

[NOT SCHEDULED FOR ORAL ARGUMENT]

Nos. 19-5094 & 19-5096 (Gresham); Nos. 19-5095 & 19-5097 (Stewart)

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

CHARLES GRESHAM, et al.,
Plaintiffs-Appellees

v.

ALEX M. AZAR II, Secretary of Health & Human Services, et al.,
Defendants-Appellants

STATE OF ARKANSAS,
Intervenor-Defendant-Appellant

RONNIE MAURICE STEWART, et al.,
Plaintiffs-Appellees

v.

ALEX M. AZAR II, Secretary of Health & Human Services, et al.,
Defendants-Appellants

COMMONWEALTH OF KENTUCKY,
Intervenor-Defendant-Appellant

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR THE FEDERAL APPELLANTS

ROBERT P. CHARROW
General Counsel

JOSEPH H. HUNT
Assistant Attorney General

KELLY M. CLEARY
Deputy General Counsel

MARK B. STERN
ALISA B. KLEIN
(202) 514-1597
Attorneys, Appellate Staff
Civil Division, Room 7235
U.S. Department of Justice
950 Pennsylvania Ave., NW
Washington, DC 20530
alisa.klein@usdoj.gov

BRENNNA E. JENNY
Deputy General Counsel
U.S. Department of Health & Human Services

**CERTIFICATE AS TO PARTIES,
RULINGS, AND RELATED CASES**

Pursuant to Circuit Rule 28(a)(1), counsel certifies as follows:

A. Parties and Amici

The plaintiffs-appellees in *Gresham* are Charles Gresham, Cesar Ardon, Marisol Ardon, Adrian McGonigal, Veronica Watson, Treda Robinson, Anna Book, Russell Cook, and Jamie Deyo. The plaintiffs-appellees in *Stewart* are Ronnie Maurice Stewart, Shawna Nicole McComas, David Roode, Sheila Marlene Penney, Hunter Malone, Sarah Martin, Althea Humber, Melissa Spears-Lojek, Linda Keith, Kimberly Kobersmith, Debra Wittig, Randall Yates, Rodney Lee, Teri Blanton, Robin Ritter, and Diika Nehi Segovia.

The federal defendants-appellants in *Gresham* are Alex M. Azar II, in his official capacity as Secretary of Health and Human Services; Seema Verma, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; the United States Department of Health and Human Services; and the Centers for Medicare & Medicaid Services. The federal defendants-appellants in *Stewart* are Alex M. Azar II, in his official capacity as Secretary of Health and Human Services; Seema Verma, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; Paul Mango, in his official capacity as Chief Principal Deputy Administrator of the Centers for Medicare & Medicaid Services; Demetrios L. Kouzoukas, in his official capacity as Principal Deputy Administrator of the Centers

for Medicare & Medicaid Services; United States Department of Health and Human Services; and the Centers for Medicare & Medicaid Services.

The State of Arkansas is intervenor-defendant-appellant in *Gresham*. The Commonwealth of Kentucky is intervenor-defendant-appellant in *Stewart*.

The following organizations participated as amici in *Gresham*: Deans, Chairs and Scholars; and National Alliance on Mental Illness.

The following organizations participated as amici in *Stewart*: Deans, Chairs and Scholars; AARP; AARP Foundation; Justice in Aging; National Academy of Elder Law Attorneys; Disability Rights Education and Defense Fund; American Academy of Pediatrics; American College of Physicians; American Medical Association; American Psychiatric Association; Catholic Health Association of the United States; March of Dimes; and National Alliance on Mental Illness.

B. Rulings Under Review

In *Gresham*, the rulings under review are the opinion and order entered on March 27, 2019 (Dkt. Nos. 57, 58); the order entering judgment pursuant to Rule 54(b) on April 4, 2019 (Dkt. No. 60); and all prior orders and decisions that merge into those. The rulings were issued by the Honorable James E. Boasberg in Case No. 1:18-cv-1900 (D.D.C.). The opinion is reported at 363 F. Supp. 3d 165 (D.D.C. 2019).

In *Stewart*, the rulings under review are the opinion and order entered on March 27, 2019 (Dkt. Nos. 131, 132); the order entering judgment pursuant to Rule 54(b) on April 4, 2019 (Dkt. No. 134); and all prior orders and decisions that merge into those. The rulings were issued by the Honorable James E. Boasberg in Case No. 1:18-cv-152 (D.D.C.). The opinions are reported at 313 F. Supp. 3d 237 (D.D.C. 2018) (*Stewart I*), and 366 F. Supp. 3d 125 (D.D.C. 2019) (*Stewart II*).

C. Related Cases

These cases were not previously before this Court. Substantially the same issues are presented in *Philbrick v. Azar*, No. 1:19-cv-773 (D.D.C.) (Boasberg, J.), which is pending in district court.

/s/ Alisa B. Klein
Alisa B. Klein

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GLOSSARY

ACA	Patient Protection and Affordable Care Act
AFDC	Aid to Families with Dependent Children
APA	Administrative Procedure Act
HHS	U.S. Department of Health & Human Services
SNAP	Supplemental Nutrition Assistance Program
TANF	Temporary Assistance for Needy Families

INTRODUCTION

Section 1115 of the Social Security Act authorizes the Secretary of Health & Human Services (HHS) to approve “any experimental, pilot, or demonstration project” proposed by a State that, “in the judgment of the Secretary, is likely to assist in promoting the objectives” of the Medicaid program. 42 U.S.C. § 1315(a). In approving such a demonstration, the Secretary may “waive compliance with any of the requirements” of the Medicaid statute set out in 42 U.S.C. § 1396a “to the extent and for the period he finds necessary to enable such State or States to carry out” the project. *Id.* § 1315(a)(1). Section 1115 was enacted to facilitate “experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients.” S. Rep. No. 87-1589, at 19 (1962) (Conf. Rep.).

These two cases involve Medicaid demonstration projects that were proposed by Kentucky and Arkansas and approved by HHS for specified time periods: five years in Kentucky and three years in Arkansas. Among other provisions, these demonstrations require certain adult Medicaid recipients to engage in 80 hours per month of work or work-related activities such as job-skills training, job search, community service, or vocational education. These requirements are modeled on the statutory requirements that, since 1996, have been conditions of eligibility for cash assistance under the Temporary Assistance for Needy Families (TANF) program and food assistance under the Supplemental Nutrition Assistance Program (SNAP). The persons who are subject to the demonstrations are largely members of the expansion

population authorized by the Patient Protection and Affordable Care Act (ACA), which means they are adults who are not receiving Medicaid on the basis of disability, advanced age, or pregnancy. The projects include additional exemptions for (among others) persons who are medically frail or experiencing an acute medical condition.

The work and work-related requirements of the demonstrations are designed to help adult Medicaid recipients to transition to financial independence and commercial coverage, including the subsidized coverage that is available on the ACA's Exchanges. The district court did not dispute that these requirements—if successful—will promote Medicaid's objectives by enabling state Medicaid programs to conserve finite resources for other persons in need. The court vacated HHS's approval, however, because it incorrectly believed that HHS did not make findings, supported by substantial evidence, that the demonstrations are likely to succeed in facilitating such transitions, and did not weigh the costs and benefits of the experiments.

The district court's decisions reflect a misunderstanding of the nature of demonstration projects in general, and of the particular demonstrations at issue here. Demonstration projects are experiments, the results of which inform future policy-making. HHS had ample reason to conclude that the Kentucky and Arkansas projects are, on balance, likely to advance the Medicaid program's objectives. Like their counterparts in other public welfare programs, the work and work-related requirements of these demonstrations are carefully tailored to allow those adults who

are subject to the requirements to succeed in fulfilling them. The “goal of these policies is to incentivize compliance, not reduce coverage,” and they include safeguards intended to minimize coverage loss due to noncompliance. JA ___ (KY AR 6729); JA ___-___ (Ark. AR 6-7). Moreover, HHS found that even adults who do not make the transition out of Medicaid will benefit from participating in work and work-related activities, which are correlated with improved health and thus may lead to reduced program expenses. The district court plainly erred in likening the demonstrations at issue here to the demonstration that was at issue in *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994), which purported to impose “work incentives” on children and persons too disabled to work. The design of the Kentucky and Arkansas experiments is sound, and their approval is well within the broad grant of discretion that Section 1115 vests in HHS.

STATEMENT OF JURISDICTION

Plaintiffs invoked the district court’s jurisdiction under 28 U.S.C. § 1331. The district court entered Rule 54(b) judgments on April 4, 2019. The federal government filed timely notices of appeal on April 10. Arkansas filed a timely notice of appeal in *Gresham* on April 10. Kentucky filed a timely notice of appeal in *Stewart* on April 11. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether, in approving the Kentucky and Arkansas demonstration projects at issue here, HHS acted within the authority conferred by Section 1115 of the Social Security Act, 42 U.S.C. § 1315.
2. Whether the relief granted was overly broad.

PERTINENT STATUTES AND REGULATIONS

Pertinent provisions are reproduced in the addendum to this brief.

STATEMENT

I. Statutory Background

A. The Medicaid Program

In various titles of the Social Security Act, Congress established a number of public welfare programs including the Medicaid program and the Aid to Families with Dependent Children (AFDC) program, which was later replaced by Temporary Assistance for Needy Families. These and other public welfare programs are jointly funded by the federal and state governments and administered by States.

