and
- ✓ Issuance of the draft STP for a 30-day public comment period, making sure the information was widely disseminated, and responding to and summarizing the comments in the STP submitted to CMS.

Review of the Key Components for Successful Implementation of the STP: Final Approval

Elements needed for Final Approval:

- ✓ Inclusion of a comprehensive summary of completed site-specific assessments of all settings serving individuals receiving Medicaid-funded HCBS, validation of those assessment results and the aggregate outcomes of these activities;
- ✓ Description of draft remediation strategies and a corresponding timeline for resolving issues that the site-specific assessment process and subsequent validation strategies identified by the end of the HCBS settings transition period (March 17, 2023);

Review of the Key Components for Successful Implementation of the STP: Final Approval (cont.)

- ✓ Detailed plan for identifying settings presumed to have institutional characteristics, as well as the proposed process for evaluating these settings and preparing information for submission to CMS for review under heightened scrutiny when the state has determined the setting does or will comply with the regulatory criteria by March 17, 2023;
- ✓ Description of process for communicating with beneficiaries currently receiving services in settings that the state has determined cannot or will not come into compliance with the HCBS settings criteria by March 17, 2023 and determining the HCBS options available for receiving services in a compliant setting; and
- ✓ Description of ongoing monitoring and quality assurance processes that will ensure all settings providing HCBS continue to remain fully compliant with the federal settings criteria in the future.

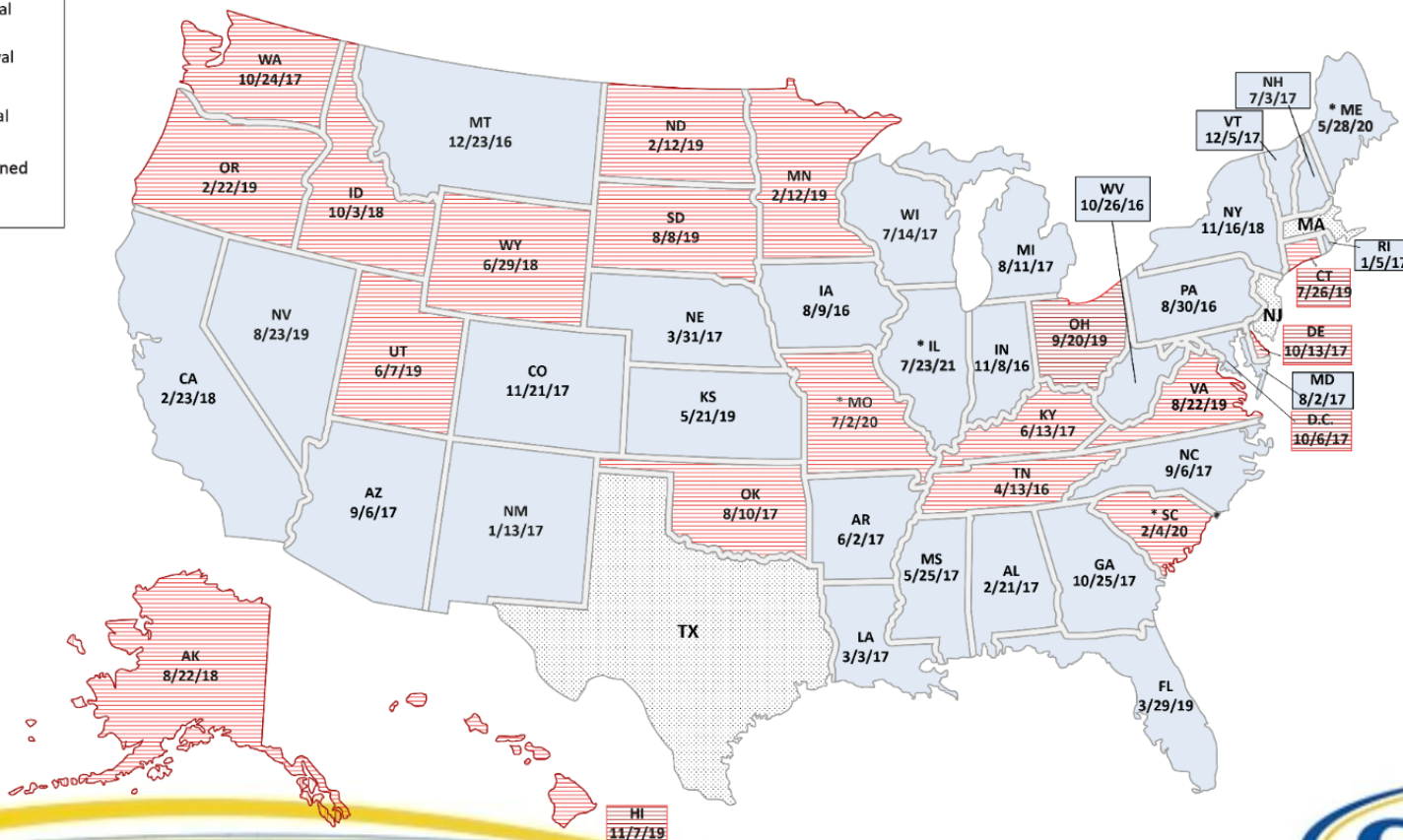
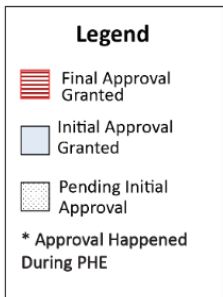
Initial and Final Approvals of Statewide Transition Plans (STPs)

