Q&A
Medicaid "Reform" Waivers and the Administrative Procedure Act[1]

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Q: My state is getting ready to submit a waiver request to the United States Department of Health and Human Services (HHS) to "reform" our Medicaid program. The request will seek to implement a "demonstration" project under section 1115 of the Social Security Act, and affected population groups will include people with chronic and disabling conditions. We are concerned that the proposed managed care delivery system will be inadequate and the cost sharing unaffordable. I understand that a federal district court recently found problems with HHS' approval of Arizona's demonstration program. Can you explain the case and how it might affect our work?

A: *Wood et al. v. Betlach & Sebelius* requires HHS to establish that it has adequately reviewed a section 1115 waiver request and finds that federal approval with no evidentiary support violates the Administrative Procedure Act. Along with a new provision in the Affordable Care Act that requires increased transparency in the waiver approval process, these developments present new opportunities for people with disabilities and their advocates to have meaningful input into the development of section 1115 health reform programs.

Discussion

The *Wood v. Betlach* opinion

On February 7, 2013, Judge David G. Campbell issued *Wood et al. v. Betlach & Sebelius*, Civ. No. 12-08098, 2013 WL 474369 (D. Ariz. Feb. 7, 2013). The case

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concerns the Secretary of HHS' October 21, 2011 approval of mandatory and heightened copayments for low-income, childless adults enrolled in the Arizona Health Care Cost Containment System (AHCCCS). AHCCCS was originally approved as a section 1115 demonstration project in the early 1980s and has operated as such since then.

Section 1115 of the Social Security Act authorizes the Secretary to waive certain Medicaid Act requirements for an "experimental, pilot, or demonstration project" that the Secretary finds is "likely to assist in promoting the objectives" of the Medicaid Act. 42 U.S.C. § 1315. The waiver allows the state's expenditures for these projects to qualify for federal Medicaid matching funding. *See Id.* at § 1315a(2)(A).

Judge Campbell found the Secretary's approval of Arizona's request to renew its demonstration project did not comply with the federal Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A). He remanded the approval back to the Secretary for a new analysis.

Prior APA litigation challenging the copayments

Notably, federal courts had already reviewed the legality of Arizona's copayments as part of the section 1115 demonstration project. Back in 2003, the Secretary approved AHCCCS' proposal to impose heightened and mandatory copayments on two groups: (1) childless adults with income up to 100% of the federal poverty level and (2) individuals in the Medical Expense Deduction group who "spend-down" their medical expenses to 40% of the federal poverty level. Low-income individuals who could not afford to pay the copayments challenged them in a case called *Newton-Nations et al. v. Betlach &* Sebelius. In 2004, Judge Earl H. Carroll certified *Newton-Nations* as a class action and issued a preliminary injunction enjoining AHCCCS from imposing the challenged copayments or allowing health care providers to refuse services to an individual unable to pay them. *See* 221 F.R.D. 509 (D. Ariz. 2004) (class certification); 316 F. Supp. 2d 883 (D. Ariz. 2004) (preliminary injunction). On March 29, 2010, however, Judge Carroll ruled against the plaintiffs. *See* No. 03-2506, 2010 WL 1266827 (D. Ariz. Mar. 29, 2010). The preliminary injunction was vacated, and AHCCCS started charging the copayments.

The plaintiffs appealed. The Ninth Circuit Court of Appeals held the Secretary's approval of the copayments violated the APA. *See Newton-Nations v. Betlach*, 660 F.3d 370 (9th Cir. 2011). The *Newton-Nations* Court recognized that the sole reason AHCCCS provided to justify the copayments was to save money and noted that demonstration waivers must have a research or experimental goal. The Court cited to the plaintiffs' expert on Medicaid and cost sharing, who stated that copayments had been studied for over 35 years and there was nothing experimental or novel about

them. The Court reviewed the administrative record and the Secretary's approval and found there was no evidence "that Arizona's demonstration project will actually demonstrate something different than the last 35–years [sic] worth of health policy research." *Id.* at 381. The Court concluded that the Secretary's approval of the copayments was "arbitrary and capricious within the meaning of the APA." *Id.* at 381-82 (citing *Motor Vehicle Mfr. Ass'n v. State Farm Ins.,* 463 U.S. 29, 44 (1983)). The case was remanded to the district court. For additional discussion of *Newton-Nations*, *see* Jane Perkins & Sarah Somers, NHeLP, *Q&A: Limiting the Cost Sharing in Medicaid-Funded Programs* (Sept. 2011) (available from TASC or NHeLP).

