



April 2019

MEDICAID DEMONSTRATIONS

Approvals of Major Changes Need Increased Transparency

Accessible Version

GAO Highlights

Highlights of [GAO-19-315](#), a report to congressional requesters

Why GAO Did This Study

Section 1115 demonstrations are a significant component of Medicaid spending and affect the care of millions of beneficiaries. The Patient Protection and Affordable Care Act required the Department of Health and Human Services (HHS) to establish procedures to ensure transparency in approvals of new demonstrations and extensions to existing demonstrations. The act did not address amendments, which are subject to long-standing guidance on public input.

GAO was asked to examine the transparency of demonstration approvals. Among other things, this report examines CMS's transparency policies and procedures for new demonstrations and extensions, and amendments to existing demonstrations. To review a variety of approval types across a large number of states, GAO examined all approvals of new demonstrations and extensions of and amendments to existing demonstrations granted from January 2017 through May 2018. GAO also conducted in-depth reviews of one approval in each of seven states, selected to include at least two approvals of each type. GAO reviewed demonstration documentation for these states, and interviewed state and federal Medicaid officials. GAO also assessed CMS's procedures against federal internal control standards.

What GAO Recommends

CMS should develop policies for ensuring transparency when states (1) submit major changes to pending demonstration applications and (2) propose amendments to existing demonstrations. HHS concurred with these recommendations.

View [GAO-19-315](#). For more information, contact Carolyn L. Yocom at (202) 512-7114 or yocomc@gao.gov.

April 2019

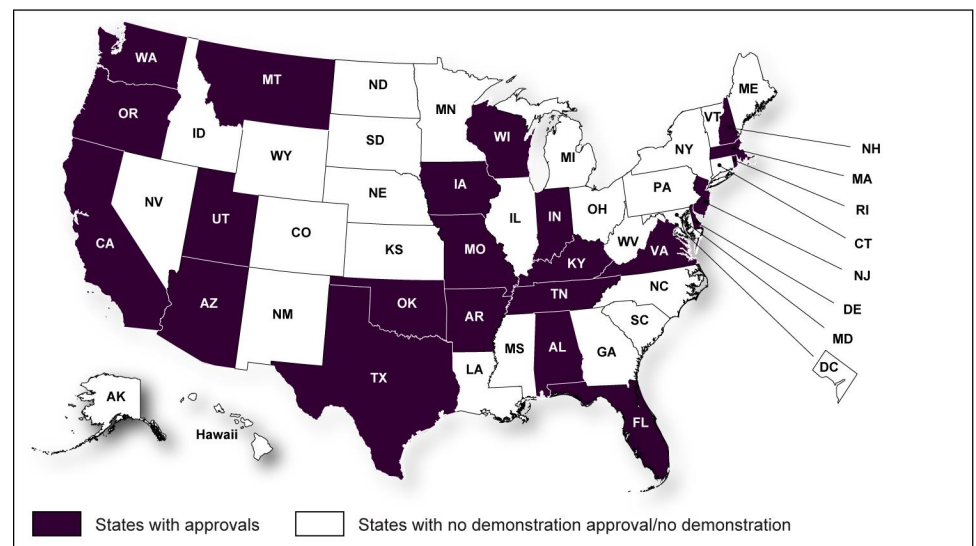
MEDICAID DEMONSTRATIONS

Approvals of Major Changes Need Increased Transparency

What GAO Found

Medicaid demonstrations allow states flexibility to test new approaches for providing coverage and delivering Medicaid services. Since 2012, the Centers for Medicare & Medicaid Services (CMS), which oversees demonstrations, has developed procedures to improve the transparency of the approval process. For example, CMS reviews demonstration applications (including for new demonstrations, extensions, and amendments to existing demonstrations) for their compliance with applicable transparency requirements, including that states seek public input on their applications.

States that Received Demonstration Approvals, January 2017–May 2018



Sources: GAO analysis of Centers for Medicare & Medicaid Services information (data); Map Resources (map). | GAO-19-315

However, GAO found weaknesses in CMS's policies for ensuring transparency.

- **Changes to pending applications for new demonstrations or extensions.** CMS lacks policies for ensuring transparency when states submit major changes to pending applications. For two of the four approvals of new demonstrations or extensions GAO reviewed in-depth, states submitted changes to their applications that could have significant effects on beneficiaries (such as disenrollment or other penalties) without first obtaining public comment on these changes at the state level.
- **Amendments to existing demonstrations.** CMS's transparency requirements for amendments are limited. For example, CMS does not require amendment applications to include how the changes may affect beneficiary enrollment or report on concerns raised in state public comments. However, states have proposed major changes—such as work and community engagement requirements—through amendments, raising concerns that major changes to states' demonstrations are being approved without a complete understanding of their impact.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
HHS	Department of Health and Human Services
LIP	Low Income Pool
PPACA	Patient Protection and Affordable Care Act
STC	special terms and conditions

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April 17, 2019

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
House of Representatives

Medicaid section 1115 demonstrations—which allow states to test and evaluate new approaches for delivering services under the federal-state Medicaid program—have become a significant feature of the program.¹ Under section 1115 of the Social Security Act, the Secretary of Health and Human Services may waive certain federal Medicaid requirements and approve new types of expenditures that would not otherwise be eligible for federal Medicaid matching funds for experimental, pilot, or demonstration projects that in the Secretary’s judgment are likely to promote Medicaid objectives.² As of November 2018, over three-quarters of states operated at least part of their Medicaid program under a section 1115 demonstration; and in fiscal year 2016, federal spending for demonstrations amounted to \$108 billion, or almost one-third of Medicaid program expenditures.

The Centers for Medicare & Medicaid Services (CMS), within the Department of Health and Human Services (HHS), oversees Medicaid section 1115 demonstrations (referred to hereafter as demonstrations) and has approved states’ use of demonstrations for a variety of purposes. For example, under demonstrations, states have extended coverage to populations or offered services not otherwise eligible for Medicaid and implemented policies aimed at improving delivery systems. Recently,

¹Medicaid is a joint, federal-state program that finances health care coverage for low-income and medically needy individuals. The program covered an estimated 75 million individuals at an estimated cost of \$629 billion in fiscal year 2018, including about \$393 billion in federal spending and \$236 billion in state spending, according to estimates from the Centers for Medicare & Medicaid Services’ Office of the Actuary.

²42 U.S.C. § 1315(a).

CMS has issued guidance to states indicating its intent to bring additional flexibilities to Medicaid, including allowing states to provide beneficiaries with incentives to work, such as by requiring beneficiary participation in work or community engagement activities to maintain their Medicaid eligibility.

To provide transparency, HHS has long had policies to seek public input at the state and federal levels on what states are proposing through demonstrations.³ The Patient Protection and Affordable Care Act (PPACA) required HHS to implement a broader set of transparency procedures. Specifically, HHS was directed to issue regulations establishing review and approval processes for demonstrations that would ensure a meaningful level of public input and transparency around demonstration goals and outcomes.⁴ In 2012, CMS issued the regulations, which include transparency requirements for states seeking approval for new demonstrations (typically approved for a 5-year period) and for extensions of existing demonstrations.⁵ The regulations also detailed the steps CMS will take to ensure transparency, including seeking and considering public input at the federal level on demonstration applications, and posting information on approvals and outcomes, such as monitoring and evaluation reports.⁶ States may also seek CMS approval to make changes to ongoing demonstrations—referred to as amendments—and states frequently do so. The statute and regulations do not establish transparency requirements for amendments, which are instead subject to long-standing HHS guidance on public input.

³In 1994, HHS published in the *Federal Register* its policies and procedures for assessing demonstration proposals, including processes for soliciting public input at the state and federal levels. See 59 *Fed. Reg.* 49,249 (Sept. 27, 1994). In past reports, we found that HHS had not consistently provided opportunity at the federal level for the public to learn about and comment on pending demonstrations in accordance with its own policies, and we made related recommendations to HHS and Congress, which have since been implemented. See GAO, *Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns*, [GAO-02-817](#) (Washington, D.C.: July 12, 2002); and *Medicaid Demonstration Waivers: Lack of Opportunity for Public Input during Federal Approval Process Still a Concern*, [GAO-07-694R](#) (Washington, D.C.: July 24, 2007).

⁴Pub. L. No. 111-148, § 10201(i), 124 Stat. 119, 922 (2010).

⁵42 C.F.R. pt. 431.

⁶All demonstrations are subject to monitoring requirements and must provide for an evaluation.

Given the significant amount of federal spending under demonstrations and the potential for demonstrations to affect beneficiaries and inform policy decisions at the state and federal levels, you asked us to examine the public transparency of CMS's demonstration approvals. This report examines CMS's

1. policies and procedures for ensuring public transparency of approvals of new demonstrations and extensions of demonstrations;
2. policies and procedures for ensuring public transparency of approvals of amendments to existing demonstrations; and
3. use of the public input it receives to make demonstration approval decisions and for ongoing monitoring and evaluation.

To examine CMS's policies and procedures for ensuring public transparency of approvals of new demonstrations and extensions, we reviewed documentation of those policies and procedures and of CMS's assessment of state compliance with transparency requirements for approvals from January 1, 2017, to May 31, 2018. We selected this time period to include a variety of demonstration approvals across a large number of states.⁷ We limited our review to comprehensive demonstrations and excluded approvals of temporary extensions.⁸ In total, we reviewed the 11 approvals of new demonstrations and extensions made during this time, comprised of approvals for new demonstrations in two states and extensions in nine states. Our review included determining whether CMS's assessment was complete and whether the agency was applying the requirements consistently. We also conducted a more in-depth review of 4 of the 11 approvals. These included the two new demonstrations—approved for Kentucky and Washington—and two of the nine extension approvals—approved for Florida and Indiana. We selected the extension approvals because they

⁷For the purposes of this report, references to states include the 50 states and the District of Columbia.

⁸Comprehensive demonstrations are those authorizing more than one category of service. Demonstrations financed solely using Title XXI funding (Children's Health Insurance Program) or limited to a narrow set of services, such as family planning or human immunodeficiency virus treatment would not be considered comprehensive. Temporary extensions of demonstrations are short-term approvals, generally involving no or limited changes to a demonstration's special terms and conditions.

included significant changes to the demonstration.⁹ For these four in-depth reviews, we examined all of the application documentation submitted by the states, including any major changes states made to the application during the course of CMS's review; documentation of CMS's review; and approval documentation to determine whether CMS was consistent in its application of the transparency requirements and to identify any gaps in transparency. We also interviewed Medicaid officials in the four states to obtain their perspectives on the transparency process. We also interviewed CMS officials about any recent or planned changes to the policies and procedures and assessed them against the federal internal control standards related to risk assessment.¹⁰

To examine CMS's policies and procedures for ensuring public transparency of approvals of amendments to existing demonstrations, we reviewed documentation of transparency requirements for amendments and procedures for assessing state compliance with those requirements. We also reviewed documentation of CMS's assessment of compliance for the 21 amendments approved in 17 states during the same January 1, 2017, to May 31, 2018, period.¹¹ We also conducted the in-depth review described above for 3 of the 21 amendment approvals—approvals for Arkansas, California, and Massachusetts. We selected these approvals to include states approved to make major changes to their existing demonstrations.¹² We also interviewed CMS officials about any recent or planned changes to the agency's policies and procedures, and assessed them against federal standards for internal control related to risk assessment.

To examine CMS's use of the public input it receives to make demonstration approval decisions and for ongoing monitoring and evaluation, we reviewed documentation for the seven approvals we

⁹In the Florida approval, changes included a large change in the spending limit for the demonstration. In Indiana, CMS approved new eligibility requirements potentially affecting a significant number of beneficiaries.

