**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| **RONNIE MAURICE STEWART, et al.,**<br><br>Plaintiffs,<br><br>v.<br><br>**ALEX M. AZAR II, et al.**<br><br>Defendants. | Civil Action No. 1:18-cv-152 (JEB) |

**MEMORANDUM IN SUPPORT OF FEDERAL DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**

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## INTRODUCTION

There are essentially two Medicaid programs: traditional Medicaid for families with dependent children and those who are aged, blind, or disabled, and expanded Medicaid for childless, non-disabled adults. The purposes of the two programs are different. This case is primarily about the expanded Medicaid population of childless, non-disabled adults.

Kentucky has developed, and the Secretary of Health and Human Services has approved, a demonstration project that requires certain individuals to meet a community-engagement requirement to receive Medicaid, based on evidence that such engagement improves health outcomes. They can satisfy the requirement by taking general education courses, obtaining job skills training, searching for a job, working, volunteering in the community, caring for a non-dependent relative, or participating in substance abuse treatment. Compliance is reported through a simple attestation. In approving this innovative and experimental project, the Secretary acted under express statutory authorization to waive Medicaid requirements for demonstration projects that, in the Secretary's judgment, are likely to assist in promoting Medicaid's objectives. Plaintiffs nevertheless argue that the Secretary acted beyond his statutory authority, and arbitrarily and capriciously.

Plaintiffs build their case on a foundation of caricatures. They mischaracterize many features of Kentucky's program; they omit critical language from their quotations of the Medicaid statute to misstate its purposes; and they advance an unjustifiably narrow view of the Secretary's broad waiver authority. After the caricatures are swept away, plaintiffs' case is revealed for what it is: a policy disagreement with an experimental project designed to test innovative methods to promote health by encouraging members of the Medicaid expansion population to engage in healthy behaviors, lifting them out of poverty, empowering them to access preventive services, and combatting the substance-abuse crisis that is devastating Kentucky.

Take plaintiffs' mischaracterizations of Kentucky's program, called KY HEALTH. Plaintiffs

say KY HEALTH "imposes a work requirement," Pls.' Mot. Summ. J. 1, ECF No. 33 ("Pls.' Mem."), and they repeat that claim dozens of times. It is false. Beneficiaries *may* work to maintain eligibility for Medicaid, but they may *also* count hours spent taking general education courses, obtaining job skills training, searching for a job, volunteering in the community, or caring for a non-dependent relative or other person with a disabling medical condition. Beneficiaries may also participate in substance abuse treatment, a particularly critical program feature given the catastrophic effects of the opioid crisis in Kentucky. By invoking the "work requirement" fiction, plaintiffs avoid confronting the actual project the Secretary approved.

The caricatures do not end there. Nowhere in their brief do plaintiffs acknowledge that the community engagement program applies only to adults who are not disabled and are *capable* of doing the activities described above. Many Medicaid-eligible individuals are categorically exempt: medically frail individuals, those diagnosed with an acute medical condition, full-time students, pregnant women, former foster care youth, primary caregivers, and individuals under 19 or over 64 years old do not have to meet the community-engagement requirement. Again, the requirement applies only to Medicaid-eligible individuals who are readily capable of community engagement.

Plaintiffs also misstate the purposes of the Medicaid program by omitting key portions of the statutory text, which were enacted before the expansion. Although they correctly point out that Medicaid's appropriations provision makes funds available to "furnish (1) medical assistance," plaintiffs excise qualifying language ("as far as practicable under the conditions in such State") that limits the furnishing of medical assistance to only what is economically and operationally practicable. 42 U.S.C. § 1396-1. In approving KY HEALTH, the Secretary appropriately considered Kentucky's unique conditions, including the Commonwealth's prediction that the costs of caring for the Medicaid expansion population could jeopardize services for the traditional Medicaid population.

Further, although the stated purpose in § 1396-1 is to furnish medical assistance on behalf of

"families with dependent children and of aged, blind, or disabled individuals" (i.e., the traditional Medicaid population), the focus of KY HEALTH is instead primarily on the *expansion* population—able-bodied adults without dependent children. Rather than explain why statutory text that refers only to the traditional Medicaid population should be extended to the expansion population, plaintiffs rewrite the statute by replacing "families with dependent children" and "aged, blind, or disabled individuals" with "[individuals]." *See, e.g.*, Pls.' Mem. 16.

Plaintiffs' view of the Secretary's demonstration authority is also unsound. They claim the waiver authority cannot be used to "transform" the Medicaid program, but that argument fundamentally misreads Section 1115. Congress has, over the years, dramatically altered Medicaid based on the results of demonstration projects that are far more transformative than the one at issue here. In 1997, relying on the results of numerous demonstration projects, Congress authorized States to deliver health care through managed care organizations. *See* Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 251 (codified as amended at 42 U.S.C. §§ 1396u-2 to 1396u-3). By definition, demonstration projects are experimental. Accordingly, the Secretary may act on the basis of a "lower threshold" of support than might otherwise be required. *Aguayo v. Richardson*, 473 F.2d 1090, 1103 (2d Cir. 1973). Since even "the experimental project that 'fails' may well assist in promoting the objectives precisely by demonstrating what will not work," *Cal. Welfare Rights Org. v. Richardson*, 348 F. Supp. 491, 497 (N.D. Cal. 1972) ("*CWRO*"), Congress vested the Secretary with wide discretion to approve demonstration projects and grant waivers.

Plaintiffs nevertheless ask the Court to substitute its judgment for the Secretary's on the wisdom of numerous features of KY HEALTH—like the potential efficacy of community-engagement requirements (Count Two), premium requirements (Count Three), cost-sharing for non-emergency use of emergency rooms (Count Four), coverage lockouts (Count Five), limits on retroactive coverage (Count Six), and limits on non-emergency medical transportation (Count

Seven)—plus the wisdom of KY HEALTH as a whole (Count Eight). They also challenge a letter from the Centers for Medicare & Medicaid Services ("CMS") to State Medicaid Directors announcing a new HHS policy generally favoring community engagement requirements (Count One), and allege a violation of the Take Care Clause of the U.S. Constitution (Count Nine).

