Section 1115 Waiver Requirements: Transparency and Opportunity for Public Comment

By Catherine McKee & Jane Perkins

Under § 1115 of the Social Security Act, the Secretary of the Department of Health & Human Services (HHS) may waive certain Medicaid requirements (those that appear in 42 U.S.C. § 1396a) to enable a state to implement an experimental, pilot, or demonstration project that is likely to assist in promoting the objectives of the Medicaid Act.[1] The Secretary may grant such a waiver to the extent and for the period necessary to enable a state to carry out the project.[2]

For decades, states and the Centers for Medicare & Medicaid Services (CMS) developed § 1115 demonstrations behind closed doors with little public oversight.[3] However, the Affordable Care Act amended § 1115 to require greater transparency and opportunity for public comment regarding any waiver request that would impact "eligibility, enrollment, benefits, cost-sharing, or financing."[4] In particular, the ACA directed HHS to promulgate regulations outlining a public notice and comment period at

[1] 42 U.S.C. § 1315(a).
[2] *Id*. For more information, *see* Jane Perkins, Nat'l Health Law Prog., *Background to Medicaid and Section 1115 of the Social Security Act* (Apr. 3, 2017), http://www.healthlaw.org/publications/browse-all-publications/background-to-medicaid-section-1115-social-security-act#.WOvXj6KkKio.
[3] *See, e.g.*, U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-6-94R, MEDICAID DEMONSTRATION WAIVERS: LACK OF OPPORTUNITY OR PUBLIC INPUT DURING FEDERAL APPROVAL PROCESS STILL A CONCERN (2007), http://www.gao.gov/assets/100/95034.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-02-817, MEDICAID AND SCHIP: RECENT HHS APPROVALS OF DEMONSTRATION WAIVER PROJECTS RAISE CONCERNS (2002), http://www.gao.gov/assets/240/235108.html.
[4] Pub. L. No. 111-148, § 10201(i), 124 Stat. 119, 917 (adding 42 U.S.C. § 1315(d)) (Mar. 23, 2010).

both the state and the federal levels that is "sufficient to ensure a meaningful level of public input."[5] HHS finalized these regulations in 2013.[6]

This Issue Brief: (1) outlines the process that states and CMS must follow when developing, reviewing, and approving a waiver request under § 1115; (2) describes requirements for monitoring approved demonstrations; and (3) highlights steps that advocates should take to ensure that states and CMS consider the proposal's potential effects on Medicaid enrollees.[7]

The importance of the transparency and public accountability requirements has never been greater, as the Secretary of HHS recently expressed a desire to approve demonstrations that include work requirements, eliminate retroactive or presumptive eligibility, and/or impose greater premiums or cost-sharing than allowed under the Medicaid Act.[8]

Application and Approval Process

State Notice/Comment & Public Hearing Period

Before submitting an application for an initial demonstration or an application to extend an existing demonstration, states must provide a 30-day public notice and comment period.[9]

[5] 42 U.S.C. § 1315(d)(2)(A), (C).
[6] Dep't of Health & Human Servs., Medicaid Program; Review and Approval Process for Section 1115 Demonstrations; Application, Review, and Reporting Process for Waivers for State Innovation; Final Rules, 77 Fed. Reg. 11,678 (Feb. 27, 2012) (codified at 42 C.F.R. Pt. 431).
[7] Under the Administrative Procedure Act, a reviewing court must set aside agency action, findings, and conclusions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Thus, when reviewing a waiver request under § 1115, HHS must consider all relevant factors. *See Newton-Nations v. Betlach*, 660 F.3d 370 (9th Cir. 2011) (finding agency approval of Medicaid waiver arbitrary and capricious where administrative record failed to show that Secretary considered whether the project had an experimental purpose and would likely promote the objectives of the Medicaid Act); *Wood v. Betlach*, 922 F. Supp. 2d 836 (D. Ariz. 2013) (finding agency approval of Medicaid waiver arbitrary and capricious where there was no evidence that Secretary considered expert comments that the proposed project had no experimental purpose).
[8] Letter from Thomas E. Price, Secretary, Dep't of Health & Human Servs. & Seema Verma, Admin., Dep't of Health & Human Servs., Ctrs. For Medicare & Medicaid Servs., to Governors (Mar. 15, 2017).
[9] 42 C.F.R. § 431.408(a).