Between the issuance of the opinion and entry of the mandate, on October 21, 2011, the Secretary approved AHCCCS' request to renew the section 1115 project. While the project included some modifications, the heightened and mandatory copayments were continued. On remand, Judge Rosslyn O. Silver dismissed the case, on grounds that it had become moot when the section 1115 project was re-authorized by the Secretary. Civ. No. 03-02506 (D. Ariz. Apr. 16, 2012). The plaintiffs have appealed this ruling to the Ninth Circuit and are awaiting a decision.

The more recent APA case

Meanwhile, unable to afford the copayments, a new group of plaintiffs filed the *Wood* case to challenge the Secretary's October 21, 2011 approval of the heightened and mandatory copayments. They claimed the Secretary did not consider their evidence that the copayments will not test anything experimental and that the copayments will cause low-income individuals irreparable harm. As had the *Newton-Nations* plaintiffs before them, these plaintiffs alleged the copayments presented barriers to low-income individuals receiving necessary medical care that their health care providers have prescribed. Indeed, unable to afford the copayments and obtain needed care, their conditions worsened, some had to go to the emergency room or the hospital. One plaintiff tried to commit suicide.

Judge Campbell certified the case as a class action. *See* 286 F.R.D. 444 (D. Ariz. 2012). Then, on February 7, 2013, he ruled that the Secretary violated the APA when she approved the project. Civ. No. 12-08098, 2013 WL 474369 (D. Ariz. Feb. 7, 2013). The decision finds that the Secretary, first, failed to consider whether the project was "an experimental, demonstration or pilot project," and, second, failed to consider whether the project would "likely assist in promoting the objectives" of the Medicaid Act.

According to the Court, the Secretary of HHS must "make some judgment that the project has a research or a demonstration value." *Id*. at *7 (quoting *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994)). The Secretary argued she met this requirement because she had identified elements of the project that would be tested with respect to

copayments. But even though the Secretary had made "some judgment" about a research value, the Court found that her approval could nevertheless be "arbitrary and capricious" if she failed to consider an important aspect of the problem, offered an explanation for her decision that ran counter to the evidence in the agency record, or that it was so implausible that it could not be ascribed to a difference of viewpoint or agency expertise. *Id.* (citing *O'Keefes, Inc. v. U.S. Consumer Prod. Safety Comm'n*, 92 F.3d 940, 942 (9th Cir. 1996).[2]

The Court found that the Secretary failed to consider the evidence plaintiffs' counsel had submitted during the administrative approval process. Counsel had submitted the declaration of Dr. Leighton Ku, an expert on cost sharing. Dr. Ku stated that numerous studies have looked at the effects of cost-sharing on the poor over the past 35 years; in fact, copayments have been the most heavily studied aspect of cost sharing. Based on his review of the research, he was not aware of any "unique or untested" aspects of cost-sharing or copayments that would be examined under this project. Dr. Ku also stated that extensive research on cost sharing for the poor has shown that copayments are not an effective cost-saving measure for states; rather, copayments cause low-income beneficiaries to forego essential and effective health services and medications, rely more on emergency room care and hospitalizations, and result in a higher incidence of serious medical conditions such as heart attacks and strokes. Plaintiffs' counsel also submitted the statements of a previous AHCCCS director noting similar findings and stating that cost sharing works at odds with a managed care system like Arizona's, which is trying to rely on other utilization control features to reduce costs and direct patients to the most effective services. *Id.* at *8-10.

The Court found no evidence that the Secretary's approval of the copayments had considered Dr. Ku's declaration concerning the lack of experimental value of the copayments or the corresponding tradeoffs when evaluating the impact of the copayments on those covered by the project. In short, the Court found no evidence that the Secretary had made any effort to address Plaintiffs' administrative objections. The *Wood* decision also noted that the Secretary had offered a post-approval declaration from an HHS official as part of the litigation effort. However, that could not cure the failure of the Secretary to review the plaintiffs' objections as part of the actual

