Improving the Quality and Timeliness of Section 1115 Demonstration Evaluations: Themes from Expert Roundtable

Medicaid and CHIP Payment and Access Commission

Kacey Buderi

Overview

- Background
  - Section 1115 demonstration authority
  - current evaluation requirements
  - recent efforts to improve evaluations
  - challenges to carrying out strong and timely evaluations
- Takeaways from roundtable discussion

Previous MACPAC Work

- Presented preliminary findings from evaluations of Medicaid expansions using Section 1115 demonstration waivers (April 2017)
- Reviewed monitoring and evaluation requirements for Section 1115 research and demonstration waivers (September 2017)
- Convened a panel of representatives from the Centers for Medicare & Medicaid Services and the U.S. Government Accountability Office (April 2018)

Background

Background on Section 1115 Authority

- Section 1115 of the Social Security Act allows the Secretary of Health and Human Services to waive federal Medicaid requirements to the extent necessary to carry out a demonstration furthering the goals of the Medicaid program
- As of November 2019, there were 62 approved demonstrations in 46 states
- Demonstrations differ in scope and the policies they implement

Evaluation versus Monitoring

- All Section 1115 demonstration waivers are subject to monitoring and evaluation requirements
  - monitoring activities provide timely and ongoing updates on implementation status and basic data on key measures
  - evaluations are intended to assess whether demonstrations achieve their objectives and to inform decision making
- Requirements for monitoring and evaluation are specified in regulation, waiver special terms and conditions, and subregulatory guidance
- Focus of the roundtable and this presentation is on evaluation

Evaluation Requirements

- Evaluation design plans specify hypotheses and research questions, methodology, and process information
  - due to CMS 120 or 180 days after demonstration approval
- Interim and summative evaluation reports include results, conclusions, and discussion
  - interim evaluations due with demonstration renewal application or one year before expiration
  - summative reports due within 18 months of the end of the demonstration period
- CMS must approve deliverables before they are final

Concerns with Evaluation Quality

- Multiple GAO studies released between 2007 and 2019 have found issues with Section 1115 evaluations related to:
  - methodological shortcomings
  - selective reporting of outcomes
  - lack of opportunity for public comment
  - CMS approval of demonstration extensions based on incomplete or inconclusive evaluation results

Efforts to Improve Evaluation Quality

- The Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) required the Secretary to establish a formal process for evaluations
  - regulations finalized in 2012
- CMS has enhanced individualized technical assistance and feedback to states
- CMS issued new guidance in 2019
  - white papers discussing common evaluation challenges
  - general evaluation design guidance
  - policy-specific guidance

Ongoing Concerns

- States experience administrative and methodological challenges to designing and carrying out strong evaluations
- Timing of evaluation deliverables limits their ability to inform policy
- Judging the strength of evidence needed to make policy decisions is difficult and there are no established standards
- Decisionmaking processes are influenced by a number of outside factors

Roundtable Discussion

Roundtable Information

- Held November 14, 2019 at MACPAC office
- Participants included
  - representatives from CMS and GAO
  - state Medicaid agency officials
  - evaluators of state Section 1115 demonstrations
    - not the same states represented by state Medicaid agency officials
  - other researchers
  - beneficiary advocates
- No consensus or recommendations

Evaluation Processes and Challenges

- CMS's 2019 guidance has been important for setting expectations for states with Section 1115 demonstration waiver authority
  - must think through a theory of change (i.e., what they are seeking to demonstrate and what they expect to see)
- The value proposition for investing time and resources into evaluations differs by state and is not always clear to state legislators and executives

Evaluation Processes and Challenges – Continued

- Evaluation budgets are often determined based on policymakers' willingness to provide funds, rather than by the cost of necessary evaluation activities or components
  - enhanced matching rate could incentivize states to provide more evaluation resources
  - opportunities exist for CMS to provide more guidance and feedback on setting an appropriate evaluation budget
- The current arrangement, in which states fund and direct evaluations, may limit the independence of evaluations

Evaluation Processes and Challenges – Continued

- Efforts to consider evaluation earlier in the waiver application and implementation process can help produce stronger evaluations
- Comparison group challenges can be addressed with better cross-state data arrangements and advance planning (e.g., phased implementation)

Standards for Evaluation Content and Timing

- Depending on data needs, states may need to begin some evaluation activities prior to implementation in order to effectively test policies
- Beneficiary surveys, or alternative ways to capture information not available from administrative data, are necessary
- Greater collaboration among evaluators would be helpful for improving evaluations and establishing collective standards of rigor

Standards for Evaluation Content and Timing – Continued

- Current requirements for the timing of interim and summative reports limit the type of data that can be included
  - data collection period in a three- or five-year demonstration may not be adequate to assess the effects of a policy (especially the case for interim evaluations)
  - implementation evaluations that collect information on process indicators may be more practical for interim evaluations

Standards for Evaluation Content and Timing – Continued

- Standards and requirements related to content, rigor, and timing of evaluation deliverables could vary by demonstration type and scope
- May want to vary standards and requirements based on risk of beneficiary harm, novelty of the approach, strength of existing evidence, federal investment, or other criteria

Evidence Needed to Inform Policy

- Evidence is lacking on the effects of many long-standing demonstration programs
- No mechanism to determine that we know enough about the effects of a demonstration policy to say that it should either be incorporated into the state plan or not used at all
- Evaluations do not capture a demonstration's effects on other aspects of the health care system or safety net, which can be significant
- Evaluations may be limited in what they can tell us, even when they are robust and timely

Transparency and Public Comment

- States have the opportunity to use public comments to inform evaluation designs, and some states are actively doing so
- Evaluators, states, and CMS could improve transparency by more widely disseminating evaluation products

Improving the Quality and Timeliness of Section 1115 Demonstration Evaluations: Themes from Expert Roundtable

Medicaid and CHIP Payment and Access Commission

Kacey Buderi