¹⁰See GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014). Internal control is a process affected by an entity's oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

¹¹Some states had more than one application type approved during our review period. We limited our review to approvals of amendments to comprehensive demonstrations.

¹²CMS refers to amendment proposals that include major changes to the demonstration as those that have significant impact.

selected for in-depth reviews—approvals of new demonstrations in Kentucky and Washington; extensions in Florida and Indiana; and amendments in Arkansas, California, and Massachusetts. (See app. I for information on the demonstrations operated in these states.) Specifically, we reviewed state summaries of issues raised through public input at the state level and the states' responses, submitted as part of the application. We also reviewed public comments submitted during the federal public input period for these applications and summaries of these comments prepared by CMS or its contractors. For each of the approvals, we reviewed CMS's approval letters and the special terms and conditions for evidence of CMS's consideration and use of the public comments, including in how CMS set monitoring and evaluation requirements. Finally, we interviewed CMS officials about their procedures for considering public comments in their approval decisions and in post-approval monitoring and evaluation efforts.

We conducted this performance audit from March 2018 to April 2019, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

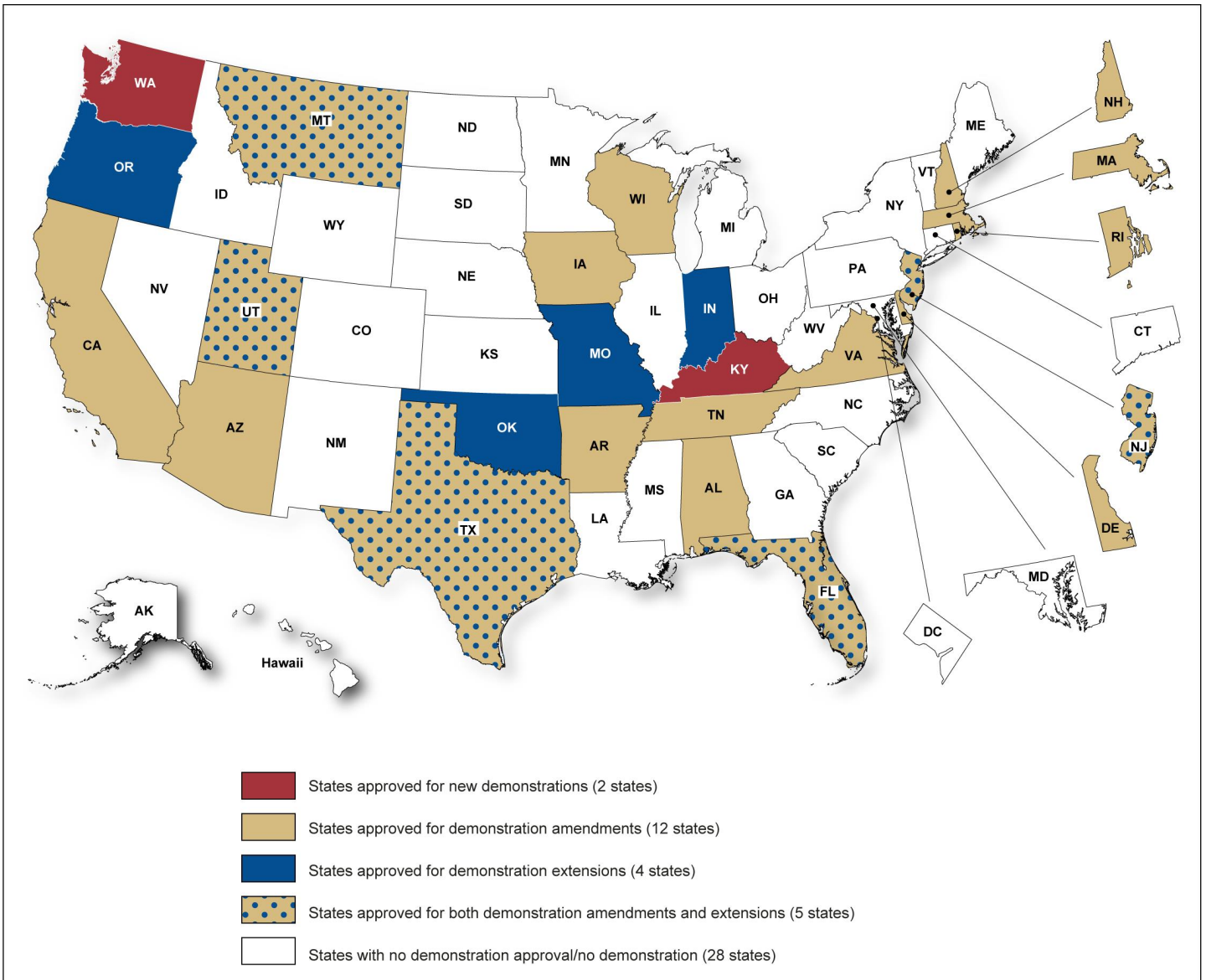
Medicaid Section 1115 Demonstrations

A total of 43 states operated at least part of their Medicaid programs under demonstrations, as of November 2018. State demonstrations can vary in size and scope, and many are comprehensive in nature, affecting multiple aspects of a state's Medicaid program. Nationally, federal spending under demonstrations represented over 30 percent of all federal Medicaid spending in fiscal year 2016. (See app. II.)

Demonstrations are typically approved by CMS for an initial 5-year period, but some states have operated portions of their Medicaid programs under a demonstration for decades. This can be achieved by a state requesting approval by CMS for one or more 3- to 5-year extensions of an existing demonstration (referred to as an extension). States often make changes to their demonstrations, either through the extension process or by requesting to amend a demonstration during the approval period (referred

to as an amendment). From January 2017 through May 2018, CMS approved applications for a new demonstration, extension, amendment, or a combination of these in 23 states. (See fig. 1.)

Figure 1: States that Received Medicaid Section 1115 Demonstration Approvals from January 2017 through May 2018, by Approval Type



Sources: GAO analysis of Centers for Medicare & Medicaid Services information (data); Map Resources (map). | GAO-19-315

Each demonstration is governed by special terms and conditions (STCs), which reflect the agreement reached between CMS and the state, and describe the parameters of the authority granted to the state. For example, the STCs may define for what populations and services funds can be spent under the demonstration, as well as specify various state reporting requirements. The STCs also include a spending limit for the demonstration that is meant to ensure the demonstration is budget neutral to the federal government; that is, the federal government should spend no more under a state's demonstration than it would have spent without the demonstration.¹³

Transparency Requirements for Demonstration Applications

Requirements for new demonstrations and extensions. As required under PPACA, HHS issued regulations in 2012 to address transparency in the approval of applications for new demonstrations and extensions. The regulations include requirements for states to seek public input on their proposals prior to submitting an application to CMS, requirements for information states must include in their public notices and applications, and procedures that CMS would follow upon receiving the application. CMS reviews the submitted application to check for compliance with these regulations, before seeking additional public input through a 30-day comment period at the federal level. (See fig. 2.) The regulations also provide CMS discretion to engage in additional transparency activities on a case-by-case basis.

¹³GAO has issued a number of reports examining CMS's policies for setting and monitoring compliance with spending limits. See GAO, *MEDICAID DEMONSTRATIONS: Federal Action Needed to Improve Oversight of Spending*, [GAO-17-312](#) (Washington, D.C.: Apr. 3, 2017); *MEDICAID DEMONSTRATIONS: HHS's Approval Process for Arkansas's Medicaid Expansion Waiver Raises Cost Concerns*, [GAO-14-689R](#) (Washington, D.C.: Aug. 8, 2014); *MEDICAID DEMONSTRATIONS: Approval Process Raises Costs Concerns and Lacks Transparency*, [GAO-13-384](#) (Washington, D.C.: June 25, 2013); and *MEDICAID DEMONSTRATIONS: Recent HHS Approvals Continue to Raise Cost and Oversight Concerns*, [GAO-08-87](#) (Washington, D.C.: Jan. 31, 2008).

Figure 2: Public Notice and CMS Review and Approval Process for Applications for New Medicaid Section 1115 Demonstrations and Extensions

<p>STEP 1: State public notice and comment</p>	<p>State holds at least a 30-day public notice and comment period.</p> <p>Prior to submitting its application to the Centers for Medicare & Medicaid Services (CMS), state holds a comment period. Notice must provide a comprehensive description of the application, including</p> <ul style="list-style-type: none"> • goals and objectives, • expected increase/decrease in enrollment and expenditures, • beneficiaries affected, • hypotheses to be tested in the evaluation, • impact on health care delivery system, and • impact on benefits and any cost sharing.
<p>STEP 2: State submits application to CMS</p>	<p>State responds to public comments and submits application to CMS.</p> <p>For new demonstrations, applications must include similar elements required in the public notice. Extension applications must include several pieces of information, including</p> <ul style="list-style-type: none"> • historical narrative summary, • changes being requested, • historical and projected expenditures, and • evaluation report, including findings to date. <p>Applications must document state’s compliance with the public notice requirements, a report of the issues raised by the public comments, and how the state considered them.</p>
<p>STEP 3: CMS compliance review</p>	<p>CMS assesses for compliance with the transparency requirements.</p> <p>CMS has 15 days to complete this review and notify the state of its determination of whether the application is complete. CMS notifies the public of the opportunity to comment.</p>
<p>STEP 4: Federal public notice and comment</p>	<p>CMS holds a 30-day comment period.</p> <p>Once the application is considered complete, CMS posts to its website the demonstration application, effective date of the demonstration, and how the public may submit comments. CMS must inform interested parties through email or a similar mechanism of the comment period, must post the written comments on its website, and review and consider all comments received by the deadline.</p>
<p>STEP 5: CMS negotiations and decision</p>	<p>CMS determines whether to approve the state’s application.</p> <p>CMS reviews the state’s application and negotiates the terms and conditions of the demonstration with the state, a process that takes no less than 45 days, but can extend to over a year. CMS documents its decision with an approval letter and special terms and conditions for the demonstration that govern how funds can be spent, the spending limit, and monitoring and evaluation.</p>

Source: GAO analysis of CMS regulations and guidance. | GAO-19-315

Note: Unless otherwise noted, the requirements listed apply to both new demonstrations and extensions.

Requirements for amendments. The 2012 regulations do not apply to states seeking to amend existing demonstrations. Instead, the transparency requirements for amendments are set by guidance HHS issued in 1994 and in the individual STCs that govern each demonstration.¹⁴ The requirements from the guidance and STCs include, for example, that the state seek public input prior to submitting its application and provide in its application an explanation of its process for notifying the public and a detailed description of what is being amended, including the impact on beneficiaries.

Transparency Requirements Post-Approval

CMS's regulations also include monitoring and evaluation requirements to ensure that the outcomes of demonstrations are transparent.

- **Monitoring.** States must perform periodic reviews of the implementation of their demonstrations, and the STCs typically require states to report those outcomes to CMS periodically.¹⁵ The regulations also require states to conduct a public forum within 6 months after the implementation date of the demonstration, and annually thereafter, to solicit public comments on the progress of the demonstration project and summarize issues raised in monitoring reports submitted to CMS. The regulations require that states submit the annual monitoring reports to CMS.
- **Evaluation.** States are required to conduct evaluations to assess whether their demonstrations are achieving the state's goals and objectives. After a demonstration is approved, states are required to submit an evaluation design to CMS for review and approval. The evaluation design must discuss the hypotheses that will be tested, the

¹⁴These standard STCs specify the information states must include in amendment requests and include a reference to guidance HHS issued in 1994 detailing the policies and procedures for assessing demonstration proposals, including processes for soliciting public input. See 59 *Fed. Reg.* 49,249 (Sept. 27, 1994). In previous reports, GAO examined CMS's implementation of these policies and procedures. See [GAO-02-817](#) and [GAO-07-694R](#).