States must issue a public notice that contains a "comprehensive description" of the application and "a sufficient level of detail to ensure meaningful input from the public."[10] The notice must include:

- The program description, goals, and objectives, including a description of beneficiaries who will be affected by the demonstration;
- The proposed health care delivery system and eligibility requirements, benefit coverage, and cost sharing required of individuals, and how such provisions differ from those in the current program;
- An estimate of the expected change in annual enrollment and annual aggregate expenditures, including historic enrollment or budget data (and for a request for an extension, a financial analysis of any requested changes to the demonstration);
- The hypothesis and evaluation parameters of the demonstration; and
- The specific waiver and expenditure authorities that the state believes are necessary to authorize the demonstration.[11]

The notice must also inform members of the public where copies of the application are available, where to send and review written comments on the application, the deadline for commenting, and when and where the state will hold public hearings on the application.[12]

States must publish information about the public notice and comment process and the planned hearings, as well as the demonstration application itself and a link to the CMS demonstration website, in a prominent location on either the main page of the state Medicaid agency website or a website established for the demonstration.[13] In addition, at least 30 days before submitting the application to CMS, the state must publish an abbreviated notice in the state's administrative record (in accordance with the state's Administrative Procedure Act) or in the newspapers of widest circulation in each city with a population of 100,000 or more.[14] The state must use additional mechanisms, such as an email list, to disseminate the notice to interested parties.[15]

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[10] *Id.* § 431.408(a)(1)(i).
[11] *Id.*
[12] *Id.* § 431.408(a)(1)(ii)-(iv).
[13] *Id.* § 431.408(a)(2)(i). If the state uses a website established for the demonstration, it must be linked in a "readily identifiable way" to the main page of the state Medicaid agency website. *Id.* The website must remain up-to-date throughout the public comment and review process. *Id.*
[14] *Id.* § 431.408(a)(2)(ii) (noting the required contents of the abbreviated notice).
[15] *Id.* § 431.408(a)(2)(iii).

At least 20 days before submitting an application, the state must hold at least two public hearings, on separate dates and at separate locations, during which "members of the public throughout the state have an opportunity to provide comments" on the demonstration application.[16] When holding the hearings, the state must use at least two of the following public forums: (1) the Medical Care Advisory Committee (MCAC);[17] (2) a commission or other similar process, where meetings are open to the public; (3) a state legislative process that would give interested parties the chance to learn about the application and to comment; or (4) a similar process for public input.[18] For at least one of the hearings, the state must allow individuals to attend by phone or by internet, unless the state can document that it has given people throughout the state a chance to participate in some other way.[19]

Tribal Consultation

In addition, before submitting an application for a demonstration that would have a direct effect on Indians, tribes, Indian health programs, or urban Indian health organizations in the state, the state must consult with these affected entities.[20] The state must document these activities in its application.[21]

Application Contents and Timing

States must follow detailed requirements regarding the contents of an application for an initial demonstration or extension, as well as the timing of an extension.

Initial Demonstration Application

To be considered complete, an application for initial approval of a demonstration project must include:

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[16] *Id*. § 431.408(a)(3).
[17] See *id*. § 431.12. *See also* Nat'l Health Law Prog., *Medicaid Medical Care Advisory Committees (MCAC): The Basics for Consumers* (2004), http://www.healthlaw.org/issues/medicaid/medical-care-advisory-mcac-fact-sheet-what-is-the-mcac#.WPD_JdIrJhE.
[18] 42 C.F.R. § 431.408(a)(3).
[19] *Id*. Holding the two hearings in different areas of the state would meet this requirement. *Id*.
[20] *Id*. § 431.408(b)(1). *See also* § 431.408(b)(2) (describing which documents govern the consultation process).
[21] In particular, the application must describe the notification process, the entities involved in the consultation(s), the date(s) and location(s) of the consultation(s), issues raised, and the potential resolution of such issues. *Id*. § 431.408(b)(3).