Comparison: Initial and Final Approvals of Statewide Transition Plans (STPs) Before the Public Health Emergency (PHE) to the Present

	As of December 31, 2019	Present
Initial Approval	46 States	48 States
Initial and Final Approval	19 States	21 States

Statewide Transition Plan Status as of November 5, 2021

Statewide Transition Plan Status as of 11/05/2021



Settings Regulation Timeline Extension, Presumptively Institutional Settings, and Revised Due Dates for Heightened Scrutiny Submissions to CMS

- Settings regulation timeline extended to **March 17, 2023**.
- Presumptively Institutional Settings:
 - Settings that are located in a building that is also a publicly or privately operated facility that provides inpatient institutional treatment (Category I):
 - Settings that are in a building located on the grounds of, or immediately adjacent to, a public institution (Category II);
 - Revised submission date to CMS for Categories I and II:
March 31, 2021.

Settings Regulation Timeline Extension, Presumptively Institutional Settings, and Revised Due Dates for Heightened Scrutiny Submissions to CMS (cont.)

- Presumptively Institutional Settings (cont.):
 - Any other settings that have the effect of isolating individuals receiving Medicaid HCBS from the broader community of individuals not receiving Medicaid HCBS (Category III):
 - If the state determines that these settings implemented remediation strategies that brought the setting into compliance with the settings criteria by **July 1, 2021**, then that setting will not need to be submitted to CMS; however, it will need to be posted for public comment with the state's determination. If there are significant issues raised in public comment CMS may review the state's findings on the setting.

Settings Regulation Timeline Extension, Presumptively Institutional Settings, and Revised Due Dates for Heightened Scrutiny Submissions to CMS (cont.)

- States may submit isolating settings that have not completed remediation for a heightened scrutiny review no later than **October 31, 2021** after completing public comment.
- In addition to reviewing a sample of the settings submitted by the state for heightened scrutiny review, CMS will also review any settings that the state requests CMS to review as well as any setting that generated significant public comment in opposition of the state's assessment.

So How Does the Heightened Scrutiny Process Work? (1 of 4)

- FAQ guidance of March 2019 remains in effect
 - Solidified criteria of a setting that isolates HCBS beneficiaries from the broader community
 - Clarified that settings in rural communities are not automatically isolating
 - Described promising practices for bringing “isolating” settings into regulatory compliance
 - Confirmed scope of information to be released for stakeholder input, adhering to HIPAA requirements
 - Described information to be submitted to CMS for a heightened scrutiny review and how CMS will conduct that review

So How Does the Heightened Scrutiny Process Work? (2 of 4)

- States are required to engage stakeholders in the heightened scrutiny process; states should consult with their HIPAA officers to develop a process to ensure compliance with the Privacy Rule.
- Stakeholder organizations may include, but are not limited, to:
 - Protection and Advocacy organizations
 - Developmental Disability Councils
 - University Centers of Excellence on Disabilities
 - Area Agencies on Aging
 - Aging & Disability Resource Centers
 - Centers for Independent Living
 - LTC Ombudsmen
 - Organizations representing individuals with mental illness or traumatic brain injury
 - Service coordinators
 - State licensure, certification and quality assurance entities
 - Advocacy organizations that include individuals who receive HCBS

