AcademyHealth

State Flexibility in a New Era

What are the research priorities for Section 1332 waivers?

Section 1332 of the Affordable Care Act (ACA) provides an opportunity for states to waive key provisions of the federal health law in service of state-specific strategies to improve coverage. These "state innovation" waivers must adhere to the overarching goals and objectives of the ACA itself: waivers that are likely to undermine the comprehensiveness, accessibility, or affordability of coverage, or that will impose additional costs on the federal government, are prohibited by statute. Yet within these limits, Section 1332 waivers may offer significant policymaking flexibility, potentially enabling states to make broad changes to their coverage systems as well as more targeted modifications to the federal regulatory framework.[1]

Though Section 1332 waivers are a potentially powerful tool, experience with the program is quite limited. The ACA's drafters designed the waiver program with a lagged start, so that 2017 was the first year in which a waiver could take effect. To date, the federal government has approved just four waiver applications, and only one state has had a waiver in place for a full year.[2] Efforts to understand how Section 1332 waivers are working in practice, and to assess their effects in relation to federal requirements and state expectations, have just begun.

In October 2017, AcademyHealth hosted an expert meeting to explore research priorities related to the evaluation of Section 1115 Medicaid demonstration waivers and Section 1332 state innovation waivers. This brief summarizes key findings from the meeting related to the evaluation of Section 1332 waivers. First, the brief provides an overview of the state innovation waiver program. It describes substantive requirements and limitations applicable to waivers; state and federal responsibilities during the waiver application process and after application approval; and similarities and differences between the new Section 1332 waiver program under the ACA and Section 1115 of the Social Security Act, which authorizes the Secretary of Health and Human Services (HHS) to undertake Medicaid demonstrations that promote Medicaid objectives. Second, the brief explores critical issues related to the evaluation of Section 1332 waivers. It identifies research priorities, methodological challenges, data requirements, and key considerations related to the timing of evaluations. It concludes with recommendations by participants to support robust waiver evaluations and improved state and federal policymaking under Section 1332.

The Innovation Waiver Framework: Substantive and Procedural Considerations

What States Can Waive, and What They Can't

Section 1332 of the ACA authorizes states to request waivers of many of the health law's core requirements, to allow states to pursue alternative strategies for achieving coverage outcomes comparable to or better than those produced without a waiver. Waivers can last for up to five years at a time and may be renewed. States may seek to modify or eliminate rules concerning:

Genesis of this Brief:
AcademyHealth hosted an expert meeting to explore research priorities related to the evaluation of Section 1115 Medicaid demonstrations and Section 1332 state innovation waivers on October 17, 2017 in Washington, D.C. This brief includes highlights from the Section 1332 discussions between meeting participants including 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 views expressed here are those of the author and do not necessarily reflect the views of the Robert Wood Johnson Foundation, the meeting participants, or the reviewers. For more information on this topic, visit academyhealth.org/stateflexibility.

- **Benefits and coverage levels**, including the ACA's definition of essential health benefits (EHB), annual limitations on cost-sharing, and metal tiers;
- **Marketplaces and rules for marketplace health plans**, including requirements related to marketplace establishment and operations as well as certification requirements for the qualified health plans (QHPs) sold through the marketplaces;
- **Subsidies (premium tax credits and cost-sharing reductions)**, including subsidy amounts and eligibility requirements; and
- **Requirements to maintain coverage (the individual and employer mandates)**, including whether and how to apply the requirements and the penalty amounts.[3]

Critically, the waiver framework also makes available federal funding in certain circumstances. If a state waiver program is forecast to reduce federal spending on subsidies, the state is entitled to have these savings passed through to it for purposes of implementing the waiver. It is this feature of the program that has driven most of the waiver applications so far submitted to and approved by the federal government.[4]

Provisions of the ACA not specifically designated as waivable in Section 1332 cannot be modified. Non-waivable provisions include rules prohibiting insurers from denying or limiting coverage because of a pre-existing condition, or charging a higher premium based on an individual's health status or gender; bans on annual and lifetime coverage limits; the requirement to cover certain preventive services without cost-sharing; and other protections barring discrimination based on health status or other factors.