- A comprehensive description of the demonstration, including goals and objectives;
- A description of the proposed health care delivery system, eligibility requirements, benefit coverage, and cost sharing, to the extent these features differ from the current program features and the requirements of the Medicaid Act;
- An estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures, including historic enrollment or budget data;
- Current enrollment data and enrollment projections expected over the term of the demonstration for each category of beneficiary affected by the demonstration;
- Other Medicaid and CHIP program features that the demonstration would change;
- The specific waiver and expenditure authorities that the state believes are necessary to authorize the demonstration;
- The research hypotheses that are related to the demonstration's proposed changes, goals, and objectives; a plan for testing the hypotheses in an evaluation; and if a quantitative evaluation design is feasible, appropriate evaluation indicators; and
- Documentation of the state's compliance with the public notice/comment and hearing requirements, with a report indicating the issues raised during the comment period and how the state considered those comments when developing its application.[22]

CMS may request, or the state may propose, modifications to the application. If the modifications result in substantial changes to the original demonstration design, the regulations provide that CMS may, at its discretion, direct an additional 30-day public comment period.[23] Notably, the regulations make clear that they do not preclude a state from conferring with CMS about a possible demonstration or from submitting a concept paper before submitting a complete application.[24]

Extension Application

The statute also contains timeframes for states to submit a request to extend an existing demonstration. For an initial extension of a state-wide comprehensive demonstration, the state must submit the extension request during the six-month period ending one year before the demonstration would otherwise expire.[25] For a subsequent extension (and unless the waiver approval indicates a different timeframe), the state must submit

[22] 42 C.F.R. § 431.412(a)(1).
[23] *Id.* § 431.412(a)(2).
[24] *Id.* § 431.412(a)(3).
[25] 42 U.S.C. § 1315(e)(2); *see also* 42 C.F.R. § 431.412(c).

the request at least 120 days before the extended demonstration would otherwise expire.[26]

A state may request an extension of up to 3 years, or for waivers involving individuals eligible for both Medicaid and Medicare, of up to 5 years.[27] To be considered complete, an extension application must include:

- A historical narrative summary of the demonstration, including the initial objectives of the project, evidence of how these objectives have or have not been met, and the future goals of the project;
- If the state asks for changes, a narrative of the changes and the objective and desired outcome of each change;
- A list and description of the waivers and expenditure authorities requested, or a statement that the state is requesting the same waiver and expenditure authorities approved in the current demonstration;
- Summaries of external quality review organization (EQRO) reports, managed care organization (MCO) and state quality assurance monitoring, and any other documentation of the quality of and access to care provided under the demonstration, such as the CMS Form 416 EPSDT/CHIP reports;
- Financial data demonstrating the state's historical and projected expenditures for the period of the extension, as well as cumulative expenditures over the lifetime of the demonstration and including a financial analysis of any requested changes to the demonstration;
- A report of evaluation activities and findings to date, plans for evaluation activities during the extension period, and if changes are requested, identification of research hypotheses related to the changes and an evaluation design for addressing the proposed changes; and
- Documentation of the state's compliance with the state public notice and comment process, as well as the post-award public input process, with a report of the issues raised during the comment periods and how the state considered the comments when developing the demonstration extension application.[28]

As is the case with an application for an initial demonstration, CMS may request, or the state may propose, modifications to an extension application. If the modifications result in substantial changes to the original demonstration design, the regulations provide that CMS may, at its discretion, direct an additional 30-day public comment period.[29] In addition, if an extension application would make substantial changes to the existing

[26] 42 U.S.C. § 1315(f)(1); *see also* 42 C.F.R. § 431.412(c).
[27] 42 U.S.C. § 1315 (e)(2), (f)(6).
[28] 42 C.F.R. § 431.412(c)(2).
[29] *Id.* § 431.412(c)(3).

demonstration, the regulations provide that CMS may, at its discretion, treat the request as an initial application for a new demonstration.[30] This would allow CMS to conduct a longer and more thorough review of the request, as described below.

