Understanding the Effects of Medicaid Innovation

Considerations for Evaluating State Medicaid Policies

NATIONAL GOVERNORS ASSOCIATION

AUTHORS

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Executive Summary

Section 1115 Medicaid demonstrations are important vehicles for experimenting with new Medicaid policies. Rigorous evaluations of these policies, if done well, can inform Governors and other state leaders, federal partners and additional stakeholders in how to shape the future of the program. Until recently, many Section 1115 Medicaid demonstration evaluations lacked precision. This is changing – as the federal focus shifts to learning from state demonstrations, evaluation plans are more thorough and rigorous.

Recognizing this evolving landscape and the importance of rigorous state evaluations, in 2018, the National Governors Association Center for Best Practices (NGA Center) launched a project titled, "Building State Capacity to Evaluate Innovative Medicaid Policies." The project's goal was to support Governors and state leaders in evaluating new Medicaid policies implemented under Section 1115 waiver authority. With funding from the Robert Wood Johnson Foundation, the NGA Center, in partnership with the University of Minnesota State Health Access Data Assistance Center, engaged in a project to support evaluation efforts in Alaska, Colorado, Illinois and New Hampshire. Drawing on that work, this brief summarizes key considerations and outlines promising tactics for states to use in evaluating new Medicaid policies.

Since the launch of this project, Governors and their staff have been responding to the unprecedented public health crisis caused by the COVID-19 pandemic. The resulting jump in unemployment, projected shortfalls in state revenue and increased rates of the uninsured will affect Medicaid programs across the country. As state leaders seek solutions to manage their Medicaid programs in the face of increased enrollment and smaller budgets, new ideas will likely emerge for how to operate the program (through Section 1115 waiver authority or otherwise). As part of that innovation, state leaders should evaluate the impact of these changes on Medicaid enrollees, cost and sustainability.

Considerations and Strategies for Governors and Their Staff in Evaluating State Medicaid Policies

Prioritizing goals for evaluation:

- Start evaluation discussions early with the Centers for Medicare & Medicaid Services (CMS).
- Consider how implementation choices affect evaluation planning and budgeting.
- Keep sight of state goals.

Developing a timeline to support evaluation:

- Focus on CMS evaluation milestones.
- Anticipate the interplay between implementation and evaluation timelines.
- Consider which state activities to include in the evaluation timeline.

Designing an evaluation plan that reflects goals and resources:

- Assess state evaluation resources.
- Invest in evaluation activities that address key goals.
- Draw heavily from CMS guidance when drafting the evaluation design.
- When evaluation questions are firm, identify relevant data sources.

Building an effective relationship with an evaluation partner:

- Discuss in advance the scope and role of the independent evaluator.
- Balance the ideal contractor-selection process with real timeline and budget constraints.

Section 1115 demonstrations and evaluations of their effectiveness are a prime example of how states serve as the laboratories of innovation. Continued cross-state learning facilitated by the NGA Center, CMS and other stakeholders is key to improving evaluation rigor and understanding the effects of Medicaid policy innovations.

Introduction

Section 1115 Medicaid demonstrations provide a critical opportunity for states to experiment with new Medicaid policies not typically allowed under federal rules.[1] As recently shown, the Centers for Medicare & Medicaid Services (CMS) has made these demonstrations (along with other types of waivers) available to states to facilitate their public health response to COVID-19. The Section 1115 evaluation requirement was intended to test the effectiveness of demonstrations within Medicaid, but the statute provides only high-level direction; for many years, emphasis on the rigor of this requirement was limited.[2] Under the Patient Protection and Affordable Care Act, Congress added new rules to enhance Section 1115 evaluation requirements. In 2017, CMS released new resources to support state monitoring and evaluation, including new guidance for evaluating substance use disorder (SUD) and eligibility and coverage demonstrations.[3,4,5,6] The evaluation landscape further evolved in response to a January 2018 U.S. Government Accountability Office report that identified limitations in the usefulness of both state and federal evaluations of approved Medicaid demonstrations.[7] Guidance directs use of an independent evaluator to complete the state-led evaluation and calls for strict penalties when evaluation milestones are not met.[8] In addition, CMS initiated federal government-led evaluations of Section 1115 demonstrations to examine the effectiveness of specific policy implementations and outcomes across states.

Recognizing the importance of rigorous state evaluation of new Medicaid policies, the National Governors Association Center for Best Practices (NGA Center) launched a project in 2018 titled, "Building State Capacity to Evaluate Innovative Medicaid Policies." The project's goal was to support Governors and state leaders in evaluating new Medicaid policies implemented under Section 1115 waiver authority. With funding from the Robert Wood Johnson Foundation, the NGA Center in partnership with the University of Minnesota State Health Access Data Assistance Center, engaged in a two-and-a-half-year project to support evaluation efforts in **Alaska, Colorado, Illinois** and **New Hampshire**. The relevance of this work is only amplified by the COVID-19 crisis and the need for state leaders to evaluate the effects of Medicaid program changes on Medicaid enrollees, costs and sustainability. This brief summarizes key considerations and outlines promising tactics for states to use in evaluating new Medicaid policies.

Prioritizing Goals for Evaluation

Given limited state resources and the complexity of many Section 1115 demonstrations, state leaders should develop their evaluations with specific goals and priorities in mind (e.g., "need to know" versus "nice to know"). State officials should consider the following points in building an evaluation that answers the questions of greatest importance to state and federal stakeholders:

Start evaluation discussions early with CMS. State leaders should initiate conversations about evaluation goals when engaging CMS for approval of their demonstration. During these often extensive negotiations, CMS and states discuss and agree to demonstration objectives, which are binding within CMS's special terms and conditions (STCs).[9] Discussing evaluation at this stage enables states to ensure that the agreed-on objectives comport with federal requirements as well as state evaluation priorities and capacity. Most recently approved demonstrations have included specific language regarding evaluation hypotheses in the STCs. Particularly for large or multifaceted demonstrations, states should seek input from CMS on the focus of the evaluation. For example, CMS may have clear evaluation priorities and/or direction on whether evaluation resources should focus on a specific policy or population. Given that states are expected to submit an evaluation design to CMS within 120 or 180 days of demonstration waiver approval, early evaluation planning is also a practical approach.[10,11,12]

Consider how implementation choices affect evaluation planning and budgeting. The independent evaluation should be on the state's radar as it is making decisions about how to implement its Medicaid demonstration. An implementation plan and monitoring report are due to CMS even before the evaluation plan and can inform the list of data sources and measures available for the evaluation. In addition, state leaders can make implementation decisions that allow for a more rigorous evaluation design. For example, phased implementation can be used to support in-state comparisons between early and late-implementation groups.[13,14] In working with CMS, state leaders should be up front about the evaluation budget and resource constraints that may affect evaluation planning and use any technical assistance (TA) and resources CMS has to offer.[15,16,17] (See Appendix A for a list of CMS monitoring and evaluation guidance documents and templates.)