Plaintiffs cannot show that they face a certainly impending injury from any of the features of KY HEALTH that they criticize. They therefore lack standing to challenge either the project as a whole or any of its individual components. In any event, the Secretary exercised his lawful authority to conclude that KY HEALTH, taken as a whole, is likely to assist in promoting the objectives of the Medicaid Act. The statute requires nothing more, and it commits that decision solely to the Secretary's discretion. Even if the Secretary's decision could be reviewed, he properly considered the relevant factors to find that the project could test useful propositions in furtherance of the statute. So defendants are entitled to judgment in their favor on Counts Two through Eight.

Count One fails too. The State Medicaid Director ("SMD") letter is a nonbinding guidance document that is not a final agency action. It is not subject to notice-and-comment requirements and, in any case, provided a reasoned explanation for the policy shift. Finally, plaintiffs' claim under the Take Care Clause in Count Nine, on which they have declined to move for judgment, should be dismissed because that Clause is not judicially enforceable.

At their core, plaintiffs' objections to KY HEALTH are rooted in policy preferences, not law. The question of community engagement for Medicaid beneficiaries is hotly disputed among policymakers. Indeed, a number of States that have declined so far to expand Medicaid are now, for the first time, considering doing so, provided that their concerns regarding community engagement are addressed. *E.g., Virginia House Passes Medicaid Expansion, Sends to Senate*, Washington Post (Apr. 17, 2018), Ex. A. In the end, the questions plaintiffs raise about community engagement "are not judicial. They are issues to be resolved in Congress and at the polls." *CWRO*, 348 F. Supp. at 497.

# BACKGROUND

## I. STATUTORY FRAMEWORK GOVERNING STATE MEDICAID PLANS

Congress created the Medicaid program in 1965 by adding Title XIX to the Social Security Act. The program authorizes federal funding to States to assist pregnant women, children, needy families, the blind, the elderly, and the disabled in obtaining medical care. 42 U.S.C. § 1396a(a)(10). To participate in the Medicaid program, a State must submit a plan for medical assistance for approval by the Secretary. § 1396a(b). A State plan defines the categories of individuals eligible for benefits and the specific kinds of medical services that are covered. §§ 1396a(10), (17). The plan must provide coverage for the "categorically needy" and, at the State's option, may also cover the "medically needy."[1] For each State with an approved plan, the Secretary provides matching federal funds for certain State expenditures, as set forth in § 1396b.

In 2010, Congress enacted the Affordable Care Act ("ACA").[2] The ACA amended the Medicaid Act to add an additional mandatory group, often called the "expansion population." §§ 1396a(a)(10)(A)(i)(VIII), (e)(14). The Secretary's approval of a State plan that covers individuals falling within the statute's mandatory groups, including the expansion population under the ACA, or within other population groups that the State has elected to cover under the Medicaid program, makes those individuals eligible for Medicaid.

The ACA "dramatically increases state obligations under Medicaid." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 575 (2012) ("*NFIB*"). While traditional Medicaid "requires States to cover

[1] "The categorically needy were persons whom Congress considered especially deserving of public assistance because of family circumstances, age, or disability. States, if they wished, were permitted to offer assistance also to the 'medically needy'—persons lacking the ability to pay for medical expenses, but with incomes too large to qualify for categorical assistance." *Schweiker v. Gray Panthers*, 453 U.S. 34, 37 (1981) (footnote omitted).

[2] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

only certain discrete categories of needy individuals—pregnant women, children, needy families, the blind, the elderly, and the disabled," the expansion requires participating States "to cover *all* individuals under the age of 65 with incomes below 133 percent of the federal poverty line." *Id.* at 575–76 (plurality). Before the ACA, many States covered adults with children only if their income was considerably lower, and did not cover childless adults at all. *See id.* at 541–42. Under the ACA, millions of childless adults—who are not blind, elderly, or disabled—are now eligible for Medicaid.

Under *NFIB*, a State can choose whether to include the ACA's "expansion population" in its State plan. *Id.* at 575–87 (plurality). A State that elects not to do so would not receive the funding that the ACA provided for that expansion population, but would continue to receive funding for its traditional Medicaid population. *See id.* Kentucky has elected to cover the expansion population.

## II. THE SECRETARY'S SECTION 1115 AUTHORITY

In 1962—before the Medicaid Act's enactment—Congress enacted Section 1115 of the Social Security Act to ensure that federal requirements did 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 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. To that end, Congress gave the Secretary the authority to approve "any experimental, pilot, or demonstration project" that, "in the judgment of the Secretary, is likely to assist in promoting the objectives" of the statute. 42 U.S.C. § 1315(a). For such projects, the Secretary may waive "compliance with any of the requirements of section … 1396a" in the Medicaid Act, and may approve waivers "to the extent and for the period he finds necessary to enable such State or States to carry out [the demonstration] project," § 1315(a)(1). Separately, the Secretary may treat a State's expenditures for an approved demonstration project that otherwise would not qualify for federal matching funds, § 1396b, as expenditures under the State plan that are eligible for federal financial assistance to the "extent and for the period prescribed by the Secretary." § 1315(a)(2)(A).

The ACA added a new provision that calls for two periods of public comment on a State's application for approval of a Section 1115 project. The first is held at the State level before submission of the waiver application, § 1315(d)(2)(A), and the second at the federal level, § 1315(d)(2)(C). The comment periods must be "sufficient to ensure a meaningful level of public input," §§ 1315(d)(2)(A) & (C), but the statute imposes no additional requirement on the States or the Secretary to address those comments, as might otherwise be required under a general rulemaking. *Compare* §§ 1315(d)(2)(A) & (C), *and* 42 C.F.R. § 431.416, *with* 5 U.S.C. § 553(c) (providing that "agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," and "[a]fter consideration of the relevant matter presented," provide "a concise general statement of the[] basis and purpose" of the rules it adopts).

## III. CMS GUIDANCE LETTER TO STATE MEDICAID DIRECTORS

On January 11, 2018, CMS issued the SMD letter as guidance for States interested in pursuing Section 1115 demonstration projects. AR 90–99. The letter "announc[ed] a new policy designed to assist states in their efforts to improve Medicaid enrollee health and well-being through incentivizing work and community engagement among non-elderly, non-pregnant adult Medicaid beneficiaries who are eligible for Medicaid on a basis other than disability." AR 90. To that end, CMS would "support state efforts to test incentives that make participation in work or other community engagement a requirement for continued Medicaid eligibility or coverage for certain adult Medicaid beneficiaries in demonstration projects." *Id.* Such projects "should be designed to promote better mental, physical, and emotional health in furtherance of Medicaid program objectives." *Id.* They are intended to give states "more freedom to test and evaluate approaches to improving quality, accessibility, and health outcomes in the most cost-effective manner." AR 92.