¹⁵Reporting requirements contained in the STCs may include regular telephone calls between the state and CMS, and regular performance reports. Performance reports include quarterly and annual reports on the topics that are listed in the STCs, which can vary by demonstration.

data that will be used, and other items outlined in the STCs. In the event that a state wishes to extend its demonstration, the state's extension application must include, among other things, a report presenting the evaluation's findings to date, referred to as an interim evaluation report. States are also required to submit final evaluation reports at the demonstration's end. All evaluation designs and reports are to be made public.¹⁶

CMS Has Developed Procedures for New Demonstrations and Extensions to Improve Transparency of Approvals, but Weaknesses Remain

CMS Has Developed Procedures to Improve the Transparency of Demonstration Approvals

We found that CMS has developed procedures for assessing states' applications for new demonstrations and extensions against the transparency requirements established in 2012 (see sidebar). Specifically, CMS's procedures involve reviewing incoming applications for new demonstrations or extensions against detailed checklists the agency designed to align with transparency requirements in the regulations. (CMS refers to these as completeness checks.) For example, the checklist for new demonstrations includes checks for whether the application included a description of the demonstration; any proposed changes to the benefits, delivery system, or eligibility requirements; information on the public hearing(s) and public comment process the state conducted; and a summary of the issues raised in the state public comment process.¹⁷ (See fig. 3.) We found that CMS completed checklist reviews for each of the 11 applications for new demonstrations or extensions that CMS approved from January 2017 through May 2018.

Transparency Requirements for New Demonstrations and Extensions

The transparency requirements for new Medicaid section 1115 demonstrations and extensions of existing demonstrations are established in federal regulations at 42 C.F.R. part 431, subpart G.

Source: Centers for Medicare & Medicaid Services regulations. | GAO-19-315

¹⁶For more information on evaluations of demonstrations, see GAO, *Medicaid Demonstrations: Evaluations Yielded Limited Results, Underscoring Need for Changes to Federal Policies and Procedures*, [GAO-18-220](#) (Washington, D.C.: Jan. 19, 2018).

¹⁷CMS officials told us that these reviews are to assess whether the state included required information and not to assess the quality of the information included.

Figure 3: Excerpt from a CMS Review Checklist for an Application for a New Medicaid Section 1115 Demonstration

"Completeness" Checklist for New Section 1115 Demonstration Applications						
[Name of State]						
As required in the recent Transparency final rule, CMS has 15 days within receipt of a State's application to determine if the application is complete. In order to be complete, the application must include the elements listed in the table below. For each element, please indicate if it was included in the State's submission. If the element is missing, or if information included is not sufficient to begin the review process, please provide a brief explanation outlining the missing element, or the insufficiency of the information.						
Application Receipt Date: [Date]						
Due to TD for Review: [Date]						
Due to Director/Deputy Director for Review: [Date]						
Deadline to Determine "Completeness": [Date]						
CFR Citation	Application Element	Sub-Elements	Included	Not Included	Included, but Insufficient Info	Notes
431.412(a)(1)(i)	Description of Demonstration	Goals	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	page 6-7, 12-19
		Objectives	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	page 6-7, 12-19
431.412(a)(1)(ii)	Description of Demonstration's Features	Delivery System	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Page 10, 35-47
		Eligibility Requirements	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Page 16, 29-34
		Benefits	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	page 29
		Cost Sharing (premiums, copayments, deductibles)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	page 29
431.412(a)(1)(iii)	Budget Neutrality	Expected increase/decrease in enrollment	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	page 35, 58
		Expected increase/decrease in annual aggregate expenditures (includes historic data if applicable)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	page 35, 58
431.412(a)(1)(iv)	Enrollment Projections	Current data (if applicable) and specify enrollment projections for each eligibility category	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	page 35, 58
431.412(a)(1)(v)	Other program features that may modify the State's Medicaid and CHIP programs		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	page 35
431.412(a)(1)(vi)	Specific waiver and expenditure authorities requested		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	pages 62-65
431.412(a)(1)(vii)	Research and Evaluation	Research hypotheses related to the Demonstration's changes, goals and objectives	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pg. 23-25
		Proposed evaluation design (plan to test the hypotheses)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Pg. 23-25
		Identification of appropriate evaluation indicators (if a quantitative evaluation design is feasible)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	N/A
431.412(a)(1)(viii)	Documentation of Public Notice Requirements in 431.408	Report of the issues raised during the State's 30 day public comment process and how the State considered the issues raised	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Appendix 7

Source: GAO recreation of a portion of Centers for Medicare & Medicaid Services (CMS) review checklist for a new section 1115 Medicaid demonstration application. | GAO-19-315

CMS has also developed and implemented procedures for seeking public input at the federal level and making that input publicly available. This includes CMS sending email notifications to individuals who have registered on the agency's website when demonstration applications are open for public comment; posting the application on the website where the public can post comments during the 30-day comment period; and maintaining the public comments on the website, which are maintained

indefinitely, according to CMS officials. We found that CMS conducted a federal comment period for all 11 of the new and extension applications in our review period.

In addition to storing the federal public comments, CMS's website contains a record of key decisions and documents for each demonstration (referred to as the administrative record). The administrative record includes states' applications, as well as CMS's approvals, denials, and decisions about the completeness of applications—a requirement under the 2012 regulations. CMS officials told us that they include additional documents as standard practice, though they are not required to be posted, such as a fact sheet on the demonstration and other official communication between the agency and the state, to support transparency. CMS first launched this section of its website in December 2011 with an aim to improve access to Medicaid program information, including information on demonstrations, and redesigned the website in 2013 to improve functionality. The administrative record provides a history, dating as far back as 2011, of what a state has tested, how the approach has evolved over time, and what has been learned from the approach.

CMS's Policies and Procedures for Ensuring Transparency of Demonstration Approvals Have Weaknesses

We identified several areas of weakness in CMS's policies or procedures for ensuring transparency in approvals of new demonstrations and extensions of existing demonstrations. These weaknesses related to the transparency of major changes made to pending applications, the transparency of changes to approved spending limits, and inconsistency in CMS's review of applications for compliance with transparency requirements for new demonstrations and extensions.

Transparency of Major Changes to Pending Applications

CMS did not apply a consistent approach to ensuring transparency in two states that made major changes to their demonstration applications mid-review. Indiana and Kentucky submitted changes to pending applications, the first for an extension and the latter for a new demonstration that had substantial potential effects for some beneficiaries. Indiana's changes included adding new eligibility requirements for some beneficiaries, and

Kentucky's changes included accelerating the effective dates of new requirements to maintain eligibility (see sidebar).

Changes to Indiana's and Kentucky's Pending Applications

Indiana: In May 2017, Indiana submitted changes to its pending application to extend its Medicaid section 1115 demonstration, including

- adding a requirement that non-disabled, working-age beneficiaries work or participate in community engagement activities 20 hours per week as a condition of maintaining eligibility, and;
- adding a provision to suspend those not meeting the requirements from the program until they comply.

Kentucky: In July 2017, Kentucky submitted changes to its pending application for a new demonstration, including:

- replacing a provision for a year-long phase-in of a proposed 20-hour per week work and community engagement requirement for beneficiaries with a 3-month phase-in of the requirement; and
- adding a provision that beneficiaries be disenrolled for 6 months for failing to timely report changes in income or other circumstances affecting eligibility.

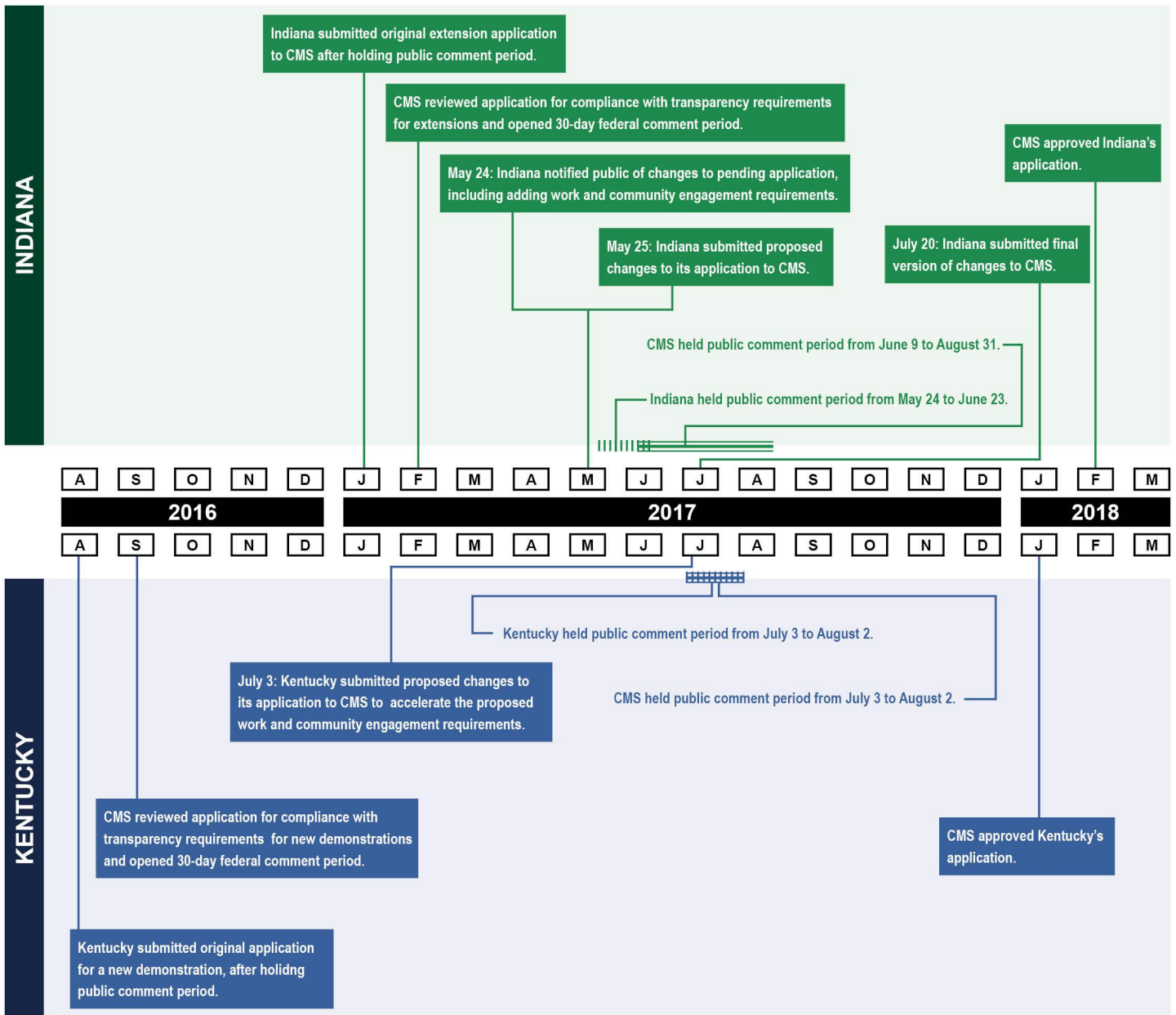
Source: GAO analysis of Centers for Medicare & Medicaid Services documents. | GAO-19-315

CMS did not require either state to solicit public input, though both states opted to hold a public comment period on the proposed changes concurrent with CMS's review. Further, CMS reviewed Indiana's proposed changes against limited transparency requirements but did not do so for Kentucky.¹⁸ Indiana submitted a final version of its application summarizing public input and the state's response, while Kentucky did not. Thus, the extent to which these comments were considered at the state and federal levels was not transparent to the public.¹⁹ Figure 4 shows a timeline of the events surrounding Indiana's and Kentucky's requests to make changes to their pending demonstration applications.

