Primer: State Plan Amendments v. Section 1115 Waivers

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To receive federal Medicaid funding, each state must have in effect a comprehensive, written state Medicaid plan that is approved by the Secretary of Health and Human Services (Secretary or HHS).[1] The state plan describes the nature and scope of the state's Medicaid program and commits the state to adhering to federal Medicaid requirements.[2] Generally, if a state wishes to change its Medicaid program, it must amend its state plan.[3]

A state can also make temporary changes to its Medicaid program through a Section 1115 project. Section 1115 of the Social Security Act authorizes HHS to waive certain provisions of the Medicaid Act to allow states to implement "experimental, pilot, or demonstration projects" that are likely to promote the objectives of the Medicaid Act.[4] Such projects must be limited to the time period necessary to carry out the experiment.

Tension and confusion can arise over how HHS allows states to change their Medicaid programs, whether through a state plan amendment (SPA) or a Section 1115 project. For example, the Affordable Care Act amended the Medicaid Act to include an option for states to submit SPAs to cover family planning and related services for individuals who are not otherwise eligible for Medicaid.[5] Nevertheless, HHS has continued to allow states to cover family planning and related services through Section 1115 projects and to restrict that coverage to a subset of the population that Congress has made eligible through the option it

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[1] *See generally* 42 U.S.C. §§ 1396a(a) (listing the required contents of a state plan), 1396b(a); 42 C.F.R. § 430.10.
[2] 42 C.F.R. § 430.10.
[3] The Medicaid Act does permit states to make certain changes through a waiver of otherwise applicable requirements. *See, e.g.,* 42 U.S.C. §§ 1396n(b) (allowing states to implement managed care using a waiver), 1396n(c) (allowing states to provide home and community-based services using a waiver), 1315(a) (described in detail below).
[4] 42 U.S.C. § 1315(a)(1).
[5] *Id.* §§ 1396a(a)(10)(A)(ii)(XXI), 1396a(a)(10)(G)(XVI), 1396a(ii).

set forth in the Medicaid Act. Another example: After some states expanded their Medicaid programs to cover uninsured adults, HHS approved Section 1115 projects allowing these states to reduce that coverage by imposing work requirements, premiums, and other coverage restrictions, even though the Medicaid Act and SPA process are designed to focus on furnishing medical assistance as far as practicable in the state.

To help guard against the improper use of Section 1115 waivers, advocates must know the distinctions between Section 1115 waivers and SPAs. These distinctions are explained below.

State Plan Amendments[6]

Use: States must submit a SPA when necessary to reflect changes in federal law or material changes in state law, policy, organization, or operation of their Medicaid program.[7] For example, if a state intends to start (or stop) covering an optional population group or service, it must amend its state plan. SPAs need not be budget neutral for the federal government.

Application and Approval Process: SPAs are developed by the state Medicaid agency. The draft SPA goes to the governor or their designee for review and comment before it is submitted to the Centers for Medicare & Medicaid Services (CMS). There are two exceptions: (1) the designee is the head of the state Medicaid agency; or (2) the SPA is a preprint developed by CMS that provides "absolutely no options for the State."[8]

Generally, federal law does not require states to provide a public comment period on a SPA. However, if the proposed SPA relates to rates paid for hospital services, nursing facility services, or services provided by intermediate care facilities, the state must provide an opportunity for the public to review and comment on the SPA.[9] In addition, before submitting

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[6] For additional discussion, *see* Jane Perkins, Nat'l Health Law Program, *CMS Updates State Plan Amendment Process* (Oct. 4, 2010), **https://healthlaw.org/resource/cms-updates-state-plan-amendment-process/**.
[7] 42 C.F.R. § 430.12(c).
[8] *Id.* § 430.12(b).
[9] 42 U.S.C. § 1396a(a)(13)(A); 42 C.F.R. § 447.250. *See also* CMS Informational Bulletin, Federal Public Notice and Public Process Requirements for Changes to Medicaid Payment Rates (2016), **https://www.medicaid.gov/federal-policyguidance/downloads/cib062416.pdf**.

a SPA that is "likely to have a direct effect on Indians, Indian Health Programs, or Urban Indian Organizations," the state must solicit advice from those entities.[10]

Note that state law might contain additional procedural and/or public notice and comment requirements. And even absent a law, interested persons can submit comments to the agency and ask that they be considered.

