



State Flexibility in a New Era

■ What are the research priorities for Section 1115 demonstrations?

Introduction

This is an important time in the evolution of Section 1115 of the Social Security Act. Added to the Act in 1962, Section 1115 pre-saged the enactment of Medicaid and was subsequently modified to enable its use in a Medicaid context. Today Section 1115 Medicaid demonstrations are being used not only to test alterations in Medicaid's basic eligibility and service delivery features but also to expand Medicaid's potential role as a tool for achieving broader social aims such as employment of the poor.

Although Section 1115 is an experimental statute, states undertaking Section 1115 experiments have been focused on the challenges of designing and implementing new approaches to program operations and policy. At the same time, Section 1115's roots in experimentation mean that evaluation represents a critical component of all Medicaid demonstrations. For this reason, in October 2017, AcademyHealth convened a group of experts, including current and former state and federal Medicaid officials and state and national Medicaid researchers and key stakeholders to discuss evaluation priorities for Section 1115 Medicaid demonstrations and Section 1332 waivers. This brief examines key issues that emerged in connection with Section 1115 demonstrations and their implications for Section 1115's role in advancing social welfare policy.

The meeting focused on two types of Section 1115 demonstrations. The first type of demonstration involves ACA Medicaid eligibility expansion under different conditions than otherwise envisioned

under law. These expansion demonstrations, which also test changes in key features of the program related to premiums and cost sharing, benefit design, and greater use of the private insurance market to provide coverage for the poor, have been undertaken in the wake of the United States Supreme Court's 2012 decision that effectively made the Affordable Care Act (ACA)'s adult Medicaid expansion optional. Following that decision, the prior Administration encouraged states to submit Section 1115 demonstration proposals that sought to test the ACA Medicaid expansion under conditions not normally permitted under law, such as use of enforceable premiums, behavioral incentives tied to cost sharing, and elimination of certain otherwise-covered benefits. As of February 1, 2018, 8 states had implemented the ACA Medicaid expansion as a Section 1115 demonstration.¹

Although the current Administration has not explicitly sought to test work requirements in the context of an ACA eligibility expansion, its 2018 Section 1115 Medicaid work demonstration solicitation certainly would appear to permit such a demonstration. Indeed there has been speculation² regarding the potential for states that until now had not implemented the ACA expansion to do so now by pairing expansion with work.

The second type of demonstration, which the current Administration has approved in both Kentucky and Indiana, is designed to test constraints on existing eligibility, that is, to add conditions of coverage for populations now eligible to receive benefits. Pursuant to the

Genesis of this Brief:

This brief is based on an expert meeting, held in Washington D.C. on October 17, 2017, to explore research priorities related to the evaluation of Section 1115 Medicaid demonstrations and Section 1332 state innovation waivers. This brief includes highlights from the Section 1115 discussions among meeting participants. Panelists included state and federal officials and national and state policy experts from the nonprofit and health services research communities. Funding for the meeting and this brief was provided by the Robert Wood Johnson Foundation. The meeting summary and common themes reflect the assessment of the authors. This summary was reviewed by the panelists but does not necessarily reflect the views of the Robert Wood Johnson Foundation, AcademyHealth, The Urban Institute, George Washington University, the meeting participants, or the reviewers. For more information about this meeting, including the agenda and presentation slides, visit academyhealth.org/stateflexibility.



State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

Administration's January 2018 Section 1115 Medicaid demonstration work solicitation,³ and as outlined by the Centers for Medicare and Medicaid Services (CMS) Administrator in a November 2017 speech to state Medicaid Directors,⁴ this type of experiment might be extended to both the ACA expansion and traditional Medicaid populations. Elements of these demonstrations – submitted by ACA expansion and non-expansion states alike – focus on matters such as enrollment time limits, expanded use of lock-out periods not only for non-payment of premiums but also for failing to report information, work and community engagement requirements, and drug testing requirements.⁵ In her speech to Medicaid Directors, CMS Administrator Seema Verma indicated her agency's interest in “proposals that would give states more flexibility to engage with their working-age, able-bodied citizens on Medicaid through demonstrations that will help them rise out of poverty...and promote community engagement and work activities.”⁶

Following an overview of Section 1115, this summary reviews the key points that emerged over the course of the discussion regarding evaluation of experiments conducted under this special federal demonstration authority. An overarching point that emerged from this discussion was the importance and value of including evaluators at the earliest possible point of demonstration development, in order to assist policymakers in establishing demonstrations that advance key objectives while also ensuring that demonstrations are evaluable—that is, that the effects of major changes in policy can be evaluated.

The Federal Policy Framework Governing Section 1115 Medicaid Demonstrations

Enacted in 1962, Section 1115 of the Social Security Act authorizes the Secretary of the Department of Health and Human Services (HHS Secretary) to carry out “experimental, pilot, or demonstration” projects that in his or her judgment are “likely to assist in promoting the objectives of” state-administered public benefit programs under the Social Security Act. Section 1115 is a blanket law that applies to multiple state-administered public benefit programs, not just Medicaid, which was enacted three years after Section 1115's passage.

