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Evaluation of Medicaid Demonstrations under New CMS Guidance:

State Considerations and Financial Resource Requirements

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I. Executive Summary

The Centers for Medicare & Medicaid Services (CMS) has formalized and strengthened requirements for evaluation of state 1115 Medicaid demonstrations, including new demonstration programs being permitted by the current administration that are both unprecedented and controversial. The increased scientific rigor reflected in this new guidance to states is essential to produce valid and reliable research findings to inform future policymaking in Medicaid. Indeed, the Government Accountability Office (GAO) and members of the research community have long raised concerns about the adequacy of demonstration evaluation approaches and results, and the guidance ushers in a new era of holding evaluation of experimentation in the Medicaid program to accepted standards of research. Though states are still in the early stages of designing their evaluations to meet new federal guidance, many state officials and researchers acknowledge that undertaking these evaluations will have implications for how evaluations are designed, budgeted and implemented. This issue brief, developed with support from the Robert Wood Johnson Foundation, identifies and, to the extent possible, quantifies implications of new standards for evaluation design and costs, and discusses mechanisms for financing states' evaluations. Manatt Health reviewed publicly available data to identify costs associated with states' current and past demonstration evaluations and interviewed state Medicaid officials, independent evaluators, researchers and CMS officials to understand the ways in which the new guidance affects evaluation complexity and, in turn, costs. The brief discusses three new drivers impacting state demonstration evaluations and related costs:

- More prescriptive and complex evaluation design requirements;
- New data requirements; and
- Earlier evaluation planning and independent evaluator engagement.

As states design, implement and define their required funding levels for demonstration evaluations, this brief is intended to serve as a resource to help states meet the evaluation standards set forth by CMS, including through exploring the range of options for financing demonstration evaluations.

II. Introduction

Over the past several years, and most recently in guidance released in March 2019,[1] the Centers for Medicare & Medicaid Services (CMS) has increased the scientific rigor required for evaluations of state Medicaid Section 1115 demonstration waivers in order to produce valid and reliable findings that inform policymaking in the Medicaid program. The new federal scrutiny and rigor are at least partially in response to concerns raised by the GAO and members of the research community about the historical inadequacies of 1115 demonstration evaluations.

The rollout of more intensive federal standards for Medicaid demonstration evaluations coincides with CMS embracing policies that give states more flexibility in administering their Medicaid programs, including through coverage demonstrations that test work and community engagement (CE) requirements, premiums, and other new conditions of eligibility. Because these new policies are controversial and, in some cases, untested in Medicaid, monitoring how these demonstrations impact beneficiary coverage and evaluating whether they achieve intended policy goals are vital to ensuring that demonstrations further the objectives of the Medicaid program.

The new CMS guidance standardizes an evaluation design framework by defining required hypotheses and evaluation research questions and setting forth expectations that states establish target and comparison groups and undertake a mix of evaluation methodologies (including both impact and descriptive analyses). With the goal of improving the quality of Medicaid demonstration evaluations, the scientific rigor that CMS now requires generates new issues and considerations for states related to evaluation design and implementation complexity, access to data, and timing for and engagement of an independent evaluator, among others. All of these factors are likely to contribute to an increased level of resources needed for states to conduct eligibility and coverage demonstration evaluations that provide credible and reliable feedback.

This issue brief is the third in a series on 1115 demonstration evaluation and monitoring developed with support from the Robert Wood Johnson Foundation. Building on two prior briefs, *Monitoring and Evaluating Work and Community Engagement Requirements in Medicaid: Data Assets, Infrastructure and Other Considerations for States*[2] and *New Federal Guidance on Monitoring and Evaluation of Work Requirements and Other Coverage Demonstrations: What Does It Mean for States?*,[3] this brief is intended to serve as a resource for states as they design, implement and define required funding for demonstration evaluations that meet new federal standards and assess policies being tested through demonstrations. This brief distills the cost implications of the new guidance, quantifies—where possible—key cost drivers, and discusses both traditional and alternative mechanisms that states can use to finance more robust and resource-intensive evaluations.

III. Project Approach

To inform this issue brief, Manatt Health researched publicly available data sources to identify costs associated with states' current and past demonstration evaluations. Manatt supplemented this research by conducting 13 interviews between July and August 2019 with state Medicaid officials and independent evaluators and researchers representing six states: Arkansas, Kentucky, New Hampshire, Ohio, Virginia and Wisconsin (see Appendix B for the complete list of interviewees). Manatt solicited feedback from the National Governors Association (NGA) and CMS on key state questions and areas of concern. Manatt also discussed with CMS their perspective on the state resources needed to meet the new rigor and reviewed key areas of guidance for states with regard to financing demonstration evaluations. Following these interviews, in September 2019, Manatt tested preliminary findings related to budget impacts of CMS' evaluation guidance and solicited state and researcher feedback through AcademyHealth's Medicaid Demonstration Evaluation Learning Collaborative Advisory Group. Manatt confirmed all findings and examples with the states cited in the issue brief.