"Guardrail" Provisions Set Limits on Flexibility

The health law conditions approval of any state waiver on the satisfaction of four requirements, generally designed to ensure that state residents are not made worse off by their state's alternative coverage approach than they would have been under the ACA's standard framework, and to limit the federal fiscal commitment to the state program. These conditions, sometimes called the waiver "guardrails," address:

- **Coverage take-up.** The state waiver program must "provide coverage to at least a comparable number of its residents" as would receive coverage without the waiver.
- **Affordability of coverage.** The state waiver program must "provide coverage and cost-sharing protections against excessive out-of-pocket spending that are at least as affordable" as would be provided without the waiver.
- **Comprehensiveness of benefits.** The state waiver program must "provide coverage that is at least as comprehensive as the coverage defined in" the ACA's EHB requirement.
- **Deficit neutrality.** The state waiver program must not increase the federal deficit.[5]

The Application Process: State Responsibilities

To gain approval for a Section 1332 waiver, a state must submit information and data sufficient for federal officials to determine that the state's proposal meets the guardrails.[6] Federal rules and guidance specify that states must include in their applications:

- **Actuarial analyses and certifications** to support the state's forecasts with respect to the comprehensiveness, affordability, and coverage guardrails;
- **Economic analyses** with respect to all four guardrails, including a detailed 10-year budget plan demonstrating federal deficit neutrality and a detailed analysis of the expected impact of the waiver on health insurance coverage in the state;
- **Data and assumptions** used to demonstrate compliance with the guardrails, including a description of the model used to produce coverage and deficit estimates;
- **An implementation timeline**;
- **An explanation of the waiver's expected effects on provisions of the ACA that are not being waived**;
- **Periodic data reporting targets** to demonstrate ongoing compliance with the guardrails; and
- **Additional supporting information**, as requested by federal officials during application review.

The state's analyses must include certain specific types of information that would support a determination that each guardrail is satisfied:

- **Coverage take-up:** the state must supply information on the number of individuals covered, by income, health status, and age groups, under current law and under the waiver, including year-by-year estimates; the application should also identify any types of individuals less likely to be covered under the waiver, compared to current law;
- **Affordability:** the state must supply information on estimated individual out-of-pocket costs by income, health status, and age groups, absent the waiver and with the waiver; the application should also describe any changes in employer contributions to health coverage or in wages expected under the waiver, and should identify any types of individuals for whom affordability of coverage would be reduced by the waiver;
- **Comprehensiveness of benefits:** the state must supply information explaining how the benefits offered under the waiver differ from the benefits provided absent the waiver, and how the state determined the benefits to be comprehensive; and

- **Deficit neutrality:** the state must supply information showing yearly changes in the federal deficit due to the waiver and a description of all costs associated with the program, including but not limited to federal administrative costs and foregone tax collections.

The Application Process: Federal Review

The Secretaries of HHS and of the Treasury (together, the Departments) share authority for reviewing and approving state Section 1332 waiver applications.[7] "[O]nly if" the Departments determine that the guardrails have been met "may" an application be granted.[8]

In 2015, the Obama administration issued guidance describing how the Departments would assess whether a waiver proposal meets the statutory guardrails (Exhibit 1). As of January 2018, this guidance remained in force, though participants observed that it might be modified—perhaps significantly—by later actions of the Trump administration.[9] The guidance specifies that officials will examine both the overall effect of a waiver and its particular effects on different groups—especially vulnerable populations. Meeting participants observed that while this framework does not prohibit tradeoffs that create policy winners and losers—for example, the fact that a waiver is likely to cause coverage to be more affordable for some residents, and less affordable for others, does not, in and of itself, require denial—proposals likely to negatively affect already vulnerable residents are impermissible.

In addition to determining whether a waiver request complies with the guardrails, federal officials must also calculate its funding ramifications. For applications that seek to capture excess federal funds that would have been spent on marketplace subsidies absent the waiver ("pass-through funds"), officials must determine the amount of funding due to the state "tak[ing] into account experience in the relevant state and similar states."[10]

State Responsibilities, Post-Approval: Reporting and Cooperation

States that are given approval for a Section 1332 waiver must comply with additional requirements designed to facilitate monitoring of the waiver and its ongoing compliance with the guardrails.[11] Within six months of a waiver's implementation and annually thereafter, states must hold a public forum to solicit comments on the waiver's progress. States must also submit quarterly and annual reports to federal officials that include, among other things, information regarding operational challenges, data relevant to an assessment of guardrail compliance, and a summary of the annual public forum, including all public comments received and the state's responses to them. States must also perform periodic reviews related to the implementation of their waivers.

