Report to Congress

The U.S. Department of Health and Human Services’ First Report on Section 1115(a) Demonstrations: Transparency in the Review and Approval of Medicaid and Children’s Health Insurance Program (CHIP) Section 1115 Demonstrations
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INTRODUCTION

This report responds to Congress’ request for the Department of Health and Human Services (HHS) to report on actions taken with respect to section 1115(a) Medicaid and Children’s Health Insurance Program (CHIP) demonstration projects. Section 10201 of the Affordable Care Act amended section 1115 of the Social Security Act (the Act) to enhance public transparency, at both the state and federal level, in developing and considering applications to implement new or to extend section 1115 demonstration projects that affect Medicaid or CHIP. Specifically, the Secretary of HHS was required to develop regulations to provide for a state and federal public notice and comment process for state applications for new section 1115 demonstration projects or to extend existing demonstrations, and also to report to Congress on actions taken with respect to section 1115 demonstrations. Thereby, this report to Congress highlights HHS’ activities since the enactment of the Affordable Care Act that have increased the opportunities for the public to not only learn about proposed section 1115 demonstrations but also to provide meaningful input on demonstration applications and extension requests submitted for HHS consideration. This report also describes the activities undertaken to increase transparency in HHS’ review process for assessing how applications for new section 1115(a) demonstrations as well as requests to extend existing demonstration projects will further the objectives of Medicaid or CHIP.

BACKGROUND AND CONTEXT

Section 1115 Demonstration Projects

Section 1115(a) of the Act gives the Secretary of HHS the authority to approve state experimental, pilot, or demonstration projects that waive requirements of section 1902 of the Act to the extent that such projects are likely to assist in promoting the objectives of the Medicaid program. These demonstration projects also allow the Secretary to provide federal financial participation (FFP) for demonstration costs that would not otherwise be considered as expenditures under the Medicaid state plan. The waiver and expenditure authorities authorized in section 1115 apply to CHIP in the same manner as they apply to the Medicaid program.

Section 1115(a) demonstrations are typically approved for an initial five (5) year period and extended for three (3) years, although HHS has discretion to approve shorter or longer approval periods. As described further below, section 1115(b)(3) of the Act and longstanding HHS policy requires that demonstrations be budget neutral to the federal government, meaning that

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2 1115(a).
3 1115(a)(2)(A).
4 Section 2107(e) of the Act. CHIP (title XXI) demonstrations must be allotment neutral meaning that federal spending for the demonstration is limited to what is available under the state's CHIP allotment.
5 Demonstrations that cover Medicare/Medicaid dually eligible individuals may be extended for five (5) years. CMS also has discretion to approve section 1115(a) demonstration extensions for five (5) years.
during the course of the project, federal Medicaid expenditures will not be more than spending without the demonstration project. Section 1115(a) authority provides states with broad flexibilities to test, with federal approval, new and innovative approaches to providing quality healthcare to beneficiaries that are not otherwise permitted under the Act in ways that support CMS’ commitment to supporting the objectives of the Medicaid program and effective stewardship of program funds.

The flexibilities afforded by section 1115 authority foster diversity in state demonstration programs. In this report, we highlight the most common demonstration projects CMS has approved that implement new and innovative approaches in response to the evolving needs of both Medicaid beneficiaries and providers in a dynamic healthcare system. For example, CMS has approved states’ use of section 1115 authority to expand coverage and provide enhanced benefits to optional Medicaid populations that vary from what is in the Medicaid state plan. We have also allowed states to implement demonstrations that are targeted to certain populations or disease/health conditions such as HIV. In support of HHS’ 2013 – 2017 Strategic Plan to advance measurable quality improvement, access to care and payment reform, CMS approved use of this authority to test innovative service delivery system models, including new forms of managed care, other integrated coverage models, and mechanisms to help providers reform how they provide care to Medicaid beneficiaries. To this end, we have approved comprehensive integrated delivery system demonstrations that have innovative care coordination components and integrate physical and behavioral health care, including home and community based services. Some of these demonstration projects also include provider payment incentives that are tied to measurable outcomes. Finally, we have approved under section 1115 authority approaches to Medicaid expansion that allows states to take up state specific approaches while maintaining consumer protections.