IV. Potential Impacts of New Evaluation Standards on State Evaluation Costs

CMS, state officials and state research partners agree that the new guidance for evaluation design and implementation elevates the floor for demonstration evaluation standards. In meeting that floor, they anticipate that states will confront higher costs for eligibility and coverage demonstration evaluations as compared to prior demonstration evaluations. Since states have only recently begun responding to the guidance in their evaluation designs, experience is limited. However, interviewees suggest that three main factors driven by the new evaluation standards will compel states and researchers to undertake more rigorous science, increasing the complexity of the evaluation and, in turn, evaluation budgets:

- More prescriptive and complex evaluation design requirements;
- New data requirements; and
- Earlier evaluation planning and evaluator engagement.

A. More Prescriptive and Complex Evaluation Design Requirements

1. Hypotheses

For the first time, CMS has enumerated specific hypotheses and research questions for individual eligibility and coverage policy areas (e.g., work/CE, premiums, etc.) that states will be expected to test as part of their coverage demonstration evaluations.[4] CMS is prescriptive in these hypotheses, and this represents a significant departure from previous guidance that gave states flexibility to define hypotheses based on the general policies they wished to test. Adequately assessing these waivers' impacts is critical, not only for states to understand how changes impact coverage, costs, health and other outcomes, but also for the

CMS Work/CE Evaluation Hypotheses

1. Medicaid beneficiaries subject to community engagement requirements will have higher employment levels, including work in subsidized, unsubsidized or self-employed settings, than Medicaid beneficiaries not subject to the requirements.
2. Community engagement requirements will increase the average income of Medicaid beneficiaries subject to the requirements, compared to Medicaid beneficiaries not subject to the requirements.
3. Community engagement requirements will increase the likelihood that Medicaid beneficiaries transition to commercial health insurance after separating from Medicaid, compared to Medicaid beneficiaries not subject to the requirements.
4. Community engagement requirements will improve the health outcomes of current and former Medicaid beneficiaries subject to the requirements, compared to Medicaid beneficiaries not subject to the requirements.

Source: CMS, https://www.medicaid.gov/medicaid/section-1115-demo/downloads/evaluation-reports/ce-evaluation-design-guidance-appendix.pdf

administration to test new policies that take the Medicaid program into uncharted territory. CMS expects their stated hypotheses "will generate strong evaluation designs,"[5] and in particular test the effects of work/CE requirements on "health, well-being, independence and sustainability of the Medicaid program" as described in a 2018 State Medicaid Director Letter.[6]

The new guidance increases the number of hypotheses and related research questions that states must include in their evaluations; this is particularly true for states testing multiple eligibility and coverage features. For example, Wisconsin's current BadgerCare Reform demonstration waiver (effective 2018 through 2023) implements work/CE requirements, policy changes related to premiums, health needs assessments, Emergency Department (ED) copayments, and coverage for substance use disorders (SUD). Wisconsin's independent evaluator—the University of Wisconsin (UW)—worked closely with the Wisconsin Department of Health Services to generate its hypotheses and research questions, using the CMS guidance as its starting point, which outlined 13 distinct hypotheses and 21 corresponding primary research questions related to the five policy areas noted above. Had Kentucky been required to design its demonstration evaluation under these evaluation standards (rather than prior to the guidance being issued), it too would have had a similar number of starting hypotheses and related research questions to test. While researchers have experience evaluating multiple waiver components in a single evaluation, interviewees note that the prescriptiveness of CMS' hypotheses for separate waiver policies creates new challenges, such as designing an evaluation that demonstrates how the policy changes result in health-related outcomes, particularly when the policy changes themselves may be relatively focused (e.g., waiver of IMD exclusion versus comprehensive changes to SUD policy), making it difficult to discern downstream impacts. CMS also recognizes this challenge, and is working with states to explore how to discern individual policy effects where that is possible.

Implications of Litigation on Demonstration Evaluations

Ongoing litigation surrounding state work/CE waivers has implications for states' demonstration evaluations. In Kentucky, evaluators had already begun pre-implementation work when the D.C. District Court vacated CMS' approval of the demonstration and halted its implementation, including designing the randomized controlled trial (RCT) and collecting baseline data. Because of litigation-related delays, Kentucky's evaluation team anticipates having to re-base the evaluation, which could involve revisiting the composition of the control and survey groups and redoing baseline surveying (assuming the litigation is resolved in Kentucky's favor), adding to the evaluation budget.

Beyond budget costs, litigation also raises questions about what happens to an evaluator's payment when states bring evaluators in to assist with evaluation planning ahead of waiver approval if the waiver gets delayed. Since states can only claim federal match once a waiver has been approved, states may need to consider their available contingency funds and structure contracts to protect themselves and evaluators should such a situation arise. The "Timing for Evaluation Planning and Engagement of an Evaluator" section of this issue brief identifies some potential options.

In addition to setting the expectation that states integrate specific hypotheses, CMS now requires states to submit a summative evaluation that includes study of all demonstration years. This is a shift from prior guidance that required states to study and submit an interim evaluation report of only the first few years of a demonstration, limiting what could be learned from the more mature phase of a demonstration period. The study of the full demonstration period and the addition of a summative report following every new period of performance significantly improve the opportunity to learn from an 1115 demonstration but also contribute to demonstration evaluation costs.

