IMPLICATIONS OF COVID-19 FOR SECTION 1115 DEMONSTRATION EVALUATIONS: CONSIDERATIONS FOR STATES AND EVALUATORS

Introduction

The Centers for Medicare & Medicaid Services (CMS) recognizes that the novel coronavirus (COVID-19) pandemic has the potential to have numerous impacts on section 1115 demonstration evaluations. CMS also appreciates that, for some states, it may be difficult to draw conclusions about the effects of demonstration policies because disentangling demonstration and pandemic effects will be challenging. CMS encourages states to continue to focus section 1115 demonstration evaluations on the effects of demonstration policies, as required by 42 CFR § 431.424 and the special terms and conditions of each demonstration. That said, states' evaluations should also provide an appropriate COVID-19 context.

Contents of this technical assistance document. To support state planning and decision making, this document outlines five evaluation activities that are likely to be affected by COVID-19, along with discussion questions that states and their evaluators can use as they consider how to proceed: (1) documenting demonstration implementation and evaluation changes, (2) collecting primary data, (3) using time trends and comparison groups, (4) isolating demonstration effects, and (5) interpreting findings.[1]

1. Documenting demonstration implementation and evaluation changes

The COVID-19 pandemic is likely to affect demonstration implementation in multiple ways, including by changing provider and beneficiary behavior and rapidly increasing the pool of Medicaid beneficiaries enrolled in demonstrations. For example, providers may have adopted telehealth strategies, changing service delivery and potentially health outcomes for demonstration beneficiaries in ways that might persist in the long term. In addition, the pandemic has caused some states to pause or delay implementation of approved section 1115 demonstration policies, such as monthly payment requirements. These implementation changes, in turn, may necessitate adjustments to evaluations.

Suggested topics and questions for state consideration. The following questions may be useful as states think through evaluation challenges caused by COVID-19 and engage with their evaluators:

- How will changes to the demonstration affect the logic models or driver diagrams that guide the evaluation? Are all expected demonstration outcomes the same as before the pandemic? What new modifying or confounding factors, such as use of telehealth, might change expected outcomes? Which of these new factors are likely to be temporary, and which are likely to be persistent?

[1] CMS acknowledges the contributions of members of the AcademyHealth Medicaid Demonstration Evaluation Learning Collaborative in providing invaluable input on the potential challenges for section 1115 demonstration evaluations due to the pandemic and on possible solutions.

- In what ways will demonstration implementation changes affect planned evaluation activities?
- How can states keep evaluators informed about demonstration changes? Are evaluators able to document changes to demonstration implementation so they can (1) consider how to amend planned evaluation activities and (2) use that information to interpret outcomes?
- How does the timing of the demonstration approval period interact with the timing of the pandemic? That is, did the demonstration start before, during, or after the pandemic, and what does that mean for the evaluation design? Are there opportunities to observe demonstration outcomes before the pandemic began?
- How can evaluators account for large numbers of new demonstration beneficiaries? Are new demonstration beneficiaries likely to differ from previously enrolled beneficiaries in systematic ways, and if so, should evaluators conduct subgroup analyses to understand how these beneficiaries interact with demonstrations?

2. Collecting primary data

The pandemic is likely to affect primary data collection—both interviews and surveys—in multiple ways. States may decide to update data collection plans to reflect respondent availability, the need to avoid in-person data collection, the need to update survey instruments to reflect changes to demonstration policies or the health care or economic landscape (for example, changes to employment opportunities given furloughs and layoffs), the likelihood of confounded responses (that is, different responses during the pandemic), and/or the need to update sample designs to account for newly enrolled beneficiaries or subgroups with disproportionately high pandemic impacts. Some states may experience high survey response rates because beneficiaries are easier to reach at home. However, beneficiaries' responses will undoubtedly be affected by the pandemic. Providers may be relatively difficult to survey or interview if they are busy with the pandemic response, although providers' availability and responsibilities are also changing rapidly.

States that planned to collect primary data in 2020 may decide to postpone it because of the factors noted above. Whether it is possible to postpone primary data collection and still use it as a data source for a given evaluation depends on the timing of the demonstration period—for example, it would not be possible to postpone a planned 2020 survey until 2021 and still use it for the evaluation of a current demonstration period that ends in 2020. In addition to timing considerations, states making the decision to postpone, change, or move forward with primary data collection must balance the budgetary impacts of changes, the usefulness of data collected, the burden to respondents, and the importance of primary data for the evaluation.

Suggested topics and questions for state consideration. Primary data collection requires a significant investment of evaluation resources. CMS encourages states to discuss the need to update data collection plans and the impact that might have on evaluation budgets with their evaluators. The following questions may be useful:

- What is the advice of evaluators on whether and how to postpone primary data collection? Does this vary by respondent type? Can data collection reasonably be postponed given unknown timing of the pandemic and the timing of the demonstration

period? What are the cost implications of timing changes and what priority should be placed on making such changes?

- Do survey instruments or interview discussion guides require updates to reflect changes to demonstration implementation or the health care or economic landscape (such as employment opportunities)? When will changes to demonstration activities be settled enough to redesign instruments? What are the cost implications of instrument changes and what priority should be placed on making such changes?
- How important is it to update survey samples to support subgroup analyses of newly enrolled beneficiaries and/or those with disproportionate pandemic impacts? How can evaluators define subgroups with disproportionate pandemic impacts for the purposes of changing the sample? What are the cost implications changing the sample design and what priority should be placed on making such changes?