¹⁸CMS reviewed the changes Indiana proposed to its application against transparency requirements for amendment applications even though the changes were to an extension application, which are subject to a broader set of requirements.

¹⁹According to CMS officials, their conversations with the state included a discussion of the trends in the state's public comments and they concluded the scope of the comments was similar to that of the federal public comments.

Figure 4: Timeline of Indiana’s and Kentucky’s Requests to Make Changes to Their Pending Medicaid Section 1115 Demonstration Applications



----- State public comment period ===== Federal public comment period

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) documentation. | GAO-19-315

Note: CMS's January 2018 approval of Kentucky's demonstration application was vacated by the U.S. District Court for the District of Columbia in June 2018. *Stewart v. Azar*, 313 F. Supp. 3d 237

(D.D.C. June 29, 2018). CMS held another federal comment period from July to August 2018 and reapproved Kentucky's demonstration in November 2018. On March 27, 2019, the U.S. District Court for District of Columbia vacated CMS's November 2018 re-approval of Kentucky's demonstration. *Stewart v. Azar II*, No. 18-152 (JEB) (D.D.C. Mar. 27, 2019). CMS is appealing this decision.

This inconsistent approach to ensuring transparency likely resulted, in part, from gaps in CMS's policies for instances when states make major changes to pending applications.

- **CMS lacks criteria for determining when a change to a pending application is considered major and warrants an additional state comment period.** Agency regulations provide CMS the discretion to require states to hold an additional 30-day comment period when a state proposes substantial changes to its application; however, CMS does not have criteria for assessing what constitutes a substantial change. Officials told us that they thought the changes made in Indiana and Kentucky were substantial and they had conversations with the states that obtaining public comment would be helpful, but they did not require the states to do so. This approach does not provide assurance that states will seek public input in cases where states propose major changes.
- **CMS does not have a policy for reassessing pending applications against transparency requirements when states make changes mid-review.** CMS officials said that the agency does not reassess applications for compliance with the transparency requirements applicable to the pending application when states make mid-review changes. CMS officials told us that such changes are considered supplementary information to the original application and not a new application.²⁰ A new review of Kentucky's revised application against the transparency requirements for new demonstrations, which call for applications to include a report of the issues raised in the state comment period and the state's response, would likely have prompted CMS to require the state to resubmit its application with a summary of the public comments and how the state addressed any concerns raised.

Federal internal control standards state that agencies should identify, analyze, and respond to risks related to achieving program objectives.²¹

²⁰CMS officials stated that unless a state requests to withdraw its original pending application and submits the changes as a replacement application, the agency does not conduct another check for compliance with the transparency requirements.

²¹See [GAO-14-704G](#).

CMS's lack of policies for when states submit major changes to pending applications puts the agency's goal of transparency for demonstration approvals at risk. In the absence of a policy that defines when states should seek public comment on proposed changes to pending applications, CMS made decisions not to require Indiana and Kentucky to solicit public input prior to submitting major changes that had the potential to affect the availability of coverage for thousands of beneficiaries. Further, by not reviewing Kentucky's revised application against transparency requirements, the agency may have missed the opportunity to identify and respond to the risk that the proposed application changes would not achieve program objectives.

Transparency of Changes to Approved Spending Limits

CMS approved a significant increase in the spending limit for a portion of Florida's demonstration—which appeared to reflect a change in the agency's position on the allowable use of the funds—without making transparent the basis for this decision. Specifically, CMS increased the spending limit for a pool of funds for payments to offset providers' uncompensated care costs by close to \$1 billion in 2017 after having reduced the limit 2 years earlier.²² In its approval letter, CMS provided limited information on the basis for this change. CMS stated that the limit was based on the state's most recent data on uncompensated care costs, but did not disclose a significant change in its methodology for setting these limits. In unpublished correspondence to Congress, CMS indicated that the calculation of the spending limit was broadly consistent with previous policy with one significant change. Specifically, the letter indicated that whether the state had opted to expand Medicaid coverage to low-income, childless adults as provided for under PPACA would no longer factor into the limit, thus allowing CMS to include uncompensated care costs for this population in setting the limit. This change led to increasing the state's spending limit to \$1.5 billion annually. (See text box.) Moreover, CMS noted plans to apply this change across all states going forward. CMS officials, however, did not indicate that they had publicly communicated this policy change to all states. In past reports, we have recommended that HHS make public the basis for demonstration approvals including the basis for elements used to set spending limits, and in 2008, we raised the issue as a matter for Congress to consider.

²²The reduction in the spending limit resulted from the agency deciding that uncompensated care pool funding should not be used to pay for costs that could be covered under Medicaid expansion.

CMS has taken a number of steps in the last several years to update and make public its policies for setting spending limits, but has not yet taken action to make public the basis of spending limits.²³

CMS Decision to Increase Spending Limit for a Funding Pool in Florida’s Medicaid Section 1115 Demonstration

<p>Approved spending limit (federal and state)</p> <p>Limit approved for state fiscal year 2016: \$1 billion</p> <p>Limit approved for state fiscal year 2017: \$608 million</p> <p>Limit approved for August 2017 – June 2022: \$1.5 billion annually</p>

In letters to Florida, CMS wrote:

- *April 14, 2015:* "...over time, CMS has had a number of concerns about the LIP [Low Income Pool], including its lack of transparency, encouragement toward overreliance on supplemental payments, and distribution of funds based on providers' access to local revenue instead of service to Medicaid patients. Last year, CMS made clear that LIP would not continue in its current form....We will approach review of a LIP proposal from Florida based on several key principles. First, coverage rather than uncompensated care pools is the best way to secure affordable access to health care for low-income individuals, and uncompensated care pool funding should not pay for costs that would be covered in a Medicaid expansion...."
- *October 15, 2015:* "...Pursuant to our June 23, 2015 agreement in principle, establishing the size, duration, and distribution methodology for the Low Income Pool (LIP)...The total computable dollar limit in demonstration year 10 (2015-2016) will be \$1 billion. In demonstration year 11 (2016-2017) the total computable dollar limit will be \$607,825,452..."
- *August 3, 2017:* "For the extension, CMS has established an amount for the low-income pool's (LIP) uncompensated care pool to be approximately \$1.5 billion annually, based on the most recent available data on hospitals' charity care costs."

In an unpublished letter to members of Congress, CMS wrote:

- *August 3, 2017:* "...The one methodological change which led to an additional increase in Florida's LIP is rooted in a policy decision not to include a previous UC [uncompensated care] adjustment based on federal funding that would have been available had the state expanded Medicaid to cover low-income adults....CMS intends to consistently apply this change across all states with UC pools moving forward..."

Source: Centers for Medicare & Medicaid Services (CMS) Medicaid section 1115 demonstration documentation. | GAO-19-315

²³See GAO, *Medicaid Waivers: HHS Approvals of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns*, [GAO-04-480](#) (Washington, D.C.: June 30, 2004); *Medicaid Demonstration Waivers: Recent HHS Approvals Continue to Raise Cost and Oversight Concerns*, [GAO-08-87](#) (Washington, D.C.: Jan. 31, 2008).

Inconsistency in CMS's Review of Applications for Compliance with Transparency Requirements

Finally, we observed some inconsistencies in CMS's reviews of states' applications for their compliance with the transparency requirements for new demonstrations and extensions.

- **Expected changes in enrollment were not always included in state public notices.** In two of the four applications for new demonstrations and extensions for which we conducted in-depth reviews (Florida's extension and Washington's new demonstration), estimates for the expected increase or decrease in enrollment were not included in the state's public notice documents as required. CMS officials told us that they are revising procedures to resolve such inconsistencies, including making additions to written standard operating procedures.
- **Evaluation information was not always included in state applications.** Although states seeking extensions are required to submit an interim evaluation report, Florida only included a statement in its application that it had recently executed an evaluation contract and had no findings to report. According to CMS, Florida's evaluation design was not approved until weeks before the extension application was due. Despite not having information on whether Florida's demonstration was meeting its goals, CMS officials considered the state's application complete, stating that Florida had met the intent of the regulation by providing its findings to date.²⁴ In 2018, we reported that there were limitations in state evaluations of demonstrations, in part, due to how CMS sets requirements for evaluations, and we made a recommendation to improve CMS's procedures.²⁵ In line with our recommendation, CMS has since developed an enhanced set of STCs that specify when evaluation reports are due, and reported in November 2018 that it is in the process of developing protocols to ensure that these requirements are consistently included in the STCs.

²⁴Agency regulations pertaining to application procedures require states to include in their extension applications an evaluation report inclusive of evaluation activities and findings to date. 42 C.F.R. § 431.412(c)(2)(vi). Agency regulations pertaining to evaluations for demonstration extensions require that the state submit an interim evaluation report as part of the request to extend the demonstration. 42 C.F.R. § 431.424(d)(1).

²⁵See [GAO-18-220](#).

CMS Applies Limited Transparency Requirements in Approving States' Amendments to Existing Demonstrations

