Section 1115 waivers have been used over the history of the Medicaid program to implement demonstration projects designed to improve the delivery of medical assistance to low-income people. Over the last year, the Trump administration and a handful of states have begun to use Section 1115 in an effort to restructure Medicaid.²

The National Health Law Program has worked with Section 1115 Medicaid waivers for over two decades. This fact sheet uses a Frequently Asked Questions format and includes a summary of the recently announced decision in *Stewart v. Azar*, vacating the administration’s approval of a Section 1115 project in Kentucky. It concludes with recommendations for ensuring that Section 1115 waivers are implemented in the “best interests of the recipients.”³

**Questions answered in this Fact Sheet:**
- What is Section 1115 and how does it affect Medicaid?
- How have Section 1115 Medicaid waivers been used in the past?
- How do recent Section 1115 Medicaid waivers differ from previous waivers?
- How can the public be involved in the Section 1115 waiver review process?
- Is the Secretary’s approval of a Section 1115 waiver committed to agency discretion, or is the approval subject to court review?
- What are the laws that plaintiffs rely upon to challenge Section 1115 waivers?
- How have courts decided challenges to Section 1115 waiver approvals?
- What is the significance of the recent district court decision in *Stewart v. Azar*?
- Recommendations for advocacy

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³ 42 U.S.C. § 1396a(a)(19).
What is Section 1115 and how does it affect Medicaid?

Medicaid is a partnership between the federal and states governments. States do not have to participate in Medicaid, but all do. Participating states are afforded generous federal funding to provide medical assistance to low-income people, so long as the state complies the Medicaid Act and implementing regulations regarding, among other things, eligibility and services. Many—though not all—of the central statutory requirements of Medicaid are contained in Section 1902 of the Social Security Act (42 U.S.C. § 1396a).

Section 1115 was added to the Social Security Act in 1962 and amended to include Medicaid when the Medicaid Act was passed in 1965. Section 1115 (42 U.S.C. § 1315) authorizes the Secretary of Health and Human Services (HHS) to approve state “experimental, pilot or demonstration” projects that are likely to promote the objectives of the Medicaid Act. The Secretary can waive provisions of 42 U.S.C. § 1396a “to the extent and for the period necessary” to carry out the experiment. According to the Medicaid Act, the purpose of Medicaid is to enable states to furnish medical assistance, as far as practicable, to individuals who lack the income and resources to meet the costs of necessary medical care and to furnish such assistance and services to help these individuals attain or retain the capacity for independence and self-care.

When Congress created Section 1115, members described it as a way to “test out new ideas and ways of dealing with the problems of public welfare recipients,” with waivers expected to be “selectively approved” on this basis.

How have Section 1115 Medicaid waivers been used in the past?

Early Section 1115 Medicaid waivers focused on experimenting with nominal cost sharing. During the 1970s, two courts upheld such waivers. After these demonstrations and court cases, Congress amended the Medicaid Act to add detailed

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4 See, e.g., Harris v. McRae, 448 U.S. 297, 301 (1980).
7 42 U.S.C. § 1315(a).
8 42 U.S.C. § 1396-1.
provisions—outside of Section 1396a—establishing states’ options for imposing premiums and cost sharing and stated its belief that this would “give[] the Secretary sufficient flexibility in this regard to make further exercise of the Secretary’s demonstration authority unnecessary.”

During the 1990s, the Clinton administration approved a number of states’ requests to implement Section 1115 waivers to expand Medicaid coverage to childless adults while transitioning the service delivery system from fee-for-service provider payments to capitated managed care. This was the first time that waivers were approved in a cookie-cutter fashion. Congress subsequently amended the Medicaid Act to describe, in detail, the states’ options for using managed care for providing medical assistance.

Over the years, Section 1115 waivers have been used during emergencies, for example 9/11 and Hurricane Katrina, to enable affected states to get Medicaid to needy individuals quickly and continuously.