Keep sight of state goals. If possible, state leaders should engage stakeholders to identify their information needs in advance of any discussions with CMS. Recognizing that no two state Medicaid 1115 demonstrations are alike, CMS may give states flexibility to structure their evaluations to address unique aspects of their demonstrations in accordance with the evaluation budget. For instance, states may need to include evaluation criteria specified in state authorizing legislation, which may be unrelated to federal goals. Federal evaluation guidance focuses on specific outcomes, but in some cases, states may consider which information (e.g., process measures) they need to facilitate effective implementation as well as identify and address early warning signs. For example, states with approved SUD demonstrations may want to report on the availability of certified providers serving Medicaid beneficiaries with SUDs, which is an interim measure of progress. In other cases, states may want to monitor and report on the rate of nonfatal overdoses in addition to the CMS requirement to track change in overdose deaths.

By clearly prioritizing state evaluation goals, state leaders can come to the CMS negotiations with a solid understanding of where state and CMS information needs are similar and where they may diverge. If the state is interested in research questions that CMS does not require, they could address them as part of a parallel state-specific effort. For example, if the budget supports it, the state could leverage their independent contractor to develop state-specific evaluation deliverables such as rapid-cycle evaluation reports or policy-focused briefs for stakeholders to inform implementation decisions **(Exhibit 1)**.

EXHIBIT 1. Commonwealth of Virginia's SUD Demonstration: Addiction and Recovery Treatment Services

The evaluation of the Commonwealth of **Virginia**'s Addiction and Recovery Treatment Services Delivery System Transformation demonstration is an excellent example of meeting CMS's criteria while supporting state information needs and evaluation priorities. Serving as the independent evaluation contractor, Virginia Commonwealth University's Department of Health Behavior and Policy included the following deliverables as part of the evaluation design: "periodic issue briefs, memos, or brief reports on specific topics as requested by CMS, the State Department of Medical Assistance Services, the Administration, or the General Assembly."[18] Although the evaluation period began in 2017, the evaluation team has already released several publications highlighting the early impacts of the intervention, including easy-to-read, three-page issue briefs aimed at a broad stakeholder audience. In addition, the evaluation team contributed to a 2020 Health Affairs article on the effects of implementation on hospital use as well as a 2020 Academy Health brief on SUD demonstration implementation issues and early results in both Virginia and **Maryland**.[19,20]

? Key questions for state policymakers when identifying state goals for evaluation:

- **In addition to answering CMS-required evaluation research questions, what other priority questions do state leaders and local stakeholders need answered to assess whether the policy or program was successful and whether it should be sustained? What information is needed to inform policy improvement?**
- **Is the state required to address information requests outlined in state authorizing legislation?**
- **What is the evaluation budget (state share and federal match), and can it be supplemented with other funding sources? Can state-specific evaluation goals be addressed within the parameters of the evaluation budget? If not, what should be prioritized?**
- **To gather information state policymakers need, should the state consider developing components of the evaluation outside the formal and required CMS reporting structure?**

Developing a Timeline to Support Evaluation

State leaders should develop a timeline to guide evaluation activities and ensure timely completion of required deliverables. States should also clarify key demonstration milestones and due dates in writing and notify CMS if delays in implementation may affect the evaluation timeline. State leaders should consider the following points in developing their evaluation timeline:

Focus on CMS evaluation milestones. As states develop their evaluation timeline, they should be aware of CMS evaluation milestones and reporting requirements **(Appendix B)**. CMS requires three major evaluation deliverables: an evaluation design, usually due within 180 days of demonstration approval; an interim evaluation report, due with a renewal application or approximately one year before demonstration expiration; and a summative evaluation report, due approximately 1.5 years after the end of the demonstration period regardless of whether the demonstration is being renewed.[21] Monitoring reporting requirements are separate and distinct from these evaluation milestones.

Anticipate the interplay between implementation and evaluation timelines. The evaluation period will vary from demonstration to demonstration. States should specify when the evaluation period data will be available and the frequency of data collection. The evaluation timeline must address the fact that the demonstration implementation timeline can affect evaluation data collection and results because outcomes cannot be measured until the policy or program implementation has stabilized. This consideration is particularly important for demonstrations that use phased implementation. In addition, CMS guidance provides specific timeline requirements for serious mental illness (SMI) and serious emotional disturbance (SED) as well as SUD evaluation cost analyses, noting that one year of pre-demonstration data may not be sufficient to assess costs during the pre-demonstration period.[22] In the event that approved demonstrations are amended, states are required to revise their approved evaluation plans to accommodate amended provisions.[23]

Consider which state activities to include in the evaluation timeline. In developing their evaluation timeline, states should consider not just the CMS milestones but also corresponding state activities, such as those outlined in **Appendix B.** For example, some demonstrations will require preperiod (baseline) observations/data collection and stakeholder engagement. Many states will need to consider the time implications of state procurement processes because decisions about contracting (discussed in more depth later in this publication) have timeline consequences. Federal and state data privacy laws can also affect the evaluation timeline. Therefore, states must build in adequate time to request access to critical data and to execute data use agreements (DUAs), as necessary.[24] States also may need to share evaluation results with stakeholders at more frequent intervals than the CMS milestones; they may also require that independent evaluators produce shorter products between the three major CMS deliverables. For example, STCs may include a provision outlining how the state will consult with tribal representatives.[25]

Key questions for state policymakers regarding the evaluation timeline:

- **Which evaluation activities could the state begin before procuring an independent evaluator (e.g., inventory existing data sources and/or reported, relevant performance measures; collect baseline information)?**
- **If implementation is phased, how will this design affect the evaluation approach, data collection and the timing of results and outcomes?**
- **Is demonstration implementation on track? If not, how will delays affect evaluation timelines?**

Designing an Evaluation Plan That Reflects Goals and Resources

Whether developing the evaluation design on their own or engaging an outside contractor, state leaders should design their evaluation plan to address their goals for evaluation (i.e., answer "need to know" questions) while balancing staff and budget constraints. This section offers considerations for designing an evaluation plan that reflects evaluation goals and the resources available to support evaluation activities.

Assess state evaluation resources. States should perform due diligence to identify the state resources that can reasonably be devoted to demonstration evaluation efforts and consider how to balance state resource constraints with federal requirements and state evaluation goals. This work includes identifying state funding but also, realistically, assessing how much staff time the state can devote to overseeing and contributing to the evaluation. In addition to state appropriations, states may seek a 50% Medicaid administrative match from the federal government to support evaluation activities.[26] States may want to investigate other sources of evaluation funding in accordance with federal rules, such as matching grants from foundations or in-kind support within state government. Alternately, they may consider approaching a university partner to provide in-kind or reduced-rate services in exchange for the opportunity to study a new policy or issue area and publish their research.[27] (**Exhibit 2** has examples of ways states can stretch evaluation resources.)