Medicaid, which was enacted in 1965 as title XIX of the Social Security Act, is a cooperative federalism program that provides medical assistance to low-income individuals. To participate in Medicaid and receive federal funding, a State submits a plan for medical assistance for approval by the Secretary. 42 U.S.C. § 1396a(b). The state plan defines the categories of persons eligible for benefits and the kinds of medical services the State covers. *Id.* § 1396a(a)(10), (17).

Since Medicaid's enactment in 1965, federal law has required participating States to cover specified benefits for specified populations, while giving States the option to cover certain additional populations and/or additional benefits. *See* 42 U.S.C. 1396a(a)(10); *Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650-51 & n.4 (2003). Under the traditional Medicaid program, state coverage was mandatory for discrete categories of low-income individuals: persons who are disabled or blind, the elderly, children, parents of dependent children, and pregnant women. *National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 575 (2012) (*NFIB*). Outside these categories, there was no mandatory coverage of most childless adults, and States typically did not offer such coverage. *Id.*

As enacted, the ACA would have required States to expand their Medicaid programs by 2014 to cover all individuals under the age of 65 with incomes below 133% of the federal poverty line. *NFIB*, 567 U.S. at 576. In *NFIB*, however, the Supreme Court concluded that the ACA's adult-eligibility expansion was in essence a new program, and ruled that Congress could not condition a State's traditional Medicaid funding on its compliance with the ACA's expansion requirement. The effect of that ruling was to make state coverage of the ACA's adult expansion population optional. *See id.* at 585 (holding that HHS cannot "withdraw existing Medicaid funds for failure to comply with the requirements set out in the expansion"). Thus, in 2012, when many States were deciding whether to expand their Medicaid

programs, HHS explained that States would “have flexibility to start or stop the expansion.” HHS, Centers for Medicare & Medicaid Services, *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* at 11 (Dec. 10, 2012) (2012 HHS Guidance).¹

B. Demonstration Projects

Section 1115 of the Social Security Act authorizes the Secretary of HHS to approve “any experimental, pilot, or demonstration project” proposed by a State that, “in the judgment of the Secretary, is likely to assist in promoting the objectives” of the program at issue. 42 U.S.C. § 1315(a). Congress enacted Section 1115 to ensure that federal requirements would not “stand in the way of experimental projects designed to test out new ideas and ways of dealing with the problems of public welfare recipients.” S. Rep. No. 87-1589, at 19.

To that end, Section 1115 authorizes the Secretary to “waive compliance with any of the requirements” of specified programs—including the Medicaid requirements in 42 U.S.C. § 1396a—“to the extent and for the period he finds necessary to enable such State or States to carry out” the demonstration project. 42 U.S.C. § 1315(a)(1). The Secretary may treat state expenditures for an approved

¹ <https://go.usa.gov/xmN4j>

demonstration project as expenditures that are eligible for federal funding, even though they would not otherwise qualify for such funding. *Id.* § 1315(a)(2)(A).

C. Work Requirements in TANF, SNAP, and Medicaid

For decades, work and work-related requirements have been a component of various public welfare programs. Demonstration projects such as the one upheld in *Aguayo v. Richardson*, 473 F.2d 1090 (2d Cir. 1973) (Friendly, J.)—which imposed work requirements as a condition of AFDC benefits—were precursors to the statutory requirements that Congress enacted in the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. No. 104-193, 110 Stat. 2105.

That 1996 welfare reform legislation established work and work-related requirements for certain recipients of benefits under three public welfare programs: the TANF program (which replaced AFDC); the Medicaid program; and the Supplemental Nutrition Assistance Program, which was formerly known as the Food Stamp Program. Although these requirements are often described as “work requirements,” they may be fulfilled not only by working but also by activities that enhance a person’s employability such as vocational education, community service, and job-skills training. *See* 42 U.S.C. § 607(d) and 45 C.F.R. § 261.30 (TANF); 42 U.S.C. § 1396u-1(b)(3)(A) (Medicaid, cross-referencing TANF); 7 U.S.C. § 2015(o) and 7 C.F.R. § 273.24 (SNAP).

Under the TANF provisions, a State may require 30 hours per week of work or work-related activities for a one-parent family and 35 hours per week for a two-parent family. 42 U.S.C. § 607(c); 45 C.F.R. §§ 261.30-261.32. Under the Medicaid statute, a State may terminate the Medicaid benefits of certain adults whose TANF benefits are terminated for failure to comply with TANF's work requirements. 42 U.S.C. § 1396u-1(b)(3)(A). And under SNAP, "able-bodied adults without dependents" are required to work and/or participate in a qualifying work program at least 20 hours per week (averaged monthly to 80 hours per month) or participate in and comply with workfare in order to receive SNAP benefits for more than 3 months in a 36-month period. 7 U.S.C. § 2015(o); 7 C.F.R. § 273.24.

In signing the 1996 welfare reform bill into law, President Clinton declared that the legislation provided "an historic opportunity to end welfare as we know it and transform our broken welfare system by promoting the fundamental values of work, responsibility, and family." *Statement on Signing the Personal Responsibility and Work Opportunity Reconciliation Act of 1996* (Aug. 22, 1996), 32 Weekly Comp. of Pres. Doc., at 1487-88 (President Clinton's Signing Statement).²

² <https://go.usa.gov/xmNjG>

II. Factual Background

As States began to participate in the ACA's adult-eligibility expansion, several asked HHS to approve demonstration projects that would include work requirements. Initially, HHS denied such requests.³ HHS subsequently revisited the issue and, beginning in 2018, it approved certain demonstration projects that include work and work-related requirements similar to the requirements in TANF and SNAP. The activities that fulfill these requirements are often described as "work and community engagement." At issue in these appeals are the Kentucky demonstration project, as approved in November 2018 for a five-year period beginning April 1, 2019, and the Arkansas project, as approved in March 2018 for a three-year period beginning June 1, 2018. *See* JA ___-___ (Kentucky approval letter); JA ___-___ (Arkansas approval letter).

A. Kentucky's Demonstration Project

The Kentucky demonstration project requires certain Medicaid recipients to spend at least 80 hours per month performing activities that include working, looking for work, job-skills training, education, and community service. JA ___ (KY AR 6721). This requirement applies to the ACA's adult-expansion population and also to some parents of dependent children within the traditional Medicaid program, but only if the parent is not the primary caregiver for a dependent child. *Id.* Thus, the requirement

³ For example, in 2016 HHS partially approved an Arizona demonstration projected but did not approve the State's request to establish a work requirement. *See* <https://go.usa.gov/xmNDx> (approval letter).

does not apply to recipients who are elderly or receiving Medicaid on the basis of disability or pregnancy. The project provides additional exemptions, including exemptions for persons who are medically frail, experiencing an acute medical condition, or full-time students. *Id.*

In approving the Kentucky proposal, HHS explained that the project requires able-bodied adults to work, look for work, or engage in other activities that enhance their employability such as job-skills training, education, and community service—potentially enabling them to transition from Medicaid to financial independence and commercial coverage, including the subsidized coverage available on the ACA’s Exchanges. JA ___-___ (KY AR 6724-25). The approval letter emphasized that by facilitating such transitions, the requirements “may enable states to stretch their resources further and enhance their ability to provide medical assistance to a broader range of persons in need,” including by expanding the services and populations they cover and preserving the optional services and coverage they have in place. JA ___-___ (KY AR 6719-20). The letter noted, for example, that the Kentucky state plan provides coverage for optional populations such as the medically needy, lawfully residing immigrant children under age 19, and adults newly eligible under the ACA, and that it also provides coverage for optional services such as over-the-counter drugs, vision benefits, and dental benefits. JA ___ (KY AR 6720). Moreover, through the demonstration project itself Kentucky is providing optional coverage for

a new substance-abuse treatment program, a matter of particular importance in Kentucky in light of the opioid crisis. JA __, __ (KY AR 6723, 6726).

The letter further explained that for adults who remain in Medicaid, work and work-related requirements correlate with improved health and thus may result in cost savings for the Medicaid program. JA __ (KY AR 6733). Other aspects of the Kentucky project—such as premiums, limits on retroactive eligibility, and limited coverage of non-emergency medical transportation—are likewise designed to encourage healthy behaviors that reduce Medicaid costs. JA __-__ (KY AR 6734-36). These components are similar to components of demonstration projects that HHS has approved in the past. *See, e.g.*, JA __, __-__ [ECF 51-8 at 2, 7-8] (2015 approval of an Indiana demonstration project that imposed premiums, limited retroactive eligibility, and limited coverage of non-emergency medical transportation).

B. Arkansas's Demonstration Project

Like the Kentucky project, the Arkansas project requires certain Medicaid recipients to spend at least 80 hours per month performing activities that include working, looking for work, job-skills training, education, and community service. JA __ (Ark. AR 2). This requirement applies to the ACA's adult-expansion population only. JA ____ (Ark. AR 21). The Arkansas project provides exemptions similar to those of the Kentucky project. JA __, __ (Ark. AR 2, 28).

The Arkansas requirements are amendments to a preexisting Arkansas demonstration project known as Arkansas Works, which included a voluntary work-referral program. JA __, __ (Ark. AR 2, 4). Arkansas found the voluntary referrals to be ineffective: only 4.7% of Medicaid beneficiaries followed through with the referral and took advantage of the programs that the Arkansas Department of Workforce Services provides to assist individuals in gaining employment, even though 23% of those who took advantage of the referral became employed. JA __ (Ark. AR 4).