In addition, states are bound to "fully cooperate" with mandatory federal evaluations of the waiver program.[12] This cooperation includes the requirement that states submit "all" data and information requested by federal officials to support the evaluations.[13]

Federal Responsibilities, Post-Approval: Oversight and Evaluation

Federal officials retain significant responsibility with respect to a state's Section 1332 waiver program after its approval and implementation. Officials must re-determine a state's pass-through funding on an annual basis; review and, as appropriate, investigate documented complaints that a state is failing to comply with the terms and conditions of the waiver; and provide comments to the state in response to its annual waiver report.

Federal officials are also charged with conducting periodic evaluations of the state's Section 1332 waiver program. This requirement is not yet well defined: no evaluation of an approved waiver has yet occurred and the statute and its implementing regulations and guidance describe only the general parameters of the evaluation process. Evaluations must involve a review of the state's annual reports, and officials have suggested that the "primary focus" of any evaluation will be on the waiver's compliance with the guardrails.[14] In the preamble to a 2012 regulation specifying certain process requirements related to Section 1332 waivers, the Departments listed a number of broad potential evaluation criteria to be used as a "starting point" for the development of more detailed guidance setting forth evaluation standards that the Departments promised to issue in the future.[15] This list suggested that evaluations should consider the impact of a waiver on:

- "Choice of health plans for individuals and employers;
- Stability of coverage for individuals and employers;
- Small businesses, individuals with pre-existing conditions, and the low-income population;
- The overall health care system in the state; and
- Other states and the federal government."[16]

To date, the Departments have not issued any additional guidance further defining these potential criteria or otherwise establishing formal evaluation standards for the waiver program.

Consistent with the federal government's approach to other waiver programs, the Departments reserve the right to suspend or terminate a waiver at any time prior to its scheduled expiration, if they determine that the state materially failed to comply with the terms and conditions of the waiver, including the guardrails.

Exhibit 1. Federal Requirements for Satisfying the Section 1332 Waiver Guardrails

Statutory Guardrail	Guidance
Coverage take-up: Waiver program must provide coverage to a comparable number of state residents as would receive coverage without it.	At least as many individuals who had minimum essential coverage (MEC) absent the waiver must be forecast to have MEC under the waiver program, in each year of the program. This assessment requires consideration of the overall impact of the waiver program on all state residents, regardless of the type of coverage they would have absent the waiver, as well as its effects across different groups of residents. In particular, this review must account for effects on vulnerable populations, including those with low incomes, elderly individuals, and those with or at greater risk of developing serious health issues. The assessment must also account for whether the waiver program sufficiently prevents gaps in or discontinuations of coverage.
Affordability: Waiver program must provide coverage and cost-sharing protections against excessive out-of-pocket spending that are as affordable as would be provided without it.	Coverage under the waiver program must be forecast to be as affordable overall for state residents as coverage absent the waiver, in each year of the program. Affordability is measured by comparing residents' net out-of-pocket spending, including premium contributions, cost-sharing, and spending on non-covered services (to the extent affected by the waiver proposal), to their income. This assessment requires consideration of the average impact of the program on all state residents, regardless of coverage type, as well as its effects on individuals with large health care spending burdens. This review must also account for effects across different groups of residents, particularly vulnerable populations, including those with low incomes, elderly individuals and those with or at greater risk of developing serious health issues.
Comprehensiveness of benefits: Waiver program must provide coverage that is as comprehensive as would be provided without it, as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the state and from comparable states about their experience with programs created by the ACA and the provisions of the ACA that would be waived.	Coverage under the waiver program must be forecast to be at least as comprehensive overall for state residents as coverage absent the waiver, in each year of the program. Comprehensive coverage is coverage that meets the ACA's EHB requirements or, as appropriate, standards under the state's Medicaid and CHIP programs. This assessment requires consideration of the impact of the waiver program on all state residents, regardless of coverage type, as well as its effects across different groups of residents. In particular, this review must account for effects on vulnerable populations, including those with low incomes, elderly individuals, and those with or at greater risk of developing serious health issues.
Deficit Neutrality: Waiver program must not increase the federal deficit.	The waiver program must be federal deficit neutral over the period of the waiver and over a ten-year budget period. A waiver that increases the deficit in any given year is less likely to meet this requirement. This analysis must account for the effect of all changes in federal revenue and spending resulting from the waiver program while holding the state's Medicaid policies constant. That is, any spending effects produced by changes to the state's Medicaid program under a Section 1115 demonstration will not be considered when evaluating the Section 1332 waiver.