Section 1115(a) authority has also been a vehicle to promote several strategies to facilitate Medicaid enrollment when the Affordable Care Act’s new streamlined eligibility and enrollment provisions took effect in 2014. Under the Affordable Care Act, all states are required to implement changes to streamline, simplify, and coordinate enrollment processes across health coverage programs regardless of a state’s decision to participate in the Medicaid coverage expansion. To this aim, CMS worked with states to use section 1115 authority to facilitate expansion of eligibility to individuals who would not otherwise qualify for Medicaid or CHIP under the state plan. For example, we approved section 1115 demonstrations for states to come into early compliance with the new Modified Adjusted Gross Income (MAGI) income standard as well as to facilitate the seamless transition of individuals previously covered under a section 1115 demonstration into the new Medicaid state plan eligibility group or into Marketplace coverage.

As of September 2015, there are 55 approved section 1115 demonstration projects in operation in 38 states. For a list of section 1115 demonstration projects refer to [http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/Waivers_faceted.html](http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/Waivers_faceted.html).
select populations or geographic areas, and 13 specifically provide family planning services to individuals who are not otherwise eligible for Medicaid.

Section 1115 demonstration authority is only one of the authorities available to states to pursue delivery system reform and improve coverage for individuals (e.g., §1915(b) managed care options, §1915(i) home and community services options, or §1945 health homes). Those alternatives are not reflected in the totals above. States can also support innovative payment and delivery approaches under Medicaid state plan authority.7

The History of Transparency

As noted above, section 1115 demonstrations can have a significant and varied impact on beneficiaries, providers, and state and local governments. They influence policy making at the state and federal level by introducing new approaches to healthcare that, once successfully implemented with demonstrated positive outcomes, can be a model for other states and lead to programmatic changes nationwide. In light of the significant impact demonstration projects can have, there has been longstanding focus on facilitating appropriate public input as applications for section 1115 demonstrations are reviewed and approved.

CMS has worked over the years to enhance policy and practice to assure the public has sufficient notice and opportunity for meaningful input on state section 1115 proposals submitted for federal consideration, while also being mindful of the need to avoid duplicative processes and unnecessary administrative burdens and delays as we work with states to test new approaches in response to rapidly evolving state and federal health policy. Prior to the Affordable Care Act, HHS set forth policy regarding the development and review of demonstrations in a September 27, 1994 Federal Register Notice that provided general principles and guidelines governing demonstration projects including a public notice process.8 In September 1994, HHS published an additional policy on public participation during the demonstration approval process in the Federal Register requiring HHS to post notice of pending demonstrations in the Federal Register. The policy also listed examples of potential approaches states could use to solicit public comments.

The Government Accountability Office (GAO) has also had a long-standing focus on the transparency of HHS’s review and approval of section 1115 demonstrations. In multiple reports issued from 2002 to 2014, the GAO expressed concerns regarding the lack of transparency and provided recommendations for how HHS should provide more clarity in the policy, process, and criteria for reviewing and approving section 1115 demonstrations; citing budget neutrality as one of the more critical areas for increased transparency.9 The GAO documented issues with

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8 See Medicaid Program; Demonstration Proposals Pursuant to Section 1115(a) of the Social Security Act; Policies and Procedures, 59 Fed. Reg. 49,249 (Sept. 27, 1994).
compliance with the federal demonstration review process described in the September 27, 1994 Federal Register notice in a 2002 report entitled “Medicaid and SCHIP – Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns.”