Arkansas thus applied to HHS for approval to amend its demonstration project to test work and work-related requirements for members of the ACA's adult eligibility expansion who are not medically frail or otherwise exempt. JA __, __ (Ark. AR 2, 7). Like the Kentucky project, the amendments to the Arkansas demonstration project are designed to "increase the sustainability of the Arkansas Works program," "test innovative approaches to promoting personal responsibility and work," "encourag[e] movement up the economic ladder, and facilitat[e] transitions from Arkansas Works to employer-sponsored insurance and Marketplace coverage," *i.e.*, coverage on the Exchange. JA __ (Ark. AR 2057) (Arkansas's application); *see also* JA __ (Ark. AR 2) (approval letter) (noting that the Arkansas project attempts to facilitate transitions between and among Arkansas Works, employer-sponsored insurance, and the Arkansas Marketplace). In addition, the amendments to the Arkansas project (which also include a limit on retroactive eligibility) are designed to improve the health of

Medicaid recipients and help to prepare adults for the commercial insurance market.

JA __, __ (Ark. AR 3, 5).

C. Other Demonstration Projects

HHS has approved demonstration projects for Arizona, Indiana, Michigan, New Hampshire, Ohio, Utah, and Wisconsin that include work and work-related requirements in various forms.⁴ Other States have pending applications for approval of such demonstration projects. In Virginia, for example, the November 2018 legislation that authorized the Commonwealth to participate in the ACA's adult-eligibility expansion also directed the Commonwealth to seek HHS approval to test work and work-related requirements for newly eligible adults through a demonstration project. The Commonwealth's application is pending with HHS.⁵

III. District Court Proceedings

A. *Stewart v. Azar*

In a suit brought by fifteen Medicaid recipients, the district court vacated HHS's approval of the Kentucky demonstration project on the ground that HHS had not adequately considered whether the project "would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid." *Stewart v. Azar*, 313

⁴ See <https://go.usa.gov/xmNWQ> (Arizona); <https://go.usa.gov/xmNW6> (Indiana); <https://go.usa.gov/xmPYt> (Michigan); <https://go.usa.gov/xmmGC> (New Hampshire); <https://go.usa.gov/xmPga> (Ohio); <https://go.usa.gov/xmNZn> (Wisconsin); <https://go.usa.gov/xmNZA> (Utah).

⁵ <https://go.usa.gov/xmNBn>

F. Supp. 3d 237, 243 (D.D.C. 2018) (*Stewart I*). After an additional period of public comment, HHS issued a new approval letter in November 2018 that explained why it determined that Kentucky's demonstration project is likely to help the State furnish medical assistance to its citizens. JA ___-___ (KY AR 6718-37).

On March 27, 2019, several days before Kentucky's project was due to begin, the district court again vacated HHS's approval of the project. *See Stewart v. Azar*, 366 F. Supp. 3d 125 (D.D.C. 2019) (*Stewart II*). The court did not question the agency's conclusion that the Medicaid program's objectives would be served by requirements that help adults transition to financial independence and commercial coverage, and thus enhance the fiscal sustainability of Medicaid. *See id.* at 148-49. The court invalidated the approval, however, because it believed that substantial evidence did not show that the experiment is likely to achieve its objectives, and because it believed that HHS did not weigh the benefits of success against the costs to those who might lose coverage as a result of noncompliance. The court expressed doubt that "education, job skills training, job search activities, and community service" can lead to employment, and also expressed doubt that beneficiaries can "get coverage on [the] labor market." *Id.* at 142. The court thus assumed that any projected reduction in Medicaid coverage would be due to noncompliance. *Id.* at 141. Likening the Kentucky experiment to the demonstration project at issue in *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994), the court treated the Kentucky experiment as a "simple benefits

cuts enacted to save money,” and declared that HHS failed to compare the benefits of savings to the consequences for coverage. *Stewart II*, 366 F. Supp.3d at 150.

B. *Gresham v. Azar*

On the same day that the district court vacated the approval of the Kentucky demonstration project, it also vacated HHS’s approval of the amendments to Arkansas Works—which had been in effect for ten months and which plaintiffs did not challenge until after the court issued its *Stewart I* decision. *See Gresham v. Azar*, 363 F. Supp. 3d 165 (D.D.C. 2019). The court incorporated by reference the reasoning of its *Stewart II* opinion. *Id.* at 181, 182. The court acknowledged that halting this ongoing three-year experiment would be disruptive, but concluded that the harm to Medicaid recipients from the demonstration outweighed the harm from its disruption. *Id.* at 182-85.

SUMMARY OF ARGUMENT

The ACA’s expansion of Medicaid eligibility brought within the ambit of state Medicaid programs a large number of non-elderly adults who are not receiving coverage on the basis of disability or pregnancy. The Kentucky and Arkansas demonstrations at issue here test work and work-related requirements for these newly eligible adults and a limited number of other Medicaid recipients, with exemptions for (among others) those who are medically frail. The requirements of the

demonstrations are modeled on requirements that have long been conditions of eligibility for cash assistance under TANF and food assistance under SNAP.

In approving these demonstrations, HHS acted within its authority to approve “any experimental, pilot, or demonstration project” proposed by a State that, “in the judgment of the Secretary, is likely to assist in promoting the objectives” of the Medicaid program. 42 U.S.C. § 1315(a). HHS explained that the requirements in these demonstrations are designed to help able-bodied adults transition to financial independence and commercial coverage, including the subsidized coverage that is available on the ACA’s Exchanges. Furthermore, HHS explained that even adults who do not make the transition out of Medicaid may benefit from participating in work and work-related activities, which correlate with improved beneficiary health and thus may reduce program expenses.

The district court recognized that the Medicaid program’s objectives would be served by measures that help adults transition out of Medicaid and conserve finite state resources for other needy persons. The court nonetheless vacated the approvals of the Kentucky and Arkansas demonstrations, because the court believed that HHS’s predictive judgments are not supported by substantial evidence, and because it believed that HHS did not weigh the demonstration projects’ potential for success against the costs to those who might lose coverage as a result of noncompliance with the requirements of the demonstration projects.

The judgments of the district court should be reversed. As an initial matter, there is no requirement that substantial evidence support HHS's predictive judgment that a demonstration project will further the Medicaid program's objectives.

Demonstration projects are time-limited experiments, and even an unsuccessful experiment can provide useful information that informs future policy-making.

In any event, substantial evidence supports HHS's judgment that the Kentucky and Arkansas projects are likely to promote Medicaid's objectives. In expressing doubt as to whether these experiments will succeed, the district court relied on comments arguing that the similar requirements in TANF and SNAP are counterproductive. But Congress plainly does not share that view of these requirements—which remain a part of the TANF and SNAP programs—and the comments cited by the district court relied were contradicted by other submissions. Moreover, HHS clearly weighed the demonstration projects' prospects for success against the risks of coverage loss due to noncompliance. HHS emphasized that the demonstrations are tailored to ensure that only adults who can meet the requirements are subject to them. The goal of the policies is to encourage compliance, and the terms and conditions of approval include safeguards intended to minimize coverage loss due to noncompliance. There is, of course, no requirement that HHS quantify the outcome of the experiments in advance. The design of these experiments is sound, and HHS had authority to approve them.

STANDARD OF REVIEW

The district court's summary-judgment orders are subject to de novo review in this Court. *Chenari v. George Washington Univ.*, 847 F.3d 740, 744 (D.C. Cir. 2017).

ARGUMENT

I. HHS Acted Within Its Section 1115 Authority in Approving the Demonstration Projects Proposed by Kentucky and Arkansas.

A. Congress Vested HHS with Broad Discretion to Determine Which Experiments Are Likely to Assist in Promoting the Objectives of the Medicaid Program.

Section 1115 authorizes HHS to approve a demonstration project which, “in the judgment of the Secretary, is likely to assist in promoting the objectives” of the Medicaid statute, 42 U.S.C. § 1315(a). This broad grant of discretion reflects the nature and purpose of demonstration projects. The projects are time-limited experiments that can “influence policy making at the State and Federal level, by testing new approaches that can be models for programmatic changes nationwide or in other States.” *Medicaid Program; Review and Approval Process for Section 1115 Demonstrations*, 77 Fed. Reg. 11,678, 11,680 (Feb. 27, 2012). The point of these experiments is to test hypotheses, and either validate a hypothesis that might lead to new innovations or else refute the hypothesis and help Congress and HHS avoid mistaken policies in the future. The costs of trying out new approaches in state-level experiments are vastly lower than the alternative of testing out new provisions

nationwide through statutory or regulatory amendments, and even unsuccessful experiments can provide useful information.⁶

In approving these experiments the Secretary does not know in advance whether they will succeed, and is not required to have substantial evidence that they will attain their goals. A central purpose of a demonstration project is to demonstrate the extent to which its approach will, in fact, further its goals. As Judge Friendly explained in *Aguayo v. Richardson*, 473 F.2d 1090, 1103 (2d Cir. 1973)—which upheld a demonstration project that established work requirements for AFDC recipients—“it is legitimate for an administrator to set a lower threshold for persuasion when he is asked to approve a program that is avowedly experimental and has a fixed termination date.”