EXHIBIT 2. Maximizing State Resources to Support Evaluation

States must decide how to support the implementation of required evaluation methods given state resources and the federal administrative match. States can consider maximizing resources to support evaluation in the following ways:

- Seek outside funding sources for the evaluation in accordance with federal rules.
- Build evaluation data-collection activities into managed care contracts, if applicable.
- Make implementation decisions that support a lower-cost experimental design.
- Use existing data and reporting streams, including relevant federal data resources.
- Direct state staff to assume some of the evaluation tasks (e.g., data runs).
- Limit primary data collection.
- Engage an independent contractor who has done a similar evaluation and is willing to provide formative investments, such as survey instruments.
- Prioritize and limit subpopulation analysis, focusing instead on key groups of interest to the state and CMS.

States should consider CMS a partner in developing and implementing their Section 1115 demonstration evaluation. Most recent guidance is specific and increasingly prescriptive, but states are nonetheless encouraged to seek TA from and engage in discussion with CMS throughout the process.

The evaluation budget must be included in the state's design deliverable. An informal review of currently approved waiver demonstrations found that budgets ranged significantly (based on scope of primary data collection, sophistication of evaluation design, relationship with independent evaluator, etc.). One state has an evaluation budget of less than $200,000 per year, though it includes in-kind support from faculty evaluators at the state university. Another state has devoted $40,000 for the evaluation design and just under $500,000 for the implementation of the evaluation, relying on state funds only. Still another state received approval for a multimillion-dollar evaluation that featured a randomized controlled trial experimental design with multiple surveys; biomeasure collection; and qualitative, in-depth interviews.

Invest in evaluation activities that address key goals. As noted above, states must identify and prioritize state and federal evaluation goals to ensure that they invest in an evaluation plan that addresses state and federal priority areas. For example, if CMS has indicated a greater interest in evaluating one component of the demonstration waiver over others, states should direct resources accordingly. Alternatively, a state that has prioritized monitoring consumer experience may choose to invest in primary data collection, such as the

administration of a beneficiary survey over time, despite its expense.

Draw heavily from CMS guidance when drafting the evaluation design. States should prioritize required hypotheses and research questions outlined in the STCs and consider the detailed and, in some cases, policy-specific, resources that CMS has issued for states (and their contractors) to support the most rigorous evaluation possible.[28] As outlined in the June 2018 eligibility and coverage policy evaluation design guidance, "robust evaluation" refers to the selection of hypotheses and research questions that meet CMS priorities and evaluation methods that support comparison of the group subject to the policy (often referred to as the "intervention group" or "treatment group") with a group not subject to the policy (referred to as the "control group"). The policy-specific guidance (introduced as appendices on CMS's webpage) identifies hypotheses and research questions, with recommended comparison groups from which states should draw. (CMS also emphasizes the development of an evaluation logic model, provides guidance on data sources and data collection and comments on subgroup analysis. Key evaluation guidance is summarized in **Appendix C.**) As suggested in CMS evaluation guidance related to SMI/SED and SUD demonstrations, states should include an approach to analyzing the costs of demonstration implementation in their evaluation design. Notably, while the guidance is framed as outlining CMS's expectations for rigor, CMS recognizes that state waiver demonstrations, evaluation budgets and timelines can and may vary. Therefore, CMS indicates a willingness to engage with and assist states if they are challenged to meet these expectations. If states are interested in additional, nonrequired hypotheses, they may want to consider addressing these elements outside the formal CMS evaluation.

When evaluation questions are firm, identify relevant data sources. States should identify existing data and reporting streams that the evaluation can use, given the high cost of primary data collection. In addition to state survey and administrative data, data for consideration should include federal survey data and national measure sets referenced in the guidance (e.g., CMS's Core Set of Health Care Quality Measures, measures endorsed by National Quality Forum). States should also use the required monitoring data, as outlined in the state's approved monitoring protocol.[29] The evaluation and monitoring metrics are separate requirements, but federal guidance notes that "monitoring data provide essential information on demonstration implementation, creating the context for evaluations and informing interpretation of results. Monitoring data can also be used as a data source for evaluation research questions focused on demonstration processes."[30]

Ideally, states can assess their data options by referencing an inventory of relevant data for use in the evaluation. If no such inventory exists, states could consider including a data inventory (i.e., a scan of state and federal data sources and measures that could be use or linked to in the evaluation, with documentation of the frequency and availability of data) as an early deliverable of the independent evaluator. During this process, it is likely that states will identify data gaps. For example, in cases where the selected hypothesis relies on a comparator, the state must ensure that data exists on an appropriate comparison group or, if needed, accommodate the collection of baseline data. In cases where the selected hypothesis or research question requires the design and administration of a new survey over time, the state must put in place techniques to gather an adequate sample to study populations of interest.

? Key questions for state policymakers when scoping their independent evaluation:

- **Which state resources (e.g., financial and staff time) are available for the evaluation? For example, does the state have analytic capacity to produce data runs for the independent evaluation contractor, or will the state need to budget for this?**
- **Which hypotheses and research questions will frame the state's evaluation design?**
- **Can other states with similar demonstration provisions and approved evaluation plans serve as examples? What are other states doing in terms of baseline data collection, primary data collection and control or comparison groups?**

Building an Effective Relationship With an Evaluation Partner

States are expected to engage an independent evaluator to conduct the state evaluation. In addition, states must explain their approach to working with an independent contractor in their evaluation plan. This section discusses considerations for selecting an independent evaluation contractor — a key partner in conducting the evaluation — and provides a list of potential skills and competencies a state should seek in their evaluator **(Exhibit 3)**.

Discuss in advance the scope and role of the independent evaluator. As states think about selecting an independent evaluator, they must weigh several considerations:

- States can *communicate their preferences* in an independent evaluator request for proposal (RFP). An evaluation kickoff meeting is another good time to discuss the state's expectations for its relationship with the independent evaluator.
- States should determine whether they have the *capacity to draft the evaluation plan* in house or prefer to contract with an independent evaluator to develop the evaluation plan. Some states have an evaluation or research unit internal to Medicaid or another state agency that may have the experience and time to develop the CMS-required evaluation plan. Others may prefer to issue an RFP to complete this work. The benefit of having the independent evaluator engaged in the evaluation design process is that the evaluator can develop early knowledge of proposed research methods and data sources.
- States should discuss their *expectations for communication* with their independent evaluator. Some states may prefer, for budgetary or other reasons, to have minimal contact with independent evaluators outside of regular project communications and deliverables. Other states may prefer a more collaborative role for independent evaluators. In these cases, independent evaluators could serve as a TA resource for implementation decisions as they relate to evaluation and data collection, contribute to state reporting to CMS and be involved in briefing state or local stakeholders on evaluation milestones. Because independent evaluations often include gathering data from a variety of stakeholders, both within and outside of state agencies, states should provide early direction to independent evaluators outlining their preferred processes for identifying and engaging stakeholders.
- Another consideration relates to the *responsibility for data management and collection tasks.* Will the independent evaluator be expected to manage all the steps for gaining access to and using state data, or does the state have capacity to support