CMS took several steps to address the GAO’s concerns and generally improve the demonstration process by strengthening education of and engagement with the public on section 1115 applications and extension requests. In 2002, CMS issued a letter to State Medicaid Directors to encourage states to facilitate public participation in the development of demonstration applications in an effort to enhance adherence to the public notice procedures outlined in the 1994 Federal Register notice. By 2006, due to widespread access to, and use of the internet, CMS transitioned from publishing pending state demonstration applications in the Federal Register to posting on the CMS website within 10 days of receipt of a state’s application. This same year, CMS also began to accept written comments on all demonstration applications at any time.

**Consultation and Coordination with Indian and Tribal Governments**

HHS also enhanced engagement with Indian and Tribal Governments on pending section 1115 applications and extension requests. In 2000, the President issued an Executive Order regarding “Consultation and Coordination with Indian and Tribal governments” that mandated establishment of regular and meaningful consultation and collaboration with tribal officials in the development of federal policies that have tribal implications. In July 2001, CMS issued a State Medicaid Director’s letter that provided direction to states that have federally-recognized tribes to allow the tribes to participate in the planning and development of Medicaid and CHIP demonstration applications and extensions.

The enactment of section 5006 of the American Recovery and Reinvestment Act of 2009 (ARRA) added an additional requirement for states that have an Indian health program and/or an urban Indian health organization. These states are required to seek advice from the Indian health programs and urban Indian health organizations concerning Medicaid and CHIP policies before submitting a Medicaid or CHIP state plan amendment, demonstration request or application that would directly affect Indian health programs and urban Indian health organizations. This provision was effective July 1, 2009, and was summarized in a January 22, 2010 letter to State...
Medicaid Directors and codified in the April 2012 final transparency regulation.\textsuperscript{16} To implement this provision, CMS required states with an Indian health program and/or an urban Indian health organization to submit a state plan amendment that memorialized the agreed upon process by which the state and the Indian health programs would consult on Medicaid or CHIP state plan amendments, demonstration requests or applications that would directly affect Indian health programs. There are currently 35 approved ARRA section 5006 state plan amendments that govern the process by which a state must seek advice and guidance from an Indian health program.

While states are largely compliant with this requirement, CMS has returned or disapproved state plan amendments and demonstration applications for failure to meet this statutory requirement. In these instances, we worked closely with states on ways to fulfill requirements for meaningful tribal consultation in the most efficient manner possible for resubmission.

**THE AFFORDABLE CARE ACT AND TRANSPARENCY**

With the enactment of the Affordable Care Act, Congress set forth additional requirements to increase the degree to which information about Medicaid and CHIP demonstration applications and approved demonstration projects is publicly available and to further enhance transparency in the federal review and approval of section 1115 demonstration applications. Specifically, the Affordable Care Act amended section 1115 of the Act by adding a new subsection (d) to require the Secretary to issue regulations that would ensure the public has sufficient opportunities to provide meaningful input into the development of state demonstration projects, as well as in the federal review and approval of state demonstration applications and renewals. This required the establishment of a process to provide for public notice and comment at the state level before a demonstration application is submitted to the Secretary and then again at the federal level once a complete application is submitted but has not yet received a final HHS determination.

The Affordable Care Act also required the Secretary to implement reporting requirements for states with approved demonstrations and to establish a process for periodic evaluation of demonstration projects to ensure that information on the outcomes of demonstration projects is available to the public. Under the Act, these requirements were to include review standards using quantitative research methods pertaining to the goals of the demonstration program, the impact of the demonstration on healthcare costs and coverage, and the state’s plan to ensure that the demonstration will comply with applicable requirements set forth in title XIX and XXI of the Act; in addition to being conducted in a manner that minimizes beneficiary impact. The Affordable Care Act also added a new requirement that the Secretary report to Congress on actions taken with respect to applications for demonstration projects submitted under section 1115 of the Act. This report to Congress outlines how the Secretary has complied with the Affordable Care Act requirements and highlights significant milestones achieved through September 2015.