2. Evaluation methods

To ensure rigorous assessment of demonstration impacts, CMS sets forth expectations that states establish target and comparison groups and undertake impact and descriptive analyses relying on both quantitative and qualitative data. States may use impact analyses to compare outcomes under the demonstration to outcomes in the absence of the demonstration (i.e., testing causal effects of the intervention),[7] while descriptive analyses, which cannot be used to determine causality, can be used to address questions about demonstration processes and provide important context to assist in interpreting findings from the impact analyses, or in more limited circumstances, used to assess demonstration outcomes.[8] CMS recommends, although does not require, that states use RCTs, experimental designs that randomly assign individual beneficiaries to groups that are either subject to or not subject to demonstration policies. While RCTs are the gold standard for program evaluation, CMS notes that states must weigh the benefits of RCT against the drawbacks, including the fact that RCTs can be costly to design and implement. CMS' caution about the expense and other challenges of conducting RCTs resonates with states and evaluators. Nonetheless, at least some states are planning to pursue RCTs.

As has been widely reported, Kentucky is using an RCT to evaluate Kentucky HEALTH, its work/CE initiative operating within its broader KY HEALTH demonstration waiver. Kentucky is randomly assigning 90 percent of its eligible beneficiaries to participate in the alternative benefits plan (Kentucky HEALTH), which includes the addition of the work/CE requirement, while the remaining 10 percent continue to receive their coverage under the existing state plan Medicaid program.[9] Kentucky did not randomize specific components of the demonstration waiver because of the complexity in doing so; rather, to assess the causal effects of each individual component (e.g., work/CE, premiums), Kentucky is embedding quasi-experiments within the larger RCT experiment. To execute on this approach, indicators in the state's eligibility system flag beneficiaries in the RCT group to allow for analysis. Current budget estimates put Kentucky's evaluation costs at approximately $16 million over the five-year demonstration period, with approximately 70 percent of the budget attributable to survey costs (see Implications of Litigation on Demonstration Evaluations).

Virginia is contemplating conducting an RCT for its work/CE and premium components of the state's proposed COMPASS waiver. The state plans to use a more traditional, quasi-experimental approach for the other features of its waiver (e.g., housing and employment supports benefit for high-need enrollees, healthy behavior incentives, and the state's Addiction and Recovery Treatment Services (ARTS) Benefit). This approach allows the state to leverage the methodological rigor of an RCT where it is most critical—for its work/CE requirements demonstration, while managing the total financial resources needed to execute an overall demonstration evaluation.

B. New Data Requirements

The evaluation design requirements for state coverage demonstrations like those related to work/CE requirements compel states to collect and analyze a significant level of data on current and former Medicaid beneficiaries. Because these demonstrations are designed to test requiring work/CE as a condition of coverage, and could result in demonstration beneficiaries losing coverage, evaluations must be designed to evaluate not only what happens to people who stay covered but also what happens to those who lose coverage or do not seek coverage. Gathering and analyzing the data needed to test the hypotheses and research questions for these two groups are other significant cost drivers for states' evaluation budgets. Evaluators emphasize that the work/CE hypotheses in particular require states to utilize a combination of quantitative and qualitative data sources, some of which are being used by Medicaid evaluators for the first time or applied in novel ways.

1. Administrative data sources

Historically, evaluators have relied primarily on Medicaid administrative data, including claims, encounters, enrollment and demonstration monitoring data, to inform their demonstration evaluations. Though Medicaid administrative data vary across states in terms of ease of access and usability, state Medicaid agencies can readily estimate the level of effort and costs associated with using these data because they are used often. However, as noted above and as extensively detailed in *Monitoring and Evaluating Work and Community Engagement Requirements in Medicaid: Data Assets, Infrastructure and Other Considerations for States*, the state data assets and infrastructure required for work/CE demonstration monitoring and evaluation are more complicated and varied, a consequence of the more complex demonstration design and need to examine the effects of exemptions and loss of coverage under these demonstrations. To support monitoring and

evaluation of coverage waivers, states will need to leverage other Medicaid data sources, such as eligibility data, as well as data sources outside of the state Medicaid agency (e.g., Temporary Assistance for Needy Families (TANF), Supplemental Nutrition Assistance Program (SNAP), workforce, tax and marketplace data), which may require new data-sharing agreements and processes to enable access. Many of these data sources have not been previously used to inform Medicaid evaluations, making it harder for states and researchers to estimate costs associated with accessing and analyzing these data.

2. Beneficiary surveys

Looking beyond administrative data, new evaluation standards emphasize the importance of states collecting and using other types of data to inform their evaluations. In particular, the guidance recommends that states use "individual and group interviews with beneficiaries and/or key informants" and "beneficiary surveys, particularly longitudinal surveys that follow current and former beneficiaries over time."[10] Though surveys are not required, they may be the only way for states to collect certain information from their Medicaid beneficiaries. For example, Kentucky does not have a complete all-payer database (APCD) at this time, but does have all claims with identified payer from hospital and freestanding ambulatory facilities. Without a claim from either a hospital or ambulatory facility, the state is unable to track a number of factors necessary to inform its evaluation hypotheses and research questions, including the extent to which Medicaid beneficiaries obtain commercial health insurance coverage after they leave the Medicaid program. As a result, fielding a longitudinal survey of Medicaid beneficiaries participating in the RCT (as well as conducting interviews) is critical to Kentucky's ability to test its demonstration hypotheses and contribute to the state's understanding of long-term impacts.