EXHIBIT 3. Potential Skills and Competencies for an Independent Evaluator

The ideal independent evaluator will have the following skills and competencies:

- Experience with complex, large-scale evaluation.
- Demonstrated experience working with state government, particularly Medicaid.
- Demonstrated experience designing and conducting evaluations that have quasiexperimental design, a mixed-methods approach and descriptive and statistical analyses that include secondary and primary data collection (quantitative and qualitative).
- Experience managing a similarly sized health-related evaluation and team.
- Knowledge and understanding of state-specific data.
- Flexibility to shift timelines in the event of demonstration approval and implementation delays.
- Ability to conduct primary data collection or demonstrate relationships with strong subcontractors.
- Demonstrated experience in developing evaluation plans that produce results for subgroups of interest (e.g., demonstrated experience conducting regional analysis or studying vulnerable populations, such as justice-involved individuals).

secondary data requests for the evaluation? A related consideration is the state's expectations in terms of investments in primary data collection, which may require specific skills (e.g., expert interviewing, survey design and administration, resources to reach participants).

- In terms of *management of the evaluation team,* if the state's evaluation is best served by partnerships between multiple organizations to meet the complex skills and expertise required, states should determine whether they prefer to manage contracts with multiple contractors (which may affect timeline and administrative lift) or ask the lead independent evaluator to assume responsibility for all subcontracted activities.

Balance the ideal contractor-selection process with real timeline and budget constraints. States should consider their evaluation timeline and budget when determining the process for selecting their evaluation partner. In an ideal world, states would issue a well-drafted RFP to select their independent evaluators, get numerous high-quality responses and have ample time to review and select the ideal contractor. In reality, timeline and budget constraints often drive these decisions. Many states consider working with an existing contractor or one with whom they have a previous relationship (e.g., public university or entity with a master contract) for expediency and ease. Advantages of this approach include having contract language already in place (including DUAs and rates negotiated); the contractor's knowledge of and experience with state policy, procedures and data; and, in some cases, established institutional review board processes. For states that want to or must seek competitive bids to select an evaluation contractor, advantages include using the creative ideas of a broad pool of applicants with "outsider" perspectives and the opportunity to compare bid approaches and budgets.

Given the time associated with the RFP process, states that choose this route may want to consider one RFP for both the design and implementation of the independent evaluation if state procurement allows it. This work could be phased, or the implementation phase could be optional so that states could seek a different contractor if they are not satisfied with the results of the design phase. If the state plans to use separate RFPs for evaluation plan design and evaluation implementation, they could consider indicating in the design RFP that the entity awarded the contract will be eligible to bid on the implementation RFP.

? Key questions for state policymakers when engaging an evaluation contractor:

- **Which agency or division will oversee the independent evaluator, and what are the state's expectations for state staff involvement in evaluation activities?**
- **Does the state prefer to develop the Section 1115 demonstration evaluation design deliverable in house or contract it out?**
- **Does the state have an existing relationship with a skilled evaluator so that the same contractor could be considered to conduct the Section 1115 demonstration evaluation?**
- **If the state seeks a competitive bid process, does the state prefer to initiate separate RFPs for the evaluation design and evaluation implementation, or does it prefer to post one RFP for both efforts?**

Looking Ahead: Using Available Resources

Section 1115 demonstrations and evaluations of their effectiveness are a prime example of how states serve as the laboratories of innovation. New guidance from CMS supports states in this role and offers clear recommendations to help ensure high-quality, rigorous evaluation. Findings from a robust evaluation not only meet the information needs of state leaders and their stakeholders but inform regional and national conversations about how to transform Medicaid to meet state and federal goals. That said, although there are important opportunities to learn from these innovations, the more recent focus on evaluation rigor can represent technical, logistical and budget challenges.

As state leaders develop Section 1115 evaluations, they should look to existing resources for support. Most importantly, state officials should review and follow the guidance provided by CMS and its contractors, which includes general and policy-specific guidance; hypotheses; and evaluation research questions as well as technical support for setting up implementation to support strong evaluation and detailed reports on various aspects of evaluation design. Several policy research organizations have high-quality resources to support state-led evaluations. In addition, opportunities exist for state leaders to learn from their peers and evaluation contractors in other states. (**Appendix D** is an annotated bibliography of select, non-CMS evaluation resources.)

States that have already embarked on this work can share informative examples of evaluation contractor RFPs, CMS-approved evaluation plans and reports, data-collection tools (such as interview protocols or beneficiary surveys, if accessible) and definitions of comparison groups. (**Appendix E** has select examples of Section 1115 SUD evaluation designs.) Continued cross-state learning facilitated by the NGA Center, CMS, Academy Health and other stakeholders is key to improving evaluation rigor and understanding the effects of Medicaid policy innovations. States should take advantage of the work and lessons learned in other states.

Looking ahead also means recognizing uncertainty. The COVID-19 pandemic has simultaneously increased demands on the Medicaid program while reducing state budgets. Not surprisingly, state and federal priorities have shifted: The pace of non-COVID-19-related Section 1115 waiver approvals or renewals has slowed, and extensions for meeting evaluation requirements are expected. At the same time, COVID-19 has spurred innovation and prompted CMS to offer flexibility in expanded coverage, reimbursement, service provisions for older persons and persons with disabilities, telehealth and other areas. CMS' most recent technical assistance resource related to 1115 demonstration evaluations acknowledges the potential effects that the COVID-19 pandemic might have on demonstration implementation and evaluation and provides considerations for states and their independent evaluators related to documenting changes, modifying data collection methods and analysis plans, and interpreting results.[31] Not all COVID-19-related changes to the Medicaid program have come through Section 1115 demonstration authority, but evaluating the impact of these changes on enrollees and the cost and effectiveness of the program is critical to informing which policies or programs should be sustained, scaled or discontinued when the pandemic is over. The resources state agencies develop to support rigorous evaluation of Section 1115 demonstrations and the experiences states have in conducting these evaluations can serve as models for monitoring, course correcting and evaluating innovation related to the pandemic.