*Regulatory Process*

\textsuperscript{16} SMDL # 10-001.
As part of its development of the regulation, CMS consulted broadly with community stakeholders and state Medicaid agencies. We also reviewed the GAO findings and various legislative proposals. Specifically in May 2010, CMS met with more than 20 stakeholders, including organizations advocating on behalf of the low-income populations served by Medicaid and CHIP, as well as organizations representing health care providers, to get their input on transparency in the demonstration application process. CMS conducted a listening session open to Medicaid agencies from 50 states, the District of Columbia and U.S Territories as well as met with the CMS Tribal Technical Advisory Group to solicit comments on the proposed rule.

This work informed the September 17, 2010 Federal Register publication of a notice of proposed rulemaking regarding the “Review and Approval Process for Section 1115 Medicaid Demonstrations” in alignment with the statutory requirement for publication of the regulations within 180 days of the enactment of the Affordable Care Act. The proposed rule was followed by a 60-day comment period which ended on November 16, 2010. CMS received 33 comments from states, consumer advocacy groups and the provider community. After consideration of the comments, CMS issued a Final Rule on February 27, 2012. The rule was effective April 27, 2012.

SUMMARY OF FINAL RULE

The Final Rule on section 1115 transparency establishes a formal process for seeking public input and increases the degree to which information about Medicaid and CHIP demonstration applications is publicly available. The regulation also establishes a process so that the development and review of demonstration applications proceeds in a timely and responsive manner. Specifically, the Final Rule discusses a state public notice process and a parallel structure for the federal government as follows:

- Establishes policies and minimum standards states must adhere to in the public notice process. These minimum public notice standards, which states may exceed at their discretion, include:
  - Posting of the state’s public notice and its demonstration application or extension request on its website;
  - Publishing notices in the state’s administrative record or in the newspaper with the widest circulation along with other mechanisms, such as an electronic mailing list, to inform the public that it is seeking public comment on its proposed demonstration application or extension request;
  - Allowing a 30-day public notice and public comment period on its demonstration application or extension request; and,

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19 42 C.F.R. 431.408
• Holding at least two public hearings at least 20 days before submitting an application or extension request to CMS.

- Establishes federal public notice to provide for increased opportunities for public input at the federal level that includes:
  - Posting all Medicaid and CHIP section 1115(a) demonstration applications and extension requests on the CMS Medicaid.gov website;
  - Notifying interested parties through a mechanism, such as an electronic mailing list, that a state’s section 1115 demonstration application or extension request is available for public comment;
  - Providing a 30-day public comment period;
  - Establishing a period of at least 45 days after the submission of a completed demonstration application or extension request, before a decision on the demonstration is made in order to ensure adequate consideration of public comments submitted during the federal comment period; and,
  - Maintaining and publishing an administrative record on the CMS website to ensure the public has access to documentation related to the demonstration.

- The Final Rule also codifies existing statutory provisions of section 5006 of the Recovery Act pertaining to tribal consultation.

CMS followed-up the release of the Final Rule on section 1115 transparency with the issuance of a State Medicaid Director/State Health Official letter on April 27, 2012 that provided an overview of the Final Rule’s key regulatory provisions and additional guidance on how these provisions would be operationalized; and included notice that CMS would additionally apply the federal transparency provisions to proposed amendments to ongoing demonstration projects. We also released a section 1115 application template for states that provides guidance on developing demonstration proposals; including a budget neutrality template with associated guidance on the financing and expenditure information most commonly required in a state’s application for consideration. This guidance is available on the section 1115 demonstrations homepage on Medicaid.gov.

Since the release of the Final Rule and supporting guidance, states have been largely compliant with the new rule and processes. However, in several instances, CMS returned applications due to a state’s failure to submit all the regulatory components of a demonstration application including public notice, tribal consultation and evaluation components. CMS regularly provides technical assistance to states prior to the submission of section 1115 requests to ensure compliance with federal transparency requirements.

