



441 G St. N.W.
Washington, DC 20548

August 4, 2015

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Subject: Responses to Questions for the Record; Hearing Entitled *Examining the Administration's Approval of Medicaid Demonstration Projects*

Dear Chairman Pitts,

This letter responds to your July 21, 2015 request that we address several questions for the record related to the Subcommittee's June 24th hearing on Medicaid demonstrations. Our responses to the questions, which are in the enclosure, are based on our previous work and knowledge on the subjects raised by the questions.

If you have any questions about the letter or need additional information, please contact me on (202) 512-7114 or at iritanik@gao.gov.

Sincerely yours,

A handwritten signature in black ink that reads 'Katherine Iritani'.

Katherine M. Iritani
Director, Health Care

Enclosure

The Honorable Representative Pitts

- 1. In approving 1115 waivers, CMS has provided expenditure authority that allowed states to make new kinds of supplemental payments through the creation of uncompensated care pools. My understanding is that in many cases this authority is necessary for some states who are shifting Medicaid populations from fee-for-service to managed care and thus no longer able to make supplemental payments without a waiver. Can you explain why the shift to managed care affects a state's ability to make supplemental payments?**

Federal Medicaid regulations generally prohibit payments by a state Medicaid agency to providers for services rendered under a contract with managed care organizations.¹ In general this means that the statewide use of managed care precludes states from making supplemental payments to providers. Some states pursuing a shift to managed care under a section 1115 demonstration have been able to retain the ability to make supplemental payments through new expenditure authorities approved by, and at the discretion of, the Department of Health and Human Services (HHS). Our work has found that some states have substantially increased the amount of supplemental payments they make under section 1115 demonstrations. For example, one reviewed state claimed federal reimbursement for about \$2.6 billion in supplemental payments in fiscal year 2011, the year prior to its demonstration and implementation of statewide managed care. Under the demonstration, which started in fiscal year 2012, the state was authorized to receive federal matching funds on \$4.2 billion in supplemental payments for uncompensated care and delivery system improvements during the first year of the demonstration, and on \$6.2 billion for each of the remaining 4 years.

- 2. At the hearing you indicated that there is no set period of time for CMS to review and respond to a request for a new 1115 demonstration application. Is there a set period of time for CMS to review and respond to state plan amendments and other waivers, namely those authorized under section 1915(b) [managed care] and 1915(c) [home- and community-based services]? If so, what is the time period established for CMS review of those state program changes and waiver applications?**

There are certain time frames established for the Centers for Medicare & Medicaid Services's (CMS) review of state plan amendments and states' proposals for 1915(b) and 1915(c) waivers.

- State plan amendments are considered approved unless, within 90 days of receiving the request, CMS either denies the request or notifies the state that additional information is needed to make a determination. If CMS requests additional information, the 90-day review period begins on the day CMS receives that information.
- The approval processes for section 1915(b) and section 1915(c) waivers are similar to those for state plan amendments. Such waivers are considered approved unless, within 90 days after the request is received, CMS denies the request or sends the state a written request for additional information. If additional information is requested, a new 90-day period begins the day the additional information is received.

In comparison, there are generally no set timeframes within which CMS must review section 1115 demonstrations.² Following the Subcommittee's June 24, 2015, hearing on Medicaid demonstration approvals, CMS issued a bulletin describing a new "Fast Track" review process for certain extensions of Medicaid and Children's Health Insurance Program section 1115

¹See 42 C.F.R. 438.60.

² Section 1115 of the Social Security Act does impose time frames for the review of certain extensions.

demonstrations.³ The bulletin states that the fast track process will be available for states applying to extend established section 1115 demonstrations that are working successfully and for which the states are not seeking any major or complex policy changes. According to CMS, the review times for such extensions will be comparable to those for section 1915 waivers or state plan amendments.

3. One frustration often voiced by State officials is the time it takes to negotiate and secure an 1115 waiver. For example, in Indiana, it took the governor 2 years to negotiate the waiver for HIP 2.0. What thoughts do you have about parameters Congress could put around the process to provide some certainty for states? What policy factors would we need to think through?