In addressing the benefits of community engagement, CMS explained that "a broad range of social, economic, and behavioral factors can have a major impact on an individual's health and

wellness, and a growing body of evidence suggests that targeting certain health determinants, including productive work and community engagement, may improve health outcomes." AR 91. Further, "approved demonstration projects that promote positive health outcomes may also achieve the additional goal of the Medicaid program to promote independence." AR 93.

CMS provided "a number of issues for states to consider" in developing demonstration projects that encourage community engagement. AR 91–98. CMS identified the following relevant factors, among others: the project's alignment with other State welfare programs; the specific portion of the Medicaid population that would be subject to any community-engagement requirements; and considerations of budget neutrality, monitoring, and evaluation. *Id.*

## IV. KENTUCKY'S DEMONSTRATION PROJECT APPLICATION

Kentucky submitted an application to the Secretary requesting waivers and expenditure authorities under Section 1115(a) to implement KY HEALTH.[3] AR 5432–33. It proposed KY HEALTH as "an innovative, transformative healthcare program" that sought "to evaluate new policies and program elements designed to engage members in their healthcare and provide the necessary education and tools required to achieve long term health and an improved quality of life." AR 5440. The application emphasized the project's primary purposes of "improv[ing] health outcomes and overall quality of life" for all Kentucky Medicaid beneficiaries while ensuring "the long-term fiscal sustainability of the program," AR 5432, and strengthening Kentucky's behavioral health delivery system—which was "critical to addressing Kentucky's substance abuse epidemic." *Id.*

The theory behind KY HEALTH is simple: Kentucky has one of the highest poverty rates in the nation, with rates of drug-related fatalities and unemployment that are among the nation's worst.

[3] KY HEALTH includes Kentucky HEALTH, a program "into which Kentucky will enroll adult beneficiaries who do not qualify for Medicaid on the basis of a disability." AR 2. Most portions of KY HEALTH that plaintiffs challenge are part of Kentucky HEALTH. *See* AR 2–3.

AR 5432. Poverty in the Commonwealth has affected rates of drug use and HIV infection. AR 5438. Kentucky predicted that increased costs of providing care to its Medicaid expansion population, beginning 2017, would jeopardize its ability both to provide health care to traditional Medicaid populations and to fund essential services like education and pensions. AR 5432, 5439–40. And Kentucky's existing delivery systems were ineffective and inefficient in achieving desirable health outcomes. AR 5439. Kentucky thus developed a comprehensive reform project to test innovative approaches to improve health and well-being in the Commonwealth while also ensuring the Medicaid program's long-term sustainability and coverage of the expansion population. AR 5432–33, 5440.

Before submitting this application, Kentucky conducted a public comment period and three public hearings in "geographically distinct areas of the state." AR 5475. Kentucky collected over 1,300 comments and provided a detailed summary of them, along with its responses, in its waiver application. AR 43–53, 5433, 5476, 5486, 5486–89 (providing "summary of waiver changes following public comment").

## V. THE SECRETARY'S APPROVAL OF KENTUCKY'S DEMONSTRATION PROJECT.

On January 12, 2018, after conducting an additional public comment period, CMS approved Kentucky's application. Among other things, the approval letter noted that CMS took public comments into account as it worked with the Commonwealth to develop the special terms and conditions of the approval ("STCs"), and that the approval was based on "specific state assurances" concerning protections for Kentucky Medicaid beneficiaries.

CMS found that KY HEALTH was likely to promote Medicaid objectives, and that the waivers and expenditure authorities sought by Kentucky were needed and appropriate to carry out the demonstration, AR 4, primarily because KY HEALTH: (1) is likely to improve health outcomes through strategies that promote preventive care and substance use disorder ("SUD") services, and address certain health determinants, AR 4–5; (2) is likely to strengthen beneficiaries' engagement in

their own health care and provide incentives for responsible decision-making in that regard, AR 5–6; and (3) will remove potential obstacles for beneficiaries to transition to commercial coverage, AR 6–7. CMS noted that KY HEALTH was designed to achieve these goals while also "ensur[ing] vulnerable individuals like people with disabilities and pregnant women continue to receive medical assistance." AR 7.

## VI. THIS ACTION

Plaintiffs raise nine claims. Count One challenges the SMD letter. Counts Two through Eight assert that the Secretary acted arbitrarily or illegally in approving KY HEALTH. Count Nine asserts a claim under the Take Care Clause of the U.S. Constitution, Art. II, § 3, cl. 5. Plaintiffs have moved for summary judgment on Counts One through Eight. ECF No. 33.

# ARGUMENT

## I. SECTION 1115 VESTS THE SECRETARY WITH BROAD DISCRETION TO APPROVE STATE DEMONSTRATION PROJECTS.

Start with the text of Section 1115:

> 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 [the Medicaid Act] in a State or States—
>
> (1) the Secretary *may waive* compliance with *any of the requirements* of [§ 1396a], to the extent and for the period *he finds necessary* to enable such State or States to carry out such project.

42 U.S.C. § 1315(a) (emphasis added); *see also* § 1315(a)(2)(A).

As many courts have recognized, this statutory language grants "broad power" and "wide discretion" to the Secretary.[4] The "only limitation" on the Secretary's authority under Section 1115 is

[4] *C.K. v. New Jersey Dep't of Health & Human Servs.*, 92 F.3d 171, 187 (3d Cir. 1996); *Aguayo*, 473 F.2d at 1104–05; *Wood v. Betlach*, 922 F. Supp. 2d 836 (D. Ariz. 2013); *Phoenix Baptist Hosp. & Med. Ctr. v. United States*, 728 F. Supp. 1423, 1426 (D. Ariz. 1989), *aff'd*, 937 F.2d 452 (9th Cir. 1991); *Ga. Hosp. Ass'n v. Dep't of Med. Assistance*, 528 F. Supp. 1348, 1355 (N.D. Ga. 1982); *Blue Cross Ass'n v. Califano*, 473 F. Supp. 1047, 1067 (W.D. Mo. 1979), *rev'd on other grounds*, 622 F.2d 972 (8th Cir. 1980).

that he, *in his judgment*, be satisfied that the project is "likely to assist" in promoting the broad goals of the pertinent chapter of the Social Security Act. *Crane v. Mathews*, 417 F. Supp. 532, 539 (N.D. Ga. 1976). The question is not whether the project is *objectively* likely to assist in promoting the statute's goals; it is whether the Secretary, in his judgment, *determined* that it is. "Congress has entrusted this judgment to the Secretary and not to the courts." *Id.* If a project *might* yield results that would suggest necessary policies or statutory amendments, then the Secretary has wide latitude to approve waivers.