20 42 C.F.R. 431.416
21 CMS’ section 1115 application template, including budget neutrality forms and guidance are available on Medicaid.gov at http://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/1115/application.html.
ADDITIONAL ACTIONS SINCE THE ENACTMENT OF THE AFFORDABLE CARE ACT

In an effort to improve accessibility of program information, CMS launched a new “Medicaid.gov” website in December 2011. One of the key features of Medicaid.gov is to provide access to summary information and current approval documents for existing demonstrations, as well as an opportunity for stakeholders to comment on pending demonstration requests during the 30-day federal public comment period. Public comments received remain available on Medicaid.gov for public review. The Medicaid.gov website also allows the public to register for the CMS electronic mailing list which notifies members of incoming state demonstration requests available for public comment.

Since the launch of Medicaid.gov, CMS has used the website not only as a means to inform the public and allow input on pending demonstration applications but also as a mechanism to receive public input on ways in which we can make the demonstration information available on the website more user-friendly. CMS assessed such feedback and embarked on a development plan to redesign the website and launched a new format on June 24, 2014.

Examples of improved functionality, quality, and management of information built into Medicaid.gov include:

- A modified search list of demonstrations/waivers that allows users to use additional criteria for searching programs. Users may now sort the demonstration/waiver list by state, statutory authority, and application status;
- Eliminated the multiple steps formerly required by a user to get to demonstration/waiver documents;
- Changed the format for how documents are displayed on the website to improve search and access to documents in the administrative record. Users no longer have to search through one voluminous file of program information but can now view a list of distinct titled documents to more quickly access specific information of interest. This new format also allows for a separate public comment forum to be directly linked to each pending demonstration action, expediting access to and review of demonstration applications open for federal public comment.
- Automated the monitoring of broken links on Medicaid.gov so CMS can quickly troubleshoot problems with document links; and,
- Improved tracking and reporting of what the public views on Medicaid.gov and what documents are being downloaded.

Specific to the public comment feature, CMS made improvements expediting the publication and availability of comments. For example:

- CMS made public comments immediately available for viewing and downloading through migration to a new platform called “GovDelivery.” (Note: CMS actively monitors for inappropriate comments and removes accordingly.)
• Public comments can now be submitted on the website via document attachments and immediately available to the public in the same way as other public comments; and,
• Public comment periods are now automatically closed at the end of the specified federal comment period, eliminating the need for manual tracking of expiring comment periods and manually closing the online comment feature.

From April 2012, the effective date of the CMS Final Rule on section 1115 transparency, through September 2015, CMS has posted information on 92 state demonstrations and has more than 1500 public comments available for viewing on demonstration actions. CMS reviews public comments received and often reaches out to commenters to further explore concerns raised about pending demonstration requests. CMS has held several meetings and telephone conferences with beneficiaries and advocacy groups to follow-up on concerns raised through the federal public comment process and has incorporated such feedback in our discussions with states.

In July 2013, CMS improved the data capacity of Medicaid.gov and began to collect statistics on public activity on the 1115 webpages. Between July 2013 and September 2015, there have been a total of 85,957 page views for the 92 posted section 1115 demonstrations requests, which include new demonstrations, extensions and amendments. To provide a point in time comparison, the number of page views for demonstrations increased by 33% and the average time spent on the 1115 landing page increased 65% from September 2013 to September 2015. See Appendix I for additional information on demonstration activity on Medicaid.gov as of September 2015.

To facilitate the demonstration/waiver application process for states and to help CMS review and assess demonstration applications, CMS posted an application template on Medicaid.gov. States can either download or complete the application template (which is in a fillable PDF format) or can use it as a guide as they complete their applications. This template is not required for submission but is an available tool for states to use at their option.