So How Does the Heightened Scrutiny Process Work? (3 of 4)

- More on HIPAA
 - States have discretion to determine whether identifying a presumptively institutional setting by name and address would constitute a release of protected health information (PHI).
 - If the state determines that PHI would be implicated in releasing the name and address of the setting, states should be providing information on the setting's compliance with the regulatory criteria to external entities when the disclosure of PHI to those entities is permissible under HIPAA, such as when required by law, or where the disclosure is to a health oversight agency.
 - State-designated Protection and Advocacy organization
 - LTC Ombudsman

So How Does the Heightened Scrutiny Process Work? (4 of 4)

- To supplement the CMS review of individual settings, CMS encourages states to submit their assessment tools for our review.
 - These are the tools that states are using to assess all settings (including presumptively institutional settings) against the regulatory criteria to determine any needed remediation.
 - Assessment tools, at a minimum should incorporate all of the settings criteria.
 - A CMS review of these assessment tools will allow us to understand how decisions are being made on individual settings, which could be helpful as CMS and states continue stakeholder discussions.
 - While submission of an assessment tool is not required, it will help to assure the sufficiency of the state's process.
 - To the extent that CMS is notified of stakeholder concerns with a state's assessment tool, we will follow up with the state directly.
 - If a state does submit its assessment tool to CMS for review, this could help to shape the sample size of individual presumptively institutional settings to undergo a heightened scrutiny review.

What Can the State Expect From CMS After Submitting Information on a Presumptively Institutional Setting? (1 of 3)

- After review, CMS will either approve the state's assessment that the setting overcame its institutional presumption; or
- Provide the state feedback on missing information, questions for clarity, or reason(s) why CMS cannot agree that a setting is able to overcome its institutional presumption.
- States will then have the opportunity to provide the additional information needed to support their assertion before a final determination by CMS.

What Can the State Expect From CMS After Submitting Information on a Presumptively Institutional Setting? (2 of 3)

- States will apply CMS' feedback to similarly situated settings to remediate other presumptively institutional settings not included in the review sample.
- CMS will make final heightened scrutiny review determinations of each setting in the sample and make available on <https://www.medicaid.gov/medicaid/home-community-based-services/statewide-transition-plans/index.html>

What Can the State Expect From CMS After Submitting Information on a Presumptively Institutional Setting? (3 of 3)

- CMS may request to review additional settings and/or suggest changes to the state's heightened scrutiny review process if there are concerns with how the state determines whether a setting overcomes its institutional presumption.
- CMS may also request additional information on any setting for which the state received public comments that conflict with the state's assessment of the setting, but was not included in the sample of settings reviewed by CMS.

What Will the State Receive From CMS After CMS' Review of the State's Submission?

An initial determination letter indicating CMS' preliminary decision regarding whether or not the state has demonstrated that the setting overcomes its institutional presumption and a summary of findings for each setting that includes:

- A brief description of the setting;
- The support submitted by the state to demonstrate the setting's progress in overcoming its institutional presumption;
- The areas found to demonstrate compliance;
- The areas where additional information will be needed, linked to the specific settings criteria, to clearly articulate that the setting meets the criteria and has overcome its institutional presumption, or will by the end of the transition period.

Status Update: Heightened Scrutiny Submissions as of November 5, 2021

- Heightened Scrutiny Submissions to CMS in Categories I and II:
 - 16 states submitted information to CMS on a total of 201 settings: 153 in Category I and 48 in Category II.
 - 2 states (includes one state also reflected above) submitted lists of 59 settings for which information has not been submitted: 47 in Category I and 12 in Category II
- Heightened Scrutiny Submissions to CMS in Category III:
 - States submitted lists containing 363 Category III settings that will be compliant prior to the end of the transition period on March 17, 2023.