3. Using time trends and comparison groups

All time trends—meaning changes in observed demonstration outcomes over time—will be affected by the pandemic, to varying degrees. Evaluation designs that use comparison groups, such as difference-in-differences and regression discontinuity designs, will be more robust than trends and time series designs because they help to adjust for changes brought about by the pandemic. However, strong comparison groups must be similar to demonstration groups, including in terms of their COVID-19 impacts. CMS recognizes that states and their evaluators may be unable to assess the similarity of COVID-19 impacts on demonstration and comparison groups because the full extent of these impacts is still unknown and the best ways to measure impacts are not yet settled. CMS further recognizes that some states using designs without a comparison groups may be unable to introduce one to their approved designs.

In some cases, using interrupted time series analysis may be a relatively robust approach, because this design uses many observations over a long period and does not require (1) a known trajectory for the pandemic or its effects or (2) a similar comparison group. CMS recommends that states avoid using pre/post designs, if possible.

Suggested topics and questions for state consideration. The following questions may be useful as states think through evaluation challenges caused by COVID-19 and engage with their evaluators:

- Which components of the planned evaluation design use comparison groups? Can evaluators feasibly assess the similarity of COVID-19 impacts on demonstration and comparison groups?
- If the evaluation design includes time-based designs, would evaluators recommend changing them to better account for the pandemic? How many observation periods can be included?
- Are there any opportunities to strengthen planned evaluation designs to account for the pandemic? If the evaluation design includes more than one analytic approach, should certain approaches receive greater focus?

4. Isolating demonstration effects

Because of the magnitude of the changes brought about by the pandemic, it will be challenging to isolate demonstration effects from pandemic effects. CMS acknowledges that, for some demonstration outcomes, pandemic effects will be much larger than demonstration effects were expected to be, making any demonstration effects impossible to observe. In those cases, states and their evaluators may judge that some planned impact analyses—depending on the timing of the pandemic during the demonstration approval period—are unlikely to produce viable evidence about demonstration effects and are not worth the resource investment. States and their evaluators should identify such demonstration outcomes and keep CMS informed with explanations of any corresponding modifications to planned evaluation activities. In such scenarios, states are still encouraged to provide data or trends that show changes to expected demonstration outcomes even if those outcomes are not attributable to demonstration policies.

Isolating demonstration effects may also be difficult if the beginning of the demonstration period coincides with the beginning of the pandemic. In that case, it will be unclear whether states should attribute observed changes to the demonstration or to the pandemic. Conversely, demonstrations ending in 2020 or those spanning 2020—for example, if data collection is planned for 2019 through 2021—may be able to exclude some months in 2020 from analyses of demonstration outcomes, or to conduct robustness checks to explore the effects of including peak pandemic months. Exact months to exclude may not be clear until more information about the trajectory of the pandemic becomes available.

Suggested topics and questions for state consideration. The following questions may be useful as states think through evaluation challenges caused by COVID-19 and engage with their evaluators:

- What is the relative expected magnitude of demonstration and pandemic effects for demonstration outcomes? Does it make sense to try to observe all planned demonstration outcomes, or only some?
- Do evaluators expect to be able to isolate demonstration effects to support conclusions about demonstration policies, and if so, how do they plan to do this?
- What covariates (measures) might be related to the pandemic, but not to the demonstration, and therefore appropriate to use as controls?
- If evaluators expect to proceed with planned analyses, is it feasible to drop certain months from those analyses, or to conduct robustness checks that assess the effect of including or excluding them?

5. Interpreting findings

Finally, even if states and their evaluators can adjust evaluation approaches in some of the ways suggested above, the severity of pandemic impacts will require cautious interpretation of observed outcomes. CMS requests that all interim and summative evaluation reports include discussions of potential confounding from the pandemic for each observed outcome or set of findings. Careful interpretation of findings is especially important because best practices for isolating demonstration effects in the context of the pandemic are not settled and because isolating demonstration effects may not be feasible for all demonstrations.

Conclusion

For states with evaluation designs that have already been approved by CMS, or are close to approval, CMS will not require states to seek formal approval of changes to those evaluation designs. CMS requests that states document demonstration implementation changes caused by the pandemic and the challenges they create for planned evaluation activities as that information becomes available. States should document this information in monitoring report narratives. If states are considering changes to evaluation activities, those changes should also be documented in monitoring reports. In addition, states and their evaluators should include in their interim and summative evaluation reports a summary of the demonstration changes that occurred as a result of the pandemic and any differences between approved and executed evaluation designs. States that would like to discuss changes to timelines for evaluation deliverables should contact their CMS demonstration team, copying the mailbox 1115MonitoringandEvaluation@cms.hhs.gov.

Section 1115 demonstration evaluations are complex, resource-intensive endeavors. CMS understands the challenges that states and their evaluators are facing as they plan and carry out evaluations and consider alterations in response to the pandemic. CMS encourages states and their evaluators to openly discuss these challenges with each other and with CMS as needed.