July 6, 2020

CMS, Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850.

RE: CMS-10341, Information Collection: Section 1115 Demonstration Projects Regulations at 42 CFR 431.408, 431.412, 431.420, 431.424, and 431.428

To Whom It May Concern:

The National Health Law Program (NHeLP) works on behalf of low-income and historically marginalized individuals and families. NHeLP advocates, educates, and litigates at the federal and state levels to advance health and civil rights in the United States.

NHeLP has a particular interest in Section 1115 demonstration projects. We have clients who are part of Section 1115 projects. Some of these clients have filed lawsuits in federal court challenging CMS's approval of particular projects. We have also witnessed state Medicaid programs' increasing reliance upon Section 1115 projects over the years—even as the Government Accountability Office has repeatedly provided evidence of inadequate, conflicting, and confusing assessment of these projects. As such, NHeLP has an interest in the information states must provide when requesting approval for, or implementing Section 1115 demonstrations. We have routinely commented on Section 1115 projects and, like other stakeholders and members of the public, are "Information Users" of the information collection CMS seeks to extend.

We offer the following suggestions:

I. Necessity and utility of the proposed information collection

NHeLP agrees that information collection CMS-10341 is "necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects." The existing collection, however, does not sufficiently address all legal requirements. For example:

Coverage loss estimates

Federal statute requires that states provide information regarding "coverage projections" as part of an initial application for or a request to extend a Section 1115 demonstration project.[1] 42 C.F.R. § 431.408(a)(1)(i)(C) specifies that states must include "[a]n estimate of the expected increase or decrease in annual enrollment."[2] States have sometimes failed to provide these estimates.[3] CMS should ensure that the information collection includes a requirement that a state provide enrollment projections for the proposed demonstration.

Specify provisions waived

States are required to include in 1115 applications a list of the waiver authorities necessary for the waiver.[4] Often, however, applications for Section 1115 demonstration projects do not specify with precision which provisions of 42 U.S.C. § 1396a they seek to waive. We encourage CMS to require states to include in their applications a waiver list that identifies the specific statutory provisions the state is asking to waive and for what purpose they seek the waiver, including an explanation of why that purpose cannot be achieved through a state plan amendment.

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[1] 42 U.S.C. § 1315(d)(2)(B)(ii). *See also* 42 C.F.R. §§ 431.400(a)(1)(ii)(B).
[2] *See also* 42 C.F.R. §§ 431.412(a)(1)(iii), (c)(2)(vii).
[3] *See, e.g.*, NHeLP, Comments on Arizona 1115 Demonstration Extension (Feb. 3, 2021), available at https://healthlaw.org/wp-content/uploads/2021/02/NHeLP-Comments-to-AZ-AHCCCS-Extension-02.03.2021.pdf; NHeLP, Comments on Amendment to Arkansas Works 1115 Demonstration (Aug. 10, 2017), available at https://healthlaw.org/resource/nhelp-comments-on-arkansas-amended-sec-1115-waiver-project/.
[4] 42 C.F.R. §§ 431.412(a)(1)(vi) (initial applications), (c)(2)(iii) (extension applications).

Proposed hypotheses, research design, and evaluation plans

The state must propose to conduct an "experimental, pilot, or demonstration" project. To evaluate whether a proposed project is a valid experiment, the Secretary needs to know what will be tested and how, at the point in time when the project is approved. "[T]he Secretary must make at least some inquiry into the merits of the experiment—she must determine that the project is likely to yield useful information or demonstrate a novel approach to program administration."[5] Accordingly, when submitting an application for a Section 1115 demonstration project states should include a comprehensive description of their hypotheses and research design. Likewise, when a state proposes an amendment to the project, the state should update its hypotheses and research design to reflect the amendment.[6] CMS should update this information collection to ensure that states provide sufficient information regarding the state's hypotheses, research design, and evaluation plans to enable CMS and the public's review.

Analysis of racial equity impacts

President Biden has set an administrative priority to "pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality."[7] Accordingly, each federal agency "must assess whether, and to what extent, its programs and policies perpetuate systemic barriers to opportunities and benefits for people of color and other underserved groups. Such assessments will better equip agencies to develop policies and programs that deliver resources and benefits equitably to all."[8]

CMS should require states to provide a detailed analysis of the racial equity impacts of their demonstration projects, at initial application, extension, and amendment. This country has a notorious history of unethical experimentation on Black, Indigenous, and

[5] *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994).
[6] *See* U.S. Gov't Accountability Office, *Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency* (2019), https://www.gao.gov/assets/gao-19-315.pdf.
[7] Exec. Order No. 13,895, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 Fed. Reg. 7009 (Jan. 20, 2021).
[8] *Id.*

other people of color.[9] Section 1115 demonstration projects, which seek to conduct experiments on people receiving Medicaid coverage (who typically cannot opt out of the project), can easily reinforce and continue this history by exacerbating racial inequities in health coverage and health outcomes, unless special care is taken to prevent those harms.[10] Accordingly, CMS should require states to provide information sufficient for the Secretary to evaluate the racial equity impacts of their Section 1115 projects.