The Obama administration approved waivers for Delivery System Reform Incentive Programs (DSRIP) designed to improve health outcomes while controlling costs. Such reforms included quality and value controls in managed care contracts, implementation of health homes for individuals with chronic conditions, and new delivery and payment models for individuals dually eligible for Medicaid and Medicare. After the U.S. Supreme Court decided National Federation of Independent Business v. Sebelius in 2012, states could not be denied federal funding if they refused to implement the Affordable Care Act’s expansion of Medicaid to adults with incomes below 133% of the federal poverty level. The Obama administration used Section 1115 waivers in a handful of states to accomplish expansion by alternative means. For example, Arkansas expanded coverage using private insurance exchanges and subsidies. Indiana

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expanded coverage but added conditions on eligibility, including premium payments, heightened cost sharing, and reduced benefits.\footnote{David Machledt, Nat’l Health Law Prog., \textit{Indiana Medicaid Demonstration Raises Concerns} (Feb. 27, 2017), \url{http://www.healthlaw.org/publications/browse-all-publications/indiana-medicaid-demonstration-raises-concerns}.}

**How do recent Section 1115 Medicaid waivers differ from previous waivers?**

The current administration has stated its intent to fundamentally transform the Medicaid program,\footnote{Seema Verma & Brian Neale, \textit{Healthy Indiana 2.0 Is Challenging Medicaid Norms}, Health Affairs Blog (Aug. 29, 2016), \url{https://www.healthaffairs.org/do/10.1377/hblog20160829.056228/full/}.} and it is using Section 1115 in that effort.\footnote{See Ctrs. for Medicare & Medicaid Servs., \textit{About Section 1115 Demonstrations}, \url{https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html} (establishing Trump administration criteria for whether to approve Section 1115 applications, including potential to “promote upward mobility, greater independence, and improved quality of life among individuals” and “[e]nhance alignment between Medicaid policies and commercial health insurance products”).} Since the beginning of 2018, the administration has enacted this policy shift, in part, by inviting states—\textit{for the first time ever}—to apply for waivers that will terminate Medicaid coverage to individuals unless they engage in work or work-like activities.\footnote{Brian Neale, Director, Ctrs. for Medicare & Medicaid Servs., \textit{Dear State Medicaid Dir. Letter RE: Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries} (Jan. 11, 2018), \url{https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf}; \textit{but see} Jane Perkins, Nat’l Health Law Prog., \textit{NHeLP Letter to CMS Regarding Work Requirements} (Jan. 11, 2018), \url{http://www.healthlaw.org/issues/medicaid/nhelp-letter-to-cms-regarding-work-requirements}.}

Kentucky was the first state to obtain a waiver under the new policies. Kentucky officials describe the “Kentucky HEALTH” project as “a comprehensive entitlement and workforce reform effort.”\footnote{Testimony of Adam M. Meier, Sec’y, Ky. Cab. for Health & Hum. Servs., before U.S. House Committee on Educ. & Workforce Subcommittee on Higher Educ. & Workforce Dev. (Mar. 15, 2018); \textit{see also}, \textit{e.g.}, Kentucky HEALTH Demonstration Application at 4 (Aug. 24, 2016), \url{https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ky/ky-health-pa.pdf} (describing purpose of waiver to “transform the Kentucky Medicaid program”).} The approval allows Kentucky to impose community engagement and work requirements and to require premium payments higher than any previously approved for mandatory Medicaid populations. There are ongoing enrollee reporting requirements (largely through online reporting). Individuals who fail to meet
the requirements will be terminated from coverage and locked out.20 The approval also eliminated retroactive coverage and non-emergency medical transportation (NEMT) and converted dental and vision benefits into “optional” benefits. The Kentucky HEALTH project is aimed at childless adults and caretaker relatives, and “medically frail” individuals are excluded from many of the restrictive policies.21

HHS subsequently approved similar Section 1115 Medicaid waivers in Arkansas, New Hampshire (work requirements only), and Indiana. Other states, including Alabama, Arizona, Mississippi, Maine, Ohio, Utah, and Wisconsin, have pending requests.22

How can the public be involved in the Section 1115 waiver review process?

