
CMCS Informational Bulletin

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FROM: Brian Neale, Director

SUBJECT: Section 1115 Demonstration Process Improvements

On March 14, 2017, Health and Human Services (HHS) and CMS issued a letter to the nation's governors to affirm our partnership in improving Medicaid and the lives of those it serves, and committing to empower states to advance the next wave of innovative solutions that focus on improving quality, accessibility, and outcomes. The letter noted key areas where we will improve collaboration with states and move towards more effective program management, while ensuring state accountability for the outcomes produced by the Medicaid program.

This informational bulletin further describes a highlight of the letter – improving federal and state program management, specifically through improvements in the review, approval, monitoring and evaluation of section 1115(a) Medicaid demonstrations. CMS recognizes the need to improve the section 1115 demonstration process to facilitate expedited approval of demonstration projects. The process improvements described below are aimed at reducing burden, increasing efficiency, and promoting transparency in the review and approval of section 1115 demonstrations. They were developed in partnership with states and after thorough review of the current approval process.

The March 14 letter also acknowledged that, despite the significant investment by states and the federal government, Medicaid's results should be better. CMS is committed to ensuring that Medicaid achieves positive health outcomes for vulnerable individuals and families, including through the innovations implemented in section 1115 demonstrations. Monitoring and evaluation are critically important for understanding the impacts of the state innovations being demonstrated. This informational bulletin describes a number of strategies CMS is implementing to strengthen the monitoring and evaluation of section 1115 demonstrations. These improvement strategies will be implemented on an on-going basis.

Background

HHS and CMS are committed to working with states to bring additional flexibilities to Medicaid in ways that support both state objectives and the objectives of title XIX of the Social Security Act (the Act). The cycle of section 1115 demonstrations – from design, application review, negotiations and approval, to implementation, monitoring, and evaluation – involves substantial time from CMS, other federal partners, and states. To improve the section 1115 demonstration review process, while also assuring adequate federal oversight and evaluation, the Center for Medicaid & CHIP Services (CMCS) is implementing a number of strategies outlined in this bulletin.

Section 1115 Application and Approval Process

Reducing Burden

CMS recognizes that the approval process for section 1115 demonstrations can be cumbersome and time consuming. Reducing burden for states throughout the approval process is a key concern that CMS aims to address through the improvements outlined below.

Review and Revision of Section 1115 Demonstration Application: CMS will revise the Demonstration Application template to streamline and simplify it. We will remove duplicative information, and ensure states are only required to provide information necessary to meet the regulatory requirements and allow CMS to adequately evaluate the proposal. As needed, CMS will offer additional guidance and technical assistance on the demonstration application process, including guidance on the specific waivers and expenditure authorities' states might need to meet their goals.

Approval Timeline: Wherever possible, CMS will work with each state to develop a timeline for the approval process to include a regular schedule of meetings, topics to be discussed and anticipated deliverables. This will help to ensure states understand the information needed to facilitate the negotiations during the approval process.

Content of Special Terms and Conditions (STCs): The STCs articulated in demonstration approval documents reflect the policy agreements between states and CMS, and describe the parameters of the authority granted to the state. They are legally binding upon the state and are designed to clearly lay out the state's commitment to its Medicaid stakeholders, and the state's implementation and financing approach to medical assistance services under the demonstration authority. The following strategies will apply to STCs:

- CMS will continue to work with states to ensure that STCs reflect the policy agreements, and do not limit states' abilities to operate their programs within the extent of flexibility permitted by law.
- STCs will focus on policies with specific milestones, performance metrics, benchmarks, and anticipated outcomes through which the state will demonstrate its success.
- CMS will offer standard approved STC language, when appropriate, across similar demonstrations.
- States are invited to submit draft STC language pertinent to the application request.

Where technical or operational information is requested by CMS, the state may, when CMS finds appropriate, instead provide assurances that the requested information and the underlying issues will be addressed with a set of goals and milestones that result in development of operational protocols and necessary data. The STCs will contain such assurances and describe the milestones, and requirements to inform CMS about progress on the milestones, and any consequences if the state does not meet milestones.

Increasing Efficiency

CMS recognizes that increased efficiency during the approval process may allow states to implement their demonstrations and advance their innovations and system reforms more quickly.