Source: Department of the Treasury and Department of Health & Human Services, "Waivers for State Innovation, Guidance," 80 Fed. Reg. 78131, Dec. 16, 2015.

Section 1332 Waivers and Section 1115 Waivers: Similarities, But Key Differences

Section 1115 of the Social Security Act authorizes states to seek federal approval to implement an "experimental, pilot, or demonstration project" that is "likely to assist in promoting the objectives" of the Medicaid program.[17] Demonstration waiver authority under Section 1115 long predates the ACA's Section 1332 waiver program and has been used frequently, particularly since the mid-1990s, to make significant changes to state Medicaid programs.[18]

Meeting participants suggested that the federal framework for Section 1115 waivers informed the development of the Section 1332 waiver program. Rules requiring public input on the waiver process and governing state reporting on waiver progress are similar, for example, and the ACA specifically provides for the coordination and consolidation of waivers under Section 1115 and Section 1332. However, participants cautioned that there are important differences between the two authorities that limit the degree to which experiences with Section 1115 demonstrations should inform expectations under Section 1332.

The core difference between waivers under the two sections lies in the degree of flexibility each provides—to states, to modify federal requirements, and to the federal government, to grant a waiver. In each case, authority under Section 1115 is significantly greater than under Section 1332. Section 1115 is, in the view of the Medicaid and CHIP Payment and Access Commission (MACPAC), perhaps "unique among waiver authorities . . . combin[ing] extensive waiver authority with a broadly defined purpose for which waivers may be granted."[19] Waiver authority under Section 1115 is not unlimited: in addition to important process and transparency requirements and limitations on the federal Medicaid provisions subject to waiver, Section 1115 proposals must be budget neutral for the federal government and are evaluated for approval under a set of non-statutory criteria designed to reflect the current objectives of the Medicaid program.[20] Nevertheless, because Section 1115 waivers are not subject to any limitation equivalent to the Section 1332 statutory coverage guardrails, requiring assessment and oversight of a waiver's impact on coverage take-up, affordability, and comprehensiveness of benefits, the flexibility offered in the Medicaid context is notably broader than what is available under Section 1332.

Participants also suggested that the two programs are intended for distinct purposes. Waivers under Section 1115 are, by definition, experiments, designed to test the effectiveness of different approaches to the provision or financing of Medicaid services in the state. Waiver applications must describe a hypothesis that the demonstration will test and that will be incorporated into the demonstration evaluation. By contrast, Section 1332 waivers are, as one participant put it, "requests to do business differently." Though participants argued that Section 1332 waivers *ought to be* premised on clearly defined policy objectives, a waiver's approval and renewal depends primarily on the satisfaction of the statutory guardrails, whatever its theory of change.

Finally, on a more practical level, participants noted that federal capacity to review and assess waivers under the two programs was highly likely to be different. Participants suggested that institutional resources and—given the newness of the program—experience supporting the Section 1332 waiver program is more limited than what is available for Section 1115 Medicaid demonstrations and there is a risk that this could affect both the speed and thoroughness of federal review.

Evaluating Innovation Waivers: Research Priorities And Challenges

Who Must (And Should) Evaluate?

Meeting participants noted that evaluation requirements have been important to understanding the impacts of state Section 1115 demonstrations and anticipated that rigorous evaluations would be especially valuable in the Section 1332 waiver context, as well. Some participants suggested that the Section 1332 evaluation framework contains an improvement over its Medicaid counterpart in that it requires that periodic evaluations be conducted by the federal government or an "independent evaluator" selected by the Departments.[21] Whereas, for Section 1115 demonstrations, it is the states that are charged with evaluating their own policy changes and a federal assessment is optional, these participants saw value in the fact that the current Section 1332 framework relies on evaluations conducted independent from the state —provided the Departments maintain sufficient resources to perform them.

