kaiser commission on medicaid and the uninsured
KEY FACTS
THE HENRY J. KAISER FAMILY FOUNDATION

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The New Review and Approval Process Rule for Section 1115 Medicaid and CHIP Demonstration Waivers

Summary

For many years, Section 1115 waivers have been used in the Medicaid program to provide states an avenue to test and implement coverage approaches that do not meet federal program rules, but there have been longstanding concerns about the lack of public input and transparency in the waiver approval process. As a result, the Affordable Care Act required the Department of Health and Human Services to issue regulations designed to ensure that the public has meaningful opportunities to provide input into the Section 1115 waiver process. On February 22, 2012, the Centers for Medicare and Medicaid Services issued final regulations addressing these provisions. This brief provides an overview of the new rule.

The new rule establishes state public notice and application requirements for new Section 1115 waivers and extensions of existing waivers.

- The state must provide a 30-day public notice and comment period.
- The state must provide a comprehensive description of the proposed waiver "that contains a sufficient level of detail to ensure meaningful input from the public."
- The state must keep a current website to share these materials and allow for any interested parties to sign up for an email list to be kept apprised of the application.
- The state must also hold at least two public hearings on separate dates in separate locations that offer the public an opportunity to learn about the application and comment on it.
- The final waiver application must include similar specifics to those provided in the initial waiver proposal. In addition, it must document the public process conducted by the state and include a report on how it considered issues raised by the public in developing the final application.

The rule also establishes federal public notice and comment requirements and a timeline for the approval process.

- Within 15 days of a state's submission of a waiver application, the federal government must send the state a notice of receipt. The notice will initiate the start of a 30-day federal comment period.
- CMS will publish the notice of receipt, the waiver application, and other relevant materials on its website along with an email address through which the public can send comments that will be made publicly available.
- To ensure that the public has adequate time to provide input, the rule also establishes that no federal decision on a waiver will be made until 45 days after the notice of receipt.

In addition, the rule specifies reporting, compliance, and evaluation requirements for operating waivers. These include periodic reviews of implementation, public forums to receive feedback on implementation, approved publicly available evaluation plans, and annual reports.

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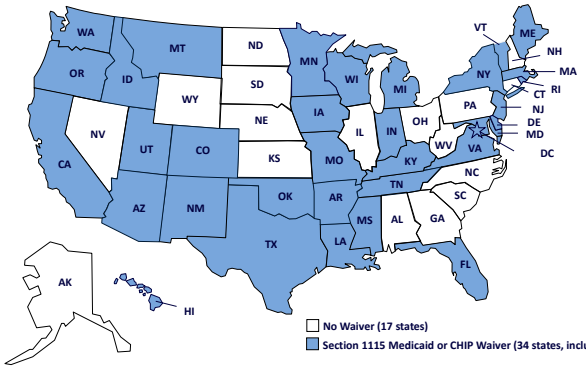
Introduction

Section 1115 of the Social Security Act establishes authority for the Secretary of Health and Human Services (HHS) to waive certain provisions of the Medicaid and CHIP statutes for a state to establish an "experimental, pilot or demonstration" project that, in the view of the Secretary, promotes the objectives of the program. Such demonstrations, usually referred to as "Section 1115 waivers" are intended to test and learn about new approaches to program design and administration.

Section 1115 waivers can have a significant impact on the structure and financing of a state's Medicaid or CHIP program and, as such, have important implications for enrollees, providers, and the state. States have obtained Section 1115 waivers that make broad changes in Medicaid eligibility, benefits, cost sharing, and delivery and payment of care. In addition, although not required by statute, all Section 1115 waivers have included a cap on federal funds to ensure that they are budget neutral for the federal government. As of February 2012, 34 states are operating at least one Section 1115 Medicaid waiver program (Figure 1).[1]

Figure 1

States with a Section 1115 Medicaid or CHIP Demonstration Waiver, February 2012



NOTE: Map denotes states with at least one comprehensive Section 1115 Medicaid or CHIP waiver demonstration program in operation. Does not include more narrowly drawn Section 1115 waivers, such as family planning waivers.
SOURCE: Centers for Medicare and Medicaid Services, "Status of Comprehensive 1115 Demonstrations, Updated 2/6/2012.

In the past, concern has been expressed about the lack of public input and transparency in the Section 1115 waiver approval process at both the state and federal level. As a result, the Affordable Care Act (ACA)[2] required HHS to issue regulations designed to ensure that the public has meaningful opportunities to provide input into the Section 1115 waiver process. The ACA also requires that Section 1115 waivers have periodic evaluations and that states submit implementation reports for operating waiver programs. On February 22, 2012, the Centers for Medicare and Medicaid Services (CMS) issued final regulations implementing these provisions of the ACA, which become effective 60 days after publication of the rule.[3] This brief provides an overview of the new waiver process rule.