Plaintiffs nevertheless assert that the statutory waiver authority is "narrow." *See, e.g.*, Pls.' Mem. 1. But Section 1115(a) does not prescribe objective criteria; it hinges on the Secretary's "judgment" and the scope of waiver "*he* finds necessary." That language creates unreviewable agency discretion. At a minimum, it reinforces the narrow scope of any review and poses a "grave obstacle" to any attempt to challenge the KY HEALTH waivers. *Crane*, 417 F. Supp. at 539.

### A. The Section 1115 Determination Is Committed to Agency Discretion By Law.

Under the Administrative Procedure Act ("APA"), final agency action is not subject to judicial review if it is "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). This exception applies where "statutes are drawn in such broad terms that in a given case there is no law to apply," S. Rep. No. 79-752, at 26 (1945), or where "a court would have no meaningful standard against which to judge the agency's exercise of discretion," *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

Section 1115(a)(1) commits the question of waiver to the Secretary's unreviewable discretion. It provides that when a demonstration project, "in the judgment of the Secretary," is likely to assist in promoting Medicaid's objectives, "the Secretary may waive compliance" with the relevant statutes "to the extent and for the period *he finds necessary*"—rather than what *is* necessary—"to enable such State or States to carry out such project." 42 U.S.C. § 1315(a)(1) (emphasis added). This language parallels the statute at issue in *Webster v. Doe*, 486 U.S. 592 (1988), which "foreclose[d] the application of any meaningful judicial standard of review." *Id.* at 600, 603 (construing language allowing termination of

employee whenever the Director "shall *deem* such termination necessary or advisable in the interests of the United States," and concluding that the decision whether discharge was "necessary or advisable" was "the Director's alone" to make). The statute contemplates a subjective assessment, based on the Secretary's familiarity with statutory objectives and his policy and technical expertise, of whether a project is likely to be useful in furthering Medicaid purposes and what waivers *he finds* necessary to carry it out. "Thus, the statute does not provide an objective standard by which a court can assess" the project; "instead, it expressly leaves that decision to the Secretary's determination." *CC Distribs., Inc. v. United States*, 883 F.2d 146, 153 (D.C. Cir. 1989); *see also Lincoln v. Vigil*, 508 U.S. 182, 193 (1993).

To be sure, the Ninth Circuit has concluded that Section 1115(a) waivers are reviewable. *Beno v. Shalala*, 30 F.3d 1057, 1067 (9th Cir. 1994). But that court brushed aside the statutory language without explanation, *see id.* at 1066, and disregarded its own conclusion that "[t]he legislative history of § 1315(a) also suggests that Congress intended to give the Secretary considerable discretion." *Id.* at 1065 n.19 (citing *Phoenix Baptist Hosp.*, 728 F. Supp. at 1426). In any event, the Ninth Circuit's holding was limited to whether a court may review the Secretary's *threshold judgment* under Section 1115(a) that a project is "likely to assist in promoting [Medicaid's] objectives." The court reasoned that its partial (and incomplete) quotation of that phrase "provide[s] meaningful standards by which the Secretary's decision can be judged." *Id.* at 1067. The Ninth Circuit expressly declined to address the separate grant of discretion in Section 1115(a)(1), which authorizes the Secretary to waive compliance with "any of the requirements" of the relevant statute "to the extent and for the period *he finds necessary*" to enable the State to carry out "such project," 42 U.S.C. § 1315(a)(1) (emphasis added). *See Beno*, 30 F.3d at 1072 ("[W]e need not … determine the precise meaning of § 1315(a)'s 'extent and period' language."); *Newton-Nations v. Betlach*, 660 F.3d 370, 380 (9th Cir. 2011).

So, even if one were to accept the premise that the threshold issue—whether the Secretary made a judgment that a project supports the Medicaid Act's objectives—is reviewable, the statute still

would preclude review of any challenge to the "extent" or the "period" of the waiver that the Secretary "finds necessary to enable" the State "to carry out [its] project." 42 U.S.C. § 1315(a)(1). The "extent" and "period" language in Section 1115(a)(1) "refers to the scope and duration of the demonstration project and identifies these as matters left to the Secretary." *Portland Adventist Med. Ctr. v. Thompson*, 399 F. 3d 1091, 1098 (9th Cir. 2005); *see also* H.R. Rep. 87-1414, at 24 (1962) ("the Secretary would be authorized to waive plan requirements to the extent *he believes* this action is necessary to carry out a demonstration or experimental project").

**B. At a Minimum, the Secretary's Determination is Owed Substantial Deference.**

Even if the Secretary's determinations under Section 1115(a) were reviewable, the standard of review should be exceedingly deferential. The D.C. Circuit has squarely held that the Secretary's approval of an amendment to a State Medicaid plan is entitled to *Chevron* deference. *See Pharm. Research & Mfrs. Am. v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004) ("*PhRMA*"). The court reasoned that the comprehensive nature of the Secretary's authority "to review and approve state Medicaid plans" evidenced a congressional "intent that the Secretary's determinations, based on interpretation of the relevant statutory provisions, should have the force of law." *Id.* at 822.