At the same time, participants cautioned that the evaluation framework for Section 1332 waivers has not been fleshed out—as noted above, guidance describing evaluation criteria and standards has been promised but not yet been issued—and it is not fully clear what a federal evaluation will look like in practice. They also pointed out that there remains significant uncertainty about possible legislative or regulatory changes to federal health policy under the Trump administration, including modifications to the Section 1332 waiver program and its key guardrail provisions. Because of these unsettled issues, and because of the potential value in exploring waiver impacts in addition to those focused on by federal regulators, participants stressed that there is a critical role to be played by entities outside of government capable of performing rigorous and independent evaluations.

Research Approaches for Federal and Third-Party Evaluators

In approaching the question of how to assess the impacts of Section 1332 waivers, meeting participants sought to distinguish between efforts to report on a waiver's progress and the task of formally evaluating its effects. Mandatory reports compiled by states with active waivers are important descriptive documents that, by supplying extensive data and other information regarding the waiver's implementation, can provide key inputs informing an evaluation. But participants were quick to note that these materials are not a substitute for a robust empirical investigation of the effects of key waiver features on a policy baseline, utilizing appropriate controls.

To this end, participants emphasized that any waiver evaluation design must be grounded by clear, testable research questions. Recognizing that demonstration hypotheses are not currently part of the Section 1332 regulatory framework, as they are under Section 1115, participants suggested that defining a clear set of evaluation criteria was, nevertheless, essential.

Participants identified three overlapping areas of research. *First*, evaluations must carefully operationalize the statutory guardrails—the critical benchmarks for any waiver program—and assess the waiver's compliance with them. The fundamental promise and limitation of Section 1332 is that "does not exempt states from accomplishing the aims of the ACA," but rather "gives them the ability (and responsibility) to fulfill [these goals] in a different manner."[22] Participants repeatedly observed that the guardrails are a statutory safeguard to ensure that a waiver's "request to do business differently" does not undermine federal objectives. The federal government thus has a core interest in determining whether a waiver has produced an environment in which coverage take-up, affordability, benefit comprehensiveness, and net federal costs are comparable to what they would have been had the state implemented federal law as written. And participants suggested that this interest remains during the life of the waiver. Just as states must demonstrate that a proposed waiver will provide coverage that meets the guardrails before such waiver may be first approved, so too must an active waiver be judged against these provisions and shown to comply with them, before it may be continued.

Yet, if assessing a waiver's adherence to the ACA's objectives, as reflected in the guardrails, should be the primary focus of federal evaluators, participants expressed that evaluations—particularly those undertaken by third parties—should investigate, *second*, how a waiver has performed against its own stated goals. Participants argued that Section 1332 waiver applications should be driven by and include explicit and concrete policy objectives that, though likely to overlap with the guardrails, should be separately treated. Whereas determining compliance with the guardrails may reveal whether a waiver has done harm, a broader evaluation that gauges the extent to which the waiver has met its own objectives may facilitate a better understanding of the relative effectiveness of the state's policies and its underlying theory of change. Such an assessment would likely have broad value: to state actors, including policymakers, stakeholders, and the public, considering whether to support a continuation of the waiver's policies, as well as to those outside of the state, weighing the merits of replicating them.

Third, participants suggested that evaluations include a qualitative component assessing a waiver's implementation. This element would likely be of particular value in the case of more complex proposals to develop and administer new coverage or subsidy systems, to aid in understanding not only the ultimate outcomes of the program, but also the operational challenges and burdens—on state government, residents, and stakeholders—of achieving them. One participant pointed to a recent Section 1332 application submitted, and later withdrawn, by the state of Iowa, to highlight this need. The Iowa proposal would have required, among other things, that the state develop and administer new tax credit eligibility and coverage enrollment processes in place of existing federal systems and conduct extensive outreach and education to state residents, all within a span of a few weeks before the start of the open enrollment period. The participant suggested that, had the Iowa application been approved, it would have been especially important for any subsequent evaluation to analyze the state's efforts to stand up its new coverage system and document residents' experiences with the program. Another participant suggested that timely monitoring and analysis of implementation would be of sufficient value that they should be undertaken, perhaps by third-party researchers, on a stand-alone basis prior to a more formal and complete waiver evaluation. Because such assessments might be produced relatively quickly, they could inform state efforts and federal oversight comparatively early in the life of the waiver, potentially facilitating prompt corrective actions to improve the program and safeguard residents.