Consistent with the broad grant of discretion and the nature of a demonstration project, Section 1115 does not require that HHS provide an explanation for its decisions. Nor does the Administrative Procedure Act (APA): a demonstration project is not the product of rulemaking, and it “does not involve ‘adjudication required by statute to be determined on the record after opportunity for

⁶ See, e.g., 77 Fed. Reg. at 11,679 (explaining that demonstrations “can document policies that succeed or fail,” and that “the degree to which they do so informs decisions about the demonstration at issue, as well as the policy efforts of other States and at the Federal level”); *C.K. v. New Jersey Dep’t of Health & Human Servs.*, 92 F.3d 171, 187 (3d Cir. 1996) (explaining that Section 1115 “experiments are supposed to demonstrate the failings or success of such programs”).

an agency hearing,’ 5 U.S.C. § 554(a), to which alone the [APA’s] requirement of findings, 5 U.S.C. § 557(c), applies.” *Aguayo*, 473 F.2d at 1107. Accordingly, the regulations that implement Section 1115 indicate that HHS “will review and consider all comments received by the deadline, but will not provide written responses to public comments.” 42 C.F.R. § 431.416(d)(2).

Thus, while Section 1115 requires that HHS have a process for public notice and comment on an application that is sufficient to ensure a meaningful level of public input, 42 U.S.C. § 1315(d)(2)(C), approval letters historically have provided little or no explanation for the agency’s decision, and, instead, inform the State of the terms and conditions of the approval. For example, in approving an Indiana demonstration project in 2015, HHS waived an array of Medicaid requirements so as to allow the State to charge premiums to Medicaid recipients; restrict their free choice of providers; limit coverage of non-emergency medical transportation; charge co-payments for non-emergency use of the emergency department; and limit retroactive eligibility. *See* JA ___-___ [ECF 51-8 at 7-8]. The approval letter was largely a description of the project’s terms and conditions, with only a passing reference to its objectives. Other approval letters have made no reference to the objectives of the project at issue. *See, e.g.*, JA ___-___ [ECF 51-4 at 2-5] (2012 approval of a Kansas project); JA ___-___ [ECF 51-7 at 4-6] (2015 approval of a Montana project); JA ___-___ [ECF 51-10 at 2-3] (2013 approval of a Wisconsin project).

The purpose of the approval letters is not to facilitate judicial review, which, as the terms of the statute make clear, is extremely limited to the extent it is available at all. Section 1115 authorizes HHS to approve a demonstration project that, “*in the judgment of the Secretary*, is likely to assist in promoting the objectives” of the Medicaid program, and to “waive compliance with any of the requirements” of 42 U.S.C. § 1396a “to the extent and for the period *he finds necessary* to enable such State or States to carry out” the project, 42 U.S.C. § 1315(a) (emphases added). This is the type of language that Congress uses when it commits determinations to an agency’s discretion, *see* 5 U.S.C. § 701(a)(2)—language that sets out “a subjective standard (whether the agency thinks that a condition has been met)” rather than “an objective one (whether the condition in fact has been met).” *Drake v. FAA*, 291 F.3d 59, 72 (D.C. Cir. 2002). In *Drake*, for example, this Court held that “[a] provision that allows the Administrator to act when she ‘*is of the opinion* that the complaint does not state facts that warrant an investigation,’ gives the FAA virtually unbridled discretion over such decisions” because the “only statutory reference point is the Administrator’s own beliefs.” This Court explained that “[w]hat may be *thought* necessary may not in fact *be* necessary, but a court may pass judgment only on the latter, not the former.” *Id.* Similarly, in *Claybrook v. Slater*, 111 F.3d 904 (D.C. Cir. 1997), this Court concluded that the applicable statute’s “plain language reinforces the conclusion that the decision whether to adjourn is committed to agency discretion.” *Id.* at 909. “Rather than

allowing adjournment when it is in the public interest, section 10(e) authorizes the agency representative to *determine* whether adjournment is in the public interest.” *Id.*

Section 1115 similarly commits to the Secretary’s discretion—and thus makes unreviewable—the judgment that a demonstration project is likely to promote the Medicaid program’s purposes, and that waiving particular requirements is necessary to facilitate the project. That conclusion is reinforced by “the nature of the administrative action at issue,” *Drake*, 291 F.3d at 70, which is a time-limited experiment intended to inform future policy. Section 1115 thus does not direct the Secretary to determine whether an experiment “will promote” the Medicaid program’s objectives, but only whether it is “likely to assist” in doing so.

Assuming, however, that HHS’s determination that a demonstration project is “likely to assist” in promoting program objectives is reviewable, “[t]he ‘arbitrary and capricious’ standard is particularly deferential in matters implicating predictive judgments.” *Rural Cellular Ass’n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009). “[P]redictive judgments about areas that are within the agency’s field of discretion and expertise” are entitled to “particularly deferential” treatment. *International Ladies’ Garment Workers’ Union v. Donovan*, 722 F.2d 795, 821 (D.C. Cir. 1983); see *FCC v. National Citizens Comm. for Broad.*, 436 U.S. 775, 813 (1978). That is especially true when, as in Section 1115, the statute offers no standards by which to measure the reasonableness of the agency’s judgment. Likewise, even assuming that the

“substantial evidence” requirement were applicable, “the threshold for such evidentiary sufficiency is not high.” *Biestek v. Berryhill*, 139 S. Ct. 1148, 1154 (2019). “Substantial evidence” means “more than a mere scintilla.” *Id.* “It means—and means only—‘such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,’” a standard the Supreme Court has likened to “the deferential clearly-erroneous standard.” *Id.*

HHS’s determination that the demonstration projects at issue here are likely to promote the Medicaid program’s objectives easily satisfies any minimal requirements imposed by the APA in this context.

B. HHS Reasonably Determined That Work and Work-Related Requirements Are Likely to Help Adults Transition to Financial Independence and Commercial Coverage, Freeing Up Resources for Others in Need.

The work and work-related requirements tested in the Kentucky and Arkansas demonstration projects are similar to the requirements in the TANF cash assistance and SNAP food assistance programs. The 1996 welfare reform legislation, which established those statutory requirements, also amended the Medicaid statute to allow States to terminate Medicaid benefits for certain adults whose TANF benefits are terminated for failure to comply with TANF’s work requirements. 42 U.S.C. § 1396u-1(b)(3)(A). Thus, such requirements have been an aspect of Medicaid for more than two decades.

The central objective of the 1996 welfare reform legislation was to break the “cycle of welfare” through “the dignity, the power, and the ethic of work.” President Clinton’s Signing Statement at 1485. The Kentucky and Arkansas projects build on existing law by testing similar requirements for other categories of adults who can reasonably be expected to fulfill them. The adults who are subject to the requirements of the demonstrations are overwhelmingly members of the ACA’s adult expansion population, which means they are not receiving Medicaid coverage on the basis of disability, advanced age, or pregnancy.⁷ Both demonstrations provide additional exemptions for (among others) persons who are medically frail, experiencing an acute medical condition, or full-time students. And like the requirements in TANF and SNAP, the requirements of the demonstration projects can be fulfilled not only by working, but also by activities that enhance a person’s employability such as education, community service, and job-skills training.

In approving these demonstration projects, HHS exercised its Section 1115 authority to approve “any experimental, pilot, or demonstration project” proposed by a State that, “in the judgment of the Secretary, is likely to assist in promoting the objectives” of the Medicaid program. HHS explained that work and work-related

⁷ The Kentucky requirement also applies to some adults who receive traditional Medicaid coverage as parents of dependent children, but only if the parent is not the primary caregiver for a dependent child. To our knowledge, all of the Kentucky plaintiffs are members of the ACA’s adult expansion population.

requirements may enable adults to transition out of Medicaid to financial independence and commercial coverage, including the subsidized coverage that is available on the ACA's Exchanges. JA ___-___ (KY AR 6724-25); JA ___ (Ark. AR 2). Such transitions conserve finite state resources and free up funds that can be used to serve other needy persons, including by expanding or maintaining coverage for optional populations and optional services. JA ___-___ (KY AR 6719-20); JA ___ (Ark. AR 2057).

There is no doubt that freeing state resources in this manner furthers the objectives of Medicaid, which appropriates federal funds “[f]or the purpose of enabling each State, as far as practicable under the conditions in such State, to furnish” medical assistance to needy individuals. 42 U.S.C. § 1396-1. The Supreme Court has long recognized that requirements that enable States to stretch limited resources promote the objectives of public welfare programs. In upholding state work requirements in the context of the AFDC program, the Supreme Court emphasized that States may “attempt to promote self-reliance and civic responsibility” in order “to assure that limited state welfare funds be spent on behalf of those genuinely incapacitated and most in need, and to cope with the fiscal hardships enveloping many state and local governments.” *New York State Dep’t. of Soc. Servs. v. Dublino*, 413 U.S. 405, 413 (1973). The Supreme Court reaffirmed that principle in the context of Medicaid, when it upheld drug-rebate and prior-authorization requirements

that were designed to keep borderline populations out of Medicaid. *See Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 663, 666-67 (2003) (plurality) (quoting the same language from *Dublino*); *see also id.* at 689 (O'Connor, J., joined by Rehnquist, C.J. and Kennedy, J.) (agreeing that Medicaid's purposes would be served by requirements intended to keep borderline populations from becoming Medicaid-eligible). This Court upheld a similar state program in *Pharmaceutical Research & Mfrs. of Am. v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004), explaining that if the program "prevents borderline populations in Non-Medicaid programs from being displaced into a state's Medicaid program, more resources will be available for existing Medicaid beneficiaries." *Id.* at 825. At a minimum, the Secretary's determination that Medicaid's objectives are served by measures that stretch state resources and preserve the program's fiscal sustainability is reasonable and entitled to deference. *See id.* at 822 (explaining that "Congress manifested its intent that the Secretary's determinations, based on interpretation of the relevant statutory provisions, should have the force of law," and that "[t]he Secretary's interpretations of the Medicaid Act are therefore entitled to *Chevron* deference").