Appendices

APPENDIX A: List of Centers for Medicare & Medicaid Services Section 1115 Demonstration Evaluation and Monitoring Guidance Documents and Templates

Type of Demonstration	Demonstration Requirements	Guidance Documents and Templates
General 1115 demonstration	Evaluation design	• Section 1115 Demonstrations: Developing the Evaluation Design • Planning Section 1115 Demonstration Implementation to Enable Strong Evaluation Designs, March 2019 • Best Practices in Causal Inference for Evaluations of Section 1115 Eligibility and Coverage Demonstrations, June 2018 • Selecting the Best Comparison Group and Evaluation Design: A Guidance Document for State Section 1115 Demonstration Evaluations, June 2018 • Implications of COVID-19 For Section 1115 Demonstration Evaluations: Considerations for States and Evaluators, August 2020
	Evaluation reports	• Section 1115 Demonstrations: Preparing the Evaluation Report
Eligibility and coverage	Implementation plan	• Medicaid Section 1115 Eligibility and Coverage Demonstration Implementation Plan
	Monitoring reports	• Medicaid Section 1115 Eligibility and Coverage Demonstration Monitoring Report Template Instructions • Medicaid Section 1115 Eligibility and Coverage Demonstration Monitoring Report • Monitoring Metrics for Demonstrations With Community Engagement and Other Eligibility and Coverage Policies • Medicaid Section 1115 Eligibility and Coverage Demonstration Monitoring Protocol — Part B • Monitoring Metrics Excel document
	Evaluation design	• Evaluation Design Guidance for Section 1115 Eligibility and Coverage Demonstrations – Appendices: Community engagement, beneficiary premiums, retroactive eligibility, noneligibility periods and sustainability • Beneficiary Survey Design and Administration for Eligibility and Coverage Demonstration Evaluations, June 2019
Serious mental illness (SMI), serious emotional disturbance (SED) or substance use disorder (SUD)	Implementation plan	**SUD:** • Section 1115 Substance Use Disorder (SUD) Demonstration: Guide for Developing Implementation Plan Protocols **SMI/SED:** • Section 1115 SMI/SED Demonstration Implementation Plan, July 23, 2019
	Monitoring protocol	**SUD:** • Medicaid Section 1115 SUD Demonstration Monitoring Protocol template and instructions • Monitoring Metrics Excel document
	Monitoring reports	**SUD:** • Medicaid Section 1115 SUD Demonstration Monitoring Report template and instructions • Monitoring Metrics for Section 1115 Demonstrations With SUD Policies **SMI/SED:** • Medicaid Section 1115 SMI/SED Demonstration Monitoring Report • Mental Health Availability Assessment Excel Document • Monitoring Metrics for Section 1115 Demonstrations With SMI/SED Policies, 2019

Type of Demonstration	Demonstration Requirements	Guidance Documents and Templates
Serious mental illness (SMI), serious emotional disturbance (SED) or substance use disorder (SUD)	Evaluation design	**SUD:** and **SMI/SED:** • Evaluation Design Guidance for Section 1115 Demonstrations for Beneficiaries With Serious Mental Illness/Serious Emotional Disturbance and Substance Use Disorders • Appendices: – Goals, Research Questions, and Analytic Approaches for Evaluating Section 1115 Serious Mental Illness/Serious Emotional Disturbance Demonstrations – Goals, Research Questions, and Analytic Approaches for Evaluating Section 1115 Substance Use Disorder Demonstrations – Approaches to Analyzing Costs Associated With Demonstrations for Beneficiaries With Serious Mental Illness/ Serious Emotional Disturbance or Substance Use Disorders

Source: Medicaid.gov. (n.d.). *1115 demonstration state monitoring & evaluation resources.* U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

Note: Select states with approved SUD Section 1115 demonstrations received and are complying with updated monitoring guidance from the Centers for Medicare & Medicaid Services.

APPENDIX B: Centers for Medicare & Medicaid Services Section 1115 Demonstration Evaluation Milestones and Concurrent Supporting State Evaluation Activities to Consider

Centers for Medicare & Medicaid Services (CMS) Milestone and Time Frame	Concurrent Supporting Evaluation Activities for State Consideration
Demonstration waiver development and CMS negotiation	• Evaluation planning, budgeting and priority setting. • State and local stakeholder engagement. • Data source and measure inventory.
Demonstration approval	• Evaluation research question identification. • Exploration of additional evaluation resources. • Development of a request for proposal for an independent evaluator, if needed (potentially earlier, if the contractor will be used to develop the evaluation design). • Baseline data collection and control group consideration.
Implementation start date	• Evaluation design development. • Stakeholder engagement. • Selection of independent evaluator.
Evaluation design draft (120 or 180 days from approval date or implementation start)	• Discussions with CMS and independent evaluator to address comments (state has 60 days). • Review of independent evaluator work plan, including data collection and analysis plan.
Evaluation design approval (publish in 30 days)	
Interim evaluation report draft (one year before demonstration expiration)	• Discussions with CMS and independent evaluator to address comments. • Possible independent evaluator state deliverable: report on a pilot project. • Possible independent evaluator state deliverables: rapid-cycle report or issue brief.
Interim evaluation report approval (publish in 30 days)	
Summative evaluation report draft (1.5 years after demonstration period)	• Discussions with CMS and independent evaluator to address comments. • Possible independent evaluator state deliverable: report on outcomes for a specific subgroup. • Possible submission to a peer-reviewed publication.
Summative evaluation report approval (publish in 30 days)	

Note: Federal quarterly and annual monitoring requirements could be supported by the state's independent evaluator and could inform state independent evaluation activities and reporting.

APPENDIX C: Summary of Centers for Medicare & Medicaid Services Section 1115 Demonstration Evaluation Requirements and Related Guidance

Table 1: General Guidance on Evaluation Design

Key Considerations	General Guidance	Guidance Specific to Substance Use Disorder (SUD)/Serious Mental Illness (SMI)/Serious Emotional Disturbance or Community Engagement Waivers
Evaluation period	The evaluation plan should clearly specify the evaluation time period and the points at which interim and summative evaluations will take place. The evaluation period will vary from demonstration to demonstration. States should specify at what point in the evaluation period data will be available and the frequency of data collection. Note that some demonstrations will require preperiod (baseline) observations/data collection.	SUD/SMI specific: The time frame for the preassessment will be set for one year before the start of the demonstration.
Target populations and subgroups	Provide information about groups affected by each policy and the inclusion and exclusion criteria for the target group. Although the target population for these policies is often current Medicaid beneficiaries, certain desired outcomes may affect both current and former beneficiaries.	Community-engagement specific: The target population is demonstration beneficiaries subject to community engagement requirements. The evaluation plan should discuss how the state would include former beneficiaries in the target group for evaluation purposes.
Comparison groups	Comparison group selection should be informed by the best opportunity to establish a counterfactual to evaluate the effects of the demonstration. Specify inclusion and exclusion criteria and sampling methods, and describe how the state will overcome drawbacks in specific comparison group strategies. If a credible comparison group is difficult to identify, request Centers for Medicare & Medicaid Services (CMS) guidance. CMS will consider, on a case-by-case basis, analytic approaches that do not require comparison groups. States may consider an other-state comparison strategy.	SUD/SMI specific: Identify groups without demonstration benefits, and compare access to and use of SUD services and SUD outcomes between groups.
Data sources and measures	Discuss data source availability, quality, limitations and statistical power calculations. Recommended qualitative and quantitative sources, including interviews and/or focus groups with beneficiaries and other key informants, beneficiary surveys over time (emphasized in CMS guidance), Medicaid administrative data (claims, encounters, enrollment, etc.), non-Medicaid administrative data (Supplemental Nutrition Assistance Program, IPUMS American Community Surveys, Temporary Assistance for Needy Families, Behavioral Risk Factor Surveillance System, Current Population Survey, etc.).	SUD/SMI and community engagement specific: Guidance includes recommended measures and data sources for all SUD/community engagement demonstrations but allows states to add measures/sources to fit their specific demonstration and state information needs.