Federal Notice/Comment Period

After receiving an application, CMS has 15 days to send a letter to the state either: (1) indicating that the application is incomplete and listing the missing elements; or (2) acknowledging receipt of a complete application, noting the date on which it was received, and informing the state of the start date of the 30-day federal public notice and comment period.[31] If the letter does the later, CMS must post the letter on its website within that same 15-day timeframe.[32] Sending the letter does not preclude CMS from determining that, based on further review, additional information is required from the state.[33]

In addition to the letter initiating the 30-day comment period, CMS must post to its website the demonstration application (including supporting documents and concept papers submitted as part of the application), the proposed effective date of the demonstration, and information about where members of the public may send questions or comments.[34] CMS must also use an email list or similar mechanism to inform interested parties of the 30-day federal comment period.[35]

CMS will review all comments received during the 30-day period but will not provide written responses.[36] CMS must publish all written comments on its website or an alternative website.[37] At regular intervals, the agency must also publish relevant information about the demonstration application, which may include status updates and a list of the issues raised during the public comment period.[38]

In addition, CMS must maintain and publish on its website a complete administrative record, which may contain: the demonstration application; written public comments sent to CMS; if CMS approves the application, the final special terms and conditions and list

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[30] *Id.* § 431.412(c)(1).
[31] *Id.* §§ 431.416(a), 431.412(b)(1)-(2).
[32] *Id.* § 431.416(a)(2).
[33] *Id.* § 431.412(b)(1)(ii). CMS must publish on its website at regular intervals the status of a demonstration application, including information received from the state while the state works with CMS to meet the application requirements outlined in the regulations. *Id.* § 431.412(b)(3).
[34] 42 C.F.R. § 431.416(b)(1).
[35] *Id.* § 431.416(b)(2).
[36] *Id.* § 431.416(d)(2).
[37] *Id.* § 431.416(d)(1).
[38] *Id.* § 431.416(c).

of Medicaid provisions that have been waived; the award letter or letter of disapproval; the state acceptance letter; progress and evaluation reports; specific requirements related to the special terms and conditions; any notice of suspension or termination of the demonstration; and any other relevant documents.[39]

CMS Review and Approval Process

In general, CMS is not permitted to make a final decision on any application until at least 45 days after sending a letter to the state initiating the federal public comment period.[40] However, CMS may grant a temporary extension for the period during which an extension application is under review, without regard to when the state submitted the application.[41] In addition, CMS may waive any part of the state or federal notice and comment process to expedite a decision on a demonstration application designed to address unforeseen circumstances resulting from a natural disaster, public health emergency, or other sudden emergency that directly threatens human lives.[42] When CMS grants a request for a disaster exemption, it must post its decision, as well as the revised timeline for public comment and/or post-award procedures, to its website within 15 days.[43]

CMS must complete its review of an extension application within a particular timeframe. With respect to an application for an initial extension of a state-wide comprehensive demonstration, if CMS fails to make a final decision within six months after the state

[39] *Id.* § 431.416(f). Notably, the record may not contain documentation of requests from CMS to the state for additional information and the state's responses to those requests. In the preamble to the final regulations, CMS stated: "While we are committed to promoting greater transparency during the demonstration review process, we also need to protect frank and candid discussions between the State and CMS. While a demonstration application is under review, we believe that publication of these discussions would inhibit the free flow of information." 77 Fed. Reg. at 11,686. However, in later guidance, CMS indicated that it would publish "formal questions that are sent to the state, as well as the State's responses" on its website as part of the administrative record. CMS, Dear State Health Official Letter (Apr. 27, 2012).