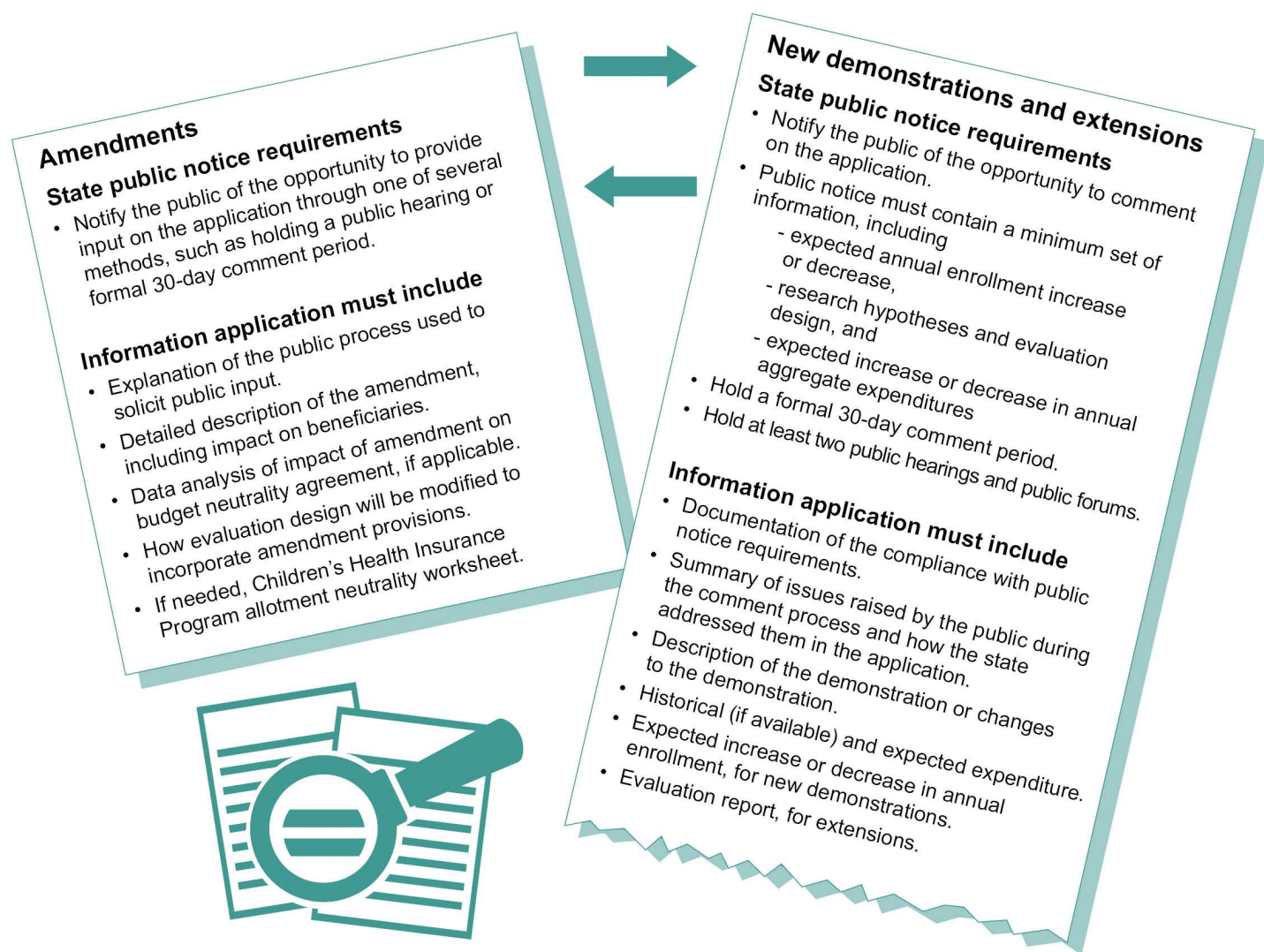
CMS applies limited transparency requirements to states' applications to amend existing demonstrations, despite the fact that states may propose significant changes to demonstrations through amendments (see sidebar). CMS does not place limits on what changes can be made through amendments. From January 2017 through May 2018, CMS approved 21 amendments in 17 states, and we found that at least 17 amendment applications were pending CMS approval as of January 2019. These 17 states made a wide range of changes to their demonstrations through amendments. For example, one state amended its demonstration to cover dental services for adults with disabilities, while other amendments included such changes as requiring beneficiaries to work or participate in community engagement activities as a condition of maintaining Medicaid eligibility, as was done through amendments in Arkansas and New Hampshire during the period we reviewed. As it does with applications for new demonstrations and extensions, CMS reviews amendment applications by using a checklist, conducting a federal public comment period, and posting state demonstration documentation on the CMS website. However, the transparency requirements for amendments applied during the checklist review are more limited than the requirements for new demonstrations and extensions. (See fig. 5.)

Transparency Requirements for Amendments

Applications for amendments to Medicaid section 1115 demonstrations are subject to requirements for seeking public input outlined in guidance the Department of Health and Human Services (HHS) issued in 1994 and those included in the special terms and conditions governing each demonstration.

Source: HHS and Centers for Medicare & Medicaid Services guidance and documentation. | GAO-19-315

Figure 5: Comparison of Transparency Requirements for Applications for Medicaid Section 1115 Demonstration Amendments with those for New Demonstrations and Extensions



Source: Centers for Medicare & Medicaid Services regulations and guidance. | GAO-19-315

The transparency requirements for amendment applications are more limited than those for new demonstrations and extensions in the following key areas, potentially limiting CMS’s ability to ensure public transparency for the approvals of amendments.

- **No requirement to hold a state public comment process or provide CMS a summary of public input received.** For amendments, states have a range of options for seeking public input

and, unlike for new and extension applications, states are not required to submit a summary of the public input received on their applications and how they responded. Instead, in amendment applications, states are only required to describe the process the state used to solicit public input. Among the three amendment approvals for which we conducted an in-depth review, California did not hold a formal public comment period and did not provide CMS information on any public input it received, neither of which is required under the transparency requirements for amendments.²⁶

- **No requirement to include expected changes in enrollment and costs.** In contrast with requirements for new demonstrations and extensions, CMS does not require states to include in amendment applications the expected increase or decrease in enrollment, and the amendment applications we reviewed included limited or no information on changes to enrollment. (See text box.) CMS also does not require information on expected changes in costs for all amendments, and we found variation in the information included in amendment applications, including limited or no information on costs.²⁷

²⁶When states apply for new demonstrations or extensions, they are required to use multiple methods to solicit public input, including holding multiple public hearings, conducting a formal comment period, and using a Medicaid advisory committee or another public forum to obtain feedback. For amendment applications, states are required to conduct one of the methods to ensure that public input has been collected on the proposed amendments.

²⁷If a state concludes that a proposed amendment would affect the demonstration's budget neutrality, the state is required to include in an amendment application an analysis of the impact of the proposed amendment on the demonstration's budget neutrality, which could include cost information. Among the amendments we reviewed, Massachusetts's included a budget neutrality analysis, as well as a discussion of expected savings and expected expenditures from the proposed changes to the demonstration through the amendment. Comparatively, Arkansas did not include any cost information and stated in its application that the state was not requesting any changes to budget neutrality.

Limited Enrollment Information Included in Medicaid Section 1115 Demonstration Amendment Applications

All three of the amendment applications for which we conducted an in-depth review had limited or no information on the expected changes to enrollment for the amendment provisions. For example, Arkansas did not include this information in its application to amend its demonstration by adding work and community engagement requirements as a condition of maintaining eligibility, information that would have been required if the state had been applying for a new demonstration or extension. The state reported that over 18,000 individuals were disenrolled in the first 6 months of implementing the requirements approved in the amendment. Implementation was halted in March 2019 when a federal district court vacated CMS's approval of the demonstration amendment.

Among the other 18 amendment applications CMS approved during our review period, we found that one other state, New Hampshire, amended its demonstration to include a work and community engagement requirement, and also did not include enrollment information in the application. As of January 2019, one additional state had received approval and at least three other states were seeking approval for this type of change through amendments.

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) and state documentation. | GAO-19-315

- **No minimum requirements for information to be included in the public notice.** Unlike the transparency requirements for new demonstrations and extensions, there are no requirements specifying what information states must include in their public notices for amendments. For example, Arkansas did not include in its public notice information on the changes to enrollment estimated from any of the amendment provisions.

In addition to the differences in the transparency requirements for amendment applications, we identified inconsistencies in how CMS applied the transparency requirements for amendment applications across states, particularly the requirements related to describing changes to the demonstration evaluations. For amendments, as is similar to extensions, states are required to describe how the demonstration's evaluation will be revised to incorporate amendment provisions. The following are examples of the inconsistencies:

- CMS determined that Massachusetts's amendment application, which proposed to waive non-emergency medical transport, eliminate provisional eligibility for most populations, and cover former foster care youth, was determined to be incomplete (that is, not in compliance with the transparency requirements), partially due to the state not submitting a revised evaluation design plan.
- In contrast, CMS determined that Arkansas's application, which did not include a revised evaluation design plan, was complete. Arkansas noted in its application that the state planned to revise its evaluation to

test two additional hypotheses.²⁸ However, the added hypotheses did not address, for example, the waiver for retroactive eligibility proposed in the application.²⁹

Among the 18 other demonstration amendment applications CMS approved during our review period, there was variation in the information the states included about the changes to the demonstration's evaluation hypotheses or design. For example:

- Iowa submitted an amendment application, which CMS determined to be in compliance with transparency requirements, to waive retroactive eligibility for all beneficiaries, and said that it was not changing the evaluation design based on the amendment provisions.
- In at least two other states' amendments—Florida and Utah—the applications, which CMS determined to be in compliance with transparency requirements, did not include any information on the changes to the evaluation due to the amendment or indicated that the state would be making changes at a later date.

The potential effects of policy changes states make through amendments can be comparable to effects of new demonstrations and extensions. CMS has considered taking further steps to ensure transparency for amendments, but has not done so. Specifically, in both its response to comments in the 2012 final rule and a subsequent letter to state Medicaid directors in 2012, CMS indicated that the agency intended to evaluate the types of amendments submitted by states and issue further guidance on how the notice and comment provisions would be applied to amendments that have a significant impact.³⁰ However, CMS did not issue such guidance and officials told us that they had no plans to do so.

CMS officials told us that including standard requirements in demonstration STCs for submitting amendment applications helps

²⁸In the development of demonstration evaluations, states are to include hypotheses that will be tested through the demonstrations, which align with the demonstration's objectives or goals.

²⁹Unless waived under Section 1115(a), states are required to provide Medicaid coverage to enrollees beginning 3 months prior to the month of their Medicaid application if the individual would have been eligible during this time.

³⁰See 77 Fed. Reg. 11,678, 11,690 (Feb. 27, 2012); CMS, State Medicaid Director Letter; Re: Revised Review and Approval Process for Section 1115 Demonstrations (Apr. 27, 2012; SHO# 12-001).

improve the transparency of amendments. However, the standard requirements that CMS has included do not ensure that states provide information to the public or CMS on the effect of an amendment on enrollment and costs, key pieces of information for amendments that have and may continue to have a significant impact. According to federal standards for internal controls related to risk assessment, federal agencies should identify and manage risks related to achieving agency objectives.³¹ Without a policy with robust transparency requirements for amendment applications with significant impacts, there is the potential that states and CMS will fail to receive meaningful public input on the amendment and thereby lack complete understanding of the impact. As a result, CMS may not be positioned to mitigate any potential risks in the demonstrations being amended or when other states request to test similar policies in the future.

CMS Has Used Public Input in Making Demonstration Approval Decisions, but the Extent to Which Input Influenced Monitoring and Evaluations Was Not Always Clear

CMS Reviewed Comments Received through the State and Federal Public Input Process for its Approval Decisions, and in Some Cases Approved Changes Consistent with the Comments

CMS reviewed state descriptions of issues raised during the state public input process and the state's response as part of its application review. Applications for six of the seven approvals for which we conducted in-depth reviews summarized themes from the comments that were

³¹See [GAO-14-704G](#).

received and included the states' responses to these comments.³² State responses included laying out changes the state made to the proposal in response to the comments, clarifying certain aspects of the proposed demonstration, or providing justification for not making a change. However, the level of detail in state summaries of their responses to these comments varied considerably. For example:

- **Washington application for new demonstration.** Washington provided an extensive summary of the comments received, categorized by themes, along with the state's responses to each of them. One commenter suggested a 1-year implementation period to ensure that sufficient planning and preparations were undertaken before the new demonstration officially went into effect. The state agreed that this was "essential to assure operational readiness and critical success of this demonstration," and revised its proposal to include a 9-month implementation period.
- **Florida application to extend demonstration.** In contrast to Washington, Florida's application to extend its managed care program provided a long list of state comments and nearly all were addressed with a standard response from the state that the comments were taken into consideration, but no changes to the existing STCs were being requested. These included concerns about access and choice under current pharmacy networks, and other access issues such as difficulties in obtaining referrals to specialists. Florida officials told us that they addressed stakeholder concerns through the state public comment process, which includes public forums, and that they are not necessarily required to provide any additional explanation in the state's application to CMS.³³ Florida officials also stated that some demonstration elements stem from state legislation, which limits their

³²One state, California, was not required to obtain input on its amendment request through an official comment period. Officials from the California Department of Health Care Services told us that they issued a public notice, which included soliciting comments from their tribal stakeholders, and also received comments through the public forums that were held. The state, however, did not include a summary of the comments received in its application. For Kentucky, CMS reviewed the state's summary of public comments for the state's first public comment period. The state did not resubmit its application with a summary of the comments received through the state's second public comment period, though CMS officials told us that the state discussed the input received with CMS.