Evaluation Design Format	General Guidance *Submit to CMS within 120 to 180 days of demonstration approval; publish to state website within 30 days of design approval.*
General Background	Includes the name of the demonstration policy, approval date, evaluation period (if different from the demonstration period), the goals of the demonstration policy, problems to be addressed and their magnitude, the population affected, a description of the demonstration policy strategies and justification for course of action, a summary of the implementation plan and any other relevant contextual factors. Specify whether this demonstration policy is a renewal or an amendment.
Hypotheses and Questions	Include hypotheses and research questions from waiver-specific design appendices and guidance as well as any state-specific hypotheses. These elements should correspond to the demonstration policy goals and be clearly written to state the direction of the expected change. Evaluators should use two-sided hypothesis tests to analyze effects in two directions. Research questions may include primary questions and subsidiary questions for greater depth and detail.
Logic Models/ Driver Diagrams	**Logic model:** Develop a logic model that depicts the relationship between the goals of the demonstration policy and goals of the evaluation, including expected short-term, intermediate and long-term outcomes. **Driver diagram:** Some guidance refers to the development of a driver diagram depicting the demonstration policy aim, the primary drivers that contribute directly to achieving the aim and the secondary drivers necessary to achieve the primary drivers for the demonstration.
Evaluation Methods	Includes an evaluation methods narrative, target and comparison populations (see above), the evaluation period, evaluation measures, data sources, a design table and any other relevant additions. **Design table:** Organized by individual hypotheses, with corresponding research questions. Columns include outcome measures, sample/population subgroups, comparison group approach (see above), data sources and analytic methods. *CMS suggests a mixed-methods evaluation design, using both qualitative and quantitative data. CMS expects a rigorous evaluation approach, such as an experimental or quasiexperimental design.*
Data Analysis Methods	Includes all analytic methods planned for evaluation. For each planned analytic approach included in the state's design tables as submitted to CMS, the evaluation plan should describe the target population, time points for data collection and outcome measures. Identify specific statistical testing or adjustment that will be undertaken for each measure or population (*t* tests, chi-square, odds ratio, analysis of variance, regression, etc.) and any propensity score matching, difference in differences calculations or sensitivity analyses used.

Table 2: Guidance on Interim and Summative Evaluation Reports

Interim and Summative Evaluation Report Format	General Guidance
Executive Summary	Summarize the demonstration, the principal results, interpretations and recommendations of the evaluation.
General Background	Include the goals of the demonstration policy, problems to be addressed by demonstration policy and magnitude, justification for the course of action, names and descriptions of demonstration policy strategies, approval date, time period of the demonstration, the population affected and a discussion of renewal/amendment.
Evaluation Questions and Hypotheses	How do demonstration policy goals relate to expected outcomes? How does this report build on previous findings? How do research questions relate to overall Medicaid program objectives? Include a driver diagram/logic model. Identify hypotheses and research questions.

Methodology/ Limitations	Include information about evaluation methods, target and comparison populations, the evaluation period, measures, data sources, analytic methods and any additional information. What are the strengths and weaknesses of the design, data sources, data collection or analyses?
Results and Conclusions	Does the demonstration effectively achieve the stated goals? What are the outcomes/ impacts of the demonstration? What should be done in the future? Visually depict results by using graphs, tables and/or charts. Include information about statistical analyses. At the interim report stage, results may be descriptive; data collection may be insufficient to report on outcome measures.
Interpretations	What are the policy implications? How did or how could this demonstration interact with other state initiatives?
Lessons Learned and Recommendations	What lessons were learned as a result of the demonstration? What would you recommend to other states that may be interested in implementing a similar approach?
Additional Requirements: Sustainability and Cost Impacts	**SUD/SMI:** Report on cost analysis, and include measures of (1) total Medicaid costs and total federal Medicaid costs; (2) SUD/SMI-institutions for mental diseases costs, SUD/SMI-other costs and non-SUD/SMI costs; and (3) inpatient costs, emergency department (ED) outpatient costs, non-ED outpatient costs, pharmacy costs and long-term care costs. **Community engagement specific:** (1) Administrative costs to implement policy, (2) effects of policy on health service expenditures and (3) effects of policy on provider uncompensated care costs.
Attachments	Include the evaluation design.

Sources:

Medicaid.gov. (n.d.). Evaluation design guidance for Section 1115 eligibility and coverage demonstrations. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/ce-evaluation-design-guidance.pdf

Medicaid.gov. (n.d.). Appendix to evaluation design guidance for Section 1115 eligibility and coverage demonstrations: Community engagement. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/ce-evaluation-design-guidance-appendix.pdf

Medicaid.gov. (n.d.). Substance use disorder (SUD) Section 1115 demonstration evaluation design — technical assistance. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-state-monitoring-evaluation-resources/index.html

Medicaid.gov. (n.d.). Evaluation design guidance for Section 1115 demonstrations for beneficiaries with serious mental illness/serious emotional disturbance and substance use disorders. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-sud-1115-eval-guide.pdf

Medicaid.gov. (n.d.). Section 1115 demonstrations: Preparing the evaluation report. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/downloads/preparing-the-evaluation-report.pdf

Medicaid.gov. (n.d.). Section 1115 demonstrations: Developing the evaluation design. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/downloads/developing-the-evaluation-design.pdf

Note: State independent evaluation requirements are separate from the requirement that states participate in any federal evaluation.

APPENDIX D: Annotated Bibliography of Other Useful Resources for Section 1115 Evaluation

1. Boozang, P., Bachrach, D., & Grady, A. (2019, February). ***Monitoring and evaluating work and community engagement requirements in Medicaid: Data assets, infrastructure and other considerations for states.*** **Manatt Health.** **https://www.manatt.com/Manatt/media/Documents/Articles/MANA-88-Work-and-Community-Engagement-Requirements-Whitepaper_v3.pdf**
This resource is the first in a series of resources funded by the Robert Wood Johnson Foundation (RWJF) on the evaluation of new Medicaid Section 1115 waiver demonstrations. The brief provides background information about the landscape of work requirement/community engagement waivers in the United States and discusses the importance of rigorous monitoring and evaluation of these yet-untested waivers. The brief details which states have approved and pending waivers and suggests metrics and data sources that states can use to understand the impact of their work requirement/community engagement waivers. These recommendations are based on the Centers for Medicare & Medicaid Services' (CMS) guidance for waiver monitoring and evaluation. Manatt categorizes metrics by impact categories, which include Medicaid coverage, work/community engagement, health and administrative processes and costs. The brief also offers suggestions for data-collection strategies and provides information about compliance with privacy standards.