Though survey costs differ considerably among states, researchers uniformly report that beneficiary surveys contribute significantly to evaluation budgets as they are more costly than pulling claims-based measures or conducting more targeted qualitative research. Significant drivers of the survey costs are the survey instrument design, identification of the survey cohort, and the recruitment effort to sufficiently power a survey; as part of the new guidance, CMS expects states to conduct power analyses to ensure their sample sizes produce reliable results. Approximately 70 percent (~$11 million) of Kentucky's total demonstration evaluation budget is attributable to designing and conducting its surveys and qualitative interviews over the five-year demonstration period. Kentucky needed a sample size of about 9,400 individuals for its baseline survey to ensure a large enough sample longitudinally, due to sample attrition. The state also opted to include biomarker measures for a set of high-risk beneficiaries, which also added to the cost of its overall survey design. Notably, the bulk of the survey costs are front loaded.

New Hampshire budgeted approximately $341,000, inclusive of direct and indirect costs, for development and fielding of three rounds of beneficiary surveys, with 2,700 participants in the baseline and 5,500 participants in each follow-up round. However, the budget was determined before CMS issued its final guidance, a challenge since the state must now rely more heavily on surveys than originally anticipated.

C. Earlier Evaluation Planning and Evaluator Engagement

CMS has now formalized requirements that states submit draft evaluation designs within 180 days of demonstration waiver approval and contract with independent evaluators to conduct their demonstration evaluations. The new guidance tightens the connection between demonstration implementation, monitoring and evaluation protocols and specifically recommends an integrated approach to monitoring and evaluation. A coordinated approach can streamline states' data collection efforts and maximize limited financial resources. For example, states' monitoring efforts generate baseline data for evaluation purposes. In order to realize the benefits of a more coordinated implementation, monitoring and evaluation approach, CMS, states and evaluators agree that it is a best practice to plan for evaluation earlier in the demonstration development process, but also concede potential challenges and cost implications of engaging in early planning.

States with in-house evaluation expertise and infrastructure may be able to engage in earlier planning with less direct financial impact. Virginia, for example, has a Chief Economist and Director of Economic Policy at the Department of Medical Assistance Services who is spearheading evaluation design and planning for the COMPASS demonstration. However states without this internal capacity may find themselves trying to balance the desire to engage in early evaluation assistance with the realities of often lengthy and complex procurement processes. States also must contend with limited financial resources to support demonstration evaluation activities prior to waiver approval, since states cannot claim a federal match for evaluation expenditures until CMS approves the waiver. States are pursuing a number of strategies to engage evaluators early, without formally contracting ahead of waiver approval. Some states are engaging external evaluation experts on a short-term basis to assist with evaluation design planning, which mitigates financial risk and, in many cases, procurement challenges.

Both Wisconsin and New Hampshire leveraged existing contracts with evaluators to support early implementation planning and evaluation design work for their waivers. Wisconsin Medicaid leveraged an ongoing interagency agreement with UW, which has served as the state's independent evaluator on previous and existing 1115 waiver demonstrations and other projects. The interagency agreement allows the state to engage in related project work without repeatedly procuring for individual elements, and without having to develop new data use agreements. Using this arrangement, the Medicaid agency could quickly pull in UW's evaluation team to support the evaluation design, prior to the Medicaid agency executing an agreement for the full evaluation project. Similarly, New Hampshire's Medicaid program undertook a nine-month procurement process to select its independent evaluator, the University of Massachusetts, to evaluate its current New Hampshire Granite Advantage Health Care Program (effective 2019 through 2023). In the interim, New Hampshire leveraged its contract with its external quality review organization (EQRO) to conduct evaluation readiness activities, including conducting qualitative data collection with semistructured interviews to help the state determine how best to communicate the new work/CE requirement to its Medicaid members. New Hampshire claimed an enhanced match rate (75/25 match allowed under the EQRO contract) for this early activity because the study also focused on a particular aspect of clinical or nonclinical services at a point in time for New Hampshire's Medicaid Managed Care population.[11]

Given the complexity of the evaluation approach now required by CMS, states that need to go through procurement to secure an independent evaluator for their demonstrations may benefit from engaging research experts to help write requests for proposals (RFPs). This approach could strengthen a state's RFP

and ensure that bidders are clear on the level of rigor they must reflect in their proposals, but engaging research expertise to provide this type of support has cost implications. As noted above, some states may be able to leverage an existing evaluator contract to support early evaluation design thinking and drafting of an RFP to procure an independent evaluator. Arkansas used this approach by having the Arkansas Center for Health Improvement, with which the state had a contract to evaluate its Arkansas Health Care Independence Program demonstration, commonly referred to as the "Private Option," draft the RFP to procure its next independent evaluator for its Arkansas Works work/CE demonstration. Notably, either of these approaches may preclude the current evaluator or researcher that assists with writing the RFP from responding to it, depending on a state's procurement rules.