CMS also recently increased transparency with respect to the criteria used in our consideration of approving expenditure authorities under demonstrations. In a recent report, the GAO recommended that HHS issue criteria for assessing whether expenditure authorities are likely to promote Medicaid objectives and document these criteria in demonstration approvals. HHS agreed that transparency is critical with respect to our demonstration approvals and CMS has published on Medicaid.gov the criteria used to evaluate how a state’s application meets the objectives of the Medicaid/CHIP program. These criteria are:

1. Increase and strengthen overall coverage of low-income individuals in the state;
2. Increase access to, stabilize, and strengthen providers and provider networks available to serve Medicaid and low-income populations in the state;

3. Improve health outcomes for Medicaid and other low-income populations in the state; and/or,
4. Increase the efficiency and quality of care for Medicaid and other low-income populations through initiatives to transform service delivery networks.

CMS also identifies in state approval documents ways in which each approved section 1115 expenditure authority supports the objectives of the Medicaid program.

All of these efforts help enhance compliance with the transparency and public notice provisions set forth in section 10201 of the Affordable Care Act. CMS continues to refine and modify the type of information being collected to strengthen the transparency process and provide opportunities for the public to provide meaningful input into the development of pending section 1115 demonstration proposals as well as how CMS can improve the availability and display of information on Medicaid.gov.

On July 24, 2015, CMS established a new “fast track” process for reviewing state proposals to extend established Medicaid and CHIP section 1115(a) demonstrations that reauthorize longstanding policies with demonstrated positive program outcomes. The “fast track” approach streamlines the federal review process to render decisions on extension requests in timeframes similar to Medicaid section 1915 waivers or State Plan Amendments, however, states must still comply with the requirements of the April 2012 final transparency regulation. CMS’ aim is to reduce barriers and administrative burden on states seeking to continue programs that have demonstrated that they meet the demonstration’s objectives and the objectives of Medicaid or CHIP as well as to facilitate faster review and approval regarding these state requests. This is an initial step we are taking to meet states’ interest in reducing barriers and furthering support of state initiatives that promote the shared goal of improving the quality and efficiency of Medicaid or CHIP. The CMS Informational Bulletin and the fast track application templates are also available on the section 1115 demonstration homepage on Medicaid.gov.24

CONCLUSION

Section 1115(a) demonstration projects are important to the federal-state partnership in developing, testing and implementing new state approaches to providing better access to high quality care and improved health at lower costs in Medicaid and CHIP. Section 1115(a) demonstrations that are successfully implemented and evaluated with proven outcomes inform future policy with regard to new approaches to coverage and care. Section 1115(a) demonstrations also provide important lessons learned when tested approaches are not successful. This report constitutes the first CMS report to Congress, as required by the Affordable Care Act, on how CMS’ transparency policy and process has evolved in an effort to ensure the public has notice, information and opportunity to provide input on the experimental approaches being piloted under section 1115 authority. The activities outlined in this report (through September 2015) represent how CMS has achieved this goal in accordance with the transparency provisions in the Affordable Care Act.

Appendix I

Medicaid.gov 1115 Demonstration Site Analytics

September 2013 — September 2015

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<thead>
<tr>
<th>Location</th>
<th>Page views</th>
<th>Sept 2013</th>
<th>Sept 2014</th>
<th>Sept 2015</th>
<th>Overall increase of...</th>
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<td>Demonstrations &amp; Waivers Search/List</td>
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<td>950</td>
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<td>Waivers Overview (i.e. 1115 and 1915 programs)</td>
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<td>371</td>
<td>425</td>
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<td>90</td>
<td>123</td>
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Total Page Views

85,957

for this three-year period

1115 Demonstrations

92

total demonstrations on the website currently

NAVIGATION SUMMARY

Top page views from the Section 1115 homepage are to:

VISITS BY STATE

Number of Pageviews by Month

0 1,000 2,000 3,000 4,000 5,000 6,000


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