Indeed, the district court did not dispute that requirements that help adults to transition from Medicaid to financial independence and commercial coverage would further the program's objectives. On the contrary, the court recognized that the Medicaid program's objectives are served by measures that enhance the program's

fiscal sustainability. *See Stewart II*, 366 F. Supp. 3d at 148-49. Nor did the district court dispute that work and work-related requirements are a permissible means to that end, which may be approved as part of a Medicaid demonstration project. *See id.* at 147 (“The Court is not suggesting a waiver application approving work requirements in some form could never be lawful[.]”). As the court acknowledged, such requirements have long been a condition of Medicaid eligibility for certain TANF recipients. *See id.* (noting that the Medicaid statute “permits termination of Medicaid benefits to those individuals who have had Temporary Assistance for Needy Families benefits terminated ‘because of refusing to work’”) (quoting 42 U.S.C. § 1396u-1(b)(3)).

Nonetheless, the district court vacated the approvals because it believed that substantial evidence did not show that the experiments are likely to achieve their objectives, and because it believed that HHS did not weigh the benefits of success against the costs to those who might lose coverage as a result of noncompliance. The court declared that HHS did not “cite evidence or otherwise provide a reasoned basis for the assertion that some number of people will transition to commercial coverage and, if so, how many he might expect.” *Stewart II*, 366 F. Supp. 3d at 142. The court indicated that it did not understand how activities such as “education, job skills training, job search activities, and community service” could lead to employment. *Id.* And the court suggested that the types of jobs that Medicaid recipients would obtain

are unlikely to provide health benefits, and that Medicaid recipients are therefore “unlikely to get coverage on [the] labor market.” *Id.* For these reasons, the court assumed that any projected reduction in Medicaid coverage would be due to noncompliance. *Id.* at 141. Likening the demonstrations at issue here to the demonstration at issue in *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994), the court treated the Kentucky and Arkansas demonstrations as a “simple benefits cuts enacted to save money,” and declared that HHS failed to compare the benefits of savings to the consequences for coverage. *Stewart II*, 366 F. Supp. 3d at 150.

As an initial matter, the district court’s reasoning reflects a fundamental misunderstanding of the nature of a demonstration project. Such projects are time-limited experiments, the results of which are meant to inform future policy-making. Thus, as explained above in Part A, there is no requirement that HHS make a finding with regard to a demonstration project’s outcome or that it substantiate a project’s hypothesis in advance.

In any event, although no such showing was required, HHS in fact addressed both issues raised by the district court. The agency’s conclusions are supported by substantial evidence.

HHS explained that education, job-skills training, job-search activities and community service enhance a person’s prospects for employment and thus financial independence. JA ___ (KY AR 6724). The same types of activities fulfill the “work”

requirements of the TANF and SNAP programs for the same reason. *See* 42 U.S.C. § 607(d) (TANF) (defining “work activities” to include education, job skills training, job search activities, and community service); 7 U.S.C. § 2015(o) and 7 C.F.R. §§ 273.24, 273.7 (SNAP) (defining “working” to include paid work, unpaid work, and qualifying education and training programs).

In expressing doubt that the requirements of the demonstrations can lead to employment, the district court relied on comments urging that the analogous requirements in the TANF and SNAP programs are counterproductive. *Stewart I*, 313 F. Supp. 3d at 274 (Appendix A); *Gresham*, 363 F. Supp. 3d at 185 (Appendix A). For example, the court relied on the comment from the Center for Law and Social Policy, which claimed to draw upon “deep experience with Temporary Assistance for Needy Families (TANF) and the Supplemental Nutrition Assistance Program (SNAP), two programs where many of the policies proposed in this waiver have already been implemented.” JA ___ (KY AR 3309). The Center argued these TANF and SNAP policies have “been shown to be significant barriers to low-income people getting and retaining benefits.” *Id.* Similarly, a comment from public-health groups on which the district court relied argued that “[t]he experience of the [TANF] program demonstrates that imposing a work requirement on Medicaid would lead to the loss of health coverage,” and that “work requirements result in little or no long-term gains in employment.” JA ___-___ (KY AR 3833-34).

Congress evidently does not share the view that the work and work-related requirements in TANF and SNAP are counterproductive. Congress has not repealed those requirements, which remain part of these programs. *See* 42 U.S.C. § 607 (TANF) (“Mandatory work requirements”); 7 U.S.C. § 2015(o)(2) (SNAP) (“Work requirement”). On the contrary, Congress has strengthened the requirements in TANF by requiring the Secretary and States to improve the verification and oversight of recipients’ work participation. *See* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 7102(c), 120 Stat. 4, 136 (2006). And, as explained above, the Medicaid statute incorporates the TANF requirements by reference, allowing States to terminate the Medicaid benefits of certain adults who fail to comply with the TANF work requirements. *See* 42 U.S.C. § 1396u-1(b)(3).

Contrary to the district court’s premise, HHS was not required to rely on comments that are at odds with Congress’s judgment as embodied in its enactments. Moreover, those comments were contradicted by other submissions. As noted in the comment from the Medicaid and CHIP Payment and Access Commission, proponents of work and work-related requirements in Medicaid demonstration projects have pointed to gains in employment among affected populations following the imposition of work requirements as part of welfare reform in 1996, and have argued that the demonstration projects likewise will help transition Medicaid enrollees off the program, conserving resources for others in need. JA __ (KY AR 4761);

JA ___ (Ark. AR 1400). Proponents also cited research indicating that “community engagement and volunteerism” enhance “an individual’s employability.” JA ___ (KY AR 25513) (Kentucky application) (noting that one study found that “volunteering increased the chances of employment by 51% among individuals without a high school diploma, and by 55% among individuals living in rural areas”). It is likewise “well understood that increased education is directly associated with higher wages.” JA ___ (KY AR 25519) (explaining that in Kentucky there is a 33% difference in median annual earnings between individuals with and without high school diplomas, and that “participation in the free General Educational Development (GED) certification exam prep classes available in every county will count as a credit towards the community engagement and employment initiative requirements”).

The district court also expressed skepticism that Medicaid recipients will obtain the types of jobs that offer health benefits. *Stewart II*, 366 F. Supp. 3d at 142. That is one of the hypotheses the demonstrations are meant to test. In any event, HHS’s approval letters made clear that employment-based coverage is not the only (or even the principal) alternative to Medicaid. Persons who transition out of Medicaid can gain access not only to employment-based coverage but also to the heavily subsidized coverage that is available through the ACA’s Exchanges. JA ___ (KY AR 6725); JA ___ (Ark. AR 2) (explaining that the Arkansas project attempts to facilitate transitions

between and among the Arkansas Medicaid program, employer-sponsored insurance, and the Arkansas Marketplace, *i.e.*, the Exchange). The ACA was specifically designed to expand coverage in the individual health-insurance market, which is the commercial market for people who lack access to employer-based coverage. *King v. Burwell*, 135 S. Ct. 2480, 2485 (2015). To make such individual plans affordable, the Act authorized billions of dollars in premium tax credits each year to help people pay for insurance sold on the Exchanges, with the amount of the tax credit based on household income. *See* ACA § 1401 (codified at 26 U.S.C. § 36B). As the Supreme Court noted, approximately 87% of people who bought insurance on a federal Exchange in 2014 did so with tax credits. *King*, 135 S. Ct. at 2493.

For the reasons set out above, HHS had ample basis to find that the Kentucky and Arkansas experiments test measures that are likely to help adults transition to financial independence and commercial coverage. The district court clearly erred in equating these projects with the AFDC demonstration project that was at issue in *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994). By its terms, that California project was a benefits cut: the State simply reduced AFDC spending to 11% below 1992 levels. *See id.* at 1062-63. Although the stated objective of that benefits cut was to give welfare recipients an incentive to find work, the cut applied to children and persons too disabled to work, prompting the Ninth Circuit to describe the purported work-incentive as “absurd.” *Id.* at 1073. Furthermore, the cut applied to 800,000 families

statewide, even though the State planned to study only 10,000 families in four counties. *Id.* at 1061. The Ninth Circuit emphasized that the Secretary herself agreed that “both the statewide scope of the benefits cut as well as the decision to cut benefits to individuals who cannot work appear wholly unjustified by any legitimate experimental goal.” *Id.* at 1072-73. Under those circumstances, the Ninth Circuit declared that “[a] simple benefits cut, which might save money, but has no research or experimental goal, would not satisfy” the requirement of Section 1115. *Id.* at 1069. Rather, “the Secretary must make at least some inquiry into the merits of the experiment—she must determine that the project is likely to yield useful information or demonstrate a novel approach to program administration.” *Id.*⁸

Beno’s reasoning confirms that the approvals at issue here are a permissible exercise of HHS’s Section 1115 authority. There is no dispute that HHS made the inquiry and determination contemplated by the Ninth Circuit. And there is no basis to reject HHS’s conclusion that these projects are likely to yield useful information and demonstrate novel approaches to the administration of Medicaid. In contrast to the purported “work incentive” at issue in *Beno*—which applied to children and persons too disabled to work—the Kentucky and Arkansas projects are tailored to ensure that only adults who can meet the requirements are subject to them. The work

⁸ The Ninth Circuit reiterated that standard in *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011), where the only explanation that Arizona offered for raising copayments was to save money.

and work-related requirements apply only to non-elderly adults who are not eligible for Medicaid on the basis of disability or pregnancy, and there are additional exemptions for (among others) persons who are medically frail. Furthermore, unlike the project in *Beno*—which was simply a statewide benefits cut—everyone who complies with the work and work-related requirements will continue to receive Medicaid benefits.