Final evaluations

Although final evaluations should be submitted for every demonstration,[11] "CMS has historically not required states to submit final, comprehensive evaluation results at the end of each demonstration cycle."[12] Instead CMS has allowed states to submit only interim evaluations. But these interim evaluations serve a different purpose from comprehensive, final evaluations. The interim evaluations typically are "based on more limited data from the early years of the demonstration cycle," and unlike a final evaluation, lack "evidence on outcomes and impacts."[13] The information collection appears to reinforce this problematic practice: it does not include any burden estimates regarding final, comprehensive evaluations, instead estimating only the time to develop

[9] *See generally*, Harriet A. Washington, *Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present* (2006); Native American Center for Excellence, *Steps for Conducting Research and Evaluation In Native* Communities, 5 https://www.samhsa.gov/sites/default/files/nace-steps-conducting-research-evaluation-native-communities.pdf (last accessed July 6, 2021); Jane Lawrence, "The Indian Health Service and the Sterilization of Native American Women," 24 AM. INDIAN QUARTERLY 400 (2000), available at www.jstor.org/stable/1185911.

[10] *See* ASPE Office of Health Policy, *Medicaid Demonstrations and Impacts on Health Coverage: A Review of the Evidence*, 1, 3-5 (2021) https://aspe.hhs.gov/system/files/pdf/265161/medicaid-waiver-evidence-review.pdf; *see also, e.g.*, NHeLP Comments on Arizona 1115 Demonstration Extension, 36 (Feb. 3, 2021), https://healthlaw.org/resource/nhelp-comments-to-arizona-ahcccs-extension-application-2021/; Dylan Scott, "How Medicaid work requirements can exempt rural whites but not urban blacks," Vox (May 3, 2018), https://www.vox.com/policy-and-politics/2018/5/3/17315382/medicaid-work-requirements-michigan-race.

[11] *See* 42 C.F.R. § 431.424(c)(2)(v) (requiring evaluation plans to include "a proposed date by which a final report on findings from evaluation activities conducted under the evaluation plan must be submitted to CMS").

[12] Gov't Accountability Office, *Medicaid Demonstrations: Evaluations Yielded Limited Results, Underscoring Need for Changes to Federal Policies and Procedures*, 15, 18 (2018), https://www.gao.gov/assets/gao-18-220.pdf.

[13] *Id.* at 18.

an evaluation plan and an interim evaluation report. CMS should update the information collection to include information regarding the final, comprehensive evaluations described in the regulations.

Amendments

The information collection only discusses requirements relating to "applications for and extensions of" Section 1115 demonstration projects. It does not discuss information collection for proposed amendments. We have seen, however, a trend of states submitting proposed "amendments" to an existing project that are, in substance, applications for significantly different projects, with components unrelated to the existing project.[14] CMS should extend the required information collections to amendments and strengthen its initial review to consistently require states to submit new applications when requesting components unrelated to the existing project.

II. Ways to enhance the quality, utility, and clarity of the information to be collected

We also offer the following suggestions for improving the quality, utility, and clarity of the information collected.

Enhance budget neutrality description

Currently the description of anticipated costs and savings associated with a proposed Section 1115 project are opaque and difficult to understand. We recommend that CMS modify the information collection to improve transparency regarding budget neutrality calculations. At a minimum, states should:

[14] *See, e.g.*, NHeLP, Comments on TennCare II Demonstration (Nov. 26, 2019), available at https://healthlaw.org/resource/letter-to-cms-concerning-tenncare-ii-demonstration/; NHeLP, Comments on Amendments to Utah's Primary Care Network Demonstration Project (Sept. 29, 2017) https://healthlaw.org/resource/nhelp-comments-on-utahs-sec-1115-waiver-project/. *See also* U.S. Government Accountability Office, *Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency*, 24 (2019), https://www.gao.gov/assets/gao-19-315.pdf.