Methodological Challenges

To assess a waiver's impacts, evaluators must compare the coverage landscape with the waiver in effect to a baseline scenario describing the expected coverage landscape in the state in the absence of the waiver. Guidelines for specifying the waiver and baseline scenarios are relatively straightforward: federal regulators have stated that the waiver scenario must take into account only the projected effects of the waiver itself and other related changes to the state's health care system that are contingent only on the approval of the waiver. The baseline scenario, by contrast, is a projection of the state of the world under current law, were the waiver not approved.

Participants noted that, in practice, specifying a rigorous baseline at the outset of the waiver would require use of significant state-specific data and warned that modeling the counterfactual in subsequent years of the waiver program was likely to be difficult. This might be

especially true if there were other significant legal or policy changes to health insurance regulation at the state or federal levels during the course of the waiver for which evaluators would need to control—not an unlikely scenario in the current environment. These types of complexities, common to policy and program evaluation more generally, including evaluations of demonstrations under Section 1115, will require evaluators to devote significant resources and employ sophisticated research methods.

Participants also described the challenge posed by attempting to unpack the effects of a complex waiver that carries out multiple policy changes. While untangling the effects of constituent parts of a waiver may not be necessary for an analysis of the program's compliance with the guardrails, participants expressed that it would be valuable to do so, as noted above, in the context of a broader investigation of the effectiveness of specific policy choices. Participants noted that certain types of implementation approaches could make this difficult task more manageable: for example, a program that staggered the implementation of key features over time might make it easier to isolate the outcomes associated with each part. However, political and potentially financing constraints were likely to make adoption of such an approach unlikely.

Data Needs

Participants noted that data requirements for a given evaluation would vary depending on the scope of the underlying waiver, but anticipated that thorough assessments might draw upon state-specific population data, health coverage and cost information for the state's private health insurance market, enrollee surveys, and informational interviews with key stakeholders and state officials.

Use of economic and demographic data, including data drawn from federal surveys, was viewed as foundational, permitting analysis of a waiver's effects on different slices of a state's population—for example, by age, income, and health status. Understanding whether a waiver produced a disproportionate impact on particular groups of residents, particularly vulnerable subgroups such as those with low-incomes, elderly individuals, and those with or at greater risk of developing serious health issues, is essential to determining ongoing compliance with the guardrails.

To study a waiver's impact on coverage take-up, evaluators may need to utilize data showing individuals' coverage status, including uninsurance and churn between insurance programs, available through federal surveys. In addition, evaluations would likely incorporate data reflecting enrollment through the state's health insurance marketplace—available from the federal government in the case of the 39 states using the federally facilitated marketplace platform, and from the state-run marketplaces in the remaining states and the District of Columbia—as well as individual market enrollment outside the marketplace. One participant noted that, in evaluating waiver effects on a state's individual market, it would be important to understand enrollment in alternative coverage products, such as short-term, limited duration coverage and healthcare sharing ministries, about which data are often lacking. The participant suggested that it should be obligatory for a waiving state to collect data, such as these, necessary to evaluate the program. Depending on the waiver's focus, evaluators might also require enrollment data for other market segments. For example, to analyze Hawaii's approved waiver of certain ACA rules related to the Small Business Health Options Program (the SHOP), evaluators may need data showing enrollment in the state's small group market.

Evaluation of residents' access to health care services, utilization, and out-of-pocket spending may be informed by federal data sources, claims and encounter data, and, depending on the nature of the waiver, evaluation-specific surveys of state residents. Claims data might be obtained from all-payer claims databases in the states that have established them or, potentially, via the data submissions made by insurers to the federal government under the ACA's risk adjustment program. To understand impacts on affordability of premiums, evaluations would need to rely on data showing federal payments for premium subsidies, as well as premium rates in the relevant markets. Participants suggested that insurers in a waiving state could be encouraged or required to provide their own estimates of the rate impacts of certain policy changes—for example, the establishment of a reinsurance program—in their annual rate submissions, which might inform, though not control, subsequent assessments.