The Affordable Care Act amended Section 1115 to require greater transparency for any waiver that could impact “eligibility, enrollment, benefits, cost-sharing, or financing.”23 Pursuant to the statute, HHS has promulgated regulations establishing public notice and comment processes at the state and the federal levels.24

These rules require states to provide a 30-day public comment period before submitting an application to HHS for either a new demonstration program or extension of an existing program.25 The process begins with the state issuing a public notice that includes:

- The program description, goals, and objectives, including a description of beneficiaries who will be affected;
- The proposed health care delivery system, eligibility requirements, and benefit coverage and how the provisions differ from the current program;

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21 See, e.g., CMS, Approval Letter for KY Health Section 1115 Demonstration (Jan. 12, 2018), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ky/ky-health-ca.pdf; id. at 2 (individuals who are medically frail exempt from premiums); id. at 6 (re: lockouts); id. at 7 (re: community engagement requirements).
22 For details and comments on approved and pending waivers, see Waivers section of National Health Law Program website, at http://www.healthlaw.org/issues/medicaid/waivers.
25 42 C.F.R. § 431.408(a).
• An estimate of the expected change in annual enrollment and aggregate expenditures, along with historic enrollment and budget data;
• The hypothesis and evaluation parameters of the demonstration; and
• The specific waivers that the state seeks.26

The notice must also include information about where copies of the application are available, where to send and review written comments on the application, the deadline for commenting, and when and where the state will hold public hearings on the application.27 This information must be published prominently on either the main page of the state Medicaid website or a website established for the demonstration.28

The state must hold at least two public hearings on separate dates and locations, at least 20 days prior to submitting the application.29 The state must consult with tribes and tribal health programs and organizations that could be affected by the demonstration.30

The state comment period is followed by a federal comment period. The federal comment period lasts a minimum of 30 days and generally commences on the day that CMS issues a letter of application completeness to the state.31 CMS’s website will show the application and supporting documents, the proposed effective date of the demonstration, and information about commenting.32 CMS must post copies of the comments it receives. CMS will also post the decision letter and, if the application is approved, the special terms and conditions and list of Medicaid provisions that have been waived, the state acceptance letter, and progress and evaluation reports.33

Is the Secretary’s approval of a Section 1115 waiver committed to agency discretion, or is the approval subject to court review?

When sued, HHS has argued that courts cannot review the decision because Section 1115 approval is committed to agency discretion. All courts to hear the argument have rejected it.34

26 Id. at § 431.408(a)(1).
27 Id.
28 Id. at § 431.408(a)(2)(i); see also Id. § 431.408(a)(2)(ii) (requiring state to publish notice in state’s administrative record or in the newspaper of widest circulation in each city with a population of 100,000 or more).
29 Id. at § 431.408(a)(3).
30 Id. at § 431.408(b)(1).
31 Id. at §§ 431.416(a), 431.412(b)(1)-(2).
32 Id. at § 431.416(b)(1).
33 Id. at § 431.416(f).
34 See, e.g., Beno v. Shalala, 30 F.3d 1057, 1067 (9th Cir. 1994) (“[T]he granting of an exemption from statutory requirements is not an area of agency discretion traditionally
As discussed below, challenges to Section 1115 are filed under the Administrative Procedure Act (APA). The APA embodies a “basic presumption of judicial review.” A decision is unreviewable only “in those rare circumstances where statutes are drawn in such broad terms that in a given case there is no law to apply.” Section 1115 contains law to apply, such as: Is the application proposing an experiment? Does it seek to waive provisions outside of Section 1396a? Is the project likely to promote the objectives of the Medicaid Act?

**What are the laws that plaintiffs rely upon to challenge Section 1115 waivers?**

Final agency actions, including the decision to approve a Section 1115 waiver, can be reviewed by federal courts under the APA. The APA requires courts to “hold unlawful and set aside agency action, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” Arbitrary and capricious review does not permit the court to substitute its judgment for that of the agency. However, it does require the court to ask whether the agency engaged in reasoned decision making. This includes, among other things, that the agency “adequately explain its result.” This requires an agency to “examine all relevant factors and record evidence.” Action is arbitrary and capricious if the agency “entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”

In *Stewart v. Azar*, currently underway in federal district court in the District of Columbia, the plaintiffs have also included a claim under the Take Care Clause of the Constitution. The Constitution provides that “All legislative Powers herein granted shall be vested in a Congress of the United States.” After a federal law is duly enacted, the President must

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38 *Overton Park*, 401 U.S. at 416.