Finally, many states and researchers note the benefits of having a consistent research partner to serve as the state's demonstration evaluator over successive demonstration evaluations. Several states interviewed for this brief cited in particular the benefits of their long-standing and trusted relationships with state university partners, which have in-depth knowledge of and experience with state agency dynamics and Medicaid policies and data. Because state universities are part of state government, they often can be engaged more quickly and without the need for a full procurement process. For example, Ohio Medicaid officials note that engaging the Ohio Colleges of Medicine Government Resource Center (GRC) as its evaluator for the current work/CE demonstration, after having used GRC to evaluate its Medicaid expansion population, enabled the state to meet the 180-day window to submit its evaluation design draft to CMS following waiver approval. According to state officials, GRC was able to leverage its state-specific knowledge to inform survey design as part of the work/CE demonstration evaluation. As described in further detail below, states also may benefit from unique financing opportunities that are available only to state entities, such as using intergovernmental transfers between the university partner and Medicaid agency to draw down federal match to support evaluation costs.

V. Developing Evaluation Budgets

States and their evaluation partners have only recently begun preparing and submitting budgets for evaluations that comport with new CMS guidance, and none of these evaluation designs, including budgets, have been approved to date. Beyond the new rigor driving higher evaluation costs, state contextual features influence the resources needed to support demonstration evaluations. These include state Medicaid program and demonstration features (e.g., program population size, demonstration population size, type and number of policy changes) and state decisions with regard to evaluation methodology (e.g., sample sizes and rounds of surveys).

States and researchers interviewed for this paper highlighted the following key cost centers:

- **Staff:** Evaluation teams typically include multiple Principal Investigators (PIs) (especially for states testing multiple waiver components), a project manager, data analyst/coordinator and/or biostatistician, supporting research associates and assistants, and administrative support staff. Depending on evaluation design, staff costs may be fairly evenly distributed across the contract period, more front loaded or more heavily concentrated in the years when interim and summative evaluation reports are due.
- **Surveys:** As noted, survey costs are a significant and highly variable portion of many states' evaluation budgets under the new CMS evaluation requirements. There are typically significant upfront costs needed

to design the survey instrument, primarily due to the cost of attempts to recruit participants. After the design is completed, costs may vary depending on the rounds of surveys a state wishes to conduct as well as the sample size. States may also provide incentives to survey participants and engage subcontractors to assist with the surveys.

- **Data collection and analysis (beyond surveys):** Beyond survey development, states utilize other qualitative and quantitative data as part of their evaluations, as described above. All data, regardless of its source, must be cleaned and analyzed, another heavy lift for states' evaluators. States may also have to purchase benchmarking or comparison data depending on the availability of certain data sources.
- **Subcontractors:** As noted above, evaluators may engage subcontractors to round out their team's subject matter expertise or skill sets. For example, evaluation teams may contract with PIs based at other institutions or consult with advisors about survey design.
- **Office expenses:** Though fairly minimal, budgets include money to cover printing, supplies, computer equipment and other office expenses.
- **Travel:** Also fairly minimal, some budgets include costs related to travel to research meetings.
- **Indirect:** Indirect costs can be relatively significant, often adding at least 10–15 percent on top of all direct costs. In some states' budgets, this is a distinct line item that is included in addition to the usual Facilities & Administrative (F&A) rate.

The chart in Appendix A provides an early look at the application of key "cost centers" and range of approximate costs associated with each for a five-year CE demonstration evaluation budget designed to meet the rigor of the new guidance.

It is important to review this information in the context of a state's demonstration features. However, states and researchers noted the value this information could provide in educating key stakeholders, such as legislators considering appropriations for evaluation costs, about potential resource needs and budget requirements. While the ideal would be to build up a budget based on the evaluation design, the practical reality of state appropriations timing—the primary funding source for evaluations—is that many states must set parameters for the evaluation budget in advance of determining evaluation design. Small states may be particularly hamstrung with fewer in-house resources and smaller Medicaid budgets.

New concerns about the costs of state demonstration evaluations, and states' abilities to adequately fund evaluations, may create potential opportunities for efficiencies and economies of scale among states and researchers. Many states and evaluators interviewed noted their participation in the AcademyHealth State-University Partnership Learning Network, which has enabled state researchers to convene to discuss evaluation standards and approaches for addressing the new rigor. Several others noted the technical assistance support provided by NGA and the State Health Access Data Assistance Center (SHADAC) as they navigated the evaluation standards and drafted their evaluation designs. While these venues provide an opportunity for sharing lessons learned and best practices, several interviewees noted that there may be opportunities to collaborate on specific evaluation tools that all states could utilize, for instance, developing a standardized beneficiary survey that could then be adapted for state-specific use or sharing code across states.

CMS' Evaluation Design and Approval Process

CMS' initial review of a state's draft evaluation design takes approximately three to four weeks. CMS compiles detailed comments and discusses those with the state (and ideally their evaluators). Working through edits is an iterative process that can take a few months. As part of its evaluation design review, CMS also reviews a state's evaluation budget with particular attention paid to the source of the state share (described in more detail below), but there is no separate approval process for a state's evaluation budget. CMS does not track the actual cost of the evaluation; rather, it is part of administrative costs claimed through the regular process.