To assess a state's implementation of its waiver, evaluators might interview state officials and government staff as well as key stakeholders, including consumer and patient advocates and individuals representing insurers and providers. Evaluators might also conduct surveys of state residents affected by the waiver to assess their understanding of and experiences with the waiver program.

Timing of Evaluations

Section 1332 waivers may run for five years before renewal and must be evaluated "periodically."[23] Federal evaluations must include a review of the annual report or reports submitted by the waiving state for the relevant time period, suggesting it may be prudent for an evaluation to occur no earlier than the time by which a state report encompassing the waiver's first year of implementation has been submitted. Yet there is likely to be value in conducting a federal evaluation relatively early in the life of the waiver. Early feedback would help federal regulators and state policymakers determine whether any mid-course corrections in implementation are warranted. Such assessments also may offer timely assistance to other states considering whether to pursue a similarly structured

waiver. Participants asserted that, in all events, a federal evaluation would need to be performed sufficiently in advance of the decision about whether to renew the program, so that results from the assessment could inform those deliberations.

Evaluations undertaken by independent entities have relatively greater flexibility in terms of process and timing, but likely would be driven by similar considerations. One participant suggested that it could be especially valuable for a third-party evaluation to occur on a timeframe that would permit the results to be presented during the waiving state's annual public forum. As noted above, a waiving state is required to respond to public comments provided during the forum and include a summary of those comments and state responses in its annual report to federal regulators. In turn, federal officials must review these annual reports as part of the periodic federal evaluation. Thus, an independent evaluation disseminated in this way could raise key issues that would inform and require action by both state policymakers and federal evaluators.

Participants also saw potential value in efforts by independent entities to assess a waiver prior to its implementation, to aid public and stakeholder understanding of a program's probable effects during the application review process. However, time and resource constraints associated with this sort of front-end analysis was expected to be considerable. Though timeframes for federal review of waiver applications have been criticized by some as slowing state efforts to innovate, participants suggested that, at least with respect to more complex waiver proposals, thorough modeling could be difficult to manage—for both federal evaluators and third-parties—even under the existing framework. The difficulty was likely to be especially acute to the extent states continue to modify their plans throughout the review process, as was the case with Iowa's proposed waiver.

Recommendations

The Section 1332 waiver program is, in effect, only a year old; no waiver approved by the federal government has yet been evaluated, and efforts to formalize the process of waiver assessment are in early stages. Meeting participants, acknowledging the newness of the program and ongoing uncertainty around the ACA, raised several suggestions to support robust waiver evaluations and improve future state and federal policy decisions under Section 1332.

- The Departments should publish guidance identifying the specific criteria that will be used for federal evaluations.
- The Departments should clarify that an approved waiver may not be renewed beyond its initial term if the most recent federal evaluation determines that the waiver does not comply with the guardrails.
- The Departments should maintain sufficient staff resources to ensure timely, thorough, and independent review of all waiver applications and to conduct multiple periodic evaluations of all approved waiver programs before they are considered for renewal.
- Each waiving state should ensure it collects and reports, timely and publicly, data and information sufficient to permit a rigorous evaluation of its waiver. Collection and public reporting should include data and information, including enrollment, describing the state's commercial insurance market and alternative coverage products available within the state. In addition, and consistent with existing federal requirements obligating the public disclosure of state draft and final annual waiver reports, states should promptly publish all federally-required quarterly reports describing waiver implementation.
- Apart from the formal federal waiver review and evaluation process, qualified non-governmental research entities should undertake independent assessments of state Section 1332 waiver applications and periodic evaluations of approved waivers. These entities should commit resources sufficient to model and timely publish the projected effects of pending waiver proposals and the observed impacts of implemented waiver programs. Entities should present key findings from periodic evaluations to states during the required annual public forum.

Conclusion

The AcademyHealth expert meeting focused on research priorities and challenges related to the evaluation of Section 1332 state innovation waivers. Participants expressed that the waiver program in its current form offers states important flexibility to develop alternative strategies for improving coverage outcomes. At the same time, they noted that significant uncertainty around the ACA and the Trump administration's approach to the waiver program made it difficult to anticipate the frequency with which states might pursue waivers or the content of their proposals. Participants agreed that it will be critical for the fledgling program to have in place a framework that requires rigorous, timely, and independent assessments of all waivers against federal law guardrail protections and ensures transparency in implementation and data reporting to enable robust waiver evaluations by researchers in the field.