Medicaid Section 1115 demonstrations have a long history; pilots and experiments conducted under Section 1115 authority by succeeding Administrations have informed the evolution of Medicaid's legislative policy framework across multiple program dimensions, including eligibility, coverage and benefits, and health care service delivery.⁷ Medicaid's transformation to a system in which most beneficiaries are enrolled in some form of managed care arrangement was informed in great part by Section 1115 experiments conducted during the 1990s.⁸

Section 1115 confers two special types of special authority on the HHS Secretary, both of which are key to experiments conducted under its auspices. The first is authority, as part of a demonstration that advances Medicaid objectives, to waive provisions of the law that otherwise would place a state program out of compliance.⁹ For example, prior to enactment of the ACA and federal recognition of low-income working-age adults as a distinct federal eligibility category, the Secretary used Section 1115 powers to enable states to cover, in a cost-neutral manner, low-income adults ineligible for Medicaid under traditional program rules. Since the 2012 Supreme Court decision, Secretarial Section 1115 powers have been used to promote state implementation of the ACA adult Medicaid expansion in ways not otherwise permitted under federal law.

The second grant of authority under Section 1115 allows the Secretary to make federal Medicaid payments to states for activities that normally would not qualify for federal funding.¹⁰ The Secretary previously used this power to authorize federal funding for expenditures made on behalf of low-income adults who did not fall into traditional eligibility categories. An example of this would be the Health Insurance Flexibility and Accountability (HIFA) demonstrations undertaken by the George W. Bush Administration,¹¹ which recognized as allowable costs for federal funding purposes coverage of adults who, prior to the ACA, would not have been considered eligible for federal Medicaid payments. Under the post-ACA Section 1115 expansion demonstrations, the federal government contributes to the cost of state expenditures for the expansion population on the same terms that apply under a standard statutory expansion, even though these demonstrations use eligibility criteria that differ from standard federal requirements.

Under longstanding policies, Section 1115 demonstrations must remain budget neutral over the life of a demonstration; that is, the total cost of the demonstration to the federal government may not exceed the anticipated cost to the government of a state's program in the absence of a demonstration.¹² The budget neutrality requirement has remained unchanged for decades, but in interpreting this requirement, Administrations have tended to take a flexible approach. Thus, for example, the Medicaid adult expansion demonstrations undertaken by the Obama Administration include costs that the federal government would have incurred had a demonstration state expanded eligibility under the state plan, consistent with federal rules. This flexible approach to budget neutrality has enabled states to obtain federal funding, even when the terms of their programs differ from those normally applicable to state plans. The Governmental Accountability Office (GAO) has noted the importance of ongoing federal oversight to ensure that budget neutrality policies are maintained.¹³ (Importantly, in its January 11, 2018 State Medicaid Directors Letter, the Trump Administration clarified that work supports for community engagement demon-

State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

strations would not qualify for federal contributions and that states would not be permitted to apply savings from reduced enrollment to other program aims).

In order to use demonstration authority, the Secretary must follow the terms of Section 1115. Demonstrations must further Medicaid program objectives, as identified by the Secretary. Furthermore, by law, Section 1115 demonstrations must include an evaluation component, a requirement that does not apply when Medicaid is operated under normal state plan operational rules. Under law, this component is distinct from ongoing program reporting, which is subject to separate federal requirements.

Federal Section 1115 Regulations

Section 1115 also requires the Secretary to promulgate special rules aimed at guiding the demonstration process;¹⁴ within these rules, the Secretary must establish “a process for the periodic evaluation by the Secretary of the demonstration project.”¹⁵

Although the statute directs the Secretary to periodically evaluate demonstrations, the regulations delegate this duty to the states (although the Secretary retains the authority to pursue independent federal evaluations). The regulations specify evaluation as a component of state demonstrations and “encourage[]” states to “use a range of appropriate evaluation strategies (including experimental and other quantitative and qualitative designs) in the application of evaluation techniques with the approval of CMS.”¹⁶

To qualify for CMS approval, the rules provide that state demonstration evaluations must include the following:¹⁷

- “quantitative research methods” to produce “empirical investigation of the impact of key programmatic features of the demonstration” (CMS will allow alternative designs when “quantitative designs are technically infeasible or not well suited to the change made by the demonstration”);
- “approaches that minimize beneficiary impact” that “minimize burden on beneficiaries and protect their privacy in terms of implementing and operating the policy approach to be demonstrated while ensuring the impact of the demonstration is measured”; and
- An “evaluation design plan” that must be published on the state’s public website within 30 days of CMS approval, along with a posting of the final approved evaluation plan. (When states initially publish their actual demonstration proposal for public comments, as required under law, their postings must also include “the hypothesis and evaluation parameters of the demonstration”;¹⁸ ultimate publication of the evaluation design follows formal CMS approval).