VI. Financing Options for Demonstration Evaluations

A. Federal Matching Authorities

State spending on demonstration evaluations is considered Medicaid administrative costs, enabling states to claim federal Medicaid matching funds at the 50 percent level.[12] Multiple states and evaluators underscore the need for CMS to consider authorizing additional federal funding for demonstration evaluation activities, such as a designated enhanced federal Medicaid match similar to that which CMS authorizes for other resource-intensive activities like information technology system development. Federal law authorizes an enhanced federal match for "mechanized claims processing and information retrieval systems" at the 90 percent level for design, development and implementation and 75 percent for maintenance and operations of these systems.[13] Following the enactment of the Affordable Care Act, CMS took regulatory action to include activities related to eligibility and enrollment systems for enhanced federal funding. In that context, CMS noted its changes were in recognition of how integral eligibility and enrollment systems were to the operation of the state's overall mechanized claims processing and information retrieval systems, and the importance of modernized systems to support the dynamic and ongoing nature of national Medicaid eligibility, enrollment, delivery system and program integrity needs.[14]

A similar case can be made that CMS should find maximum flexibility in current definitions of "mechanized claims processing and information retrieval systems" to enable access to the enhanced federal Medicaid match for at least some waiver evaluation activities, such as the programming and coding, data analysis, and systems development, as well as related planning for these activities. Regulations currently define "mechanized claims processing and information retrieval system" as "a system of software and/or hardware used to process claims for medical assistance and to retrieve and produce service utilization and management information required by the Medicaid single state agency and Federal government for program administration and audit purposes. **It may include modules of hardware, software, and other technical capabilities that are used by the Medicaid Single State Agency to manage, monitor, and administer the**

Medicaid enterprise, including transaction processing, information management, and reporting and data analytics"[15] (emphasis added). In subregulatory guidance released in June 2019, CMS states that enhanced federal match "is available to support reasonable costs associated with systems development activities related to 1115 demonstrations."[16] Further, recognizing that states may need to undertake systems work prior to demonstration approval, CMS affirms that "reasonable IT investments can be approved under an Advance Planning Document (APD) and associated expenditures made while CMS is reviewing the demonstration, prior to approval."[17] CMS could pursue regulatory action to augment its definition of mechanized claims processing and information retrieval systems to reflect the broader scope of waiver monitoring and evaluation activities as supported by the recent subregulatory guidance, facilitating access to an enhanced federal Medicaid match for overall waiver evaluation and monitoring activities.

As noted above, states may also have limited opportunities to leverage EQRO activities to inform and support some aspects of their evaluations. States must engage an entity independent of the state Medicaid agency and managed care plans to conduct external quality review activities for their managed care programs. These quality oversight activities include compliance reviews, validation of plan performance measures, validation of encounter data, and administration or validation of consumer or provider surveys relating to quality of care and are eligible for federal Medicaid matching funds at the 75 percent level.[18,19]

B. State Share

States report that the nonfederal Medicaid share for evaluation spending generally comes from direct state appropriations. States and evaluators note that due to timing of budget cycles and legislative activity, state appropriations are commonly authorized for demonstrations, including evaluation funding, prior to demonstration approval. In some cases, these early appropriations may constrain evaluation design.

States and researchers also highlight alternative sources of financing that states are leveraging to fund their share for evaluation costs, including contributions from other state partners and private foundations. For example, Ohio's evaluation is being funded through state funding, including an in-kind contribution from Ohio State University, which was federally matched. Virginia is pursuing philanthropic support for its planned RCT as part of its COMPASS demonstration evaluation.

In leveraging these alternative sources, states will need to be mindful of federal rules for Medicaid financing. States have flexibility in how they fund the nonfederal share of their Medicaid programs. However, specific federal rules govern "provider-related donations."[20] These rules are intended to ensure that healthcare providers and their related entities do not receive related financial benefits or "kickbacks" from their support of the nonfederal share of certain Medicaid expenditures. For states seeking to leverage contributions and donations from outside sources, CMS will assess the source and nature of these arrangements to ensure that financing does not run afoul of provider donation rules.

A first order of that assessment is understanding whether the contributing organization is considered a healthcare provider or a healthcare provider-related entity. Federal regulations define a healthcare provider as an individual or entity that receives payment for healthcare items or services and a healthcare provider-related entity as an entity or individual related to, or a supplier of, a healthcare provider.[21] Healthcare provider donations are permitted as a source of funding for the nonfederal share so long as they qualify as a "bona

fide" donation,[22] meaning that the provider donation must have no "direct or indirect relationship" to Medicaid payments made to the following:

- The healthcare provider making the donation;
- Any entity or individual related to, or a supplier of, the healthcare provider making the donation;[23] or
- Other providers furnishing the same class of services as the provider or entity (to avoid providers agreeing to "donate" funds for the nonfederal share of each other's Medicaid payments).[24]

A donation is considered to have a direct or indirect relationship to Medicaid payments if the donations are returned to the individual provider, a related entity, or another provider of the same class through a "hold harmless" provision or practice, which exists if:

- The donation is positively correlated with the amount of a non-Medicaid payment, even if that positive correlation is not consistent over time and even if the correlation is not dollar-for-dollar;
- Any portion of the Medicaid payment to the donor, provider class or related entity varies only based on the amount of donation, including if the Medicaid payment is conditional on receipt of the donation; or
- The state provides for a payment, offset or waiver such that there is, in effect, a guarantee to return a portion of the donation (e.g., the state offsets a provider's income taxes or makes a grant to the provider, in effect returning a portion of the donation).[25]

In considering donations, particularly from state university partners, states will need to consider whether those partners could be determined to be provider-related entities, and how best to meet CMS guardrails with respect to donations.