Background: The Waiver Approval Process

Waivers are approved through a series of negotiations between a state and HHS. The process for obtaining a Section 1115 waiver officially begins with a state submitting an application to the Centers for Medicare & Medicaid Services (CMS), although states often discuss waiver ideas with CMS or submit concept papers before submitting an application. Staff members from CMS review the waiver application sometimes with the involvement of other HHS agencies and the Office of Management and Budget. During this time, significant negotiation may occur between the state and HHS. If a waiver is approved, CMS issues an award letter to the state, along with attachments listing the specific sections of the Social Security Act and applicable regulations that are being waived or modified and the types of expenditures allowed as well as the "terms and conditions" of approval, including a budget neutrality agreement. There has been significant variation in the length of time it takes to get final approval of a waiver. There is also variation across states in the role of state legislatures in the waiver approval process—with some states requiring authorizing legislation for waivers and others having little or no involvement of the state legislature.[4]

Section 1115 waivers generally are approved for an initial five-year period.[5] At the end of the initial approval period, a state must obtain a renewal or extension to continue waiver operations. Waiver extensions typically are for a three-year period. Some waivers have been continually renewed over many periods, allowing waiver operations to continue for many years.

Given the significant program changes that can occur under waivers, the transparency of the waiver approval and renewal process is important. In the mid-1990s, efforts were made to establish public process policies at the federal and state level by providing regular notice of waivers in the Federal Register with a comment period and requiring states to describe processes used to obtain public input as part of their waiver proposals.[6] However, commitment to these practices faded over time, and analyses by the Government Accountability Office in 2002 and 2007 concluded that the public did not have sufficient opportunity to learn about and comment on pending waivers at the federal level and that there was significant variation in public input opportunities at the state level.[7] As a result of these concerns, the ACA directed HHS to issue regulations to increase the transparency of the Section 1115 waiver approval and renewal process and to provide the opportunity for meaningful public input. These final regulations were released on February 22, 2012.

Key Components of the New Waiver Process Rule

The new rule establishes a state and federal public notice process for Section 1115 waiver applications and extensions as well as reporting, compliance, and evaluation requirements for operating waivers. The new rule applies to all new Section 1115 Medicaid and CHIP waiver proposals as well as extensions of existing waivers, although some distinctions apply with respect to the length of time needed to consider an extension request.[8] The new rule does not apply to amendments to existing Section 1115 waivers; CMS indicates that future guidance will address the review and approval process for waiver amendments. The rules also do not apply to other Medicaid waivers such as Section 1915 waivers, nor do they apply to state plan amendments.

State public notice and application requirements. A state's waiver application for a new waiver or extension of an existing waiver must document compliance with the following requirements to be considered complete by CMS.[9]

- ***Public notice and comment period.*** The state must provide a 30-day public notice and comment period.
- ***Waiver proposal.*** For purposes of public comment, the state must provide a comprehensive description of the proposed waiver "that contains a sufficient level of detail to ensure meaningful input from the public."[10] At a minimum, this includes a description of the current or new beneficiary groups that will be impacted by the demonstration, the proposed health delivery system, benefit and cost-sharing requirements, and increases or decreases in enrollment and expenditures. In addition, the state must share details of the hypothesis and evaluation parameters of the proposal and the specific waiver and expenditure authorities it is seeking.
- ***State website.*** The state must keep a current website to share these materials and allow for any interested parties to sign up for an email list to be kept apprised of the application.
- ***Public hearings.*** The state must also hold at least two public hearings on separate dates in separate locations. Meetings of the Medical Care Advisory Committee, a commission, a state legislative process or other similar process will satisfy this requirement, as long as they offer the public an

opportunity to learn about the application and comment on it. The state must use telephonic and/or web conferencing capabilities for at least one of these hearings to ensure statewide accessibility for the hearing. (The rule also codifies prior statutory provisions ensuring that Indian tribes and Indian health organizations are consulted prior to the submission of a waiver application.[11])

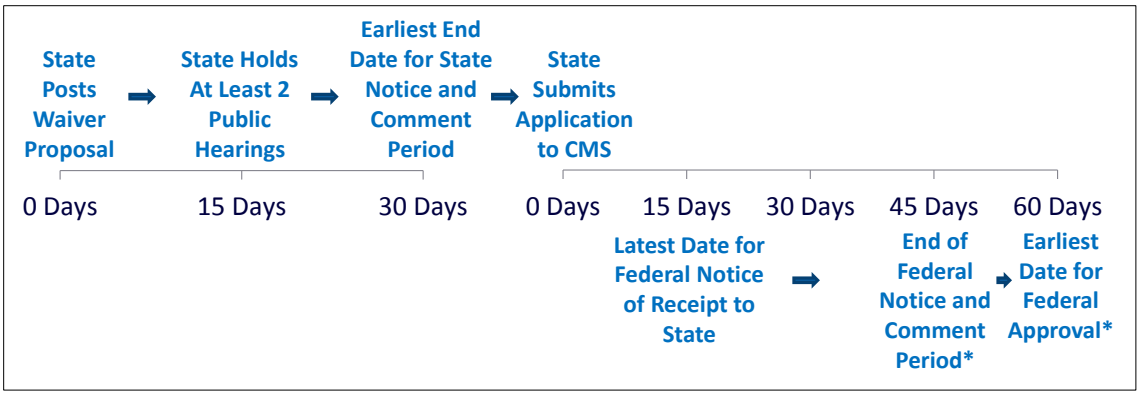
- ***Final waiver application.*** The final waiver application must include similar specifics to those provided in the initial waiver proposal. In addition, it must document the public process the state conducted and include a report on the issues raised by the public during the comment period and how the state considered those comments in developing the final application.[12] These requirements also apply to an extension request to continue an existing waiver. In addition, states are required to include certain specified data in extension requests, such as summaries of external quality review organization and other quality assurance reports, as well as EPSDT performance data (Form CMS-416) for the period the waiver has been in operation.