2. Boozang P., & Grady, A. (2019, May 24). ***New federal guidance on monitoring and evaluation of work requirements and other coverage demonstrations: What does it mean for states?*** **JD Supra.** **https://www.jdsupra.com/legalnews/new-federal-guidance-on-monitoring-and-90671**
This resource is the second in a series of resources funded by the RWJF on the evaluation of new Medicaid Section 1115 waiver demonstrations. This brief summarizes many of the key takeaways from the CMS evaluation guidance for states' Medicaid Section 1115 eligibility and coverage demonstrations. It outlines and describes the components of a comprehensive monitoring and evaluation strategy for these Medicaid demonstrations and offers a summary table of monitoring metrics and links to resources states can use throughout their evaluation development process. Manatt also interprets the implications for the newly published guidance on demonstration timing, analytics, costs and procurement of an evaluator.

3. Boozang, P., Lam, A., & Traub, A. (2019, November). ***Evaluation of Medicaid demonstrations under new CMS guidance: State considerations and financial resource requirements.*** **Manatt Health.** **https://www.manatt.com/Manatt/media/Documents/Articles/MANA-89-Evaluation-of-Medicaid-Demonstrations-under-New-CMS-Guidance_FIN.pdf**
This resource is the third in a series of resources funded by the RWJF on the evaluation of new Medicaid Section 1115 waiver demonstrations. This final brief focuses on the costs associated with the increased rigor expected of Medicaid demonstration evaluation. Manatt quantifies changes in the cost of evaluation design that stem from this new guidelines and explores options for financing evaluation strategies. In addition to reviewing costs associated with previous evaluation efforts, the brief discusses new spending drivers introduced in the updated guidance, which include "more prescriptive and complex evaluation design requirements," "new data requirements" and "earlier evaluation planning and independent evaluator engagement."

4. Cunningham, R. (2019, January 25). Research insights. Medicaid and personal responsibility waivers: Opportunities and challenges in evaluating potential impacts. AcademyHealth. **https://www.academyhealth.org/sites/default/files/medicaid_personal_responsibility_waivers_feb2019.final_.pdf**
This resource, part of the Agency for Healthcare Research and Quality's project titled "Research Insights," summarizes a roundtable discussion among policy analysts and public officials focused on the challenges and opportunities associated with evaluating newer waiver policies. Roundtable participants discuss the impact of premiums, cost-sharing policies, work requirements and healthy behavior incentives on enrollment numbers and administrative costs.

5. Medicaid and CHIP Payment and Access Commission. (2020, March). ***Chapter 3: Improving the quality and timeliness of Section 1115 demonstration evaluations*** **(Report to Congress on Medicaid and CHIP).** **https://www.macpac.gov/wp-content/uploads/2020/03/Improving-the-Quality-and-Timeliness-of-Section-1115-Demonstration-Evaulations.pdf**
This chapter, part of the Medicaid and CHIP Payment and Access Commission's (MACPAC) March 2020 report to Congress on Medicaid and the Children's Health Insurance Program, begins by describing the intent of the Section 1115 demonstration evaluations that CMS requires and the limitations of past evaluations in terms of rigor and use of findings. It then describes the guidance that CMS has given to states to aid in increasing the quality of the evaluations performed. It raises continued challenges for states, such as resource or methodologic constraints, and acknowledges that improvements in evaluation design, implementation and use will take time. This section relies heavily on the discussion at the November 2019 roundtable of policy analysts and public officials hosted by MACPAC. At this time, MACPAC does not identify a need for further regulatory steps to address Section 1115 demonstration evaluations.

6. Weiss, A. F. (2018, March 19). ***There's a lot to learn from state Medicaid experiments, but only if they're carefully evaluated.*** **Health Affairs Blog.** **https://www.healthaffairs.org/do/10.1377/hblog20180314.287490/full**
This blog post from the Health Affairs Blog details the emerging experimental Medicaid waiver landscape and the changing approaches to providing insurance coverage to low-income Americans. In the wake of the innovations, the author emphasizes the need to prove that demonstrations accomplish their established goals and adhere to the tenets of the Medicaid program. Before these waiver strategies proliferate, states need to understand what works and how well. The author claims that, according to new guidance, evaluations of Medicaid demonstrations must be transparent, thorough, inclusive, robust and timely to "spread practical, accurate information" about these waivers.

APPENDIX E: Examples of Approved State Evaluation Design for Substance Use Disorder Section 1115 Demonstrations

State	Evaluation Design	Resource Location
Indiana	Health Indiana Plan Substance Use Disorder Waiver Evaluation Design	https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-sud-eval-dsgn-20190606.pdf
Kansas	KanCare 2.0 Substance Use Disorder Evaluation Design	https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ks-kancare-cms-sud-eval-des-appvl.pdf
Massachusetts	MassHealth Evaluation Design	https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ma/MassHealth/ma-masshealth-cms-apprvd-eval-desgn-01312019.pdf
Michigan	Michigan Behavioral Health Demonstration Evaluation	https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/mi-pathway-integration-appvd-sud-eval-des-10012019.pdf
North Carolina	North Carolina Medicaid Reform Demonstration Evaluation Design	https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nc/Medicaid-Reform/nc-medicaid-reform-demo-eval-des-appvl-01152020.pdf
New Hampshire	Recovery Treatment and Access Demonstration Evaluation Design	https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nh/sud-treatment-recovery-access/nh-sud-treatment-recovery-access-sud-tra-eval-design-appvl-05222019.pdf
New Jersey	New Jersey FamilyCare Comprehensive Demonstration Evaluation Design	https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/nj/Comprehensive-Waiver/nj-1115-request-eval-des-appvl-10012019.pdf
New Mexico	Centennial Care 2.0 Substance Use Disorder Evaluation Design	https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/nm-centennial-care-cms-eval-des-appvl-04022020.pdf
Rhode Island	Rhode Island Comprehensive Demonstration Evaluation Design	https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ri-global-consumer-choice-compact-cms-eval-des-appvl.pdf
Utah	Primary Care Network Substance Use Disorder Amendment Evaluation Design	https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ut/Primary-Care-Network/ut-primary-care-network-eval-design-appvl-10162019.pdf
Washington	Medicaid Transformation Project Evaluation Design	https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/wa-medicaid-transformation-sud-eval-des-appvl-08012019.pdf
West Virginia	Continuum of Care for Medicaid Enrollees With Substance Use Disorders Evaluation Design	https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/wv/continuum-care/wv-creating-continuum-care-medicaid-enrollees-sud-final-eval-design-20190927.pdf

ENDNOTES

1 Section 1115 waiver demonstrations are subject to review and approval by the Secretary of Health and Human Services, who determines whether the policies (or changes in expenditure authority) are consistent with the administration's objectives and budget neutral to the federal government.