In its draft evaluation design plan, the state must discuss “the demonstration hypotheses that are being tested including monitoring and reporting on the progress towards the expected outcomes.”¹⁹ The state’s plan also must identify the data it will use as well as the baseline value for each measure and its data collection methods. Additionally, the state must describe how demonstration effects will be separated and measured apart from other changes in the state, through the use of comparison or control groups to measure the impact of “significant aspects of the demonstration.”²⁰ Evaluation requirements apply to demonstration extensions as well.

Finally, CMS rules provide that within 30 days of receiving materials, CMS will post or provide links to all evaluation materials, including research and data collection, in order to share findings with the public.²¹ While component requirements of the rule as described above are explicit, adherence and level of specificity of adherence to evaluation designs, fidelity of assessment, and summaries of results have varied widely.

The Meeting Discussion

Welcome and Introduction: Opening Remarks

Meeting conveners, Enrique Martinez-Vidal of AcademyHealth and Mona Shah of the Robert Wood Johnson Foundation, identified increased interest by states in using Section 1115 Medicaid demonstrations to address coverage and quality and promote other goals as stated by the Administration as the basis for the meeting. They noted that the meeting was intended to provide a forum for participants to discuss findings, ramifications, data issues, research priorities, goals, policies, and strategies, along with evaluation methods, for demonstrations. This meeting, they clarified, would explore evaluation issues in connection with eligibility and coverage rather than service delivery and payment reform.

Panel One: Envisioning Medicaid’s future and the Role of Section 1115 Demonstrations to Get Us There

Panel discussants John McCarthy, Cindy Mann, and Joel Cantor reviewed the origins of Section 1115 and its evolution under past Presidential Administrations, including the Clinton-era waivers to expand eligibility, and succeeding demonstrations under the President George W. Bush era, which focused on eligibility expansion, managed care, and cost-saving techniques such as benefit reductions and cost-sharing. They noted that by the end of the Bush Administration, 45 states and the District of Columbia were operating, at least in part, under Section 1115 authority. They also noted that the roots of Massachusetts’ health reform legislation that preceded enactment of the Affordable Care Act can be traced to a Section 1115 Medicaid demonstration. Another notable use of Section 1115 authority has involved provision of temporary Medicaid coverage for individuals displaced or adversely affected by catastrophic events such as Hurricane Katrina. In addition, they noted, the prior Administration used Section 1115 authority to permit seven states

State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

to adopt ACA Medicaid adult eligibility expansions under terms that departed from normal Medicaid state plan requirements.

Joel Cantor observed that Section 1115 demonstrations can be viewed as a form of “executive federalism” that not only help states innovate but also allow the federal government to advance a particular policy agenda with state help. Even in a mature phase for Section 1115, questions continue to arise related to Section 1115’s purpose and scope and the concept of budget neutrality. The panel also noted that limited resources to conduct evaluations led to a de-emphasis on evaluation as a component of Medicaid Section 1115 demonstrations.

Cantor further observed that the prior Administration used demonstrations to encourage resistant or reluctant states to adopt the ACA Medicaid expansion by placing emphasis on demonstrations permitting market-oriented expansions and promoting beneficiary personal responsibility. These demonstrations have emphasized cost sharing, the use of health savings accounts, healthy behavior incentives, the substitution of premium assistance toward the cost of enrollment in private plans in lieu of Medicaid managed care, and the use of limited premiums. In other words, the demonstrations represent alternative approaches to expansion, coupling adoption of the ACA eligibility expansion with certain limitations on eligibility and coverage not normally permissible under law.

Panelists further observed that the current Administration was expected to move demonstration policy in the direction of demonstrations designed to promote individual responsibility and reduce dependence on Medicaid. These demonstrations would enable both expansion and non-expansion states to test eligibility and enrollment standards that differ from specified in Medicaid law for both traditional and expansion populations. Areas of interest anticipated were work requirements and community engagement, lock-out periods, and expanded cost sharing for both traditional and newly eligible beneficiaries.

The panel discussed the fact that in approving demonstrations—and consistent with federal regulatory requirements—CMS provides guidance to states regarding permissible evaluation designs. The panel also discussed Obama Administration guardrails, including cost-sharing limits, limits on coverage as a result of non-payment, enrollment caps and lifetime benefit limits, and state-based voluntary rather than federally-approved mandatory work requirements. The panel flagged as an issue that could arise in future demonstrations the question of whether to allow a reconfiguration of Medicaid into a more market-based model built on the types of enrollment restrictions (such as fixed, annual open enrollment periods and elimination of retroactive eligibility) that are features of private health insurance plans.