SPAs are reviewed by CMS regional staff. Once a SPA is submitted, CMS determines whether it complies with relevant federal statutes, regulations, and policy.[11] Federal regulations contain a review process that is designed to achieve quick approval. A SPA is deemed approved unless CMS, within 90 days of receiving the SPA, sends the state a notice of disapproval or a request for additional information.[12] If CMS does request additional information, it must take action on the SPA within 90 days of receiving that information.[13] While SPA approvals occur at the regional level, only the CMS Administrator, in consultation with the Secretary, can disapprove a SPA.[14]

Effective Date: SPAs that add population groups or services or increase payment rates can take effect retroactively, but the effective date: (1) cannot be earlier than the first day of the quarter in which the SPA was submitted to CMS; and (2) with respect to expenditures for medical assistance, cannot be earlier than the first day in which the SPA is in operation on a statewide basis.[15] For other SPAs, the effective date can be any date requested by the state and approved by CMS.

Duration: In general, SPAs do not expire. A SPA remains in effect unless and until congressional authorization for the SPA expires or the state withdraws the SPA or replaces it through submission of a subsequent SPA.

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[10] 42 U.S.C. § 1396a(a)(73).
[11] *See* 42 C.F.R. §§ 430.14, 430.15.
[12] *Id.* § 430.16(a)(1).
[13] *Id.* § 430.16(a)(2).
[14] *Id.* §§ 430.15(b), (c).
[15] *Id.* § 430.20(b)(1).

Section 1115 Waivers

Use: Section 1115 of the Social Security Act gives the Secretary the authority to waive compliance with the requirements in 42 U.S.C. § 1396a in certain circumstances. The Secretary can only grant a waiver for an "experimental, pilot, or demonstration" project that is likely to assist in promoting the objectives of the Medicaid Act.[16] By its terms, the law is a grant of power from Congress to the Secretary to allow states to rigorously test the impact of novel approaches to promoting Medicaid's objectives. Section 1115 "was not enacted to enable states to save money or to evade federal requirements but to test out new ideas and ways of dealing with the problems" of program enrollees.[17]

In addition, the Secretary can only grant a waiver to the extent and for the period necessary to enable the state to carry out the experiment.[18] Historically, CMS has approved initial projects and extensions for up to 5 years. By longstanding CMS policy and in contrast to SPAs, Section 1115 projects must be budget neutral to the federal government.[19]

Application and Approval Process:[20] Before submitting an application for an initial demonstration or an application to extend an existing demonstration, states must provide a 30-day public notice and comment period and hold at least two public hearings on the proposal.[21] In addition, if the project would have "a direct effect on Indians, tribes, on Indian

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[16] 42 U.S.C. § 1315(a).
[17] *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994) (internal quotations and citation omitted); *see also*, *e.g.*, *Stewart v. Azar*, 366 F. Supp. 3d 125, 140 (D.D.C. 2019) (quoting *Beno*).
[18] 42 U.S.C. § 1315(a).
[19] *See, e.g.*, Dear State Medicaid Director Letter # 18-009 (Aug. 22, 2018), **https://www.medicaid.gov/federal-policy-guidance/downloads/smd18009.pdf**.
[20] For more detailed information about the application and approval process, *see* Catherine McKee & Jane Perkins, Nat'l Health Law Program, *Section 1115 Waiver Requirements: Transparency and Opportunity for Public Comment* (2017), **https://healthlaw.org/resource/sec-1115-waiver-requests-transparency-opportunity-for-public-comment/**.
[21] 42 C.F.R. § 431.408(a).

health programs, or on urban Indian health organizations," states must consult with these affected entities.[22]

Section 1115 applications are reviewed by the Secretary and/or their designee, typically the CMS Administrator. After receiving an application, CMS has 15 days to determine whether it is complete. Once an application is deemed complete, CMS must provide a 30-day public notice and comment period.[23] Generally, CMS cannot make a final decision on an application until at least 45 days after initiating the comment period.[24]

While these procedural requirements do not apply directly to an application to amend an existing Section 1115 project, CMS has encouraged states to comply with the state public notice and comment process and has committed to accepting public comments on all amendments.[25]

When CMS approves a Section 1115 application, it indicates which provisions of the Medicaid Act (in Section 1396a) it is waiving and for what specific purpose, and states must continue to comply with Medicaid provisions that CMS does not expressly waive.[26] States must also comply with numerous Special Terms and Conditions (STCs) that govern the project.[27]