VII. Conclusion

Monitoring Medicaid demonstration outcomes and evaluating their impacts is paramount to meaningfully assess new policies that states and CMS seek to test and generate lessons for other states and CMS. As new coverage demonstrations that place new and unprecedented eligibility conditions on Medicaid beneficiaries are implemented nationally, CMS' evaluation standards significantly raise the bar for states, requiring increased monitoring and evaluation accountability in exchange for greater flexibility to test new policies in their Medicaid programs. These higher standards will have implications for state demonstration design and the financial resources that states will need to execute evaluations. Importantly, it remains to be seen whether and how CMS will hold states accountable if their evaluation design and implementation efforts fall short of meeting the new expectations. Prior evaluations have been put to only limited use by policymakers, in some cases because of evaluation designs not meeting research standards that are now reflected in CMS guidance, selective reporting of outcomes and delays in releasing evaluation reports. States, CMS and other stakeholders will need to work collaboratively to ensure these new evaluations are produced with the rigor CMS intends and produce findings that can be used by policymakers to advance effective policies and, conversely, end policies that fail to benefit or, worse, harm the Medicaid program and the people it serves.

Appendix A: Comparing States' Proposed Budgets for Work/CE Demonstration Evaluations

Cost Centers	Arkansas	Kentucky	New Hampshire	Ohio
Current Waiver Scope and Effective Period	• Waiver provides certain adult Medicaid beneficiaries with premium assistance to purchase qualified health plan (QHP) coverage through the Health Insurance Marketplace. Current waiver amendment implements work/CE requirements for most waiver beneficiaries and also includes premiums and cost-sharing for certain populations and limiting retroactive eligibility to 30 days. • Effective Period: 2017–2021[26]	• Waiver encompasses several initiatives, including work/CE, premiums for certain populations, lockout for failing to complete annual redetermination, disenrollment and lockout for failing to report change in circumstance, waiver of retroactive eligibility, waiver of NEMT, and waiver of IMD exclusion for SUD population. • Effective Period: 2019–2023[27]	• Waiver provides for work/CE as a condition of continuing Medicaid eligibility for adults in the new adult group population, and a waiver of retroactive coverage for the new adult group. • Effective Period: 2019–2023[28]	• Waiver provides for work/CE as a condition of Medicaid eligibility for new adults. • Effective Period: 2019–2024[29]
Evaluation Scope and Features	• Separate evaluation for work/CE component of waiver	• Work/CE and other components • Uses RCT	• Work/CE and other components	• Work/CE only
State Medicaid/CHIP Enrollment as of June 2019[30]	• 841,102	• 1,338,471	• 175,951	• 2,647,784

Cost Centers	Arkansas	Kentucky	New Hampshire	Ohio
Waiver Evaluation Population	• ~280,000[31] (~70,000 for work/CE)	• 437,249[32]	• ~51,000[33]	• ~605,000[34]
Total Budget Across Evaluation (Direct + Indirect)	**~$887,000 (1 year, with option to renew for up to 6 additional years)[35]**	**~$16,000,000[36]**	**~$1,500,000 (SFY 2021–26)[37]**	**> $5,000,000[38]**
Staff Costs (including PIs, project manager, data analyst, etc.)	-	-	~$271,000 (~18% of total budget) • Implementation plan: ~$31,000 • Monthly/ quarterly/annual reports: ~$40,000 • Draft/final interim reports: ~$78,000 • Policy briefs/ presentation: ~$40,000 • Draft/final summative reports: ~$82,000	• Years 1–6: 8% • Year 7 (evaluation wrap-up): 45%
Office Costs (e.g., printing, supplies, computer equipment)	-	-	-	• Years 1–7: 2-3%
Survey Costs (including incentive payments to participants, subcontractors, as applicable)	-	-	~$275,000 (~18% of total budget) • $263,000 (beneficiary) • $12,000 (provider)	• Years 1–6: 77% • Year 7: 4%

Cost Centers	Arkansas	Kentucky	New Hampshire	Ohio
Survey Detail	-	Sample size: 9,400[39]	3 rounds of beneficiary surveys:[40] • Baseline (1,350 treatment (T), 1,350 comparison (C)) • Wave 1 follow-up (3,500 T, 2,000 C) • Wave 2 follow-up (3,500 T, 2,000 C)	Fielding survey each year
Other Data Costs (i.e., related to data purchasing that falls outside of survey costs)	-	-	~$605,000 (~40% of total budget) • ~$32,000 (data analytic plan) • ~$430,000 (data cleaning/analyses) • ~$143,000 (qualitative and quantitative data collection)	-
Subcontractor costs not captured above	-	-	-	• Years 1–6: 4% • Year 7: 39%
Travel (e.g., for research meetings)	-	-	-	-
Indirect Costs	-	-	~$349,000 (~23% of total budget)	• Years 1–7: 10%