The same deference is warranted here, as Congress expressly conferred on the Secretary sweeping authority to evaluate and approve Medicaid demonstration projects. 42 U.S.C. § 1315(a)(1), (a)(2). Congress provided that the determination whether "any experimental, pilot, or demonstration project" is "likely to assist in promoting [Medicaid Act] objectives" be made "*in the judgment of the Secretary*." § 1315(a) (emphasis added). Through this "express delegation of specific interpretive authority," *United States v. Mead*, 533 U.S. 218, 229 (2001), Congress manifested its intent that the Secretary's interpretation of his Section 1115(a) authority should have the force of law. Congress also implicitly granted the Secretary discretion to interpret "experimental, pilot, or demonstration project," as well as the "objectives" of the Medicaid Act. The familiar two-step framework of *Chevron U.S.A.,*

*Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984), therefore applies here.[5]

The Secretary is also owed deference for his predictive, discretionary judgments under Section 1115(a). The "distinction between the exercise of a particular condition as an 'objective fact,' on the one hand, and an administrator's determination of the existence of that condition, on the other, has an ancient and honorable lineage." *Kreis v. Sec'y of the Air Force*, 866 F.2d 1508, 1513 (D.C. Cir. 1989). Where a statute "draw[s] a … distinction between the objective existence of certain conditions and the Secretary's determination that such conditions are present," courts should use "an unusually deferential application of the 'arbitrary or capricious' standard." *Id.* at 1513, 1514. So even if "the broad grant of discretion implicated here does not entirely foreclose review of the Secretary's action, the way in which the statute frames the issue for review does substantially restrict the authority of the reviewing court to upset the Secretary's determination." *Id.* at 1514. *See also Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009) ("The 'arbitrary and capricious' standard is particularly deferential in matters implicating predictive judgments."). The Secretary's predictive judgment involves his exercise of policy and scientific expertise to decide a question that Congress vested squarely in his discretion—that is, a project's likely research utility in furthering broader Medicaid goals. Judicial deference is therefore at its apex.

## II. THE SECRETARY COMPLIED WITH ALL APA STANDARDS.

The Secretary's decision to grant certain waivers to enable Kentucky to carry out its demonstration project met all APA standards. In deeming a demonstration project "likely to assist" in promoting the objectives of the Medicaid Act, the Secretary is not held to standards of scientific precision, nor is he required to make any findings. Rather, the statute calls upon him to review the

[5] The approval of the state's application is an adjudication, and it is settled that an agency may elucidate the meaning of a statute through adjudication. *See, e.g.*, *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *see also City of Arlington v. FCC*, 569 U.S. 290, 306 (2013).

project *as a whole* to "reach an overall 'judgment'" as to the advisability of the demonstration project. *Aguayo*, 473 F.2d at 1103; *see C.K.*, 92 F.3d at 185) (upholding Section 1115 demonstration where program purposes were likely to pursue statutory goals, "in the aggregate"). "Whether [the court] would have been convinced by the State's case if [it] had been in the Secretary's shoes is immaterial. 'The court is not empowered to substitute its judgment for that of the agency.'" *Aguayo*, 473 F. 2d at 1107 (quoting *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated in part on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977)).

### A. KY HEALTH Is an "Experimental, Pilot, or Demonstration Project."

"Section 1115 of the Social Security Act … vests in the Secretary broad power to authorize projects which do not fit within the permissible statutory guidelines of the standard public assistance programs." *Crane*, 417 F. Supp. at 539. Recognizing the virtues of federalism and the importance of State demonstrations in formulating national policy, the Secretary has authorized waivers for wide-ranging purposes. In the half-century since Medicaid's enactment, States have used demonstrations to expand coverage, change delivery systems, alter eligibility and benefits, impose cost-sharing, and modify provider payments. Many States used demonstrations to transform Medicaid from a fee-for-service program into a managed-care program—a dramatic change based largely on reducing Medicaid program costs.[6] Section 1115 is a core structural feature of the Medicaid program, and its repeated use for decades has shown time and again that "states are in the best position to design solutions that address the unique needs of their Medicaid-eligible populations." AR 3.

As in those cases, CMS has explained that Section 1115 demonstrations "present an

[6] *See* Ex. B, KanCare (reform implemented to change to managed care delivery system); Ex. C, Hawaii QUEST (same); Ex. D, Utah Primary Care Network (eliminating mandatory benefits and imposing cost-sharing); Ex. E, Montana Basic Medicaid for Able-Bodied Adults (eliminating mandatory benefits); Ex. D, Utah (imposing cost-sharing); Ex. F, Indiana (same); Ex. G, Maine Medicaid Section 1115 Health Care Reform Demonstration for Individuals with HIV/AIDS.

opportunity for states to institute reforms that go beyond just routine medical care," propose "novel approaches designed to promote Medicaid's objectives," and "demonstrate and evaluate state-specific policy approaches to better serving Medicaid populations." AR 114. In its waiver application, the Commonwealth did just that. It proposed KY HEALTH as "an innovative, transformative healthcare program" that sought "to evaluate new policies and program elements designed to engage members in their healthcare and provide the necessary education and tools required to achieve long term health and an improved quality of life." AR 5440, 2. It outlined five broad goals for the program, AR 5447, including to "improve members' health and help them be responsible for their health"; to "[e]ncourage individuals to become active participants and consumers of healthcare who are prepared to use commercial health insurance"; to "[e]mpower people to seek employment and transition to commercial health insurance coverage"; to "[i]mplement delivery system reforms to improve quality and outcomes; and to "[e]nsure long-term fiscal sustainability." *Id.* Further, the Commonwealth proposed detailed hypotheses to test for each program goal, AR 5447, 5516–19, and described the methods it intended to use, and the data it would collect, to do so, AR 5516–19.

CMS concluded that the project "will help inform future state demonstrations seeking to draw on Kentucky's novel approaches to Medicaid reform," and emphasized the agency's interest in "learning from the outcomes of [the] demonstration project." AR 1. The Special Terms and Conditions ("STCs") appended to the approval letter recognized the project's "demonstration goals" that would "inform the state's evaluation design hypotheses." AR 19–20. Among other things, steps should be taken to "ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses" of the demonstration, AR 58–60; and Kentucky must publish an evaluation design and provide interim and summative evaluation reports explaining its conclusions. *Id.* Thus, far from being the sort of "simple benefits cut" at issue in *Beno*, 30 F.3d at 1069, KY HEALTH has a research and experimental goal, and the Secretary reasonably determined that the project as a whole

is likely to yield useful information and demonstrate a novel approach to program administration.