In considering whether to impose parameters around the section 1115 waiver review process, it is important to balance the need for certainty and speed with transparency and effective oversight, given the complexity and scope of section 1115 demonstrations. These demonstrations—accounting for close to one-third of total Medicaid expenditures in fiscal year 2014—have been characterized as unique among Medicaid’s waiver authorities because of the broad flexibilities granted to states in designing demonstrations. Unlike other waivers that have defined timeframes for HHS’s review process, section 1115 demonstrations can have a much larger scope and involve more complicated changes to a state’s Medicaid program. They can be narrowly tailored to specific services or populations or can cover most of a state’s Medicaid program. Furthermore, states can use section 1115 waivers to alter the parameters of the Medicaid program for beneficiaries by increasing cost-sharing or reducing Medicaid benefits, and GAO’s work has found that many waiver requests have sought to make such changes. In addition, given the broad flexibility HHS has to allow federal matching for costs not otherwise eligible for Medicaid funds, section 1115 demonstrations can have significant implications for federal Medicaid expenditures.

Given the flexibilities with section 1115 demonstration waivers, the timeframe for the review process, as we have noted in prior work, may be affected by a number of factors.⁴ For instance, in some cases, prior to commencing a formal review, a state may submit concept papers to receive technical assistance, which may result in an extended dialogue between the state and HHS. The completeness of the application can also affect timeframes. If applications lack important details or data, HHS may request extensive clarification, and states may require additional time to respond. In our prior work, we found that HHS review times for section 1115 demonstrations varied significantly. In 2013, we found that for 46 reviews that HHS completed between January 2007 and May 2012, reviews took from 47 days to almost 4 years and averaged 323 days from the date of application to the date of the review decision; however, the majority—about 72 percent—of the reviews took a year or less to complete.

Flexibility and program experimentation must also be accompanied by accountability, including public input. In our past work, we raised concerns about the transparency of the demonstration approval process and recommended that the Department provide opportunity for public input

³Centers for Medicare & Medicaid Services, *CMCS Informational Bulletin: Implementation of a “Fast Track” Federal Review Process for Section 1115 Medicaid and CHIP Demonstration Extensions* (Baltimore, Md.: July 24, 2015). See <http://www.medicare.gov/Federal-Policy-Guidance/downloads/CIB07242015-Fast-Track.pdf>.

⁴GAO, *Medicaid Demonstration Waivers: Approval Process Raises Cost Concerns and Lacks Transparency*. GAO-13-384 (Washington, D.C.: June 25, 2013).

into HHS's consideration of section 1115 proposals.⁵ The Patient Protection and Affordable Care Act included a provision requiring HHS to address this concern. HHS established a 30-day public comment period for section 1115 demonstration proposals under consideration and must wait at least 45 days before making a final determination.

As we noted above, CMS recently established a "fast track" process for reviews of certain extensions of section 1115 demonstrations that the agency considers to be less complex. Under the fast track process, states will submit streamlined application documents and, in reviewing these, CMS will observe timeframes comparable to those it uses to make decisions on section 1115 waivers or state plan amendments. CMS has identified specific policy areas as inherently complex and has excluded them from the fast track process. These areas include, among others, Medicaid expansion programs tied to enhanced federal medical assistance percentage, delivery and payment reforms that cannot be authorized under state plan authority, state programs, and enrollment caps and eligibility limitations. Our work would support CMS's decision to not apply a fast track process for complex waiver proposals.

- 4. In your testimony, you noted that demonstration approvals varied in the extent to which they provided assurances that Medicaid funding for state programs would not duplicate other potential sources of federal funding. As a result, these demonstrations run the risk of resulting in billions of dollars of duplication of federal funding. What can CMS do to avoid such potential for duplication?**

In our April 2015 report, we recommended that HHS take steps to ensure that demonstration approval documents provide assurances that states will avoid duplicative federal spending.⁶ In our review, we found that the approval documents for some but not all states included detailed information about the state programs approved for funding, in what HHS refers to as "claiming protocols." The claiming protocols for these states identified all other federal and nonfederal funding sources for each state program. Further, they included specific instructions on how the states should "offset" other revenues received by the state programs related to eligible expenditures. We believe HHS needs to ensure that all approval documents provide assurances—such as through claiming protocols—that states will avoid duplicative spending by offsetting as appropriate all other federal revenues received when claiming federal Medicaid matching funds. HHS concurred with our recommendation, stating that it will require all future section 1115 approvals to include clear claiming protocols for both new and previously authorized state programs to verify there is no duplication of federal funding. Since the release of the final report, HHS has told us that additionally, for all current approvals, CMS will work with states to document how there is no duplication of federal funding as CMS processes demonstration actions.