[40] 42 C.F.R. § 431.416(e).

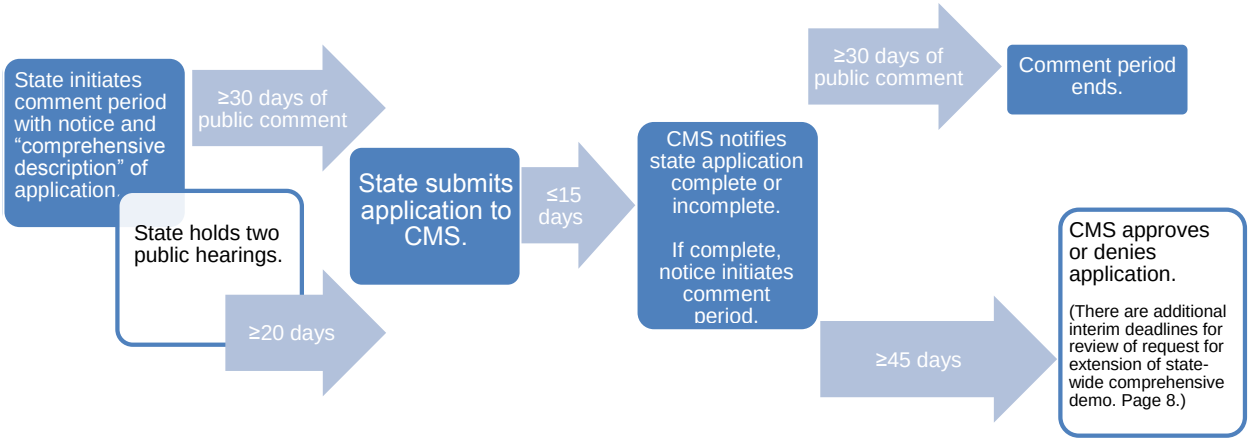
[41] *Id.* § 431.412(c)(4).

[42] *Id.* § 431.416(g). To receive a disaster exemption, the state must show that: (1) it acted in good faith and in a diligent, timely, and prudent manner; (2) the circumstances constitute an emergency that could not have been reasonably foreseen; and (3) delay would undermine or compromise the purpose of the demonstration and be contrary to the interests of beneficiaries. *Id.* § 431.408(g)(3). The state is still expected to follow the basic requirements related to the contents of the application and the process for its submission to CMS. *Id.* § 431.408(g)(2)(i).

[43] *Id.* § 431.408(g)(4).

submits an application, the extension is deemed to have been granted.[44] In general, CMS must approve an initial extension on the same terms and conditions as the original waiver. However, if one of the original conditions was that the project be budget neutral, CMS must make whatever changes are necessary to ensure that the project remains budget neutral during the extension.[45]

As for an application for a subsequent extension of a state-wide comprehensive demonstration, CMS must inform the state if it intends to review the terms and conditions of the demonstration within 45 days of receiving the request. If CMS plans to do so, it must provide a second notice, within 45 days of the first, informing the state of proposed changes to the terms and conditions.[46] CMS and the state then have 30 days to agree upon revised terms and conditions.[47] If CMS fails to provide the first or second notice, the request is deemed approved.[48] CMS must issue a final decision on the request no more than 120 days after the state filed its application, unless the Governor has agreed to a later deadline. If CMS does not make a decision within 120 days (or by the later deadline agreed upon), the application will be deemed approved.[49]



[44] 42 U.S.C. § 1314(e)(3).
[45] *Id.* § 1315(e)(6)-(7). In addition, for both initial and a subsequent extension request, the deadline for submittal of a final report under the waiver shifts to one year after the waiver project would have otherwise expired. CMS must then release an evaluation of the project within a year after receiving the final report. § 1315(e)(4)-(5), (f)(7).
[46] *Id.* § 1315(f)(2)-(3).
[47] *Id.* § 1315(f)(4).
[48] *Id.* § 1315(f)(2)-(3).
[49] *Id.* § 1315(f)(5)(B).