³³CMS officials said they sent the state follow-up questions to better understand the state's strategy for addressing the public comments received. CMS received written answers and discussed them with the state, but these responses were not included in the public record.

ability to make changes in response to comments.

According to CMS officials, historically, the agency has not requested the full set of comments that are submitted to the states. None of the states that we reviewed attached the actual comments that were received to the application—only summaries—though some posted them on their website or had them available upon request, according to state officials. CMS officials told us the agency has not consistently requested that states provide the actual comments received; however, in the last year and a half the agency has been making more of an effort to request the full set of comments instead of solely relying on the summaries provided in the applications. Officials said they anticipate that this will be the agency's standard practice going forward.

In making demonstration decisions, CMS reviews and summarizes all input received during the federal comment period. CMS created a summary of comments received for all seven of the demonstrations we reviewed. Officials said that these summaries are used to brief CMS leadership as part of the decision-making process.³⁴ We found that the level of detail in the summaries we reviewed varied, ranging from bulleted lists identifying and detailing common themes in support, opposition, or both, to a few brief sentences covering all comments. This variation often reflected the differences in the number of comments received and the significance of the concerns raised. For example:

- CMS received about 100 comments on Washington's application during the federal comment period that were predominantly supportive of the new demonstration, and CMS's summary was a brief overview.
- In contrast, CMS received thousands of comments on Kentucky's application for each of the three federal comment periods held for that new demonstration, with many opposed to or concerned with certain aspects of the application. CMS's summaries of comments received on the Kentucky application provided an overview of the issues raised, along with counts of how many fell within different themes and how many were in support, opposition, or unrelated to what was being proposed.

³⁴CMS said the summaries are created internally or in some instances in conjunction with outside contractors.

CMS officials explained that there are unique circumstances surrounding each demonstration—a comment period with many concerns raised or conflicting viewpoints will necessitate a longer and more detailed summary than one that has broad support and few, if any, areas of disagreement.

We found instances where CMS approved changes to certain aspects of the demonstrations that were in line with concerns raised by the comments. Among the seven demonstrations we reviewed in-depth, CMS received comments for four demonstrations that included concerns about the state’s proposal: Arkansas, Indiana, Kentucky, and Massachusetts.³⁵ For Arkansas and Kentucky, CMS either approved more limited changes than what the state initially proposed or required that certain beneficiary protections be in place.

- **Arkansas:** In its amendment application, Arkansas requested a waiver of the requirement to provide retroactive eligibility, among other things. Commenters were concerned that the state’s proposal to eliminate retroactive eligibility would result in gaps in coverage, adverse health outcomes, and medical debt for members. In CMS’s approval, the agency acknowledged these concerns and allowed the state to reduce the period for retroactive eligibility from 90 days to 30 days but not eliminate it completely. (See fig. 6.)
- **Kentucky:** In Kentucky, some commenters were concerned about the state’s proposal to implement a work and community engagement requirement as a condition of Medicaid eligibility, noting that individuals need to be healthy to work or look for a job. CMS said in its January 2018 approval that Kentucky was exempting medically frail individuals from this requirement, but CMS would also be requiring that the state add certain protections for vulnerable individuals, including maintaining a system that identifies, validates, and provides reasonable accommodations.

³⁵CMS received comments that were supportive of Washington’s demonstration application; CMS received no comments in the federal comment periods for Florida’s extension application and California’s amendment application.

Figure 6: Examples of Concerns Raised through the Public Input Process for Arkansas’s Medicaid Section 1115 Demonstration Application and CMS’s Response



Source: Centers for Medicare & Medicaid Services (CMS) documentation. | GAO-19-315

Notes: The examples track concerns raised in the public comments and addressed by CMS in its approval letter. While CMS can receive comments from both individuals and organizations, only organizations submitted comments on this application.

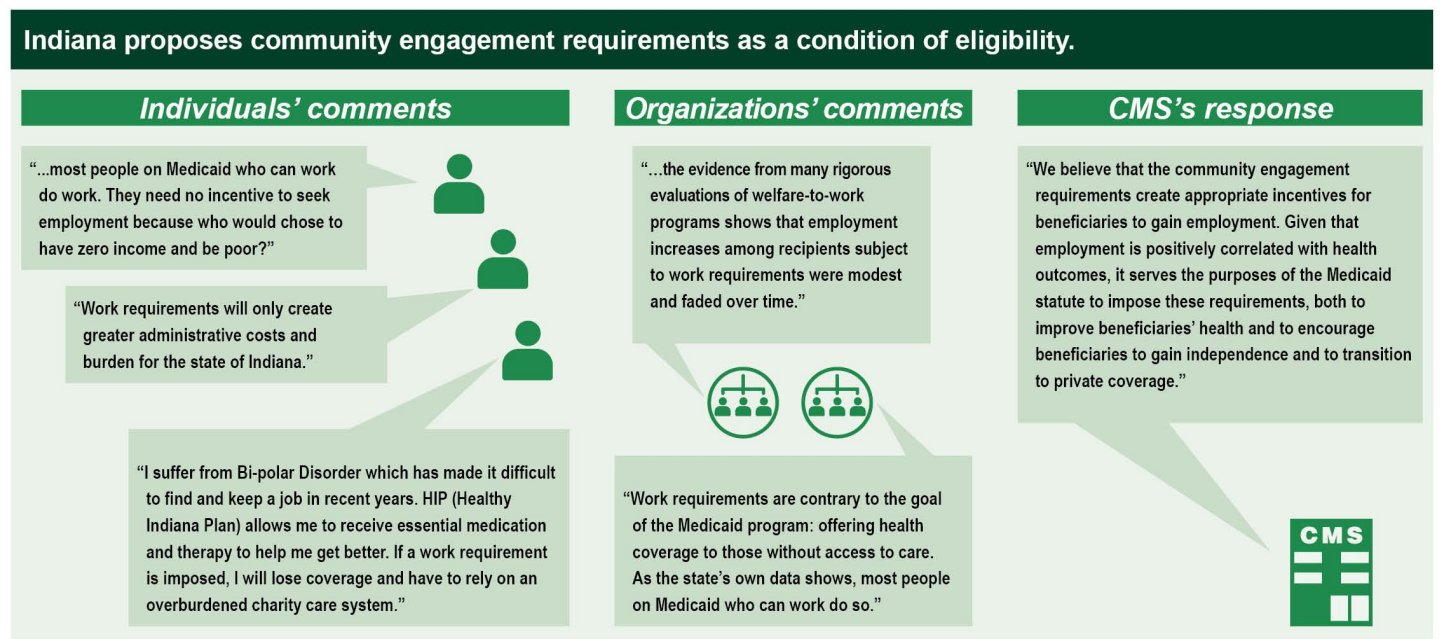
We also found there were instances where CMS approved certain aspects of the demonstrations despite concerns raised by the comments. CMS’s rationale for those decisions varied across demonstrations. For example, CMS noted in one instance that sufficient controls were planned to address the concerns raised, and in another instance noted that the potential benefits of the demonstrations outweighed the risks. The following are examples of when CMS approved aspects of states’ demonstrations without changes.

- Arkansas:** In Arkansas, some commenters were opposed to the enforcement mechanism for the state’s proposal to institute a work and community engagement requirement as a condition of maintaining eligibility. The state proposed to disenroll beneficiaries who fail to fulfill these requirements for any 3 months during a calendar year and lock them out from coverage until the start of the next calendar year. CMS approved this proposal and provided an explanation of the circumstances under which it would happen, underscoring that individuals have three opportunities (each of the

months they fail to fulfill the requirements) to rectify the situation or seek an exemption before they would ultimately lose coverage. CMS indicated in the approval letter to Arkansas that it believed the health benefits of community engagement outweigh the health risks with respect to those who fail to respond.

- Indiana:** In Indiana, some commenters were opposed to the state’s proposal to institute a work and community engagement requirement as a condition of maintaining eligibility. They argued, in part, that beneficiaries who are able to work are already doing so and the requirement is unnecessarily burdensome. CMS responded that employment is positively correlated with health outcomes and imposing these requirements serves the purposes of the Medicaid statute. (See fig. 7.)

Figure 7: Examples of Concerns Raised through the Public Input Process for Indiana’s Medicaid Section 1115 Demonstration Application and CMS’s Response



Source: Centers for Medicare & Medicaid Services (CMS) documentation. | GAO-19-315

Note: The examples track concerns raised in the public comments addressed by CMS in its approval letter.

In an effort to improve transparency around its approvals, CMS began providing a high-level summary and response to public comments in the demonstration approval letters beginning in January 2018. Agency officials said this will be their standard practice going forward. Our review

of the approval letters sent between January 1, 2018, and July 31, 2018, confirmed that CMS included a discussion of some of the issues that were raised in 10 of 11 letters.³⁶ For example, the approval letters explained the decision to reduce the period of retroactive eligibility in Arkansas instead of eliminating it completely, as well as the decision to approve Indiana’s proposal to implement work and community engagement requirements. However, the approval letters do not respond to every concern raised.³⁷ For example, a number of commenters were concerned with a request in Arkansas’s amendment application to no longer offer presumptive eligibility, but CMS did not respond to these concerns in the approval letter.³⁸ CMS officials told us that the agency is striking a balance between transparency and processing applications in a timely manner.

The Extent to Which CMS Used Public Comments to Inform Monitoring and Evaluation Decisions Was Not Always Clear

Among the four demonstration approvals for which we conducted in-depth reviews and where public comments raised concerns—approvals for Arkansas, Indiana, Kentucky, and Massachusetts—we observed instances where CMS added specific monitoring requirements to the STCs that aligned with these concerns and other cases where the agency did not. For example:

- The STCs required Arkansas to submit a monitoring plan for its work and community engagement requirement in order to monitor eligibility operations and the impact on beneficiaries reapplying for coverage after being disenrolled for noncompliance.

³⁶TennCare II received one federal comment—a letter of support—that was not mentioned in the February 2018 approval letter. The demonstrations that had an approval letter during this time frame, but did not receive any federal comments, were not included in the count.

³⁷In our review of the approval letters, we did not conduct an assessment of the completeness or sufficiency of CMS’s summary of and response to the public comments.

³⁸Presumptive eligibility allows qualified entities, such as health care providers and government agencies, to make on-the-spot, temporary Medicaid eligibility decisions based on an assessment of family income. It is designed to provide immediate access to needed health care services without delay, while the individual completes the regular application process for ongoing coverage.

- In contrast, CMS did not require a monitoring plan for the Indiana and Kentucky demonstrations, which also included work and community engagement requirements where the public raised concerns about the effects on beneficiaries. This remains the case for Indiana; however, CMS's new approval of Kentucky's demonstration in November 2018 included additional monitoring requirements.³⁹ Specifically, the November 2018 STCs required Kentucky to submit a monitoring protocol that includes measures for monitoring enrollment, disenrollment, and eligibility suspension, among other things.

In other cases where public comments raised concerns about the impact of demonstrations on beneficiaries, including changes in eligibility requirements (e.g., retroactive eligibility), we did not observe specific monitoring requirements included in the STCs. Though CMS did not provide any specific examples, officials told us that they consider public input when making decisions about monitoring requirements. Officials also said they were developing monitoring metrics and tools that they plan to use consistently going forward for states implementing work and community engagement requirements. As of January 2019, officials said these materials were in draft form and under review.⁴⁰

Regarding evaluations, the extent to which CMS considered concerns raised through public comments for the four demonstration approvals was also not always clear, including how input informed the evaluation requirements in the STCs. For example, commenters on the applications submitted by Indiana and Kentucky raised concerns about aspects of the work and community engagement requirements proposed by each state, such as the requirements for reporting work or other activities and the circumstances under which beneficiaries would lose coverage.