In terms of budget neutrality, the panel focused on the limits of a methodology that excludes potential savings from other social sectors, such as reduced special education or child welfare costs.

The panel also addressed the importance of evaluation, including the renewed interest in more robust evaluations, and the challenge of balancing the need for thorough evaluation against states’ desire to replicate demonstrations and pilots already underway in another state prior to the completion of the index evaluation and assessment of programmatic impact. One panelist expressed the view that state innovation should take precedence over completed evaluation, in order to not hamper state efforts, and because of the real-world impact of deferring forward motion in some states while others were permitted to proceed. The question was raised as to whether more complete evidence would emerge if multiple states simultaneously received approval to implement similar provisions.

The panel stressed that the approval process and the evaluation process are distinct; that is, HHS does not condition new demonstrations on the results of completion of evaluations undertaken for similar ongoing demonstrations. The panel acknowledged the value of considering how the various aspects of a demonstration will be evaluated, and that the process of developing the evaluation should be part of the negotiation over demonstration design and scope; it is during this process that crucial decisions are made regarding whether, and which aspects, of a demonstration are particularly important to include in an evaluation. Panelists observed that evaluators can play a key technical advisory role during the federal/state negotiation process over the contours of the demonstration and its evaluation, while also cautioning that ultimately, the scope and elements of the evaluation, like the demonstration itself, are a core part of the federal/state negotiation process, not determined independently by the evaluators. One panelist expressed the concern that including the evaluation team in those deliberations could make it difficult for them to maintain the degree of independence needed to impartially evaluate the demonstration. The issue of whether evaluation is an inherent element of Section 1115, and questions of what can and cannot be evaluated, how to structure a demonstration so that it lends itself to rigorous evaluation, and how to design an evaluation for a demonstration that is not implemented with a structure that lends itself to rigorous evaluation methods, emerged as recurring themes throughout the session.

Other issues emerged during the first panel and the ensuing discussion:

1. How to design waivers to support a robust evaluation of impacts;
2. How to construct a counterfactual for measuring the impacts of demonstrations and how to define what constitutes a successful waiver;

State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

3. How to ensure that evaluations fully capture impacts on both actual beneficiaries and those who do not enroll or do not stay enrolled because of the program changes;
4. How to ensure that demonstrations focus on matters that truly merit evaluation such as changes in policy whose impact has not been tested before and is not known;
5. How to ensure that demonstrations in fact can be properly evaluated as required under CMS rules; and
6. What is the role of evaluations in shaping subsequent Congressional modification of federal law?

Panel Two: What Policies and Strategies are Federal and State Policymakers Seeking to Test for the Future of Medicaid Using Section 1115 Demonstrations?

The second panel, moderated by Sara Rosenbaum and Joe Antos, offered presentations by Judith Cash of CMS, and Rose Naff (AR), Michael Heifetz (WI),²² and Stephen Miller (KY). At the time of the panel, these three state officials were overseeing programs that had Section 1115 demonstration proposals under review at CMS that include provisions affecting Medicaid eligibility. This panel dove more deeply into the question of the policy goals and strategies that undergird demonstrations and their evaluations. The panel explored numerous questions: What outcomes should be evaluated? Should demonstration elements be more deliberately grouped for evaluation purposes, for example, the use of premiums, behavior incentives including cost-sharing, and the use of high deductible plans linked to health savings accounts? Should work requirements be tested? Should HHS pursue demonstrations designed to more closely align Medicaid with commercial insurance principles on matters such as open enrollment and special enrollment, coverage design? Should time limits and eligibility conditions related to drug testing be pursued? Should alternative state approaches be tested as a multi-state group of demonstrations to be evaluated under consistent study designs?

Judith Cash noted that the purpose of Section 1115 is to test demonstrations that are likely to advance Medicaid program goals. It is the job of CMS, on behalf of the Secretary, to determine whether proposed demonstrations meet this standard. To that end, the March 2017 letter from then-HHS Secretary Price and CMS Administrator Seema Verma identified the types of demonstrations that, in their view, would promote such objectives: using Medicaid to increase employment; aligning Medicaid with commercial insurance principles, which do not recognize special eligibility criteria such as retroactive eligibility or enrollment at the time of health care utilization; instituting enforceable premiums; waiving coverage of non-emergency medical transportation; testing alternative cost-sharing designs. Cash also noted the increased importance placed on evaluation

by CMS and the requirement that state demonstrations include an evaluation component.

Cash reported that, as part of regular monitoring of Section 1115 demonstrations, CMS intends to focus on obtaining and analyzing data on the implementation process, including whether a demonstration is being implemented as proposed, how demonstration implementation is proceeding in relation to the demonstration design, whether changes in enrollment and spending are occurring, whether midcourse corrections are necessary, and whether and what insights about the policy are emerging in the short-run.