Because the district court wrongly dismissed—as “legerdemain”—the possibility that able-bodied adults may transition successfully out of Medicaid, *Stewart II*, 366 F. Supp. 3d at 141, the court mistakenly assumed that any projected reduction in Medicaid coverage under the demonstrations would be due to noncompliance with their requirements. For example, the court emphasized that Kentucky’s budget-neutrality worksheet projected a 5% decrease in the total member months covered over the duration of the project, which, the court noted, is mathematically equivalent to eliminating one year of coverage for 95,000 persons over the course of the five-year demonstration. *Id.* That member-months figure does not mean that 95,000 individuals were expected to lose coverage. Nor is there any basis to assume that the figure represents coverage loss due to noncompliance with work and work-related requirements. On the contrary, the figure reflected a number of factors “including beneficiaries transitioning to commercial coverage.” JA __ (KY AR 6731); *see also* JA __ (KY AR 6725) (noting that a significant number of individuals

are “estimated to move between Medicaid eligibility and Exchange coverage”). In addition, the projections in the budget-neutrality worksheet “were made prior to the inclusion of changes made to the demonstration at approval, including additional beneficiary guardrails expected to help beneficiaries maintain enrollment.” JA ___ (KY AR 6731).⁹

The district court was likewise wrong to declare that HHS did not weigh the projects’ potential for success against the risk that some recipients will lose coverage due to noncompliance. HHS explicitly recognized that “some individuals may choose not to comply with the conditions of eligibility imposed by the demonstration, and therefore may lose coverage,” as occurs when individuals fail to comply with existing statutory requirements such as participating in the eligibility redetermination process. JA ___ (KY AR 6729). HHS explained, however, that “the goal of these policies is to incentivize compliance, not reduce coverage,” and that the special terms and conditions include safeguards “intended to minimize coverage loss due to noncompliance.” *Id.*; *see also* JA ___, ___-___ (Ark. AR 5, 6-7). The demonstrations are “designed to make compliance” with their “requirements achievable.” JA ___ (KY AR 6727); *see also* JA ___, ___-___ (Ark. AR 5, 6-7).

⁹ The district court incorrectly stated that HHS’s approval letter did not take these additional protections into account. *See Stewart II*, 366 F. Supp. 3d at 143. The approval letter specifically cited the “changes made to the demonstration at approval.” JA ___ (KY AR 6731).

HHS concluded that “the incentives to meet the requirements, if effective, may result in individuals becoming ineligible because they have attained financial independence—a positive result for the individual” as well as for Medicaid. JA ___ (KY AR 6728). But even if the results of the experiment ultimately prove disappointing, that would not undermine HHS’s judgment that “the features of this demonstration are worth testing.” JA ___ (KY AR 6729). The essence of an experiment is to test a prediction, and possibility that the experiments will not succeed is no basis for shutting them down.

In weighing the potential impact on coverage, it was also appropriate for HHS to take into account the fact that state coverage of the adult expansion population became optional as a result of the Supreme Court’s decision in *NFIB*. JA ___ (KY AR 6731). In other words, Kentucky and Arkansas are not required to provide any coverage to the vast majority of beneficiaries subject to the demonstrations (including, so far as we are aware, all of the plaintiffs). Although the district court emphasized that “the *entire* Medicaid program is optional for states,” *Stewart II*, 366 F. Supp. 3d at 140, the Supreme Court in *NFIB* found that States have no realistic option to withdraw from the traditional Medicaid program. *See* 567 U.S. at 581-82. By contrast, more than a dozen States have not elected to participate in the ACA’s

adult eligibility expansion. *See* Advisory Board, *Where the states stand on Medicaid expansion* (Apr. 1, 2019).¹⁰

Contrary to the district court's understanding, HHS did not suggest that it would approve any demonstration project proposed for the adult expansion population simply because that coverage is optional. Indeed, the court correctly noted that HHS did not approve Arkansas's proposal to reduce income eligibility for the expansion population from 133% to 100% of the federal poverty level. *Gresham*, 363 F. Supp. 3d at 172; *see also* JA ___ (Ark. AR 3) ("CMS is not at this time approving Arkansas's request to reduce income eligibility for Arkansas Works beneficiaries to 100 percent of the federal poverty level (FPL)."). But a number of States are participating in the expansion with the expectation that they may test work and work-related requirements for newly eligible adults through a demonstration project, and it is permissible for HHS to take the optional character of the coverage into account when considering such applications. *See* p.13, *supra*.

Furthermore, HHS emphasized that it is committed to partnering with States "to ensure that the demonstration advances the objectives of Medicaid." JA ___ (KY AR 6729). The difficulties encountered during the rollout of the Arkansas project are illustrative. The district court noted that upon that rollout, approximately 16,900 Medicaid recipients temporarily lost coverage (which has since been made available

¹⁰ <https://www.advisory.com/daily-briefing/resources/primers/medicaidmap>

again to all who initially lost it). *Gresham*, 363 F. Supp. 3d at 174, 183-84. But those coverage losses were apparently due in large part to the fact that participants could report compliance through an online portal only—a problem that Arkansas addressed by expanding the reporting options to allow reporting by phone and in person. *See* JA __ ¶ 135 (complaint) (alleging that the only-online reporting was “difficult, and for some impossible, due to lack of internet access, trouble using computers, and problems working with the online portal”); *Gresham*, 363 F. Supp. 3d at 172 (emphasizing that only 12.3% of non-exempted persons reported any kind of qualifying activity); *id.* at 174 (recognizing that Arkansas changed its policy to allow reporting by phone or in person as well as online). The experience with the rollout of the Arkansas project underscores the value of testing experiments at the local level—where refinements and corrections can be made quickly—before policies are established nationwide.

C. HHS Reasonably Determined that Work and Work-Related Requirements May Improve the Health of Medicaid Recipients, Which Reduces Program Expenses.

HHS found that even adults who do not transition out of Medicaid are likely to benefit from participating in work and work-related activities, which are correlated with improved beneficiary health. JA __, __ (KY AR 6724; Ark. AR 4). HHS explained that improved beneficiary health has intrinsic benefits, and that requirements designed to improve health and wellness may reduce the volume of

services consumed, as healthier, more engaged beneficiaries tend to consume fewer medical services and are generally less costly to cover. JA __ (KY AR 6719).

The district court did not dispute that these hypotheses may prove valid. The court nonetheless rejected this rationale for approving the Kentucky and Arkansas experiments, because the court did not believe that improving beneficiary health is a legitimate objective of the Medicaid program. *Stewart II*, 366 F. Supp. 3d at 143-45. As HHS explained, however, it is well established that a Medicaid demonstration may aim to improve beneficiary health. JA __ (KY AR 6724). For example, in 2012, HHS specifically encouraged States to develop demonstrations “aimed at promoting healthy behaviors” as well as “accountability tied to improvement in health outcomes.” *Id.* (quoting 2012 HHS Guidance at 15). And in 2016, HHS approved an Arizona demonstration that required Medicaid recipients to pay premiums, which recipients could avoid by adopting healthy behaviors.¹¹ HHS’s approval letter explained that the Arizona demonstration project “will test the use of incentives to build health literacy, achieve identified health targets and encourage appropriate care.”¹²

The ACA itself authorized grants for States that give Medicaid recipients incentives for various “healthy behaviors,” including “[c]easing use of tobacco products,” “[c]ontrolling or reducing their weight,” “[l]owering their cholesterol,” or

¹¹ <https://go.usa.gov/xmNDx>

¹² *Id.*

“[a]voiding the onset of diabetes, or, in the case of a diabetic, improving the management of that condition.” ACA § 4108 (codified at 42 U.S.C. § 1396a note). And in the very comment on which the district court relied, an array of public-health organizations recognized that improving “health outcomes” is a proper objective of a Medicaid demonstration. JA __, __ (KY AR 3833, Ark. AR ____) (comment jointly submitted by the American Congress of Obstetricians & Gynecologists and other public-health organizations). See *Stewart I*, 313 F. Supp. 3d at 274 (Appendix A) (relying on this comment); *Gresham*, 363 F. Supp. 3d at 185 (Appendix A) (same).

There should thus be no doubt that improving beneficiary health is legitimate objective of a Medicaid demonstration. Although the district court deemed it a “sleight of hand” to treat improved beneficiary health as among the Medicaid statute’s objectives, *Stewart II*, 366 F. Supp. 3d at 144, the court did not provide any sound basis for rejecting the consistent understanding of HHS and the public-health community—particularly in light of the *Chevron* deference that is owed to HHS’s interpretation of the Medicaid statute. See *Pharmaceutical Research & Mfrs. of Am.*, 362 F.3d at 822.