Effective Date: Generally, approval of a project is prospective only, and federal funding is not available for changes to a project that have not been approved by CMS.[28]

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[22] *Id.* § 431.408(b); *see also* 42 U.S.C. § 1396a(a)(73). There are also specific requirements regarding the timing of an application to extend a state-wide comprehensive demonstration project. *See* 42 U.S.C. §§ 1315(e)(2), (f)(1); 42 C.F.R. § 431.412(c).
[23] 42 C.F.R. §§ 431.412(b)(1), 431.416(a), (b).
[24] *Id.* § 431.416(e). The statute requires HHS to respond to a request to extend a state-wide comprehensive demonstration project within a particular timeframe. *See* 42 U.S.C. §§ 1315(e)(3), (f)(2)-(5).
[25] *See* CMS, Dear State Health Official Letter #12-001, at 5 (Apr. 27, 2012), **https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/SHO-12-001.pdf**. Note that the Special Terms and Conditions for a project also outline the procedural requirements for amending the project.
[26] 42 C.F.R. § 431.420(a)(1).
[27] *Id.* §§ 431.420(a)(2), (d)(1).
[28] *Id.* § 431.412(d).

Duration: The Secretary cannot grant a waiver for any longer than necessary to enable the state to carry out its proposed experiment.[29] In addition, Section 1115 places limits on the extension of state-wide, comprehensive demonstration projects. The Secretary can grant one initial extension and one subsequent extension, each lasting up to 3 years (or 5 years for a project involving individuals eligible for both Medicaid and Medicare).[30]

The Secretary can suspend or terminate a project in whole or in part before its expiration date if the state has materially failed to comply with the terms of the project.[31] The Secretary can also withdraw waivers based on a finding that the project "is not likely to achieve the statutory purposes."[32]

Monitoring and Evaluation: States must perform periodic reviews of the implementation of an approved project.[33] Within six months after implementation begins, and on an annual basis thereafter, the state must hold a public forum to solicit comments on the project's progress.[34] In addition, states must submit annual reports on the project to CMS.[35]

States must also evaluate the results of an approved project and make that evaluation available to the public.[36] When a state requests to extend a project, it must submit an interim evaluation report to CMS as part of its application.[37] Prior to conducting an evaluation, states must receive approval from CMS of its evaluation design plan.[38]

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[29] 42 U.S.C. § 1315(a)(1).
[30] *Id.* §§ 1315(e)(2), (f)(6). Despite the statutory language, in 2017, CMS announced its intent to "[w]here possible, . . . approve the extension of routine, successful, non-complex" Section 1115(a) waivers for a period up to 10 years. CMS, Informational Bulletin, Section 1115 Process Improvements 3 (Nov. 6, 2017) ("2017 Informational Bulletin"), **medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib110617.pdf**. CMS subsequently approved several projects for a period of 10 years. The policy announced in the Bulletin should be disregarded because it conflicts with Section 1115.
[31] 42 C.F.R. § 431.20(d)(1).
[32] *Id.* § 431.420(d)(2).
[33] *Id.* § 431.420(b)(1).
[34] *Id.* § 431.420(c).
[35] *Id.* § 431.428. Generally, the STCs require states to submit a report more frequently – quarterly or semi-annually. *See* 2017 Informational Bulletin at 6-7.
[36] 42 C.F.R. § 431.424. States must also cooperate fully with any federal evaluation of any component of the project. *Id.* § 431.420(f).
[37] *Id.* §§ 431.424(d), 431.412(d)(2)(vi).
[38] *Id.* §§ 431.424(c), (e).

Conclusion

In summary, the Medicaid Act anticipates that states will update and revise their Medicaid programs through the SPA process. That process is designed to review and approve SPA submissions as quickly as possible. Most SPAs can take effect retroactively. Approved SPAs do not expire.

By contrast, Section 1115 of the Social Security Act is intended to allow states to test novel approaches to Medicaid administration—activities that qualify as experimental, pilot, or demonstration projects, and as such, are to be time-limited. Section 1115 projects cannot be applied retroactively. Approved Section 1115 projects are subject to numerous Special Terms and Conditions, including reporting requirements and requirements that they be budget neutral to the federal government.