2 Kaiser Family Foundation. (2009). The role of Section 1115 waivers in Medicaid and CHIP: Looking back and looking forward [Issue paper]. Kaiser Commission on Medicaid and the Uninsured. https://www.kff.org/wp-content/uploads/2013/01/7874.pdf

3 Social Security Act, 42 U.S.C. § 1115(d) (2010), as added by § 10201(i) of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf

4 Public Health, 42 C.F.R. § 431.420 (2013). https://www.govinfo.gov/content/pkg/CFR-2013-title42-vol4/pdf/CFR-2013-title42-vol4-sec431-420.pdf

5 Neale, B. (2017, November 6). Section 1115 demonstration process improvements [CMCS informational bulletin]. https://www.medicaid.gov/federal-policy-guidance/downloads/cib110617.pdf

6 The Centers for Medicare & Medicaid Services continues to work with a contractor, Mathematica Policy Research, secured under the Obama administration, to develop evaluation guidance and provide technical assistance for states to support more robust and comparable evaluation. This contractor is also supporting the identification of standard monitoring measures associated with certain demonstration types to encourage more consistent monitoring of similar demonstrations.

7 U.S. Government Accountability Office. (2018, January). Medicaid demonstrations: Evaluations yielded limited results, underscoring need for changes to federal policies and procedures (U.S. Government Accountability Office Publication No. GAO-18-220). https://www.gao.gov/assets/690/689506.pdf

8 Mayhew, M. C. (2018, November 13). Re: Opportunities to design innovative service delivery systems for adults with a serious mental illness or children with a serious emotional disturbance (CMS Publication No. SMD #18--011). U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/federal-policy-guidance/downloads/smd18011.pdf

9 Medicaid and CHIP Payment and Access Commission. (n.d.) Section 1115 research and demonstration waivers. https://www.macpac.gov/subtopic/section-1115-research-and-demonstration-waivers

10 Medicaid.gov. (n.d.). Section 1115 demonstrations: Developing the evaluation design. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/downloads/developing-the-evaluation-design.pdf

11 Medicaid.gov. (n.d.). Evaluation design guidance for Section 1115 eligibility and coverage demonstrations. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/ce-evaluation-design-guidance.pdf

12 Medicaid.gov. (n.d.). Evaluation design guidance for Section 1115 serious mental illness/serious emotional disturbance and substance use disorders. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-sud-1115-eval-guide.pdf

13 Buderi, K. (2019, December 12). Improving the quality and timeliness of Section 1115 demonstration evaluations: Themes from expert roundtable. Medicaid and CHIP Payment and Access Commission. https://www.macpac.gov/wp-content/uploads/2019/12/Improving-the-Quality-and-Timeliness-of-Section-1115-Demonstration-Evaluations-Themes-from-Expert-Roundtable.pdf

14 Medicaid and CHIP Payment and Access Commission. (2020, March). Chapter 3: Improving the quality and timeliness of Section 1115 demonstration evaluations (Report to Congress on Medicaid and CHIP). https://www.macpac.gov/wp-content/uploads/2020/03/Improving-the-Quality-and-Timeliness-of-Section-1115-Demonstration-Evaulations.pdf

15 Medicaid.gov. (n.d.). 1115 demonstration monitoring & evaluation. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/index.html

16 Neale, B. (2017, November 1). RE: Strategies to address the opioid epidemic (CMS Publication No. SMD # 17-003). U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf

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18 Lynch, C. (2020, July 9). Building and transforming coverage, services, and supports for a healthier Virginia (CMS Publication No. 11-W-00297/3). U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/1115/downloads/va/va-gov-access-plan-gap-ca.pdf

19 Barnes, A. J., Cunningham, P. J., Saxe-Walker, L., Britton, E., Sheng, Y., Boynton, M., Harper, K., Harrell, A., Bachireddy, C., Montz, E., & Neuhausen, K. (2020). Hospital use declines after implementation of Virginia Medicaid's Addiction and Recovery Treatment Services. Health Affairs, 39(2), 238–246. https://doi.org/10.1377/hlthaff.2019.00525

20 Cunningham, P., Woodcock, C., Clark, M., Middleton, A., Barnes, A., Idala, D., Zhao, X., & Donohue, J. (2020, April). Expanding access to addiction treatment services through Section 1115 waivers for substance use disorders: Experiences in Virginia and Maryland. AcademyHealth. https://www.academyhealth.org/sites/default/files/expandingaccesstoaddictiontreatmentthrough1115waivers_april2020.pdf

21 Buderi, K.(2018, April 20). Panel discussion on Section 1115 waiver evaluations. Medicaid and CHIP Payment and Access Commission https://www.macpac.gov/wp-content/uploads/2018/04/Panel-Discussion-on-Section-1115-Waiver-Evaluations.pdf

22 Medicaid.gov. (n.d.). Appendix C: Approaches to analyzing costs associated with Section 1115 demonstrations for beneficiaries with serious mental illness/serious emotional disturbance or substance use disorders. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/smi-sed-sud-cost-appendix-c.pdf

23 U.S. Government Accountability Office. (2019, April). Medicaid demonstrations: Approvals of major changes need increased transparency (U.S. Government Accountability Office Publication No. GAO-19-315). https://www.gao.gov/assets/700/698608.pdf

24 Boozang P., & Grady, A. (2019, May 24). New federal guidance on monitoring and evaluation of work requirements and other coverage demonstrations: What does it mean for states? JD Supra. https://www.jdsupra.com/legalnews/new-federal-guidance-on-monitoring-and-90671

25 Lynch, C. (2019, September 3). Alaska Substance Use Disorder and Behavioral Health Program (SUD-BHP). U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ak/ak-behavioral-health-demo-ca.pdf

26 Section 1903 (a)(7) of the Social Security Act provides a 50% match for the "remainder of the amounts expended during such quarter as found necessary by the Secretary for the proper and efficient administration of the State plan." Social Security Act, 42 U.S.C. § 1903 (a)(7) (1969).

27 Boozang, P., Lam, A., & Traub, A. (2019, November). Evaluation of Medicaid demonstrations under new CMS guidance: State considerations and financial resource requirements. Manatt Health. https://www.manatt.com/Manatt/media/Documents/Articles/MANA-89-Evaluation-of-Medicaid-Demonstrations-under-New-CMS-Guidance_FIN.pdf

28 Centers for Medicare & Medicaid Services Section 1115 waiver evaluation resources are posted at https://www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/evaluation-designs-and-reports/index.html

29 States are required to submit monitoring measures quarterly and annually. Reporting instructions, templates and monitoring measures are developed in conjunction with the Centers for Medicare & Medicaid Services (CMS) and based on the monitoring protocol and report templates CMS provides. See Appendix A for a list of these CMS guidance documents.

30 Medicaid.gov. (n.d.). Evaluation design guidance for Section 1115 eligibility and coverage demonstrations. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/ce-evaluation-design-guidance.pdf

31 Medicaid.gov. (2020). Implications of COVID-19 for Section 1115 demonstration evaluations: Considerations for states and evaluators. U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/1115-covid19-implications.pdf

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