Cash also noted the importance of measuring outcomes through the use of robust evaluation designs. In this context she specifically identified the need to rigorously evaluate the impact of work requirements on health outcomes and sustainable employment. She noted that CMS expects states to evaluate which healthy behavior incentives work. Additionally, CMS was interested in testing the effects of several additional reforms: aligning Medicaid with private insurance; estimating the effects of cost sharing on beneficiaries; and estimating the effects of losing (or not gaining) Medicaid eligibility.

The three state officials stressed the importance in their view of demonstrations that test: (1) policies to promote self-sufficiency to prepare people for the “next step on the ladder”; (2) ways to better align Medicaid with private insurance policy given, in their view, the greater stability of the private insurance market; (3) alternative approaches to primary care delivery, including the use of behavioral health providers to deliver primary care; (4) time limits and healthy behaviors; (5) the use of premiums and cost-sharing; and (6) drug testing aimed at getting people into treatment so that they can maintain employment.

According to the state officials, their proposed Section 1115 Medicaid demonstrations have several fundamental goals: (1) to increase the extent to which the population is working in “family-sustaining” jobs; (2) to limit the use of Medicaid to cover adults who can work in jobs offering employer-sponsored benefits, through time limits, work requirements, and other incentives aimed at shortening program enrollment for this population; and (3) to contain the size and growth of Medicaid in response to state fiscal concerns about Medicaid spending. Therefore, in their view, demonstrations should aim to encourage community engagement (a concept reflected in the Administration’s Section 1115 initiative announcement subsequent to the meeting), short coverage periods and transitions off the program, and workforce development. As noted by one panel member, a core common feature across all of the demonstrations is the desire to test the effects of altering the circumstances under which medical assistance should be provided.

State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

During the discussion period, participants focused on several matters. The first was the role of the mandatory public comment period that is part of the special regulatory standards that apply to Section 1115 demonstrations. Judith Cash noted the importance of public comments and CMS's focus on how states have altered their proposals in response to public comments, with particular attention to issues noted as problematic by state commenters. She also noted that the federal comment period that follows the state comment period tends to yield similar comments and indicated that the federal period tends to draw more, and a greater variety of, commenters. Of significance, Cash further noted that CMS receives very few comments on issues of evaluation and the extent to which a state's proposed demonstration lends itself to a robust evaluation of implementation and impact. In particular, few comments were received on the degree to which evaluations can separate out the distinct effects of a demonstration on participants, consistent with CMS rules.

In response to a question regarding the utility of community and population-based monitoring, as opposed to efforts that focus just on Medicaid enrollees and their experiences, the state officials observed that such efforts should be part of the formal evaluation. Such community information could shed light on unintended consequences regarding how the impact of the demonstration was actually playing out and could be valuable in addressing implementation challenges as they arose. Questions also arose on the types of outcomes in which states were particularly interested (evidence of feasibility or lack thereof; evidence of health impact), and what to do with desired outcomes that could be highly elusive to measure, that is, that might not be evaluable, such as self-sufficiency and dignity. Participants also observed the importance of understanding the impact of losing health coverage as a result of demonstration eligibility limits and restrictions.

Participants were interested in knowing what types of outcomes the Medicaid officials would consider evidence of negative impacts associated with their demonstrations, raising increases in substance use relapse rates as an example of a potentially negative outcome. Questions also emerged regarding how states measure the risks and benefits of demonstrations on their populations as they proceed to develop their demonstrations, particularly for provisions that could cause coverage disruption or termination. In the context of these discussions, the state official panelists clarified that aspects of their demonstrations that some might consider risks (e.g., shortened eligibility) could be viewed in their states as benefits since they would reduce state spending in Medicaid.

Participants noted the value of multi-state research designs and of designs that can provide information about outcomes in the early stages of implementation of the demonstration as well as informa-

tion about the longer-term effects of a demonstration. Alignment or lack thereof in state and federal programmatic goals was noted in designing evaluations for approved demonstrations. One participant questioned the conceptual value of Medicaid work demonstrations, observing that the aim of such demonstrations seems to be to reduce public spending in Medicaid while ensuring access to coverage through employment, when in fact the evidence does not suggest that working at low-wage jobs or in volunteer and job training activities will reduce the need for Medicaid. This participant suggested that if the goal is to reduce Medicaid enrollment, a better focus would be on policies that improve access to private insurance among low-wage workers. Another participant noted that a concept such as drug testing as a means of altering behavior might have merit but that evaluation might show that even meritorious concepts can face challenges that prevent their practical utility because they cannot be implemented. In the case of drug testing, for example, the lack of adequate resources and services to assist people overcome dependency could prove a binding constraint on implementing a drug-free standard for Medicaid eligibility.