- 5. To what extent has the use of 1115 waivers and Medicaid expenditures related to these waivers increased over time? Can you please provide a chart demonstrating their growth (in number of waivers and total dollars governed by a waiver)?**
- a. Does the increase in 1115 waivers point to the need for more state flexibility in Medicaid?**

⁵GAO, *Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns*, GAO-02-817 (Washington, D.C.: Jul. 12, 2002). See also, GAO, *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).

⁶GAO, *Medicaid Demonstrations: Approval Criteria and Documentation Need to Show How Spending Furthers Medicaid Objectives*, GAO-15-239 (Washington, D.C.: Apr. 13, 2015).

b. To what extent is the increase in expenditures related to 1115 waivers a result of the waivers not being budget neutral?

CMS's website does not capture summary statistics on either the use of 1115 waivers or total spending governed by waivers. We can glean some information on the general trends in use of these waivers from published reports.

Based on inventories conducted by the Congressional Research Service (CRS), the number of approved section 1115 demonstrations has increased over time. Specifically, CRS reported that in 2004 there were 19 states with comprehensive section 1115 demonstrations.⁷ In 2008, CRS reported that this number had increased to 32 comprehensive section 1115 demonstrations across 26 states.⁸ Our recent work suggests that the use of Medicaid 1115 waiver authority among states is still high.⁹ In our April 2015 report, we identified 25 states that received approval for new comprehensive demonstrations or renewals or amendments to ongoing demonstrations, in a relatively short period (June 2012 to October 2013).¹⁰ Although section 1115 demonstrations can provide states considerable flexibility to modify their Medicaid programs, we do not know all of the reasons states seek 1115 waivers, and believe these reasons are complex. Our recent work has shown that many states through 1115 demonstrations obtained flexibility to use federal funds to pay for services not typically covered under Medicaid. States have been approved to implement different coverage strategies or impose new cost sharing for certain beneficiary populations, and many states in recently approved demonstrations have also sought flexible funding for otherwise non-covered purposes such as new types of supplemental payments.

Summary information from CMS captured in GAO's reports also suggests that the amount and proportion of Medicaid expenditures made under section 1115 demonstrations has increased in recent years.

- In fiscal year 2011, \$57.5 billion in federal funds, or about one-fifth of the \$260 billion in federal Medicaid expenditures, were under section 1115 demonstrations.¹¹
- In fiscal year 2013, \$70 billion in federal funds, or about one-fourth of the \$265 billion in federal Medicaid expenditures, were under section 1115 demonstrations.¹²
- In fiscal year 2014, an estimated \$89 billion in federal funds were spent under section 1115 demonstrations, which accounted for close to one-third of total Medicaid expenditures.¹³

⁷Congressional Research Service, *Medicaid and SCHIP Section 1115 Research and Demonstration Waivers*, CRS Report for Congress (Washington, D.C.: March 5, 2004). When speaking of 1115 demonstrations, we and others typically distinguish comprehensive demonstrations from those that provide for a single category of services, such as family planning.

⁸Congressional Research Service, *Medicaid and SCHIP Section 1115 Research and Demonstration Waivers* (update), CRS Report for Congress (Washington, D.C.: Sept. 11, 2008).

⁹See CMS's website for demonstrations at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/1115/section-1115-demonstrations.html>.

¹⁰See GAO-15-239.

¹¹See GAO-13-384.

¹²See GAO, *Medicaid Demonstrations: HHS's Approval Process for Arkansas's Medicaid Expansion Waiver Raises Cost Concerns*, [GAO-14-689R](#) (Washington, D.C.: Aug. 8, 2014).