“take Care that the Laws be faithfully executed.”44 The Stewart plaintiffs argue that the Clause is being violated because the Executive Branch is using Section 1115 to accomplish its stated intent to undermine the Affordable Care Act, of which the Medicaid expansion is a part, and to transform Medicaid —a fundamental alteration that can only be accomplished by Congress.

How have courts decided challenges to Section 1115 waiver approvals?

Section 1115 approvals have been challenged in a limited number of cases. The notable appellate courts cases are annotated below.

In a case from 1973, the Second Circuit Court of Appeals held in Aguayo v. Richardson that approval of work requirement and referral programs in New York’s Aid to Families with Dependent Children (AFDC) program was permissible where the state responded in writing to criticisms and alternatives offered by those opposing the waiver.45 The court held that the Secretary’s response evidenced sufficient consideration and that there was no evidence of a “clear error in judgment.”46 Notably, when Aguayo was decided, the courts could more easily apply a relaxed standard of deference because Section 1115 demonstration populations were subject to federal human experimentation protections which, among other things, required written informed consent and review board oversight.47 Those protections are no longer applied.

In C.K. v. New Jersey Department of Health and Human Services, the Third Circuit considered a waiver that allowed the state to eliminate a mandated increase in AFDC benefit amounts based on family size as part of a project to encourage self-sufficiency.48 The court noted that the AFDC statute identified an objective to promote “self-support and personal independence” and concluded that the Secretary could reasonably find that the reduction in benefits might encourage this self-support and independence.49 The opinion cited Aguayo favorably.

Spry v. Thompson (2007) challenged a Section 1115 approval that permitted Oregon to impose premiums and copayments that exceeded the limits contained in the Medicaid

44 U.S. Const., art. II, § 3. See Angelus Milling Co. v. Comm’r, 325 U.S. 293, 296 (1945) (“Insofar as Congress has made explicit statutory requirements, they must be observed and are beyond the dispensing power of [the Executive Branch].”).
45 Aguayo v. Richardson, 473 F.2d 1090, 1105–06 (2d Cir. 1973).
46 Id. at 1106.
47 See 42 U.S.C. § 3515b; see also 45 C.F.R. §§ 46.107-.124 (requiring HHS research on human subjects include prior review of a project by an Institutional Review Board (“IRB”) and informed consent).
49 Id. at 184-85.
Act. The requirements applied to childless adults — a population group that, at the time, was not described in the Medicaid Act. Spry held that no waiver was needed because the project applied to populations that were “statutorily ineligible for Medicaid under federal law.” The reasoning of this case is limited in general and also limited because the affected population, childless adults, is now described in the Medicaid Act as a mandatory coverage group.

Other courts have taken a more searching review. In Beno v. Shalala, the Ninth Circuit rejected approval of an AFDC work-incentive waiver as arbitrary and capricious. The court noted that the record “contain[ed] a rather stunning lack of evidence that the Secretary gave plaintiffs’ objections” adequate consideration. Rather, the State’s application emphasized cost savings from the waiver. However, the court found that “[a] simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy” the requirement for an experiment. The opinion also noted that, when reviewing Section 1115 approvals, courts are not dealing with concerns of federalism and states’ rights:

[W]e doubt Congress would enact such comprehensive regulations, frame them in mandatory language, require the Secretary to enforce them, and then enact a statute allowing states to evade these requirements with little or no federal agency review. Rather, Congress intended that the Secretary would selectively approve state projects.