- In the STCs for Indiana, CMS did not include specific hypotheses that the state would be required to test related to its work and community

³⁹CMS's initial January 2018 approval of Kentucky's demonstration application was vacated by the U.S. District Court for the District of Columbia in June 2018. *Stewart v. Azar*, 313 F. Supp. 3d 237 (D.D.C. June 29, 2018). CMS held another federal comment period in July-August 2018 and reapproved Kentucky's demonstration in November 2018. On March 27, 2019, the U.S. District Court for District of Columbia vacated CMS's November 2018 re-approval of Kentucky's demonstration. *Stewart v. Azar II*, No. 18-152 (JEB) (D.D.C. Mar. 27, 2019). CMS is appealing this decision.

⁴⁰In March 2019, CMS released this guidance, which included a monitoring report template and monitoring metrics, some of which address the impact of demonstrations on beneficiaries.

engagement policies. Instead, CMS noted that the state's goals should inform the evaluation, subject to CMS approval. For example, Indiana's goals included determining whether implementing work and community engagement requirements will lead to sustainable employment and improved health outcomes among beneficiaries.

- In the STCs for Kentucky's initial approval in January 2018, CMS included the same language as in Indiana—that the goals should inform the state's evaluation. However, in the STCs approved for Kentucky in November 2018, CMS added some broad guidance for Kentucky's draft evaluation design. Specifically, CMS included a variety of hypotheses that the state must evaluate, such as the effect of work requirements on enrollment and the impact of the demonstration on uncompensated care costs.

When approving evaluation designs, the extent to which CMS considers areas of risk identified through public input is also unclear at this time. As of January 2019, evaluation designs for the Arkansas and Indiana demonstrations were under review at CMS and Kentucky had not yet submitted one.⁴¹

- Regarding Arkansas's evaluation design, CMS sent a letter to the state providing comments and feedback that seem to align with some of the concerns raised about the demonstration through public input.⁴² Specifically, the November 2018 letter from CMS raised concerns with the state's "broadly defined" expected outcomes of the demonstration, which included culture of work and personal life stability. CMS recommended that the state revise the design to include a list of quantifiable outcomes and measures that capture the important features, such as increased employment (e.g., hours worked, wages) and improved health (e.g., health care utilization).
- For Massachusetts, the one demonstration with an approved evaluation design, the extent to which CMS considered public input

⁴¹Arkansas's evaluation design has been under review since August 2018, but the approval of its demonstration amendment was vacated in March 2019. *Gresham v. Azar*, No. 18-1900 (JEB) (D.D.C. Mar. 27, 2019). Indiana submitted an evaluation design in November 2018. A draft evaluation design was due 180 days after Kentucky's January 2018 approval, but the approval was vacated in June 2018. Kentucky's new approval from November 2018 required a draft evaluation design within 180 days, but the approval was vacated in March 2019. *Stewart v. Azar II*, No. 18-152 (JEB) (D.D.C. Mar. 27, 2019).

⁴²Arkansas submitted a draft evaluation design specifically for the work and community engagement component.

during approval was unclear. For example, with regard to Massachusetts's proposal to discontinue provisional eligibility for most adults, commenters raised concerns about the potential effects on beneficiaries' timely access to coverage and care; however, the evaluation design did not include plans to examine the effects of the policy on beneficiaries.⁴³

Though CMS did not provide specific examples of how public input had informed evaluation designs, CMS officials said requirements for evaluations have been evolving as they have gained experience in understanding the public's concerns. Officials also said they were developing robust evaluation guidance that they plan to use consistently going forward for states implementing work and community engagement requirements. As of January 2019, officials said this guidance was in draft form and under review.⁴⁴

Conclusions

While CMS has long recognized the importance of public input in the demonstration approval process, the agency has developed more robust procedures for ensuring transparency since the beginning of 2012. Despite this progress, CMS's approach to ensuring transparency when states propose major changes to their demonstrations has significant gaps. The lack of policies for ensuring transparency when states make major changes to pending applications and limited transparency requirements applied for amendments—which are being used by some states to make major changes to their demonstrations—puts CMS's goal of transparency at risk. These gaps may leave the agency and the public without key information to fully understand the potential impact of the changes being proposed, including on beneficiaries and costs. These risks take on increased importance given that CMS is encouraging states to use the flexibility provided under demonstrations to test changes to their Medicaid programs that could have significant effects for beneficiaries and other stakeholders.

⁴³Provisional eligibility allows individuals to self-attest to income and other eligibility factors. The evaluation design includes an examination of the effects of discontinuing provisional eligibility on cost-savings.

⁴⁴In March 2019, CMS released this guidance, which addresses evaluating demonstrations with work and community engagement requirements, as well as other types of eligibility and coverage policies.

Recommendations for Executive Action

We are making the following two recommendations to CMS:

The Administrator of CMS should develop and communicate a policy that defines when changes to a pending section 1115 demonstration application are considered major and should prompt a new review of the application against the transparency requirements applicable to the pending application. (Recommendation 1)

The Administrator of CMS should develop and communicate a policy whereby applications for section 1115 demonstration amendments that may have significant impact are subject to transparency requirements comparable to those for new demonstrations and extensions. (Recommendation 2)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for review and comment. HHS concurred with both recommendations. HHS's comments are reproduced in appendix III.

Regarding our first recommendation concerning when states submit major changes to pending demonstration applications, HHS stated that it will develop (1) standards for determining when such changes are so substantial that it would be appropriate for HHS to solicit additional public input, and (2) a process for informing states and the public about the additional comment period. These steps appear to formalize the approach CMS has already been taking as demonstrated by the agency's response to the changes submitted by Indiana and Kentucky to their applications. Our recommendation, however, requires additional actions. In particular, we recommended that CMS develop and communicate a policy that includes standards for when changes are substantial enough to warrant a new review of the application against the transparency requirements. The transparency requirements, among other things, call for states to provide for public notice and input at the state level before they submit their applications. As such, holding an additional federal comment period would not be sufficient to meet our concerns.

Regarding our second recommendation—concerning transparency requirements for amendment applications that may have significant impacts—HHS said that it has implemented enhanced processes to

improve transparency and will review its current processes and develop additional policies and processes, as needed, to enhance the transparency of such applications. However, the enhanced processes HHS referred to do not apply to amendments. Thus, HHS's planned review of its policies alone would not be sufficient to meet our concerns. HHS's efforts should also result in actions to develop and communicate a policy that ensures amendments with significant impacts meet transparency requirements comparable to those for other applications, namely new demonstrations and extensions.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the appropriate congressional committees, and other interested parties. In addition, this report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-7144 or yocomc@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Major contributors to this report are listed in appendix IV.



Carolyn L. Yocom
Director, Health Care

Appendix I: Information about Selected Medicaid Section 1115 Demonstration Approvals, January 2017– May 2018

State	Information
Arkansas	<p>Demonstration name: Arkansas Works (formerly Arkansas Health Care Independence Program or the Private Option)</p> <p>Demonstration history: In 2013, CMS approved Arkansas’s 3-year demonstration that expanded eligibility to adults newly eligible under the Patient Protection and Affordable Care Act (PPACA). The demonstration allowed the state to use Medicaid funds to support beneficiaries in purchasing private coverage through the state health insurance exchange. In the years since, Arkansas’s demonstration has been extended once.</p> <p>Type of application approved between January 2017 and May 2018: Amendment</p> <p>Key features of approval: Allows the state to require certain beneficiaries, ages 19 through 49, to participate in work and community engagement activities to maintain Medicaid eligibility. Beneficiaries must participate in and document 80 hours of work or community engagement activities per month in order to maintain eligibility for Arkansas Works. Beneficiaries who fail to meet this requirement for any 3 months during a plan year will be disenrolled from coverage until the following plan year (which begins in January each year).</p> <p>Approval date: March 5, 2018</p> <p>Effective date: March 5, 2018–December 31, 2021; work and community engagement requirements became effective June 1, 2018, but were halted in March 2019 when a federal district court vacated CMS’s approval of the demonstration amendment.^a</p>
California	<p>Demonstration name: California Medi-Cal 2020 (formerly Bridge to Reform)</p> <p>Demonstration history: In 2005, CMS approved California’s “Medi-Cal Hospital/ Uninsured Care Demonstration” to create a safety net care pool that provided federal matching funding for uncompensated care. In the years since, the demonstration has been extended twice and multiple amendments have been approved. Core elements of the current demonstration include a global payment program for services to the uninsured in designated public health systems, a delivery system transformation and alignment incentive program for public hospitals, a dental transformation incentive program, and a program providing integrated care for high-risk populations.</p> <p>Type of application approved between January 2017 and May 2018: Amendment</p> <p>Key features of approval: Allows the state to require beneficiaries who elect to receive Health Home Program services to enroll with the managed care plan offered by the health home provider.</p> <p>Approval date: December 19, 2017</p> <p>Effective date: December 19, 2017–December 31, 2020</p>

**Appendix I: Information about Selected
Medicaid Section 1115 Demonstration
Approvals, January 2017–May 2018**

State	Information
Florida	<p>Demonstration name: Managed Medical Assistance</p> <p>Demonstration history: In 2005, CMS approved Florida’s demonstration, “Medicaid Reform,” which included a requirement that most beneficiaries enroll in a managed care plan. The state implemented the demonstration in two counties and then expanded the program. The demonstration also established a Low-Income Pool to help finance uncompensated care costs for certain providers. In 2011, the demonstration was extended to include enhanced managed care requirements, and a continuation of the Low-Income Pool. In 2013, the state received approval to amend the demonstration to expand managed care statewide and rename the demonstration the Managed Medical Assistance program.</p> <p>Type of application approved between January 2017 and May 2018: Extension</p> <p>Key features of recent approval: Allows the state to continue the Managed Medical Assistance program and the Low-Income Pool with an annual expenditure limit for the pool of \$1.5 billion.</p> <p>Approval date: August 3, 2017 Effective date: August 3, 2017–June 30, 2022</p>
Indiana	<p>Demonstration name: Healthy Indiana Plan</p> <p>Demonstration history: In 2007, CMS approved Indiana’s Healthy Indiana Plan demonstration to allow the state to enroll low-income individuals (effective 2008), including a capped number of childless adults, into a high-deductible health plan and require them to pay monthly premiums into a health savings account. In 2015, Indiana was approved to expand the demonstration to include low-income, childless adults, newly eligible for Medicaid under PPACA. Under the demonstration, certain beneficiaries with incomes from 101-133 percent of the federal poverty level who failed to pay their premiums were disenrolled after a 60-day grace period and locked out for 6 months.</p> <p>Type of application approved between January 2017 and May 2018: Extension</p> <p>Key features of approval: Allows the state to continue the Healthy Indiana Plan and to implement work and community engagement requirements as a condition of maintaining eligibility for non-exempt beneficiaries, ages 19 through 59. Once phased in, beneficiaries subject to the requirement must complete 20 hours of work or community engagement activities per week for 8 months of the calendar year; those who fail to meet the requirement will have their eligibility suspended in the new calendar year until the month following notification to the state that they have completed a calendar month of required hours. Members can end suspension if they gain an exemption.</p> <p>Approval date: February 1, 2018 Effective date: February 1, 2018–December 31, 2020; work and community engagement requirements became effective January 1, 2019 and are being phased in gradually through July 2020.</p>
Kentucky	<p>Demonstration name: Kentucky Helping to Engage and Achieve Long Term Health (KY HEALTH)</p> <p>Type of application approved between January 2017 and May 2018: New</p> <p>Key features of approval: Allows the state to implement work and community engagement requirements as a condition of maintaining eligibility for non-exempt beneficiaries, ages 19 through 64. Non-exempt beneficiaries must complete 80 hours per month of work or community engagement activities. Failure to do so will result in a suspension of coverage until the first day of the month after the requirements are met or the beneficiary completes a health or financial literacy course. Other features of the demonstration include incentives for beneficiaries to engage in healthy behaviors, loss of coverage for 6 months for failure to provide the necessary information during the annual eligibility redetermination process; a waiver of retroactive eligibility, except for pregnant women and former foster care youth; and a waiver of the requirement to provide non-emergency medical transportation for non-exempt groups.</p> <p>Approval date: Initially approved January 12, 2018; re-approved November 20, 2018^b Effective date: January 12, 2018–September 30, 2023; work and community engagement requirements were scheduled to become effective April 1, 2019 but were halted when a federal district court vacated CMS’s re-approval of the demonstration in March 2019.</p>