Federal public notice and approval process.[13] The rule also establishes federal public notice and comment requirements and a timeline for the approval process.

- ***Federal comment period.*** Within 15 days of a state's submission of a waiver application, the federal government must send a state a notice of receipt. This notice will indicate the start date of a 30-day federal comment period.
- ***Public notice and comments through CMS website.*** CMS will publish the notice of receipt, the waiver application, and other relevant materials on its website along with an email address through which the public can send comments. CMS will also provide information, such as status updates, through its website at regular intervals. Once comments are received, CMS will make them publicly available through its website, but, unlike the state, CMS is not required to provide a written response to the comments.
- ***Timeframe for approval.*** To ensure that the public has adequate time to provide input, the rule also establishes that no federal decision on a waiver will be made until 45 days after the notice of receipt. The rule does include an "emergency exemption," which allows CMS to waive this timeframe and the public notice process in whole or in part if an expedited decision is needed because a proposed demonstration addresses a natural disaster, public health emergency, or other sudden threat to human life.

Figure 2 summarizes the timeline of the key process requirements established by the rule.

Figure 2:
Timeline of Minimum Public Comment and Approval Process Requirements for Section 1115 Waivers



* If the federal government provides the notice of receipt to the state earlier than within 15 days of the state submission, the timelines for the end of the federal notice and comment period and earliest date for federal approval could be shorter.

Implementation reports, compliance, and evaluation. The new rule also specifies requirements related to implementation reports, compliance, and evaluation for operating waiver programs.

- ***Implementation reviews and compliance.*** As part of the "terms and conditions" that will be agreed to by the federal and state governments in the waiver negotiations, states will be required to conduct periodic reviews of implementation.[14] CMS will also review any documented complaints of failures to comply with those terms and conditions. As is customary in waiver agreements, in the rule, CMS reaffirms that all provisions of the Social Security Act that are not specifically waived by the waiver terms and conditions remain in effect.
- ***Public input on implementation.*** Within six months of the implementation date of the waiver, and annually thereafter, the state must hold a public forum to solicit feedback. The state may use a meeting of its Medical Care Advisory Committee, a commission, or other similar process to satisfy this requirement as long as the meetings adhere to certain requirements similar to those required for public hearings on waiver proposals (described above).
- ***Evaluation.*** Because Section 1115 authority is intended for research and demonstration purposes, the rule requires a state to have an approved evaluation strategy in place that is publicly available.[15] States must also submit an annual report to HHS that includes, among other things, a description of the changes occurring and their impact on outcomes, quality, and access; beneficiary satisfaction surveys; grievance and appeals data; financial data; audits; and other relevant developments.[16]

Conclusion

Section 1115 Medicaid and CHIP demonstration waivers are intended to allow for research and demonstration projects to test new approaches in program design and administration. Given the significant program changes that can occur under waivers, the transparency of the waiver approval process is important. As required by the ACA, the new regulations establish a state and federal public notice process designed to enable the public to stay better informed about proposed waiver changes and provide meaningful public input.

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[1] This does not include more narrowly focused Section 1115 waivers, such as family planning waivers. Centers for Medicare and Medicaid Services, "Status of Comprehensive 1115 Demonstrations," Feb. 6, 2012.
[2] §10201(i) of P.L. 111-148 added a new subsection (d) to Section 1115 of the Social Security Act.
[3] 42 CFR Part 431 where a new Subpart G is added.
[4] National Health Law Program and National Association of Community Health Centers, "Role of State Law in Limiting Medicaid Changes," April 13, 2006.
[5] Some recent waivers have been approved for shorter periods to transition to the Medicaid expansion in 2014.
[6] Mann, C., "The New Medicaid and CHIP Waiver Initiatives," Kaiser Commission on Medicaid and the Uninsured, Feb. 2002.
[7] Government Accountability Office, "Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns," July 12, 2002, GAO-02-817" and Government Accountability Office, "Medicaid Demonstration Waivers: Lack of Opportunity for Public Input During Federal Approval Process Still a Concern, July 24, 2007, GAO-07-694R.
[8] §431.412(c).
[9] §431.408, §431.412
[10] §431.408(a)(1)(i)
[11] Enacted in the American Recovery and Reinvestment Act (P.L. 111-5).
[12] §431.412(a)(1)(viii)
[13] §431.416
[14] §431.420
[15] §431.424
[16] §431.428

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