In Newton-Nations v. Betlach, the Ninth Circuit held that the Secretary acted arbitrarily and capriciously in approving heightened copayments in Arizona’s Medicaid program. Citing Beno, the Court found that the administrative record did not establish that the project “will actually demonstrate something different than the 35-years worth of health policy research” on the effects of cost-sharing on people with low income. The Court also held that Arizona’s emphasis on the expected cost savings, as opposed to any benefit to Medicaid-eligible populations, could not satisfy the requirement to “make some judgment that the project has a research or a demonstration value.” Moreover, the Secretary’s “sparse statement” assuring “wider health benefit coverage to low-

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50 Spry v. Thompson, 487 F.3d 1272 (9th Cir. 2007).
51 Id. at 1274.
52 Beno v. Shalala, 30 F.3d 1057 (9th Cir. 1994).
53 Id. at 1074.
54 Id. at 1069.
55 Id. at 1068-69 (internal quotations and citations omitted).
56 Newton-Nations v. Betlach, 660 F.3d 370 (9th Cir. 2011). The plaintiffs were represented by the National Health Law Program and the William E. Morris Institute for Justice.
57 Id. at 381.
58 Id. at 381, citing Beno, 30 F.3d at 1069.
income populations” was not sufficient to show that the Secretary considered the impact the program would have on beneficiaries.\textsuperscript{59} The case was remanded to the district court with instructions to vacate the approval and remand to the Secretary.\textsuperscript{60}

In \textit{Pharmaceutical Research & Manufacturers of America v. Thompson}, the District of Columbia Circuit Court of Appeals, without extensive discussion, held, “Although the Act [§ 1115] authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of section 1396r-8’s rebate provision or the [§ 1396o] requirement that Medicaid beneficiaries contribute no more than a ‘nominal’ amount to the cost of medical benefits they receive.”\textsuperscript{61}

**What is the significance of the recent district court decision in \textit{Stewart v. Azar}?**

\textit{Stewart v. Azar} was filed by 16 Kentucky Medicaid beneficiaries, following the Secretary of HHS’s approval of the Kentucky HEALTH waiver. On June 29, 2018, the U.S. District Court for the District of Columbia decided cross motions for summary judgment filed by the parties and held the Secretary of HHS’s approval was arbitrary and capricious.\textsuperscript{62}

At the center of the case, the Medicaid beneficiaries contended—and the Court agreed—that the Secretary failed to adequately consider whether the Kentucky HEALTH project was likely to assist in promoting Medicaid’s objectives.\textsuperscript{63}

Like other courts, the Court in \textit{Stewart} looked to the Medicaid Act itself—specifically 42 U.S.C. § 1396-1—as a primary source for discerning the objectives of Medicaid. The text of that section establishes that increasing coverage to beneficiaries is a primary goal of the Medicaid Act.\textsuperscript{64} The Court separated the coverage issue into two sub-issues and found the Secretary failed to consider both: the risk of coverage losses and the possibility of promoting coverage.\textsuperscript{65} In particular, the Court criticized the federal defendant for ignoring the degree to which an estimated 95,000 people losing Medicaid coverage would conflict with, rather than further, the objectives of the Medicaid Act.\textsuperscript{66}

\textsuperscript{59} \textit{Id.}
\textsuperscript{60} \textit{Id.} at 382.
\textsuperscript{61} \textit{Pharm. Research & Mfrs. of Am. v. Thompson}, 251 F.3d 219, 222 (D.C. Cir. 2001)
\textsuperscript{62} \textit{Stewart v. Azar}, 2018 WL 3203384 (D.D.C. June 29, 2018). The plaintiffs are represented by the National Health Law Program, Kentucky Equal Justice Center, Southern Poverty Law Center, and Jenner & Block LLP.
\textsuperscript{63} 2018 WL 3203384, at *27.
\textsuperscript{64} \textit{Id.} at *33.
\textsuperscript{65} \textit{Id.}
\textsuperscript{66} \textit{Id.}
The Court also rejected the adequacy of the factors that the federal defendants claimed to consider in approving Kentucky HEALTH, including among others supposed increases in self-sufficiency, noting that even while they “may all be worthy goals,” the “notable omission” of “whether Kentucky HEALTH … would help provide health coverage for Medicaid beneficiaries” necessarily meant that the Secretary “entirely failed to consider” a factor necessary to approve the program.\(^{67}\)