Monitoring and Enforcement

Unless CMS expressly grants a waiver of a provision in § 1396a when approving a demonstration application, the state must continue to comply with the provision.[50] In addition, states must comply with the special terms and conditions of the demonstration.[51] The regulations establish reporting and monitoring procedures designed to ensure that CMS has adequate information concerning both a state's compliance with these requirements and the effectiveness of the demonstration.

Post-Award Public Forums & Annual Reports

The state must perform periodic reviews of the demonstration. Within six months after implementation begins, and on an annual basis thereafter, the state must hold a public forum to solicit comments on the demonstration's progress.[52] The state must publish the date, time, and location of the public forum in a prominent location on the state's website at least 30 days in advance.[53] If CMS receives a complaint that a state is failing to comply with special terms and conditions, it will review the complaint and share it with the state.[54]

In addition, the state must submit an annual report to CMS. Among other things, the annual report must include: outcomes of care, quality of care, cost of care, and access to care for demonstration populations; the results of any beneficiary satisfaction survey conducted during the reporting year; beneficiary grievances and appeals; and all public comments received during the post-award public forum.[55] Unless otherwise specified in the special terms and conditions, the state must submit a draft annual report to CMS within 90 days after the end of each demonstration year and post the draft report on its website within 30 days after submission.[56] The state must submit the final report to CMS within 60 days of receiving CMS's comments on the draft.[57] Once CMS approves the final report, the state has 30 days to post it on its public website.[58]

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[50] 42 C.F.R. § 431.420(a)(1).
[51] *Id.* § 431.420(a)(2).
[52] *Id.* § 431.420(c)(1). The state must use an MCAC, a commission, or other similar process for the public forum. *Id.* § 431.420(c)(3)(i)-(ii).
[53] *Id.* § 431.420(c)(3)(iii).
[54] *Id.* § 431.420(b)(2)-(3).
[55] *Id.* § 431.428(a).
[56] *Id.* § 431.428(b).
[57] *Id.* § 431.428(b)(1).
[58] *Id.* § 431.428(b)(2).

Evaluations

Given that CMS grants § 1115 waivers to enable states to pilot or experiment with new approaches, states must evaluate the results of an approved demonstration and make that evaluation available to the public.[59] CMS must post or provide a link to all evaluation materials, including research and data collection, on its website within 30 days of receiving the materials from the state.[60]

Prior to conducting an evaluation, states must submit an evaluation design plan to CMS and post the plan to its public website within 30 days of CMS approval.[61] Notably, the regulations do not require the state or CMS to give the public an opportunity to comment on the design plan. However, as highlighted above, states must include some information about the evaluation in its application materials.[62] Thus, the state and federal public notice and comment periods provide an opportunity for members of the public to raise suggestions or concerns about evaluation methods and prior evaluation results.

Enforcement

The Secretary may suspend or terminate all or part of a demonstration if the state has "materially failed to comply" with the special terms and conditions. The Secretary may also withdraw approval after finding that a project is not in fact likely to achieve the purposes of the Medicaid Act.[63]

In addition, the statue requires the Secretary to submit a report to Congress each year that outlines action taken on § 1115 applications.[64]

Conclusions and Steps for Advocates

Given these requirements, advocates have the opportunity to be involved in the design and review of § 1115 waiver requests. Obviously, the earlier that you get involved, the