Another participant sought to elicit thoughts from the panel about key elements of Section 1115 demonstrations that do not appear to have evaluation components, such as multiple states with approvals that waive retroactive eligibility, and how the absence of evaluation components for changes in eligibility and coverage might, in turn, affect the degree to which Section 1115 achieves its legislative objective of producing information to inform program modification. Other discussion focused on the need for states to survey individuals who lose Medicaid coverage under the demonstration and to track outcomes for individuals in the income range targeted by Medicaid who may be deterred from enrolling under the demonstration.

The group also discussed the value of increasing CMS capacity to bring a greater level of uniformity to evaluations; Judith Cash noted CMS' growing emphasis on use of national data sets such as T-MSIS and interest in greater standardization of demonstration performance indicators.

Panel Three: Lessons from Current Section 1115 Coverage Expansion Demonstration Evaluations that Can Inform Future Efforts

This panel, moderated by Genevieve Kenney, offered presentations from three researchers leading evaluation efforts of Section 1115 expansion demonstrations approved in 2014 under the Obama administration in Michigan (Richard Hirth), Arkansas (Joseph Thompson), and Iowa (Peter Damiano), as well as reaction from John Graves. All three state evaluators are part of research teams that are addressing numerous questions about these waivers and were asked to focus, where possible and applicable, on findings from those demonstrations that are relevant to demonstrations currently under consideration. Key areas of focus because of their rel-

State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

evance to current demonstration proposals were healthy behavior incentives, health savings account-type arrangements, cost sharing, and waiver of retroactive eligibility.

Richard Hirth began his presentation by describing the features of Michigan's Section 1115 demonstration. Hirth presented evidence regarding the impact of the demonstration on enrollment, hospital uncompensated care burdens, and employment and economic activity following implementation of the Michigan expansion demonstration. He also presented findings related to the provision of risk assessments, understanding and knowledge of MI Health Accounts, perceptions of cost sharing, and employment status of enrollees and their perception of the role Medicaid coverage played in helping them obtain a better job or look for work.

Joseph Thompson presented findings from the Arkansas Section 1115 demonstration, describing the demonstration and the motivation behind the reliance on a premium assistance model for the expansion. Thompson also shared findings related to clinical care outcomes, emergency room and other types of health care visits, average prices, budgetary impacts for the state and federal government, and the take up and administrative costs associated with the Health Independence Accounts which were subsequently discontinued.

Peter Damiano described the features of Iowa's Section 1115 demonstration and presented findings on the incentives and disincentives that were implemented for members and providers with respect to wellness exams and health risk assessments and changes in the structure of dental visits. John Graves raised the importance of understanding how provisions of Section 1115 waivers are operationalized, including ways to minimize administrative complexities (say imposing cost sharing as premiums as opposed to at the point of service as copays) and for considering impacts on provider decisions and networks.

Questions from the audience focused on numerous aspects of evaluation. Participants were interested in how evaluators make decisions on where to focus the evaluation effort. The panel response was both guidance from CMS as well as attention to evaluation design in order to anticipate the questions of the greatest policy and political significance and to then design a data collection strategy that could help address these needs. The panel noted the constraints imposed by limited evaluation budgets and difficulties raised when evaluation consultants without deep knowledge of the state become involved even though they may be unfamiliar with state data sources.

Panelists also noted their concerns with demonstrations that involve complexity with respect to implementation, such as healthy behavior incentives. Under these demonstrations, beneficiaries

and providers may possess a limited understanding regarding how the incentives are supposed to work and therefore are unable to implement the terms as specified in the waiver or respond to the incentives in a meaningful way. This, it was pointed out, could mean that while the inclusion of incentives in waiver proposals might satisfy political objectives, they could remain non-evaluable because they prove to be incapable of being implemented as designed and financed.

Beyond that, there was discussion of the fact that what is actually implemented can evolve and change and may not closely align with what was proposed or approved. Panelists stressed the importance of understanding actual implementation in relation to what might have been planned, particularly implementation choices that have the potential to materially alter key results, such as permitting third parties to make premium payments on behalf of the poor, which would enable them to maintain their Medicaid enrollment when they otherwise could not do so. Also discussed was the importance of disseminating the findings from these evaluations with policymakers and researchers in other states in a more time-sensitive and digestible manner so that they benefit from the early experiences of states that are testing out new provisions.

Panel Four: Data and Methodological Challenges for Section 1115 Demonstration Evaluations

This panel, moderated by Kosali Simon, included Anthony Goudie, Maggie Colby, and Coady Wing, three researchers who have conducted Section 1115 evaluations. Its purpose was to focus on data and methodological challenges for Section 1115 demonstration evaluations and approaches for matching the evaluation approach with the specific goals and circumstances of the demonstration. Presenters emphasized the importance of using quasi-experimental design methods that include comparison groups and data collection efforts that support the implementation of these research methods (e.g., regression discontinuity, comparative interrupted time series, and difference in differences, combined with covariate and trend matching) as the basis for developing robust impact estimates. They highlighted the many dimensions along which a particular policy can vary which can pose challenges for synthesizing findings across states and the need for measurement of both short- and long-term effects.