The Court rejected the Secretary’s contention that some baked-in exemptions were adequate to address the risk of coverage losses, particularly because most of the exemption had been announced prior to the public comment periods, and commenters repeatedly complained that the exemptions were not adequate beneficiary protections.\(^{68}\) The Court also found fault in the unsubstantiated claim that individuals who lost coverage might somehow transition to private or employer-sponsored insurance.\(^{69}\)

The Court expressly rejected several counterarguments offered by federal and State governments. First, the Court held that the purported Medicaid objective of promoting health or wellness represented “little more than a sleight of hand” wherein the Secretary “impermissibly conflated ‘improv[ing] health and wellness’ … with the Medicaid Act’s more specific stated purpose of ‘furnish[ing] … medical assistance’ and ‘rehabilitative and other services.’”\(^{70}\) In doing so, the Court endorsed the Medicaid beneficiaries’ view that while, health improvements are a desirable outcome of covering health care costs, the Secretary “cannot choose his own means to that end.”\(^{71}\) The Court further rejected the governments’ appeal to deference, holding that the “Secretary’s interpretation here runs counter to the statute’s plain text, its structure, and its legislative history, and would thus fail at \textit{Chevron} step 1.”\(^{72}\)

\(^{67}\) \textit{Id.} at *36.
\(^{68}\) \textit{Id.} at *38-40.
\(^{69}\) \textit{Id.} at *40.
\(^{70}\) \textit{Id.} at *44, quoting 42 U.S.C. § 1396-1.
\(^{71}\) \textit{Id.}
\(^{72}\) \textit{Id.} at *47. In \textit{Chevron v. Natural Resources Defense Council}, 467 U.S. 837 (1984), the Court set out a two-step process for the interpretation of regulatory statutes: “First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute.” \textit{Id.} at 842-43 (footnotes omitted).
The Court similarly found the defendants’ appeals to cost savings, including the idea that dramatic coverage losses for certain adults could be justified by a supposed (though notably unproven) resulting preservation of funding for “traditional” Medicaid populations, to be inadequate in light of the failure to consider impacts on coverage. In doing so, the Court affirmed that the Medicaid Act’s objective of providing coverage to mandatory eligibility groups included expansion populations described under the ACA and, in the Medicaid Act, Congress had not favored some covered population groups over others.

Concluding that the failure to consider the effect the demonstration would have on medical coverage “infected [the Secretary’s] entire approval,” the Court granted the Medicaid beneficiaries full relief. The Court granted Plaintiffs’ motion for summary judgment, vacated approval of Kentucky HEALTH, and remanded to the agency for reconsideration.

Recommendations for advocacy

Section 1115 Medicaid waivers have the potential to bring great change—positive or negative — to the state’s Medicaid program and those who depend on it for their health coverage; thus:

- Know whether a waiver is in the works by attending Medical Care Advisory Committee or other public Medicaid meetings and making connections with state employees and reporters on the health beat.
- Monitor the state Medicaid agency’s website for section 1115 waiver activity.
- When a Section 1115 waiver application is posted, become familiar with the details of the federally required state and federal public participation processes. Submit state and federal comments and attend and testify at state public hearings. It is important to submit comments as part of the federal review process because these comments will form the administrative record upon which the Secretary must base his decision.
- When filing comments, focus on discussing research and studies that support your points. If possible include copies of, or active links to, studies cited. Include personal experiences and stories, if available.
- Educate clients and interested organizations about the Section 1115 application, its implications, and the review process. Work with other organizations.

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73 Stewart, 2018 WL 3203384, at *48.
74 Id. at *49.
75 Id. at *54-55.
76 Id. at *58.
• If the waiver is approved, review the approval letter and special terms and conditions to determine whether the approval is consistent with the requirements of Section 1115. The National Health Law Program is available to assist with this review and determining next steps, if any.