### B. Plaintiffs' Claims Are All Based on a Fundamental Misunderstanding of the Purpose of Section 1115 Demonstrations and the Scope of KY HEALTH.

Plaintiffs claim that the Secretary impermissibly sought to "transform or restructure Medicaid" by approving KY HEALTH. Pls.' Mem. 13. But Section 1115 is designed to allow States to be bold by "test[ing] out new ideas and ways of dealing with the problems of public welfare recipients." S. Rep. No. 87-1589, at 19 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 1943, 1961. Indeed, many States tested innovative welfare-reform initiatives through demonstration waivers under Aid to Family and Dependent Children ("AFDC"), leading Congress to incorporate these policies into the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996, the legislation that replaced AFDC with the Temporary Assistance for Needy Families (TANF) program. Likewise, Section 1115 demonstration projects that allowed States to implement managed care and benchmark plans informed the addition of Section 1932 to the Social Security Act in the Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 251. And, after demonstration projects tested the efficacy of family-planning services, the ACA adopted those into an optional eligibility group that States can include in their plans, *see* 42 U.S.C. § 1396a(a)(10)(A)(ii)(XXI). *See CWRO*, 348 F. Supp. at 498 ("the co-payment project is designed to collect data which may well be of significance both in the administration of the present Medicaid program and in the process of proposing legislative modifications to it. As such, the project meets the requirements imposed by § 1115"). Plaintiffs cannot explain how this history is consistent with their erroneous view of the Secretary's waiver authority; instead, they ignore it.

Plaintiffs do not explicitly challenge the Secretary's determination that the KY HEALTH waivers were necessary, in scope and duration, to implement Kentucky's proposal, perhaps because they recognize this is a discretionary determination that Congress has committed to the Secretary's discretion. Instead, they cite a dictionary definition of "waive" to argue that Section 1115 does not authorize the "restructuring of the Medicaid program via a state demonstration project approval."

Pls.' Mem. 15. This argument is a straw man.[7] The Secretary did not "fundamentally modify, amend, or change statutory provisions." Pls.' Mem. 14. He did what Section 1115 expressly authorizes him to do—waive compliance with specific provisions of § 1396a to the extent and for the period he found necessary to implement Kentucky's demonstration. AR 3, 13–15. The Secretary identified the waivers he found necessary to implement the project, AR 13–16, and the expenditure authorities to enable the Commonwealth to implement the demonstration, AR 11–12. He limited those waivers and expenditure authorities to the period for which he approved the demonstration—that is, from January 12, 2018, through September 30, 2023. AR 2, 11 & 13. And each of the requirements he waived is found in § 1396a, consistent with the express grant of authority in Section 1115(a)(1).

Plaintiffs' principal grievance with KY HEALTH lies with the project's community-engagement requirements. They emphasize that Congress did not adopt "work requirements" in the Medicaid Act itself. Pls.' Mem. 18–21. But that is the *point*, as the central idea of Section 1115 is to authorize the Secretary to *waive* certain provisions of the Medicaid Act. In any event, plaintiffs' argument rests on the "work requirements" fiction that plaintiffs invoke throughout their brief. As the approval letter and STCs emphasize, participation in general education, community service, caregiving services, or substance abuse treatment satisfies the community-engagement requirement. AR 42. The list is non-exhaustive, and "[p]articipation in any one or combination" of the qualifying activities is permitted. *Id.* Thus, Congress's adoption of "work requirements" in other statutory programs, Pls.' Mem. 20, in no way suggests that it foreclosed the Secretary from authorizing

[7] The case on which plaintiffs rely distinguishes itself. In *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218 (1994), the Court construed an agency's authority to "modify" statutory requirements, which the Court held did not authorize "basic and fundamental" changes. *Id.* at 225. Section 1115, by contrast, grants the Secretary authority to "waive" provisions of the Medicaid Act in their entirety, not simply to "modify" them. Recognizing the breadth of the waiver authority, Congress required that the Secretary limit those waivers to the extent and time that he found necessary to implement the project. 42 U.S.C. § 1315(a)(1). There is no contention here that the Secretary violated that limit.

community-engagement provisions on an experimental basis under a Section 1115 waiver.

Similarly, plaintiffs' assertion that this is "the first time such a [work] requirement has been permitted in the 50-year history of the Act," Pls.' Mem. 1, provides no basis to restrict the Secretary's authority to approve community-engagement requirements. Like any federal agency, HHS may apply its authority flexibly and adapt its policies to the "changing needs" of the nation. *See Am. Trucking Ass'ns v. Atchison, Topeka & Santa Fe Ry. Co.*, 387 U.S. 397, 416 (1967). Here, the agency's policy is consistent with the "changing needs" of the nation. Many able-bodied adults are now covered under the Medicaid expansion, and it make sense now for the Secretary to test whether community-engagement requirement will achieve health benefits for these individuals, even if it there might not have been a reason to do so before for the vulnerable individuals who were the focus of traditional Medicaid. In any event, the point of Section 1115 is to test novel methods for implementing the Medicaid program; if the statute only permitted the Secretary to test projects that have already been tested, the statute would be meaningless. "[T]he Secretary, in [his] discretion, is allowed to change [his] mind over time regarding the wisdom" of Medicaid requirements that incentivize work and other forms of community engagement. *C.K.*, 92 F.3d at 187.

Plaintiffs further miss the mark in contending that Congress, by declining to adopt legislative proposals to add work requirements to the Medicaid Act, somehow forbade the Secretary from authorizing demonstration projects with community-engagement requirements through his Section 1115 authority. Pls.' Mem. 18–21. "Congressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction, including the inference that the existing legislation already incorporated the offered change." *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 299 n.4 (D.C. Cir. 2003) (internal citation omitted). Here, Congress could easily have so inferred, given that it was aware that State-level demonstrations could be useful for making future policy choices and evaluating potential national reforms. *CWRO*, 348 F. Supp. at 497. Plaintiffs are also mistaken

that Congress ratified the prior Administration's views on community-engagement provisions. Pls.' Mem. 21. Section 1115 has not been re-enacted or amended since the prior Administration announced its views, and Congress could not have ratified those views through legislative silence. *See Pub. Citizen, Inc. v. U.S. Dep't of Health & Human Servs.*, 332 F.3d 654, 668–70 (D.C. Cir. 2003); *see also Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 214 (D.C. Cir. 2011)).