The district court was likewise wrong to declare that HHS failed to weigh the expected health benefits of the demonstrations against potential harms to health. See *Stewart II*, 366 F. Supp. 3d at 145. The court believed that “loss of coverage appears, from the record in this case, to be how the Commonwealth would save money.” *Id.*

at 150. But as HHS emphasized in its approval letters, measures that encourage “healthy behaviors and preventive care” are not designed to eliminate coverage but “to lead to higher quality care at a sustainable cost.” JA ___ (KY AR 6726) (explaining that “[p]romoting improved health and wellness ultimately helps to keep health care costs at sustainable levels”); *see also* JA ___ (Ark. AR 3) (explaining that Arkansas is testing requirements designed to lead to “improved health outcomes and greater independence”). HHS explained that to the extent that policies including work and work-related requirements “help individuals achieve improved health and financial independence,” they may “make these individuals less costly” to care for, “further advancing the objectives of the Medicaid program by helping” the States to stretch “limited Medicaid resources, ensure the long-term fiscal sustainability of the program, and ensure that the health care safety net is available to” those “who need it most.” JA ___ (KY AR 6726). Moreover, HHS noted that under the Kentucky project, beneficiaries that engage in certain healthy behaviors, including participating in work or work-related activities for more than the required 80 hours per month, will gain access to additional benefits, including vision benefits, dental benefits, over-the-counter medications, and gym memberships. JA ___ (KY AR 6721).

Contrary to the district court’s premise, Section 1115 does not require HHS to “quantify” the anticipated “uptick” in healthy behaviors and savings, nor is the agency required to quantify the risks. *Stewart II*, 366 F. Supp. 3d at 143. Section 1115

authorizes experiments, the results of which cannot be known in advance. HHS clearly took into account the risks and benefits of the Kentucky and Arkansas demonstrations, and there is no basis to overturn the agency's judgment that their features are "worth testing." JA __ (KY AR 6729).

II. The District Court Compounded Its Errors by Issuing Overly Broad Relief.

The district court exacerbated the impact of its errors by vacating the approvals of the Kentucky and Arkansas demonstration projects wholesale. The Supreme Court recently reaffirmed that a court's "constitutionally prescribed role is to vindicate the individual rights of the people appearing before it," and "[a] plaintiff's remedy" accordingly "must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1933, 1934 (2018); *see also Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) ("[S]tanding is not dispensed in gross," and "a plaintiff must demonstrate standing . . . for each form of relief that is sought.") (citations and internal quotation marks omitted). Likewise, the Supreme Court has held that principles of equity prohibit remedies that are "more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979).

To the extent that any of the plaintiffs will experience injury, it would be as a result of the application of particular project requirements to them. The application of project requirements to particular plaintiffs is thus the only proper subject of

judicial review, *see Lujan v. National Wildlife Fed'n*, 497 U.S. 871, 891 (1990), and enjoining that application marks the outer limit of any relief, *see Whitford*, 138 S. Ct. at 1930, 1933-34. Because prohibiting application of those requirements to the plaintiffs would fully redress their own injuries, both Article III and equitable principles precluded the district court from imposing a broader remedy.

The district court nevertheless vacated both projects in their entirety, as to all affected Medicaid recipients in Kentucky and Arkansas. That was error. The court did not identify a proper basis for extending relief to nonparties. The court recognized that standing “is not dispensed in gross,” but deemed that principle inapplicable because plaintiffs asserted a “global challenge” to the project’s approval. *Stewart II*, 366 F. Supp. 3d at 136-37. But as explained above, it is the scope of the plaintiffs’ redressable injuries—not the breadth of their legal theories—that determines the constitutional and equitable limit of relief.

Moreover, the district court recognized that equitable relief is discretionary under the APA, *see Stewart II*, 366 F. Supp. 3d at 155, and here several considerations weigh decisively against vacating the projects wholesale even if the court had authority to do so. By disrupting the statewide implementation of these demonstration projects, the district court unnecessarily deprived the federal and state governments of valuable experimental learning. The court’s remedy also unnecessarily put at risk the optional coverage of hundreds of thousands of persons who are not before the court,

even though the court recognized that States have discretion to terminate their ACA adult-eligibility expansions.

The district court did not identify any valid countervailing justification in these circumstances for granting global relief that extends to nonparties. It did not suggest, for example, that categorical relief is warranted because of a prospect of “a flood of duplicative litigation.” *National Mining Ass’n v. U.S. Army Corps of Engineers*, 145 F.3d 1399, 1409 (D.C. Cir. 1998). And for good reason: other members of the ACA’s expansion population who did not join these suits may not wish to put their own coverage at risk. Nor did the district court suggest that the APA compelled wholesale vacatur of the demonstrations here notwithstanding constitutional and equitable limitations on relief. The APA is not properly construed to displace the general rule that equitable remedies should go no further than necessary to redress plaintiffs’ own injuries. *See* 5 U.S.C. § 703; *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982) (“[W]e do not lightly assume that Congress has intended to depart from established principles.”). To the extent that *National Mining Association* suggests otherwise, we respectfully disagree and preserve the issue for further review.

Even assuming arguendo the district court had authority and a valid basis for granting relief beyond the parties to these cases, it still erred by invalidating the projects in toto rather than confining relief to the particular components that it found had caused the plaintiffs’ injury in fact and as to which they had raised a valid legal

objection. The Supreme Court has made clear that judicial relief is “limited to the inadequacy that produced [the plaintiffs’] injury in fact.” *Whitford*, 138 S. Ct. at 1930 (quoting *Lewis v. Casey*, 518 U.S. 343, 357 (1996)) (brackets omitted); *see Lewis*, 518 U.S. at 357-358 (plaintiff lacked standing to challenge, and court lacked power to enjoin, practices that “ha[d] not been found to have harmed any plaintiff in this lawsuit”). And the Supreme Court has emphasized that courts “have no business answering” questions about the validity of provisions that concern only “the rights and obligations of parties not before the Court.” *Printz v. United States*, 521 U.S. 898, 935 (1997); *see also Murphy v. NCAA*, 138 S. Ct. 1461, 1485-87 (2018) (Thomas, J., concurring). Here the only “inadequac[ies]” (*Whitford*, 138 S. Ct. at 1930) that the district court had authority to redress were at most the particular project requirements that the court found had injured particular plaintiffs in these cases. Even if the court could validly vacate those particular requirements as to all persons, it had neither authority nor any basis to invalidate other requirements that do not injure any plaintiff before it.

Although the district court acknowledged that “a plaintiff’s standing to challenge one statutory provision does not necessarily establish her standing to challenge another,” *Stewart II*, 366 F. Supp. 3d at 137 (citing *Davis v. FEC*, 554 U.S. 724, 734 (2008)), the court granted relief encompassing all project requirements, without regard to whether each one had been shown to injure any plaintiff such that

invalidating that requirement was necessary to redress the plaintiff's harm. Indeed, the court invalidated aspects of the projects—including limits on retroactive eligibility, limits on non-emergency medical transportation, and premiums—that are similar to components of demonstration projects that HHS has approved in the past. *Compare Stewart II*, 366 F. Supp. 3d at 132-33; *Gresham*, 363 F. Supp. 3d at 172, with JA ___, ___-___ [ECF 51-8 at 2, 7-8] (2015 approval of Indiana demonstration project that limited retroactive eligibility, limited coverage of non-emergency medical transportation, and imposed premiums).

To be sure, *the Secretary* considers a demonstration project as a whole in determining which (if any) parts to approve and in turn which statutory requirements to waive under 42 U.S.C. 1315(a). But that has no bearing on the constitutional and equitable limits on the authority of *a court* to grant relief beyond what is necessary to redress the plaintiffs' injuries, and provided no basis for the district court here to vacate components not shown to injure any plaintiff. If a particular project component is properly held invalid, a court may at most prohibit application of those components. Congress vested the Secretary with discretion to determine whether demonstrations should proceed, and accordingly the determination whether to proceed with the remaining components lies with the Secretary, in consultation with the affected State. As the government explained below, *see* Dkt. 122 at 22-23, if any project components that cause plaintiffs injury are ruled invalid, the appropriate

course would be to so declare and remand so that the Secretary may determine how to proceed.

CONCLUSION

The judgments of the district court should be reversed.

Respectfully submitted,

ROBERT P. CHARROW

General Counsel

JOSEPH H. HUNT

Assistant Attorney General

KELLY M. CLEARY

Deputy General Counsel

MARK B. STERN

/s/ Alisa B. Klein

ALISA B. KLEIN

(202) 514-1597

Attorneys, Appellate Staff

Civil Division, Room 7235

U.S. Department of Justice

950 Pennsylvania Ave., NW

Washington, DC 20530

alisa.klein@usdoj.gov

BRENNAN E. JENNY

Deputy General Counsel

U.S. Department of Health & Human Services

MAY 2019

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief uses a proportionately spaced, 14-point font and contains 10,872 words according to the count of this office's word processing system, and thus complies with Rule 32(a)(7)(B)(i) of the Federal Rules of Appellate Procedure.