Questions from participants were wide-ranging. One focused in the feasibility of adopting cross-sectoral approaches that bring in a broader set of outcomes and take into account the impacts of the demonstrations on other non-healthcare sectors. Panelists noted that data limitations may constrain evaluation efforts, such as the ability to track the same people as they move in and out of Medicaid enrollment in order to have comprehensive information to assess the impacts of program changes. Another question focused on the need for different research methods in evaluating long term

State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

and short term demonstration impacts. For example, participants emphasized the importance of aligning evaluation designs to match the time frames being evaluated. Participants noted that before considering which research designs make sense, it is important to think about the time period over which any particular impact might reasonably be expected to occur.

As with the prior panel, the question of whether the demonstration design in fact took place as intended—i.e., whether implementation mirrored the policy intent—emerged as an important and distinct area for evaluation, particularly given the Section 1115 demonstration authority whose purpose is to inform changes in policy that might better achieve program objectives. At the same time, panelists noted, the question of how many resources to devote to implementation evaluation is a difficult one given the limits on resources and the interest in tracking outcomes.

Panelists were interested in promoting multi-state evaluations that could strengthen the power of evaluation on impact questions while also promoting interstate comparisons. It was noted that such evaluations would hinge on states' willingness to share data. Finally, the panel noted the importance of structuring the demonstration implementation design in order to create the conditions under which an evaluation could produce valuable evidence—e.g., staggering implementation across groups to provide a greater ability to establish impacts. The question of how the field could do a better job at sharing information also arose in this discussion.

Common Issues and Themes

The discussions yielded common issues and themes. One theme to emerge was the idea that **demonstration design matters**. In order for an evaluation to produce robust results and create usable knowledge relevant to social welfare policy, a demonstration design should be implementable. That is, the demonstration must be one that does not hinge on implementation schemes so complex that the design cannot be implemented and evaluated using quasi-experimental design methods.

A second theme is that **implementation evaluation matters, as does the evidence gained from evaluation**. Section 1115 authorizes experimental reform; for this reason it is central to the law that Section 1115 demonstrations produce new knowledge, not only regarding the outcome of the experimental model to be tested but whether the experimental model is, in fact, capable of being implemented in a manner that comports with the hypotheses to be tested through the demonstration design. This double-layered approach to evaluation is key to enabling understanding of whether the outcomes of a demonstration actually connect to its demonstration design and to permitting meaningful cross-state analyses. Imple-

mentation evaluation also allows researchers and policymakers to be able with some certainty to eliminate other factors not associated with the demonstration itself as the underlying drivers of results.

A third concept to emerge was that **multi-state evaluations would create a more robust research environment for understanding implementation issues and impacts**. Where a single concept is tested in multiple states, a multi-state demonstration that coordinates evaluation plans, sources of data, and data access would ultimately produce stronger results than single-state evaluations.

A fourth theme was **the importance of understanding both short term and longer term effects** so that policymakers can gain a fuller sense of the potential effects of a policy change.

Finally, a key issue to emerge is that **the evaluation process and purpose are distinct from Section 1115's requirements regarding ongoing information reporting**. Evaluation is fundamentally different from reports about program details and facts. Unlike those program reports, the evaluation has the goal of identifying the causal impact of the demonstration, the actual process of implementation in relation to demonstration design, and an assessment of both short and longer term effects of the demonstration on important outcomes.

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Endnotes

1. Marybeth Musumeci et al., Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers (Kaiser Family Foundation, 2018), available at <https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-demonstration-waivers-the-current-landscape-of-approved-and-pending-waivers/> (Accessed online February 5, 2018).
2. Jeff Stein, How Trump may end up expanding Medicaid, whether he means to or not (Washington Post, January 28, 2018) available at https://www.washingtonpost.com/business/economy/how-trump-may-end-up-expanding-medicaid-whether-he-means-to-or-not/2018/01/28/df2ee6e8-01e1-11e8-8acf-ad2991367d9d_story.html?hpid=hp_rhp-top-table-main_statemedicaid-820pm%3Ahomepage%2Fstory&utm_term=.6de3132f9e39 (Accessed online February 5, 2018).