Although we do not know the extent that increased spending under demonstrations stems from HHS's approval of spending limits in excess of what was justified, we believe potential cost savings from HHS implementing more rigorous criteria and methods for reviewing spending limits could be in the tens of billions of dollars. For example, for five states' demonstrations we reviewed in our 2013 and 2014 reports, had HHS followed its budget neutrality policy, an estimated \$33 billion in excess spending, with a federal share of approximately \$22 billion, could have been avoided.¹⁴

- 6. The Affordable Care Act included a provision that addressed a 2002 recommendation GAO made to increase the transparency of the waiver approval process. Specifically, the ACA provision, which was the result of a bipartisan effort, required HHS to issue regulations designed to ensure that the public has the opportunity to provide input on proposed section 1115 demonstration processes. In response to this provision, CMS issued regulations in February 2012. While this provision and the resulting regulations are a positive step in addressing GAO concerns, am I correct that this only addresses a rather small portion of the concerns GAO has raised with the 1115 waiver process? If so, what other changes to the 1115 waiver process has GAO recommended that have yet to be addressed?**

GAO has long-standing concerns about HHS's demonstration approval process, and while HHS has implemented several recommendations to improve accountability and transparency in its processes, HHS has yet to take actions that fully address the majority of the more than a dozen recommendations we have made about section 1115 demonstrations since the early 2000's. These recommendations have generally fallen into the following categories: ensuring budget neutrality, furthering Medicaid objectives, and ensuring that demonstrations are appropriately monitored and evaluated.

Ensuring Budget Neutrality: We have made multiple recommendations to HHS aimed at improving its process for approving demonstration spending limits, making determinations more transparent, and issuing an up-to-date written policy and making it widely available. HHS disagrees with the need for these recommendations, which remain unimplemented. HHS policy requires that section 1115 demonstrations be budget-neutral to the federal government—that is, that demonstrations should not increase federal spending over what it would have been if the state's existing Medicaid program had continued. Between 2002 and 2014, GAO reviewed HHS's approvals of over a dozen states' demonstration spending limits and found that HHS had approved spending limits that we estimated were billions of dollars higher than what federal spending would have been if the states' existing Medicaid programs had continued. In particular, we found that HHS has allowed states to use questionable methods and assumptions in developing their estimated costs without providing adequate documentation to support them. Between 2002 and 2004, we recommended that HHS (1) clarify criteria for reviewing and approving states' demonstration spending limits, (2) ensure that valid methods are used to demonstrate budget neutrality, and (3) document the basis for approval. Because HHS disagreed with or did not implement these recommendations, in 2008 we suggested that Congress consider requiring the Secretary of HHS to improve the process by, for example, better ensuring that valid methods are used to demonstrate budget neutrality and documenting

¹³See GAO-15-239. Calculation is based on expenditures for medical assistance payments only, which for fiscal year 2014 were \$146.8 billion for section 1115 demonstrations and \$466.5 billion for total Medicaid expenditures, as reported in the Medicaid Budget and Expenditure System, as of January 2015.

¹⁴See GAO-13-384 and GAO-14-689R.

and making public the basis for such approvals. In 2013, we found additional problems with HHS's written budget neutrality policy (most recently updated in 2001) not reflecting HHS's actual practices, and therefore made further recommendations. We recommended that HHS update its written budget neutrality policy to reflect the actual criteria and processes used to develop and approve demonstration spending limits and ensure the policy is readily available to state Medicaid directors and others. As with the earlier recommendations regarding clarifying its criteria, allowing only valid methods for developing spending projections, and making the basis for approvals transparent, HHS disagreed with this new recommendation.¹⁵ We continue to believe that HHS must take actions to improve the transparency and accountability of its demonstration approvals and should fully implement our recommendations.