/s/ Alisa B.Klein
Alisa B. Klein

CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2019, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Alisa B. Klein
Alisa B. Klein

ADDENDUM

42 U.S.C. § 1315

(a) Waiver of State plan requirements; costs regarded as State plan expenditures; availability of appropriations

In the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of subchapter I, X, XIV, XVI, or XIX, or part A or D of subchapter IV, in a State or States--

(1) the Secretary may waive compliance with any of the requirements of section 302, 602, 654, 1202, 1352, 1382, or 1396a of this title, as the case may be, to the extent and for the period he finds necessary to enable such State or States to carry out such project, and

(2)(A) costs of such project which would not otherwise be included as expenditures under section 303, 655, 1203, 1353, 1383, or 1396b of this title, as the case may be, and which are not included as part of the costs of projects under section 1310 of this title, shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under the State plan or plans approved under such subchapter, or for administration of such State plan or plans, as may be appropriate, and

(B) costs of such project which would not otherwise be a permissible use of funds under part A of subchapter IV and which are not included as part of the costs of projects under section 1310 of this title, shall to the extent and for the period prescribed by the Secretary, be regarded as a permissible use of funds under such part.

In addition, not to exceed \$4,000,000 of the aggregate amount appropriated for payments to States under such subchapters for any fiscal year beginning after June 30, 1967, shall be available, under such terms and conditions as the Secretary may establish, for payments to States to cover so much of the cost of such projects as is not covered by payments under such subchapters and is not included as part of the cost of projects for purposes of section 1310 of this title.

(b) Child support enforcement programs

(1) In the case of any experimental, pilot, or demonstration project undertaken under subsection (a) to assist in promoting the objectives of part D of subchapter IV, the project--

(A) must be designed to improve the financial well-being of children or otherwise improve the operation of the child support program;

(B) may not permit modifications in the child support program which would have the effect of disadvantaging children in need of support; and

(C) must not result in increased cost to the Federal Government under part A of such subchapter.

(2) An Indian tribe or tribal organization operating a program under section 655(f) of this title shall be considered a State for purposes of authority to conduct an experimental, pilot, or demonstration project under subsection (a) to assist in promoting the objectives of part D of subchapter IV and receiving payments under the second sentence of that subsection. The Secretary may waive compliance with any requirements of section 655(f) of this title or regulations promulgated under that section to the extent and for the period the Secretary finds necessary for an Indian tribe or tribal organization to carry out such project. Costs of the project which would not otherwise be included as expenditures of a program operating under section 655(f) of this title and which are not included as part of the costs of projects under section 1310 of this title, shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under a tribal plan or plans approved under such section, or for the administration of such tribal plan or plans, as may be appropriate. An Indian tribe or tribal organization applying for or receiving start-up program development funding pursuant to section 309.16 of title 45, Code of Federal Regulations, shall not be considered to be an Indian tribe or tribal organization operating a program under section 655(f) of this title for purposes of this paragraph.

(c) Demonstration projects to test alternative definitions of unemployment

(1)(A) The Secretary shall enter into agreements with up to 8 States submitting applications under this subsection for the purpose of conducting demonstration projects in such States to test and evaluate the use, with respect to individuals who received aid under part A of subchapter IV in the preceding month (on the basis of the unemployment of the parent who is the principal earner), of a number greater than 100 for the number of hours per month that such individuals may work and still be considered to be unemployed for purposes of section 607 of this title. If any State submits an application under this subsection for the purpose of conducting a demonstration project to test

and evaluate the total elimination of the 100-hour rule, the Secretary shall approve at least one such application.

(B) If any State with an agreement under this subsection so requests, the demonstration project conducted pursuant to such agreement may test and evaluate the complete elimination of the 100-hour rule and of any other durational standard that might be applied in defining unemployment for purposes of determining eligibility under section 607 of this title.

(2) Notwithstanding section 602(a)(1) of this title, a demonstration project conducted under this subsection may be conducted in one or more political subdivisions of the State.

(3) An agreement under this subsection shall be entered into between the Secretary and the State agency designated under section 602(a)(3) of this title. Such agreement shall provide for the payment of aid under the applicable State plan under part A of subchapter IV as though section 607 of this title had been modified to reflect the definition of unemployment used in the demonstration project but shall also provide that such project shall otherwise be carried out in accordance with all of the requirements and conditions of section 607 of this title (and, except as provided in paragraph (2), any related requirements and conditions under part A of subchapter IV).

(4) A demonstration project under this subsection may be commenced any time after September 30, 1990, and shall be conducted for such period of time as the agreement with the Secretary may provide; except that, in no event may a demonstration project under this section be conducted after September 30, 1995.

(5)(A) Any State with an agreement under this subsection shall evaluate the comparative cost and employment effects of the use of the definition of unemployment in its demonstration project under this section by use of experimental and control groups comprised of a random sample of individuals receiving aid under section 607 of this title and shall furnish the Secretary with such information as the Secretary determines to be necessary to evaluate the results of the project conducted by the State.

(B) The Secretary shall report the results of the demonstration projects conducted under this subsection to the Congress not later than 6 months after all such projects are completed.

(d) Regulations relating to applications for or renewals of demonstration projects

(1) An application or renewal of any experimental, pilot, or demonstration project undertaken under subsection (a) to promote the objectives of subchapter XIX or XXI in a State that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing with respect to a State program under subchapter XIX or XXI (in this subsection referred to as a “demonstration project”) shall be considered by the Secretary in accordance with the regulations required to be promulgated under paragraph (2).

(2) Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations relating to applications for, and renewals of, a demonstration project that provide for--

(A) a process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input;

(B) requirements relating to--

(i) the goals of the program to be implemented or renewed under the demonstration project;

(ii) the expected State and Federal costs and coverage projections of the demonstration project; and

(iii) the specific plans of the State to ensure that the demonstration project will be in compliance with subchapter XIX or XXI;

(C) a process for providing public notice and comment after the application is received by the Secretary, that is sufficient to ensure a meaningful level of public input;

(D) a process for the submission to the Secretary of periodic reports by the State concerning the implementation of the demonstration project; and

(E) a process for the periodic evaluation by the Secretary of the demonstration project.

(3) The Secretary shall annually report to Congress concerning actions taken by the Secretary with respect to applications for demonstration projects under this section.

(e) Extensions of State-wide comprehensive demonstration projects for which waivers granted

(1) The provisions of this subsection shall apply to the extension of any State-wide comprehensive demonstration project (in this subsection referred to as “waiver project”) for which a waiver of compliance with requirements of subchapter XIX is granted under subsection (a).

(2) During the 6-month period ending 1 year before the date the waiver under subsection (a) with respect to a waiver project would otherwise expire, the chief executive officer of the State which is operating the project may submit to the Secretary a written request for an extension, of up to 3 years (5 years, in the case of a waiver described in section 1396n(h)(2) of this title), of the project.

(3) If the Secretary fails to respond to the request within 6 months after the date it is submitted, the request is deemed to have been granted.

(4) If such a request is granted, the deadline for submittal of a final report under the waiver project is deemed to have been extended until the date that is 1 year after the date the waiver project would otherwise have expired.

(5) The Secretary shall release an evaluation of each such project not later than 1 year after the date of receipt of the final report.

(6) Subject to paragraphs (4) and (7), the extension of a waiver project under this subsection shall be on the same terms and conditions (including applicable terms and conditions relating to quality and access of services, budget neutrality, data and reporting requirements, and special population protections) that applied to the project before its extension under this subsection.

(7) If an original condition of approval of a waiver project was that Federal expenditures under the project not exceed the Federal expenditures that would otherwise have been made, the Secretary shall take such steps as may be necessary to ensure that, in the extension of the project under this subsection, such condition continues to be met. In applying the previous sentence, the

Secretary shall take into account the Secretary's best estimate of rates of change in expenditures at the time of the extension.

(f) Application for extension of waiver project; submission; approval

An application by the chief executive officer of a State for an extension of a waiver project the State is operating under an extension under subsection (e) (in this subsection referred to as the “waiver project”) shall be submitted and approved or disapproved in accordance with the following:

(1) The application for an extension of the waiver project shall be submitted to the Secretary at least 120 days prior to the expiration of the current period of the waiver project.

(2) Not later than 45 days after the date such application is received by the Secretary, the Secretary shall notify the State if the Secretary intends to review the terms and conditions of the waiver project. A failure to provide such notification shall be deemed to be an approval of the application.

(3) Not later than 45 days after the date a notification is made in accordance with paragraph (2), the Secretary shall inform the State of proposed changes in the terms and conditions of the waiver project. A failure to provide such information shall be deemed to be an approval of the application.

(4) During the 30-day period that begins on the date information described in paragraph (3) is provided to a State, the Secretary shall negotiate revised terms and conditions of the waiver project with the State.

(5)(A) Not later than 120 days after the date an application for an extension of the waiver project is submitted to the Secretary (or such later date agreed to by the chief executive officer of the State), the Secretary shall--

(i) approve the application subject to such modifications in the terms and conditions--

(I) as have been agreed to by the Secretary and the State; or

(II) in the absence of such agreement, as are determined by the Secretary to be reasonable, consistent with the overall objectives of the waiver project, and not in violation of applicable law; or

(ii) disapprove the application.

(B) A failure by the Secretary to approve or disapprove an application submitted under this subsection in accordance with the requirements of subparagraph (A) shall be deemed to be an approval of the application subject to such modifications in the terms and conditions as have been agreed to (if any) by the Secretary and the State.

(6) An approval of an application for an extension of a waiver project under this subsection shall be for a period not to exceed 3 years (5 years, in the case of a waiver described in section 1396n(h)(2) of this title).

(7) An extension of a waiver project under this subsection shall be subject to the final reporting and evaluation requirements of paragraphs (4) and (5) of subsection (e) (taking into account the extension under this subsection with respect to any timing requirements imposed under those paragraphs).