[59] *See id*. § 431.424.
[60] *Id*. § 431.424(g).
[61] *Id*. § 431.424(c), (e). The deadline for this submission should be included in the special terms and conditions.
[62] *Id*. §§ 431.408(a)(1)(D) (state public notice); 431.412(a)(1)(vii) (initial application); 431.412(d)(2)(vi) (extension application); 431.424(d) (extension application must include interim evaluation).
[63] *Id*. § 431.420(d)(1)-(2). The terms and conditions must detail a state's notice and appeal rights in the event of termination, suspension, or withdrawal of waivers or expenditure authorities. *Id*. § 431.420(d)(3).
[64] 42 U.S.C. § 1315(d)(3).

better. Listed below are some steps you can take to obtain information about and ultimately influence § 1115 activity in your state:

1. Monitor your state Medicaid agency website and the CMS website for developments. Also, contact Medicaid agency staff and ask to be included on email lists used to alert interested parties about § 1115 activity.

Be aware that, in the past, in an effort to avoid the transparency requirements outlined in the regulations, states have characterized an application for a new demonstration or an application for an extension of an existing demonstration as nothing more than an "amendment" to an existing demonstration.[65] If your state does this, submit comments on the "amendment" directly to the Secretary of HHS and, if applicable, state legislators responsible for oversight of the Medicaid program, and explain in your comments how the state failed to comply with the transparency requirements.[66] CMS has committed to posting and accepting public comments on all amendments.[67]

2. Review all § 1115 documents available online. Review the public notice, the application, and all other relevant documents. For an extension application, be sure to read interim or prior evaluations and prior annual reports.

3. Consult with experts and the relevant social science literature. The literature can help bolster an argument that a particular proposal does not have an experimental purpose.[68] In addition, experts may be able to assist you in determining if prior evaluations are accurate and meaningful and/or if plans for future evaluations are sufficient.

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[65] CMS has confirmed that the regulations do not apply to a request for an amendment, but has nevertheless encouraged states to comply with the state notice and comment process. *See* 77 Fed. Reg. at 11690; CMS, Dear State Health Official Letter 5 (Apr. 27, 2012). CMS indicated that it would release further guidance regarding how best to solicit public input on a request for an amendment. *Id*. To our knowledge, CMS has not done so.

[66] *See, e.g.*, Letter from Emily Spitzer, Exec. Dir., Nat'l Health Law Program to Ctrs. For Medicare & Medicaid Servs. (Dec. 18, 2013) (on file with author).

[67] CMS, Dear State Health Official Letter 5 (Apr. 27, 2012).

[68] For example, studies conducted over several decades have examined the effects of cost-sharing on the poor, contradicting state arguments that imposing cost-sharing requirements in excess of those permitted under the Medicaid Act holds some experimental value. *See* Dave Machledt & Jane Perkins, Nat'l Health Law Program, *Medicaid Premiums and Cost Sharing* (2014), http://www.healthlaw.org/publications/search-publications/Medicaid-Premiums-Cost-Sharing#.WM_kSfkrJhE; *see Newton-Nations,* 660 F.3d at 381; *Wood*, 922 F. Supp. 2d. at 846-48.

4. Participate in state public hearings and submit written comments, supported by expert opinions and research, to the state Medicaid agency. Be precise regarding your concerns and objections. Specifically ask the head of the Medicaid agency to accept your recommendations or, if he or she is going to reject them, to explain why.

5. Submit written comments, supported by expert opinions and research, directly to the Secretary of HHS. If the state Medicaid agency did not accept your recommendations, repeat your concerns and objections. Also, if the state failed to follow procedures outlined in the regulations or failed to offer a process that was "sufficient to ensure a meaningful level of public input," cite the requirements and explain how the process was deficient. Again, specifically ask the Secretary to accept your recommendations or, if he is going to reject them, to explain why.

6. Monitor implementation of an approved demonstration and comment on problems during the annual public forum. Ask the state to include and address your comments in the annual public report. Also, if the state is failing to comply with special terms and conditions, send a complaint to CMS. If the problems are serious enough, CMS could be pressed to suspend or terminate the demonstration, or the state could be subject to enforcement actions. NHeLP's section 1115 team is available to assist with these issues.