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Endnotes

1. See, e.g., D. Bachrach, J. Ario, and H.E. Davis, "*Innovation Waivers: An Opportunity for States to Pursue Their Own Brand of Health Reform*," The Commonwealth Fund, Apr. 2015.
2. The federal government has approved waivers for Hawaii (effective for 2017), Alaska, Minnesota, and Oregon (all for terms beginning in 2018). Centers for Medicare & Medicaid Services (CMS), "*Section 1332: State Innovation Waivers*," last visited Jan. 24, 2018.
3. Under recently enacted federal legislation, beginning in 2019, the tax penalty for individuals who do not maintain minimum essential coverage is reduced to zero, effectively eliminating the individual mandate.
4. J. Giovannelli and K. Lucia, "*Status of State ACA Innovation Waivers*," The Commonwealth Fund, Nov. 10, 2017.
5. 42 U.S.C. § 18052(b)(1)(A)-(D).
6. An applying state must also identify a state law that provides the state with authority to implement its proposed waiver. 42 U.S.C. § 18052(a)(1)(C); 45 C.F.R. § 155.1320(f)(3)(ii); 31 C.F.R. § 33.120(f)(3(ii).
7. Formally, the Secretary of the Treasury is responsible for reviewing any portion of an application that requests to waive a provision or provisions of the Internal Revenue Code, while the Secretary of HHS is responsible for reviewing all other aspects of the application. 42 U.S.C. § 18052(a)(6). In practice, however, the impact of a waiver is evaluated as a whole and the Departments jointly assess a state's full application.
8. 42 U.S.C. § 18052(b)(1).
9. While formal federal review processes and criteria have so far remained unchanged, participants noted that states' practical experiences with the waiver application process have, in the view of state officials and some outside observers, varied widely.
10. Department of the Treasury and Department of Health & Human Services, "Waivers for State Innovation, Guidance," 80 Fed. Reg. 78131, 78134, Dec. 16, 2015; 42 U.S.C. § 18052(a)(3).
11. State and federal obligations during the term of the waiver are memorialized in a terms and conditions document executed by the waiving state and the Departments and made publicly available by CMS. See CMS, "*Section 1332: State Innovation Waivers*," last visited Jan. 24, 2018.
12. 45 C.F.R. § 155.1320(f)(1); 31 C.F.R. § 33.120(f)(1).
13. 45 C.F.R. § 155.1320(f)(2); 31 C.F.R. § 33.120(f)(2).
14. Department of the Treasury and Department of Health & Human Services, "Application, Review, and Reporting Process for Waivers for State Innovation, Final Rule," 77 Fed. Reg. 11700, 11711, Feb. 27, 2012 ("Process Requirements for State Innovation Waivers, Final Rule").
15. Process Requirements for State Innovation Waivers, Final Rule, 77 Fed. Reg. at 11711.
16. Process Requirements for State Innovation Waivers, Final Rule, 77 Fed. Reg. at 11711.
17. 42 U.S.C. § 1315(a). Section 1115 Medicaid "demonstration" projects are frequently described informally as Medicaid "waivers." These terms are used interchangeably in the text.
18. In fact, Section 1115, enacted in 1962, predates the Medicaid program itself. For more information regarding state waiver efforts under Section 1115, see, e.g., E. Hinton, M. Musumeci, R. Rudowitz, et al. "*Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers*," Kaiser Family Foundation, Dec. 13, 2017.
19. Medicaid and CHIP Payment and Access Commission, "*Waivers*," last visited Jan. 24, 2018.
20. CMS, "*About Section 1115 Demonstrations*," last visited Jan. 24, 2018.
21. 45 C.F.R. § 155.1320(f)(1); 31 C.F.R. § 33.120(f)(1).
22. H. Howard and G. Benshoof, "Section 1332 Waivers and the Future of State Health Reform," *Health Affairs Blog*, Dec. 5, 2014.
23. 45 C.F.R. § 155.1328(a); 31 C.F.R. § 33.128(a); see also 42 U.S.C. § 18052(a)(4)(B)(v).