Expediting Approval Processes: CMS remains committed to good faith negotiation and timely approval of demonstrations that meet states' needs and further the objectives of the Medicaid program. We will continue to work towards approval in such a way so as not to unnecessarily delay states' implementation schedules through the following strategies:

- CMS will develop parameters for expedited approval of certain waiver authorities under demonstrations (or particular elements of demonstrations) that are substantially similar to those approved in other states, while preserving Administration discretion to approve these demonstrations, recognizing that each state is unique and that similar provisions may be implemented and affect individual states differently. These parameters will reflect CMS' judgment that demonstrations that fall within the parameters are generally presumed to be consistent with the statutory requirements for section 1115 demonstrations (e.g., that they promote the objectives of the Medicaid statute, and qualify as a legitimate experiment or research project). Through the approval process, CMS will verify that the demonstration falls within these parameters and meets the statutory requirements in the given state.
- CMS will provide technical assistance to states to ensure timely identification of novel elements of a demonstration proposal that might preclude use of expedited approval procedures.
- Where possible, and subject to the public notice and transparency requirements, CMS may approve the extension of routine, successful, non-complex section 1115(a) waiver and expenditure authorities in a state for a period up to 10 years; with the flexibility to approve more complex waiver and expenditure authorities for shorter periods to allow CMS to assess the impact and continuation of these authorities.
- To support and expedite state/federal negotiations, we invite states to submit draft STC language for CMS consideration in new or changing demonstrations.
- To facilitate joint review and clarify understanding of STC language, CMS will offer to host virtual working meetings with states using a shared desktop or webinar format.
- States and CMS share responsibility for good faith negotiations and both parties must commit to timely responses to requests for information.

Supporting States to use Fast Track Process

CMS has an established *fast track* process for reviewing proposals from states to extend established Medicaid and CHIP section 1115 demonstrations that reauthorize longstanding policies with proven program outcomes.

- The *fast track* approach streamlines the federal review process to render decisions on certain demonstration extension requests in timeframes similar to Medicaid section 1915 waivers or State Plan Amendments through the use of an abbreviated application template.
- The *fast track* process is designed to expedite review of and decisions regarding state requests to extend established section 1115 demonstrations that meet specified criteria.
- This process is available for the renewal/extension of demonstration programs that:
 - have had at least one full extension cycle without substantial program changes;
 - are in compliance with reporting requirements, including submission of T-MSIS data;
 - are found by CMS to have positive monitoring and evaluation results that indicate that the demonstration is promoting the objectives of the Medicaid program and demonstrating positive health outcomes;
 - are not proposing major or complex changes; and,
 - are submitted using the *fast track* extension template developed by CMS for this purpose.
- In order to ensure access to this mechanism for all states in appropriate circumstances, CMS will remove the requirement that states must have had at least one full extension cycle without substantial program changes. This change means that, at first extension (e.g., after demonstration year (DY) 4 or 6, instead of after DY9 at the end of the first extension), states would be eligible for fast track if the demonstration meets the other criteria.

Separating Components of Complex Demonstrations: In some cases, if states and CMS agree, extension requests can be segmented to allow for the approval of routine, non-complex waiver and expenditure authorities on an expedited timeframe, while more complex waiver and expenditure authorities would be considered under traditional section 1115 timeframes.

Promoting Transparency

Transparency in the Review Process: Transparency and consistency in communications are crucial to the success of the state/federal partnership. States should be made aware of the demonstration approval process from beginning to end and should have sufficient time between approval and implementation of a demonstration action to facilitate success. Therefore, CMS plans to implement the following:

- CMS will continue to offer states the opportunity for technical assistance in advance of formal submission of a demonstration application as they are considering changes to their Medicaid programs.
- CMS will post and share with states a transparency review checklist used to assess whether a demonstration request meets the transparency requirements. This will assist

states in ensuring that their demonstration proposals meet all of the transparency requirements.

- When applicable during the demonstration review process, CMS will share a working list of open issues with states. This will help ensure that states are always aware of any gaps in information needed to process an action in an expeditious manner, and will serve as documentation of the final resolution on issues to mitigate any confusion in the future.
- CMS will work with states on the development of demonstration-specific timelines, based on the state's needs for demonstration approval, and will ensure that meetings with states to address demonstration issues have jointly defined agendas and expectations, including expectations related to follow up and accountability.