### C. The Secretary Properly Judged Kentucky's Demonstration to Be "Likely to Assist in Promoting" Medicaid "Objectives."

Contrary to plaintiffs' assertion, Congress nowhere specifically defined the "objectives" of the Medicaid Act. *CWRO*, 348 F. Supp. at 494. But courts often look to the Act's appropriation section as a source from which statutory purposes can be inferred. *See* 42 U.S.C. § 1396-1. That section authorizes Congress to appropriate funds:

- to furnish "medical assistance on behalf of families with dependent children and of aged, blind, or disabled individuals, whose income and resources are insufficient to meet the costs of necessary medical services," and
- to furnish "rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care,"
- "[f]or the purpose of enabling each State" to accomplish those goals "as far as practicable under the conditions in such State." *Id.*

Those are some purposes of the Medicaid Act, but they are not the Act's sole purposes; indeed, the appropriations section itself contemplates other purposes in the Act. *See id.* (sum appropriated must be "sufficient to carry out *the purposes* of this subchapter" (emphasis added)). The Act's overarching purpose, of course, is to promote public health and well-being. The funds made available under § 1396-1 are a means to that end. And other provisions in "this subchapter" illuminate the meaning of the "as far as practicable under the conditions in such State" qualification in § 1396a-1, and highlight that the Act also takes considerations of efficiency and economy into account. *See, e.g.*, *id.* §§ 1396a(a)(4)(A), (a)(24), (a)(42)(B)(ii)(IV); § 1396b(a)(2)(A).

The determination whether a demonstration project "is likely to assist in promoting the objectives" of Medicaid, § 1315(a), does not depend on any one factor, but instead rests on the Secretary's "overall judgment" of how the competing goals of the program might best be served.

> That judgment could rationally be made with respect to a project which was directed to promoting one of several objectives, even if another objective would suffer by reason of the project's operation, so long as the Secretary concluded that *on balance* the objectives considered together were likely to be advanced. It is not necessary to find that one project will promote all the objectives in order to sustain the Secretary's approval of it.

*CWRO*, 348 F. Supp. at 497; *see also Aguayo*, 473 F.2d at 1103. Here, CMS found four factors to be relevant to its evaluation of KY HEALTH, including whether the proposed demonstration was likely to assist in improving health outcomes, would address behavioral and social factors found to influence health outcomes, and would incentivize beneficiaries to engage in their own health care in a way that could have the effect of achieving better health outcomes. AR 4. CMS also considered whether the Commonwealth's proposal would equip beneficiaries with the knowledge and tools to more easily transition from Medicaid coverage to commercial coverage. *Id.* Based on a reasoned consideration of these factors, the Secretary made the "overall judgment" that KY HEALTH is "designed to empower individuals to improve their health and well-being," AR 7, and is likely to assist in promoting Medicaid objectives. Specifically, he found that the project, if successful in its objectives, would:

- "improve health outcomes, promote increased upward mobility and improved quality of life,"
- "increase individual engagement in health care decisions,"
- "prepare individuals who transition to commercial health insurance coverage to be successful in this transition,"
- "ensure vulnerable individuals like people with disabilities and pregnant women continue to receive medical assistance," and
- "lessen[] dependence on government assistance and promot[e] individual self-sufficiency," and thereby "help[ing] to promote the fiscal sustainability of the program to better protect services for the Commonwealth's most vulnerable."

AR 7. Each of these goals is premised on improving health outcomes, while balancing the objectives of providing coverage and ensuring that States are able to manage their healthcare costs efficiently and in a way that protects services for the most vulnerable populations. These outcomes unquestionably promote the purposes of the Medicaid Act, and "[i]t is impossible to deny that attainment of these goals, or even some of them, would meet the test of [Section 1115]." *Aguayo*, 473 F.2d at 1105; *see C.K.*, 92 F.3d at 185 (program purposes were likely to pursue statutory goals, "in the aggregate").

### D. Plaintiffs' Interpretation of Medicaid Objectives Is Inconsistent with the Statutory Language.

In an attempt to evade the deference owed to the Secretary's reading of the Medicaid Act, plaintiffs (erroneously) contend that Congress "expressly defined" Medicaid's objectives in § 1396-1, and they argue that the Secretary tried to "rewrite" those objectives by approving KY HEALTH. The only "rewriting" here is by plaintiffs. They repeatedly ellipt portions of § 1396-1 that undermine their case. The Secretary properly applied the full statutory language, rather than plaintiffs' set of snippets.

*First*, plaintiffs excise the phrase "under the conditions in such State," 42 U.S.C. § 1396-1, which demonstrates that State budgetary and administrative concerns are necessarily a part of Medicaid's purposes. *See, e.g.*, Pls.' Mem. 4, 16. This key statutory qualification is conspicuously absent from plaintiffs' brief. And the "conditions in" the Commonwealth cannot be ignored. Kentucky has one of the highest poverty rates in the nation, with rates of drug-related fatalities and unemployment that are among the nation's worst. AR 5432. Kentucky's existing delivery systems were ineffective in achieving desirable health outcomes. AR 5439. The Commonwealth also predicted that costs of providing care to Kentucky's Medicaid expansion population would jeopardize its ability to provide health care to the traditional Medicaid population, as well as other essential services. AR 5432, 5439–40. It noted that the Commonwealth could not "afford the cost of the Medicaid expansion program without this demonstration waiver." AR 5440. The Commonwealth thus developed its project to test innovative approaches to improve its residents' health and well-being in a way that ensured the

Medicaid program's long-term sustainability. AR 5432–33, 5440. The Secretary concluded that if improved use of SUD and preventive services indeed resulted in a lower overall cost of care for Medicaid-eligible populations (as hypothesized), the project may have the additional benefit of enabling the Commonwealth to "stretch its Medicaid resources as far as possible." AR 5.

*Second*, plaintiffs repeatedly replace the phrase "on behalf of families with dependent children and of aged, blind, or disabled individuals," 42 U.S.C. § 1396-1, with "[individuals]," suggesting that the "medical assistance" goal applies equally to the expansion population. (Indeed, their brief contains no reference whatsoever to this critical language.) This rewriting stretches the statute to its breaking point. Had Congress wanted to add "adults who are eligible on grounds other than disability" to § 1396-1, it would have done so when it enacted the Medicaid expansion. But § 1396-1, as written, applies explicitly to the *traditional* Medicaid population, while the community-engagement initiative applies, in large part, to the *expansion* population, with specific exemptions for the primary caregiver of a dependent, the medically frail, the disabled, and other vulnerable groups.