State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

3. Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf> (Accessed online February 2, 2018).
4. Available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-07.html> (Accessed online February 2, 2018).
5. Elizabeth Hinton et al., Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers (Kaiser Family Foundation, 2017) available at <https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-demonstration-waivers-the-current-landscape-of-approved-and-pending-waivers/>.
6. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-11-07.html>.
7. Marybeth Musumeci, Section 1115 Medicaid Expansion Waivers: A Look at Key Themes and State Specific Waiver Provisions (Kaiser Family Foundation), available at <https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-expansion-waivers-a-look-at-key-themes-and-state-specific-waiver-provisions/> (Accessed online November 22, 2017).
8. Sara Rosenbaum et al., How Will Section 1115 Medicaid Expansion Demonstrations Inform Federal Policy? (Commonwealth Fund, 2016), available at <http://www.commonwealthfund.org/publications/issue-briefs/2016/may/how-will-section-1115-medicaid-expansion-demonstrations-inform-federal-policy> (Accessed online January 2, 2018).
9. 42 U.S.C. § 1315 (a)(2).
10. 42 U.S.C. § 1315 (a)(2).
11. Teresa Coughlin et al., An Early Look at Ten State HIFA Medicaid Waivers. Health Affairs Web Exclusive, available at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.w204> (Accessed online December 22, 2017).
12. Sara Rosenbaum et al., How Will Section 1115 Medicaid Expansion Demonstrations Inform Federal Policy? (Commonwealth Fund), available at <http://www.commonwealthfund.org/publications/issue-briefs/2016/may/how-will-section-1115-medicaid-expansion-demonstrations-inform-federal-policy> (Accessed online, November 22, 2017).
13. Governmental Accountability Office, Medicaid Demonstrations: Federal Action Needed to Improve Oversight of Spending (GAO 17-312, April 2017). Available at <https://www.gao.gov/assets/690/683888.pdf> (Accessed online February 2, 2018).
14. 42 U.S.C. § 1315 (d).
15. 42 U.S.C. § 1315 (d)(2)(E).
16. 42 C.F.R. § 431.424.
17. 42 C.F.R. § 431.424 (b).
18. 42 C.F.R. § 431.408 (a)(1)(i)(D).
19. 42 C.F.R. § 431.424 (c).
20. Id.
21. 42 C.F.R. § 431.424 (g).
22. Mr. Heifetz has since stepped down from his position as Medicaid Director.

State Flexibility in a New Era: What Are the Research Priorities for Section 1115 Demonstrations?

Endnotes

- 1 Marybeth Musumeci et al., Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers (Kaiser Family Foundation, 2018), available at <https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-demonstration-waivers-the-current-landscape-of-approved-and-pending-waivers/> (Accessed online February 5, 2018)
- 2 Jeff Stein, How Trump may end up expanding Medicaid, whether he means to or not (Washington Post, January 28, 2018) available at https://www.washingtonpost.com/business/economy/how-trump-may-end-up-expanding-medicaid-whether-he-means-to-or-not/2018/01/28/df2ee6e8-01e1-11e8-8acf-ad2991367d9d_story.html?hpid=hp_rhp-top-table-main_statedicaid-820pm%3Ahomepage%2Fstory&utm_term=.6de3132f9e39 (Accessed online February 5, 2018)
- 3 Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf> (Accessed online February 2, 2018)
- 4 Available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-11-07.html> (Accessed online February 2, 2018)
- 5 Elizabeth Hinton et al., Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers (Kaiser Family Foundation, 2017) available at <https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-demonstration-waivers-the-current-landscape-of-approved-and-pending-waivers/>
- 6 <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-11-07.html>
- 7 Marybeth Musumeci, Section 1115 Medicaid Expansion Waivers: A Look at Key Themes and State Specific Waiver Provisions (Kaiser Family Foundation), available at <https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-expansion-waivers-a-look-at-key-themes-and-state-specific-waiver-provisions/> (Accessed online November 22, 2017)
- 8 Sara Rosenbaum et al., How Will Section 1115 Medicaid Expansion Demonstrations Inform Federal Policy? (Commonwealth Fund, 2016), available at <http://www.commonwealthfund.org/publications/issue-briefs/2016/may/how-will-section-1115-medicaid-expansion-demonstrations-inform-federal-policy> (Accessed online January 2, 2018)
- 9 42 U.S.C. § 1315 (a)(2)
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- 11 Teresa Coughlin et al., An Early Look at Ten State HIFA Medicaid Waivers. Health Affairs Web Exclusive, available at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.w204> (Accessed online December 22, 2017)
- 12 Sara Rosenbaum et al., How Will Section 1115 Medicaid Expansion Demonstrations Inform Federal Policy? (Commonwealth Fund), available at <http://www.commonwealthfund.org/publications/issue-briefs/2016/may/how-will-section-1115-medicaid-expansion-demonstrations-inform-federal-policy> (Accessed online, November 22, 2017)
- 13 Governmental Accountability Office, Medicaid Demonstrations: Federal Action Needed to Improve Oversight of Spending (GAO 17-312, April 2017). Available at <https://www.gao.gov/assets/690/683888.pdf> (Accessed online February 2, 2018)
- 14 42 U.S.C. § 1315 (d)
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- 16 42 C.F.R. § 431.424
- 17 42 C.F.R. § 431.424 (b)
- 18 42 C.F.R. § 431.408(a)(1)(i)(D)
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- 20 Id.
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