Coordinated Efforts across CMCS: CMCS, like state Medicaid agencies, includes multiple components with expertise in the policy, implementation and performance-related complexities of Medicaid and CHIP. As part of our efforts to improve the federal-state partnership, CMCS will implement a more formalized team approach with the goal of better and more efficiently coordinating federal efforts with respect to a demonstration proposal through the following strategies:

- If a state's demonstration action requires concurrent action across CMS (e.g., approval of a state plan amendment or a contract change), where possible, CMS will work to complete all actions on a coordinated and efficient timeframe that will be developed with the state and facilitated with the regional offices.
- CMS will work with states to determine whether other federal Medicaid authorities (state plan amendment, section 1915 waivers) may be available, instead of or in combination with section 1115 authority, in order to meet state policy goals.
- Where possible, CMS will work with the state to identify any other federal funding sources that may be available to support efforts already underway (e.g., systems development as approved in Advance Planning Documents (APD)).
- CMS will encourage early discussions about expectations for demonstrations, and state capacity to produce and report required data and conduct evaluations. CMS will provide targeted technical assistance as necessary.

Budget Neutrality: Budget neutrality can be complex. CMS will clarify expectations in this area and may provide additional written guidance to states on both policy and methodology for demonstrating budget neutrality. Specifically, CMS will use the following strategies:

- We will continue to offer technical assistance calls to any state that needs a budget neutrality overview, as well as address specific questions regarding budget neutrality.
- The current [budget neutrality template](#) and [budget neutrality policy](#) (described in an easy-to-follow slide deck) are available on Medicaid.gov.
- CMS will standardize budget neutrality STCs to clearly state which populations, services and costs were included in the budget neutrality agreement, and whether the state's historical trends or the President's Budget trend rate was used to project growth in the final agreement.

CMS is interested in increased transparency in budget neutrality and is considering providing more detail on CMS's budget neutrality policies in formal guidance. We welcome states' input in the development of this guidance. States are encouraged to reach out to us to specify the types of information that would be most helpful, and the challenges associated with the budget neutrality calculations.

Demonstration Monitoring and Evaluation

Consistent with HHS' commitment to ensure state accountability for the outcomes produced by the Medicaid program, CMS has implemented several enhancements to the monitoring and evaluation of section 1115 demonstrations. These enhancements are designed to:

- Target monitoring and evaluation resources to focus on the most significant program and policy priorities;
- Improve and standardize measurement sets, where appropriate to facilitate state data development, collection and reporting capacity;
- Strengthen CMS' capacity to identify demonstration implementation challenges and focus on mid-course correction; and
- Strengthen state evaluation designs to
 - produce more robust data and analyses; and
 - better understand demonstration impacts to inform future Medicaid policy within and across states.

To inform the improvements in monitoring and evaluation, CMS implemented a State Technical Advisory Group (TAG). This group of state-identified experts has advised CMS on monitoring and evaluation processes and on the development of standard metric sets for major categories of section 1115 demonstrations.

Demonstration Monitoring

In order to minimize the reporting burden on states, CMS has reduced the number of monitoring reports for all demonstrations by combining the fourth quarterly reports with annual reports. CMS will further reduce the frequency of reports (i.e., from quarterly to semi-annual or annual) for selected demonstrations that meet the following requirements:

1. Are long-standing, non-complex, and unchanged
2. Have previously been rigorously evaluated and determined successful, without issues or concerns that would require more regular reporting;
3. Include a small number of enrollees (approximately 500 or less);
4. Have been operating smoothly without administrative changes;
5. Have been challenged in only a minimal number of appeals and grievances;
6. Have no state issues with CMS 64 reporting or budget neutrality; and/or
7. Do not have a Corrective Action Plan (CAP) in place.

CMS is also working on standardized templates that will be customizable to meet the data, monitoring, and measurement needs of a state's specific demonstration design, reducing the need for states to speculate about what information to provide to CMS.

Core metric sets are also being developed for high priority demonstrations to further streamline the reporting requirements and improve transparency on reporting expectations

Demonstration Evaluation

CMS has generated general evaluation design and evaluation report guidance for all section 1115 demonstrations and states will typically see standardized monitoring and evaluation STCs, where appropriate, in their demonstrations. CMS will also provide technical assistance in the development of hypotheses and evaluation designs that reflect joint commitment to rigorous evaluation of and accountability for the results of demonstrations.

Additional enhancements to evaluation include:

- Encouraging states to use existing nationally recognized metric sets where appropriate, to support alignment across programs;
- Consideration of quality measures states already track and report, integration of those measures into the reporting for demonstration populations;
- Technical assistance in the development of milestones and performance metrics to fill gaps as needed.

In order to minimize disruption in existing monitoring and evaluation plans under current demonstrations, the improvement strategies described above will be phased in as existing demonstrations are renewed and new demonstrations are approved by CMS.

CMS looks forward to continuing to work with states to implement innovations and experiments, and to test new policies that promote the objectives of the Medicaid program. If you have any questions, please contact Judith Cash, Acting Director, State Demonstrations Group, at 410-786-9686.