Status Update: Heightened Scrutiny

Approvals as of November 5, 2021

- To date, CMS has sent approval or conditional approval for fifteen (15) settings, in categories I and II, in four (4) states. This work was impacted by the pandemic, even as efforts continued behind the scenes.
 - Conditional approval denotes that CMS agrees with the state's determination that the setting will overcome any institutional presumption and meet all the HCBS settings criteria on or before the end of the transition period based on proposed remediation.
 - For newly constructed settings, required to be fully compliant before providing HCBS, the state will describe how the setting adheres to the regulation for any non-Medicaid-eligible individuals receiving services, and attest to the date when the setting begins to provide Medicaid-funded HCBS to individuals, along with an assurance that individuals have a person-centered service plan that meets requirements outlined at 42 CFR § 441.301(c)(1)-(3) in place at that date

Trends in Heightened Scrutiny Feedback to States (1 of 4)

- CMS reviews the information submitted by states describing a presumptively institutional setting's compliance with each component of the regulation.
- States can enhance the quality of the information submitted:
 - By ensuring a complete and thorough assessment tool and process is used, and
 - By ensuring each element of the settings criteria is clearly supported by the state's review of person-centered plans, setting activity records/notes, direct on-site observation, and/or interviews of participants residing in the setting.

Trends in Heightened Scrutiny Feedback to States (2 of 4)

- If the state does not provide information addressing each of the components, CMS cannot determine that the settings requirement is met. In the following example, states commonly provide information that individuals have options for private rooms, but the other two pieces of the regulatory criterion are frequently lacking.
- In reviewing the information provided to demonstrate compliance with 42 CFR 441.301(c)(4)(ii), CMS will review the state's information that:
 - 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.

Trends in Heightened Scrutiny Feedback to States (3 of 4)

Other common requirements that are lacking in information submitted include:

- 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. [42 CFR 441.301(c)(4)(i)]
 - The setting's support to facilitate the individual's access to transportation is also reviewed as a component of the community integration requirement as it is a key method by which individuals access the greater community, as described in the FAQ guidance.

Trends in Heightened Scrutiny Feedback to States (4 of 4)

Information supporting adherence to the following two regulatory criteria is also frequently insufficient:

- Units have entrance doors that are lockable by the individual, with only appropriate staff having keys to doors. [42 CFR 441.301(c)(4)(vi)(B(1))]
- Any modification of the additional conditions under 42 CFR 441.301(c)(4)(vi)(A) through (D), must be supported by a specific assessed need and justified in the person-centered service plan.

Resources to Assist States

- To facilitate CMS' heightened scrutiny reviews and avoid follow-up questions, states should review available resources, including the continued use of an assessment tool that provides a methodical, thorough and consistent analysis, to help determine if a setting meets the requirements to overcome its institutional presumption.
- CMS Exploratory Questions to Assist States in Assessment of Residential and Non-Residential HCBS Settings may serve as a basis for an assessment tool.

Sample Checklist Based on CMS Guidance (1 of 4)

- A sample checklist for state reviews of presumptively institutional settings might include questions such as:
 - Did you provide information on how the state determined that a setting overcame the presumption that it has the qualities of an institution?
 - Did you submit information that demonstrates how the setting meets all the regulatory criteria of an HCBS setting?
 - Did you review CMS' exploratory questions in the Toolkit to help the state determine the type of information to submit?
 - Did you describe the setting's proximity to and scope of interactions in and with the broader community?

Sample Checklist Based on CMS Guidance (2 of 4)

- Did you describe the state's review of a sample of individuals' daily activities, person-centered service plans, and/or interviews to determine if there is a variation in the scope, frequency and breadth of an individual's interactions and engagement in and with the broader community?
- Did you include a copy of the procedures (e.g., the types of activities, transportation and staffing in place) and services provided that indicate evidence of access to and demonstrated support for an individual's integration into community activities consistent with the person-centered service plan (PCSP)?
- Did you describe processes in place or actions taken by Direct Support Professionals to support, monitor, improve, and enhance an individual's integration in and with the broader community over time?
- Did you provide a summary of examples of how individuals are involved in local community activities with people not receiving Medicaid HCBS?

Sample Checklist Based on CMS Guidance

(3 of 4)

- Did you describe procedures in place to routinely monitor individual access to services and activities in the broader community to the extent identified in the PCSP?
- Did you describe how staff are trained and monitored on their understanding of the settings criteria and the role of person-centered planning, consistent with state standards as described in the waiver or state plan amendment or in community training policies and procedures established by the state?
- Did you describe the setting's proximity to public transportation or how transportation is facilitated?
- Did you include a description of the setting's remediation plan to achieve compliance by the end of the transition period, along with the state's oversight to ensure compliance of actions?