[2] In discussing the Secretary's failure, the Court relied heavily on *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994). In *Beno*, the Ninth Circuit found the APA had been violated because, even though the administrative record showed that HHS had put "a good deal of thought" into the 1115 project, it contained no evidence that the Secretary had responded to the substance of the plaintiffs' objections.

administrative review. *Id*. at *10. The Judge remanded the case to the Secretary for re-evaluation of the copayments.[3]

The Affordable Care Act (ACA) Provision

The ACA amends section 1115 of the Social Security Act to require states and the Secretary of HHS to do a better job of considering public input as part of the section 1115 review and approval process. *See* ACA § 10201(i) (adding 42 U.S.C. § 1315(d)). The provision applies to the application or renewal of any Medicaid or CHIP demonstration project that would have "an impact on eligibility, enrollment, benefits, cost-sharing, or financing" and requires such projects to be subjected to public notice and comment at the state and federal levels. The requirement of the statute is "to ensure a meaningful level of public input." *Id.*

The ACA required the Secretary to publish regulations. These were finalized in February 2012. *See* 77 *Fed. Reg*. 11678 (Feb. 27, 2012) (amending 42 C.F.R. part 431); 75 *Fed. Reg*. 56946 (Sept. 17, 2010) (proposed rule).

Of particular note, to be considered complete, the state's application or renewal must verify that:

- A 30-day public notice and comment period occurred.
- At least two public hearings have occurred on separate dates and in separate locations.
- The state described the proposal in sufficient detail to ensure meaningful public comment.
- The state is maintaining a website to share materials.

See 42 C.F.R. §§ 431.408(a), 431.412. At the federal level, activities must include:

- A notice of receipt to the state within 15 days after the state submits a waiver. Except in emergencies, a federal decision cannot be made on the waiver until 45 days after sending the notice of receipt.
- A 30-day public notice and comment period following receipt of the state's waiver application or renewal.
- A federal website that contains the application and other relevant materials and an email address for the public to send comments.

[3] The Plaintiffs are represented by the William E. Morris Institute for Justice and the National Health Law Program.

Id. at § 431.16. Finally, the regulations require states to conduct periodic reviews of implementation. Within six months of the date the waiver is approved, and annually thereafter, the state must hold public forums to solicit feedback. *Id.*at § 431.420(b).

Conclusions and recommendations

For decades, the federal and state governments have developed section 1115 waivers behind closed doors and with little public oversight. *See*, *e.g.*, Government Accountability Office, *Medicaid Demonstration Waivers: Lack of Opportunity or Public Input during Federal Approval Process Still a Concern* (July 24, 2007), http://www.gao.gov/assets/100/95034.pdf; Government Accountability Office, *Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns* (July 2002) (GAO-02-817), http://www.gao.gov/assets/240/235108.html. Recent decisions from the courts and the publication of federal regulations demand accountability and transparency and, thus, can improve the situation. Here are some steps you can take:

1. Monitor state and federal websites for section 1115 project developments. Also, be in contact with individuals within the Medicaid agency who can keep you informed of activities and timing. Review section 1115 project outlines, applications, and other public documents.

2. Review the new federal rules for public participation in section 1115 project applications and renewals. As noted above, these rules were promulgated in final form at 77 Fed. Reg. 11678 (Feb. 27, 2012).

3. As you review waiver documents, consult with experts and the research literature if there are concerns.

4. Participate in public hearings held in the state and submit written comments to the state agency.

5. Submit written comments directly to the Secretary, supported by expert opinions and research. Be precise regarding your concerns and objections. Specifically ask the Secretary to accept the recommendations or, if she is going to reject them, to explain why.

   The waiver statute, 42 U.S.C. § 1315(d), and implementing regulations require the state's process to be sufficient to garner meaningful input from the public. If the state's procedures have not met this standard, cite these laws and explain the problems. For example, the process would arguably be legally deficient if the state failed to respond to consistent, well-supported objections to a structural aspect of managed care proposal. Ask that the waiver not be acted upon it is clear that meaningful input has been received.

6. With respect to cost sharing, continue to object to section 1115 proposals that include heightened and mandatory copayments for low-income people. Over three decades of research overwhelmingly establishes that even small copayments make it harder for low-income people to afford medical services. *See*, *e.g.*, NHeLP Comments, *Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing* (Feb. 21, 2013), *at* http://www.healthlaw.org/images/stories/NHeLP_Exchange_and_Medicaid_reg_comments.pdf.