**Appendix I: Information about Selected
Medicaid Section 1115 Demonstration
Approvals, January 2017–May 2018**

State	Information
Massachusetts	<p>Demonstration name: MassHealth</p> <p>Demonstration history: In 1995, CMS first approved Massachusetts’s MassHealth demonstration (effective 1997), and over the years, the demonstration has evolved through numerous amendments and extensions. The components include various coverage expansions, a Safety Net Care Pool, and a Delivery System Reform Incentive Payment program.</p> <p>Type of application approved between January 2017 and May 2018: Amendment</p> <p>Key features of approval: Allows the state to discontinue providing provisional eligibility, which allows individuals to self-attest to income and other eligibility factors, for certain adult applicants. Also allows the state to provide coverage to certain former foster care youth under age 26.</p> <p>Approval date: December 14, 2017</p> <p>Effective date: December 14, 2017–June 30, 2022</p>
Washington	<p>Demonstration name: Medicaid Transformation Project</p> <p>Type of application approved between January 2017 and May 2018: New</p> <p>Key features of approval: Allows the state to establish Accountable Communities of Health, which are regional, self-governing organizations focused on improving health and transforming care delivery for the populations within their region. The organizations—composed of managed care, provider, and other community organizations—conduct needs assessments and coordinate and oversee projects aimed at improving care for Medicaid beneficiaries through a Delivery System Reform Incentive Payment program. The demonstration authorizes other expenditures, including for services supporting unpaid caregivers and for certain designated state health programs.</p> <p>Approval date: January 9, 2017</p> <p>Effective date: January 9, 2017–December 31, 2021</p>

Source: GAO summary of documents from the Centers for Medicare & Medicaid Services (CMS) | GAO-19-315

^aSee *Gresham v. Azar*, No. 18-1900 (JEB) (D.D.C. Mar. 27, 2019). CMS is appealing this decision.

^bThis approval was vacated by the U.S. Federal District Court for the District of Columbia in June 2018. *Stewart v. Azar*, 313 F. Supp. 3d 237 (D.D.C. June 29, 2018). CMS held another federal comment period from July to August 2018 and reapproved Kentucky’s demonstration on November 20, 2018, with an effective date of April 2, 2019–September 30, 2023. This re-approval was vacated by the U.S. District Court for the District of Columbia in March 2019. *Stewart v. Azar II*, No. 18-152 (JEB) (D.D.C. Mar. 27, 2019). CMS is appealing this decision.

Appendix II: Federal Spending for Medicaid Section 1115 Demonstrations, by State, Federal Fiscal Year 2016

State	FY 2016		
	Expenditures for demonstrations (dollars in millions)	Total Medicaid expenditures (dollars in millions)	Percentage of Medicaid spending for demonstrations
n/a			
Alabama	31.2	3,824.0	0.8
Alaska	0.0	1,160.3	0.0
Arizona	8,318.7	8,395.7	99.1
Arkansas	1,697.6	4,668.0	36.4
California	22,849.1	53,123.7	43.0
Colorado	0.0	4,859.2	0.0
Connecticut	0.0	4,303.0	0.0
Delaware	852.5	1,169.9	72.9
District of Columbia	42.9	2,058.0	2.1
Florida	8,959.9	13,202.9	67.9
Georgia	3.8	6,585.7	0.1
Hawaii	1,332.4	1,409.6	94.5
Idaho	0.0	1,204.1	0.0
Illinois	0.4	11,482.8	0.0
Indiana	1,937.6	7,420.3	26.1
Iowa	47.3	2,944.6	1.6
Kansas	1,709.0	1,829.1	93.4
Kentucky	0.0	7,575.7	0.0
Louisiana	791.5	5,430.3	14.6
Maine	31.6	1,565.8	2.0
Maryland	4,924.9	6,361.7	77.4
Massachusetts	5,210.9	9,199.8	56.6
Michigan	3,643.7	12,220.3	29.8

**Appendix II: Federal Spending for Medicaid
Section 1115 Demonstrations, by State,
Federal Fiscal Year 2016**

State n/a	FY 2016		
	Expenditures for demonstrations (dollars in millions)	Total Medicaid expenditures (dollars in millions)	Percentage of Medicaid spending for demonstrations
Minnesota	72.4	6,270.3	1.2
Mississippi	74.9	4,017.2	1.9
Missouri	436.7	6,224.9	7.0
Montana	150.7	914.4	16.5
Nebraska	0.0	1,009.7	0.0
Nevada	217.4	2,554.4	8.5
New Hampshire	596.0	1,176.2	50.7
New Jersey	7,384.8	8,689.2	85.0
New Mexico	3,768.3	4,244.7	88.8
New York	707.6	33,459.6	2.1
North Carolina	0.1	8,064.5	0.0
North Dakota	0.0	734.8	0.0
Ohio	0.0	14,936.1	0.0
Oklahoma	1,430.4	2,783.6	51.4
Oregon	4,913.6	6,380.0	77.0
Pennsylvania	3.2	16,476.2	0.0
Rhode Island	967.5	1,374.3	70.4
South Carolina	0.0	4,262.1	0.0
South Dakota	0.0	464.0	0.0
Tennessee	5,138.9	6,209.2	82.8
Texas	18,433.5	22,728.3	81.1
Utah	122.8	1,475.9	8.3
Vermont	995.1	995.4	100.0
Virginia	17.0	4,268.7	0.4
Washington	1.2	6,655.2	0.0
West Virginia	0.0	2,841.1	0.0
Wisconsin	579.1	4,458.6	13.0
Wyoming	0.0	293.2	0.0
National total	108,396.2	345,956.2	31.3

Source: GAO analysis of Centers for Medicare & Medicaid Services data, as of January 3, 2018 | GAO-19-315

Note: Total Medicaid expenditures reflect federal spending and do not include state spending. We included data on medical spending and excluded administrative costs. States have 2 years to report spending; therefore, states may have reported expenditures for the fiscal year (FY) even if the state did not have an active demonstration that year. The data reflect adjustments to prior years of spending, both positive and negative; therefore, the data may overstate or understate spending in the given year. Data for New York likely understate total spending as the state's expenditure reporting was incomplete.

Appendix III: Comments from the Department of Health and Human Services

**Appendix III: Comments from the Department
of Health and Human Services**



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

MAR 29 2019

Carolyn Yocom
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Yocom:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency*" (GAO-19-315).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. D. Bassett".

Matthew D. Bassett
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – MEDICAID DEMONSTRATIONS: APPROVALS OF MAJOR CHANGES NEED INCREASED TRANSPARENCY (GAO-19-315)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report on Medicaid section 1115 demonstrations. HHS takes seriously its role in oversight and approval of Medicaid demonstrations and ensuring that interested parties have a meaningful opportunity to provide input to inform these processes.

Sections 1115 and 2107(e)(2) of the Social Security Act give the Secretary of HHS authority to approve experimental, pilot, or demonstration projects that, in the judgment of the Secretary, are likely to assist in promoting the objectives of Medicaid and the Children's Health Insurance Program (CHIP). These demonstrations give states additional flexibility to design and evaluate innovative approaches to improve their Medicaid and CHIP programs, including alternative eligibility and coverage, service delivery, and financing policies that, in the Secretary's judgment, are likely to improve beneficiary health and financial independence, and at the same time, are likely to allow states to maintain the long-term fiscal sustainability of their Medicaid programs.

Federal regulations on section 1115 transparency at 42 C.F.R. part 431, subpart G establish minimum standards for state and federal public notice and input processes. Both under the regulations and through its case-by-case review of section 1115 applications, HHS has broad discretionary authority to require, as a part of its application review, additional transparency processes occur at the state and federal levels. It is important to note that HHS' broad discretionary authority allows for a certain amount of variability in the review of section 1115 demonstration applications. However, HHS has also taken additional measures to improve consistency across all pending section 1115 application reviews. For example, both through its regulations and through the special terms and conditions that govern approved demonstration projects, HHS has established processes for ensuring public input on the development and approval of new section 1115 demonstrations, extensions of existing demonstrations, and amendments to existing demonstrations. These processes help to ensure that information about Medicaid and CHIP demonstration applications and approved demonstration projects is publicly available at the state and federal levels. Further, HHS' approval process is designed to ensure that the public will have an opportunity to provide comments on any state demonstration application submission that HHS has determined to be complete in accordance with regulation.

In addition, HHS released an informational bulletin in 2017 to states to outline process improvements in the review, approval, monitoring and evaluation of section 1115 Medicaid demonstrations.¹ The bulletin contains information about assistance available to states as they work to complete the demonstration application process, including transparency requirements. This assistance includes technical assistance in advance of a formal submission of a demonstration application, as well as several tracking tools such as a transparency review checklist.

GAO's recommendations and HHS' responses are below.

¹ <https://www.medicaid.gov/federal-policy-guidance/downloads/cib110617.pdf>

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – MEDICAID DEMONSTRATIONS: APPROVALS OF MAJOR CHANGES NEED INCREASED TRANSPARENCY (GAO-19-315)

Recommendation 1

The Administrator of CMS should develop and communicate a policy that defines when changes to pending section 1115 demonstration applications are considered major and should prompt a new review of the application against the transparency requirements applicable to the pending application.

HHS Response

HHS concurs with this recommendation.

HHS will develop standards for determining when changes to a pending section 1115 demonstration application are so substantial that it would be appropriate for HHS to solicit additional public input on the application. HHS will also develop an associated process to inform the state and public about the additional comment period and review and consider the input provided during that comment period.

Recommendation 2

The Administrator of CMS should develop and communicate a policy whereby applications for section 1115 demonstration amendments that may have significant impact are subject to transparency requirements comparable to those for new demonstrations and extensions.

HHS Response

HHS concurs with this recommendation.

HHS has already implemented processes to help improve the transparency of section 1115 amendment applications². HHS will review the implementation of these process enhancements and develop additional policy and associated processes, as needed, to enhance the transparency relating to applications for section 1115 demonstration amendments that propose substantial changes to existing demonstrations.

² 42 C.F.R. part 431, subpart G

Appendix IV: GAO Contact and Staff Acknowledgements

GAO contact:

Carolyn L. Yocom, (202) 512-7114 or yocomc@gao.gov

Staff Acknowledgements

In addition to the contact named above, Susan Barnidge (Assistant Director), Linda McIver (Analyst-in-Charge), Michael Moran, and Jessica L. Preston made key contributions to this report. Also contributing were Drew Long, Vikki Porter, and Emily Wilson.

Appendix V: Accessible Data

Agency Comment Letter

Accessible Text for Appendix III Comments from the
Department of Health and Human Services

Page 1

MAR 29 2019

Carolyn Yocom Director, Health Care

U.S. Government Accountability Office

441 G Street NW

Washington, DC 20548

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