Sample Checklist Based on CMS Guidance

(4 of 4)

- Did you provide an attestation that the state reviewed provider-owned or controlled settings and concluded through observation during an onsite visit and/or through a sample of consumer interviews or through a review of PCSPs that any modifications to the settings criteria are documented in the PCSPs?
- Did you include other information that the state deems helpful to demonstrate that the setting overcomes its institutional presumption, such as photos of the setting (not of individuals or other identifying information)?
- Did you include a summary or other description of stakeholder comments received in response to the state's solicitation of public feedback?
- Did you describe how the state will monitor a particular setting to ensure completion of remediation?
- Did you identify the milestones for the completion of activities to bring the setting(s) into compliance and report to CMS in an agreed upon schedule on the progress toward achieving those milestones?

CMS Monitoring of Settings to Ensure Compliance BY March 17, 2023

Use of Different Monitoring Mechanisms by CMS:

- Throughout the transition period, CMS will reference the state's *process* to ensure identified remediation is completed, including the steps and timelines as described in the STP to bring providers into compliance, when discussing ongoing monitoring with states.
- Information submitted to CMS for heightened scrutiny review of a *particular presumptively institutional setting* includes:
 - How the state will monitor to ensure that setting's completion of remediation;
 - The identification of milestones for the completion of activities to bring that setting into compliance;
 - Agreed upon scheduled reporting to CMS on the progress toward achieving milestones; and
 - How the state will continue to monitor the setting ongoing to ensure it continues to meet the settings criteria.

CMS Monitoring of Settings to Ensure Compliance by March 17, 2023 (cont.)

- **CMS does not intend to extend the expiration of the transition period beyond this date.**
- States should be working backwards from this date, to complete the following activities:
 - Assessments of provider compliance, including for presumptively institutional settings;
 - Identification of needed provider remediation, monitoring of provider progress implementing modifications, and submission of information to CMS for any heightened scrutiny reviews; and
 - Determination of timing by when individuals will need to transition out of settings that won't achieve compliance by the end of the transition period, selecting among individually-specific options available for receiving services in a compliant setting.

Ensuring Compliance Through Ongoing Monitoring AFTER March 17, 2023

- Incorporate settings-specific performance measures into the quality improvement section of the various appendices found in the 1915(c) waiver application, renewal or amendment submissions;
- The quality improvement strategy in the 1915(i) state plan HCBS benefit also includes a requirement for the state to address how it will ensure that the HCBS settings requirements are met.
- States might consider options for ongoing monitoring such as incorporating the settings requirements into state policies and procedures including existing licensing, certification, credentialing, case management and quality assurance processes.

Ensuring Compliance Through Ongoing Monitoring AFTER March 17, 2023 (cont.)

- Examples of state ongoing monitoring activities include on-site or virtual visits to observe settings and individual integration into the community, record reviews, individuals served and staff interviews; consumer satisfaction surveys linked to specific areas; managed care organizations' performance monitoring.
- States should use data to ensure accurate and consistent monitoring across settings and HCBS programs; the ability to collect, track and trend data is the foundation of effective quality performance management and improvement across HCBS programs.

Ending on a Strategic Note

- As states develop approaches for using the increased federal funds for HCBS available under section 9817 of the American Rescue Plan, implementation of the HCBS settings rule needs to factor prominently in those decisions.
- Increased federal funding can be used for capital investments, including for non-disability specific housing options, in furtherance of complying with the settings criteria.
- States should also be thinking about leveraging increased federal funding for other implementation activities such as provider assessments and trainings, and activities to further ongoing monitoring of provider compliance.

Resources

- CMS Baltimore Office Contact—Division of Long-Term Services and Supports:
HCBS@cms.hhs.gov
- To request Technical Assistance:
HCBSsettingsTA@neweditions.net
- Exploratory Questions to Assist States in Assessment of Residential and Non-Residential Home and Community-Based Service (HCBS) Settings available in the CMS Toolkit found at:
www.Medicaid.gov/Medicaid/hcbs/guidance/settings/index/html

Resources (cont.)

- Frequently Asked Questions (FAQs): Home and Community-Based Settings Regulation Implementation, Heightened Scrutiny Reviews of Presumptively Institutional Settings, issued by CMS on March 22, 2019:

<https://www.medicaid.gov/federal-policy-guidance/downloads/smd19001.pdf>

- Home and Community-Based Settings Regulation—Implementation Timeline Extension and Revised Frequently Asked Questions State Medicaid Director Letter, SMD # 20-003, issued by CMS on July 14, 2020:

<https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd20003.pdf>