(1) include all assumptions used to set the baseline cost estimates, including specifying whether the state expects to rebase its cost estimates when requesting an extension,

(2) specify what trend rates the state is using to calculate expected growth in program costs, and

(3) specify the amount of anticipated savings, and if any, how the state plans to use the savings.[15]

Require Estimates of Administrative Costs

States can incur substantial administrative costs when implementing Section 1115 projects.[16] For instance, some projects require changes to the state's information technology or eligibility systems. Others require an increase in case worker review. Yet, currently, CMS does not require states to estimate administrative costs.[17] We encourage CMS to require states to include an estimate of the expected administrative costs associated with the demonstration project in a separate line item.

Strengthen quality of evaluations

While CMS has issued some guidance regarding how states design their evaluations, we recommend additional ways states could improve their evaluation design to avoid methodological weaknesses and increase the usefulness of the evaluations.[18]

First, CMS should require a state's evaluation design to include reporting outcomes separately for each population impacted by a project. We have noticed that some

[15] *See generally* Gov't Accountability Office, *Medicaid Demonstrations: Federal Action Needed to Improve Oversight of Spending*, 18-19 (2017), https://www.gao.gov/products/gao-17-312.
[16] *See, e.g.*, Jennifer Wagner & Judith Solomon, Ctr. on Budget & Pol. Priorities, *States' Complex Medicaid Waivers Will Create Costly Bureaucracy and Harm Eligible Beneficiaries* (2018), https://www.cbpp.org/research/health/states-complex-medicaid-waivers-will-create-costly-bureaucracy-and-harm-eligible.
[17] *See generally* Gov't Accountability Office, *Medicaid Demonstrations: Actions Needed to Address Weaknesses in Oversight of Costs to Administer Work Requirements* (2019), https://www.gao.gov/assets/gao-20-149.pdf.
[18] *See also* Gov't Accountability Office, *Medicaid Demonstrations: Evaluations Yielded Limited Results, Underscoring Need for Changes to Federal Policies and Procedures* (2018), https://www.gao.gov/assets/gao-18-220.pdf.

evaluations do not provide this disaggregated data, which minimizes the utility of the evaluations.

Second, CMS should require an evaluation design to test each individual component of the waiver, as well as the waiver as a whole. In the past, CMS has approved amendments without requiring updates to the evaluation plan to address the new components.[19] Failure to include evaluations of each component undermines the ability to draw any useful conclusions from the demonstration – which is a central purpose of Section 1115.

Standardize how states address comments from the state-level comment period

States are required to provide a "report of the issues raised by the public during the [state] comment period" and describe "how the State considered those comments when developing the demonstration application."[20] There is wide variation among states regarding how they share information regarding the state public comment period. Some states attach copies of all comments to their 1115 applications, others merely summarize the main concerns raised. Likewise, some states provide individualized responses to comments, while others provide only generalized answers. We suggest CMS provide guidance to states that they should provide individualized responses to each concern or suggestion raised in the comments and explain how the state considered the comments. Such guidance, if issued, would affect the nature and scope of CMS's information collection.

III. Burden estimates

The existing burden estimates do not sufficiently account for the scope of information states should be providing as part of their 1115 applications.

First, as discussed above, CMS's information collection does not include any discussion of the time it would take a state to complete the final, comprehensive evaluations required at the end of a demonstration cycle. CMS should incorporate final evaluations into its information collection.

[19] *See* U.S. Gov't Accountability Office, *Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency*, 23 n. 28-29 (2019), https://www.gao.gov/assets/gao-19-315.pdf.
[20] 42 C.F.R. § 431.412(a)(1)(viii).

Second, 70 hours annually, per demonstration, to conduct the ongoing reviews of implementation required by 42 C.F.R. § 431.420(b) seems far too low. This reflects less than two full work weeks for an individual employee to monitor the implementation of what can be complex and state-wide demonstrations with multiple components, impacting hundreds of thousands of Medicaid beneficiaries. CMS should set the expectation that ongoing monitoring and implementation will be a more rigorous activity requiring more time from states, as Section 1115 projects should not reflect "business as usual" for a state.

Third, even assuming the continued heavy role of consultants, 160 hours to develop an evaluation plan for a new demonstration or an interim evaluation report is too low to prepare a rigorous evaluation design. More time is needed to ensure that states' evaluations meet standard research norms and will produce objective, quantitative data on the demonstration's outcomes, rather than descriptive or summary information.

Fourth, CMS should increase its burden estimates for developing and publishing the notices for a state public comment period to capture the time it takes to conduct the required public hearings and to meaningfully review and respond to public comment.

Finally, because the initial applications and extension applications should include more robust information regarding evaluation design and costs those time estimates likely need to be increased as well.

We appreciate your consideration of our comments. If you have questions about these comments, please contact Sarah Grusin (grusin@healthlaw.org) or me.

Respectfully submitted,

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