Furthering Medicaid Objectives: In our April 2015 report, as discussed in the June testimony, we had three recommendations. HHS agreed with two of these, and partially agreed with the third. HHS has reported to us in recent weeks on the status of its actions on our recommendations. We will examine HHS's actions and report publicly as to the status. Our three recommendations and HHS's responses were as follows:

- We recommended that HHS better ensure that section 1115 furthers Medicaid objectives by issuing criteria for assessing whether section 1115 expenditure authorities are likely to promote Medicaid objectives. HHS partially agreed with this recommendation, noting that all section 1115 demonstrations are reviewed against "general criteria" to determine whether Medicaid objectives are met. However, HHS did not indicate plans to issue these general criteria in writing, and we maintained that more-specific guidance is needed to improve transparency.
- We also recommended that HHS ensure that the use of these criteria is documented in its approvals of demonstrations; HHS concurred with this recommendation. In July of this year, HHS informed us of steps it had taken since the release of our report to clarify and document in approvals the criteria used to determine whether Medicaid objectives are being met. According to HHS, it has identified in recent approvals which of the general criteria each approved expenditure authority promotes. While this may add some transparency, we still regard HHS's general criteria as not sufficiently specific enough to inform stakeholders of the department's interpretation of its section 1115 authority. Moreover, these criteria are still not available as written guidance.
- Finally, in our report we recommended that HHS take steps to ensure that its approval documentation consistently provide assurances that states will avoid duplicative spending between federal Medicaid funds for demonstrations and other federal funds available to states for the same or similar purposes. As noted above, HHS agreed with our recommendation and told us in July 2015 that CMS will be requiring all future 1115 approvals to include information to verify that there is no duplication of federal funding and will work with states to document how there is no duplication of federal funding as it processes demonstration actions.

¹⁵Based on our broader concerns, we have also made several recommendations that HHS reconsider the spending limits approved for different state demonstrations examined in our work. In total between 2002 and 2013 we have made three state-specific recommendations covering five different state demonstrations. In each case, HHS disagreed with and has not implemented our recommendations.

Monitoring and Evaluating the Demonstrations: Finally, in our past work from the mid-2000's we recommended that HHS take certain actions to improve monitoring and evaluation in states' section 1115 demonstrations.¹⁶ Specifically, we recommended that HHS ensure states develop rigorous evaluation designs and implement them by collecting and reporting the information needed for a full evaluation of the demonstration objectives. This recommendation was based on our review of demonstrations in four states that provided a prescription drug benefit to certain populations. In this review, we found that states had taken few steps toward implementing their evaluation plans, which were required as a condition of approval, and that HHS had not ensured that progress reports submitted by states contained sufficient information for monitoring whether the demonstrations were functioning as intended. HHS concurred with this recommendation at the time, but we closed this recommendation as unimplemented when the particular demonstration type was ended and no action had been taken.

7. GAO's report entitled "Medicaid Demonstrations: Approval Criteria and Documentation Need to Show How Spending Furthers Medicaid Objectives" raised concerns about overlap and duplication of programs funded under 1115 demonstrations with other federal funding. To what extent will GAO further review the extent of overlap and duplication resulting from 1115 demonstrations and CMS's actions to address the overlap and duplication in its annual reports on Duplication and Cost Savings?

In our next annual report on fragmentation, overlap, and duplication in the federal government, we plan to summarize our April 2015 report findings on approved expenditure authorities under section 1115 demonstrations and the gaps in the documentation with regard to how the approved spending would further Medicaid objectives and not duplicate other federal funding streams for similar purposes. We believe that if HHS were to take action to respond to our recommendations there is potential for significant federal cost savings.

8. States using Medicaid managed care do not, all things being equal, have CMS approval to provide federal financial participation for state programs (at least for the managed care population) that are unrelated to health care or medical services. So, it seems to me that the use of managed care would prioritize federal dollars being spent *directly on care* or its related expenses, rather than lower-priority state programs which are, at best, only tangentially connected to Medicaid's objectives. Would you agree?

We would agree that, consistent with federal requirements, Medicaid payments under state plans should be used to finance Medicaid-covered items and services for eligible individuals, and that payments under section 1115 demonstrations should be used for services that help promote Medicaid objectives. In our review of recently approved section 1115 demonstrations, we found that expenditure authorities allowing states to claim federal matching funds for state programs were established separately from other authorities, including those allowing states to deliver services through managed care.

¹⁶GAO, *Medicaid Waivers: HHS Approvals of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns*, [GAO-04-480](#) (Washington, D.C.: June 30, 2004).