Appendix B: List of Interviews Conducted

Name	Title/Affiliation
CMS	
Judith Cash	Director, State Demonstrations Group
Danielle Daly	Social Science Research Analyst, State Demonstrations Group
Teresa DeCaro	Deputy Director, State Demonstrations Group
Kristin Fan	Director, Financial Management Group
Janet Freeze	Deputy Director, Financial Management Group
State Medicaid Agencies and State Associations	
Patrick Beatty	Deputy Director, Chief Policy Officer, Ohio Department of Medicaid
Susan Kennedy	Senior Manager, AcademyHealth
Patrick McGowan	Administrator, Medicaid Quality Program, New Hampshire
Ellen Montz	Chief Economist and Director of Economic Policy, Virginia Department of Medical Assistance Services
Adam Mosey	Policy Analyst, Health Division, National Governors Association
Caroline Picher	Policy Analyst, Health Division, National Governors Association
Hemi Tewarson	Director, National Governors Association
Elizabeth (Betsy) Truex-Powell	Health Innovations Manager, Ohio Department of Medicaid
Evaluators & Researchers	
Marguerite Burns	Associate Professor, Department of Population Health Sciences, University of Wisconsin School of Medicine and Public Health
Donna Friedsam	Health Policy Programs Director, UW Institute for Research on Poverty
Genevieve (Jenny) Kenney	Senior Fellow & Vice President of Health Policy, Urban Institute
Elizabeth Lukanen	Deputy Director, SHADAC
Michael Nau	Research Scientist, Ohio Colleges of Medicine Government Resource Center
Timothy Sahr	Director of Research & Analysis, Ohio Colleges of Medicine Government Resource Center
Joe Thompson	President and CEO, Arkansas Center for Health Improvement
Atheendar Venkataramani	Assistant Professor of Medical Ethics and Health Policy Assistant Professor of Medicine, University of Pennsylvania; Evaluator for Kentucky Department for Medicaid Services
Christina Worral	Senior Research Fellow, SHADAC

Appendix C: Catalog of CMS Guidance on Medicaid Demonstration Monitoring and Evaluation

Component	Type of demonstration and applicable guidance documents/templates
Implementation plan	**Work/CE:** Medicaid Section 1115 Eligibility and Coverage Demonstration Implementation Plan[41] **SUD:** Section 1115 Substance Use Disorder (SUD) Demonstration: Guide for Developing Implementation Plan Protocols[42] **SMI/SED:** Section 1115 SMI/SED Demonstration Implementation Plan[43]
Monitoring protocol	**SUD:** Medicaid Section 1115 SUD Demonstration Monitoring Protocol Template[44]
Monitoring reports	**Eligibility and coverage:** Medicaid Section 1115 Eligibility and Coverage Demonstration Monitoring Report[45] Monitoring Metrics for Demonstrations with Community Engagement and Other Eligibility and Coverage Policies[46] **SUD:** Medicaid Section 1115 SUD Demonstration Monitoring Report[47] Monitoring Metrics for Section 1115 Demonstrations with SUD Policies[48] **SMI/SED:** Medicaid Section 1115 SMI/SED Demonstration Monitoring Report – Part B[49] Mental Health Availability Assessment[50] Monitoring Metrics for Section 1115 Demonstrations with SMI/SED Policies[51]
Evaluation design guidance	**General:** Section 1115 Demonstrations: Developing the Evaluation Design[52] Planning Section 1115 Demonstration Implementation to Enable Strong Evaluation Designs[53] Best Practices in Causal Inference for Evaluations of Section 1115 Eligibility and Coverage Demonstrations[54] Selecting the Best Comparison Group and Evaluation Design: A Guidance Document for State Section 1115 Demonstration Evaluations[55] Beneficiary Survey Design and Administration for Eligibility and Coverage Demonstration Evaluations[56]

Component	Type of demonstration and applicable guidance documents/templates
Evaluation design guidance	**Eligibility and coverage:** Evaluation Design Guidance for Section 1115 Eligibility and Coverage Demonstrations[57] Appendices on community engagement,[58] beneficiary premiums,[59] retroactive eligibility,[60] noneligibility periods[61] and sustainability[62] **SUD:** Substance Use Disorder (SUD) Section 1115 Demonstration Evaluation Design–Technical Assistance[63] Appendix B: Goals, Research Questions, and Analytic Approaches for Evaluating Section 1115 Substance Use Disorder Demonstrations[64] **SMI/SED:** Evaluation Design Guidance for Section 1115 Demonstrations for Beneficiaries with Serious Mental Illness/Serious Emotional Disturbance and Substance Use Disorders[65] Appendix A: Goals, Research Questions, and Analytic Approaches for Evaluating Section 1115 Serious Mental Illness/Serious Emotional Disturbance Demonstrations[66] **SUD, SMI/SED Cost Guidance:** Appendix C: Approaches to Analyzing Costs Associated with Section 1115 Demonstrations For Beneficiaries with Serious Mental Illness/Serious Emotional Disturbance or Substance Use Disorders[67]
Evaluation reports	**General:** Section 1115 Demonstrations: Preparing the Evaluation Report[68]

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[14] 80 Fed Reg 75820.

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[20] Social Security Act 1903(w); 42 CFR 433.52, 433.54.

[21] 42 CFR 433.52.

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