That is sensible. While a community-engagement initiative would make little sense for vulnerable low-income individuals likely to need medical assistance, there is nothing irrational in requiring able-bodied adults who are capable of performing community service, working, or going to school to do so as a condition of Medicaid eligibility. The requirement is not about *penalizing* Medicaid beneficiaries, as plaintiffs suggest. It is about promoting public health by encouraging members of the expansion population to engage in behaviors associated with healthy outcomes. That beneficiaries may satisfy the community-engagement requirement by seeking substance-abuse treatment illustrates that point. AR 42.

The community-engagement initiative also promotes § 1396-1's goal of providing "medical assistance" to the traditional Medicaid population by allowing the Commonwealth to focus more of its finite resources on that population. *See* Pls.' Mem. 7, 16. The ACA expansion "placed able-bodied

adults into a program designed for vulnerable populations who were more likely to require long-term care under Medicaid," AR 5437, making the Commonwealth's Medicaid program fiscally unsustainable. Kentucky thus sought to promote a pathway out of welfare dependence for certain adults to focus its finite resources on its more vulnerable, traditional Medicaid population.

Plaintiffs cannot evade the statutory focus on vulnerable populations by invoking what they describe as the ACA's goal to increase the number of individuals covered by Medicaid. *See, e.g.*, Pls.' Mem. 10 & 15. The place to look for Medicaid's "objectives" is the Medicaid Act, not the ACA. *Cf. Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 645–46 (1990) (courts cannot require agency "to take explicit account of public policies that derive from federal statutes other than the agency's enabling Act"); *C.K.*, 92 F.3d at 184–85. In any event, the goals of the project are consistent with the ACA's goals. Although plaintiffs call it a simple benefits cut, KY HEALTH is not designed to withdraw health insurance coverage from vulnerable people. Rather, it is designed (in part) to help people transition, or graduate, to commercial coverage. Giving more people access to commercial health care coverage is a central goal of the ACA. *See, e.g.*, 42 U.S.C. § 18031. The ACA's goal is not to keep people dependent on government programs throughout their lives.

*Third*, in their initial discussion of Medicaid's "stated purpose," *see* Pls.' Mem. 7, plaintiffs edit out the phrase "to help such families and individuals attain or retain capability for independence or self-care," 42 U.S.C. § 1396-1, language which emphasizes Congress's intent that the Medicaid program help vulnerable individuals and provide a safety net—not serve as a permanent welfare program. When the red-penciled language is restored, it shows that the purpose of providing "rehabilitative or other services" applies to the vulnerable populations identified in the previous clause, as evidenced by its reference to "such families and individuals." *Id.* And given that "independence" and "self-care" are express congressional objectives for "aged, blind, or disabled individuals," the Secretary certainly acted well within his discretion to conclude that they are appropriate goals for the

able-bodied individuals that Congress added through the ACA's expansion.

Plaintiffs quote the omitted language elsewhere in their brief, but fail to meaningfully address the Secretary's explanation that KY HEALTH requirements encouraging "upward mobility" and "greater independence" would lead to improved "health and wellness" and "improved health outcomes." AR 4. Quite the opposite, plaintiffs selectively cite portions of the approval letter to suggest that the Secretary's approval turned only on goals of "financial independence" and the "transition to commercial market coverage." Pls.' Mem. 7, 17. But the letter addresses these goals as an additional benefit—a desirable side effect—of the primary goal of promoting health and well-being. AR 5 ("*In addition to promoting improved health outcomes* … the demonstration may also promote individual independence and reduce reliance on public assistance by creating incentives for individuals to obtain and maintain coverage through private, employer-sponsored insurance." (emphasis added)).

Plaintiffs' reading of the statutory objectives fails to give effect to all the language. By contrast, the Secretary's construction gives effect to the full text of § 1396-1, and is supported by the statutory context and purpose. His reading of the scope of his authority under Section 1115 is at least reasonable, and merits deference. *See City of Arlington*, 569 U.S. at 296 n.4.

## III. THE CLAIMS CHALLENGING INDIVIDUAL COMPONENTS OF KY HEALTH ARE NON-JUSTICIABLE AND NON-REVIEWABLE, AND FAIL ON THEIR MERITS.

In an attempt to evade the deference owed to the Secretary's "overall judgment" under Section 1115(a), plaintiffs slice KY HEALTH into individual components in Counts Two through Seven to demand, in essence, that every aspect of the project be "necessary" in terms of a goal that *they* regard as legitimate. These claims fail at the outset because the question of what waivers are "necessary" is vested in the Secretary's discretion. *See supra* Part I(A); *cf. Portland Adventist Med. Ctr.*, 399 F. 3d at 1098 (§ 1315(a)(1) "refers to the scope and duration of the demonstration project and identifies these as matters left to the Secretary"). Once the Secretary has judged a project to satisfy

Section 1115(a)'s general standard, Section 1115(a)(1) broadly authorizes him to waive "*any* of the requirements of section … 1396a," to the extent and for the period he finds necessary to implement the project. 42 U.S.C. § 1315(a)(1) (emphasis added). Here, having concluded that the project was likely to promote Medicaid objectives, the Secretary properly exercised his discretion by identifying the specific waivers he found necessary to implement the project, AR 13–16, as well as the expenditure authorities to enable the Commonwealth to implement the project, AR 11–12, and limiting the waivers to the period for which he approved the demonstration.

Further, although it is axiomatic that "a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought," *Davis v. FEC*, 554 U.S. 724, 734 (2008), plaintiffs merely speculate about potential future injuries they might incur as a result of the approval, and thus lack standing to challenge any of the individual waivers granted by the Secretary.

And at all events, Counts Two through Seven fail on their merits, as they are founded on the erroneous premise that each component of the project independently must merit approval under Section 1115 standards. The statute simply does not countenance such a "myopic analysis." *Wood*, 922 F. Supp. 2d at 843. Viewing the project as a whole, the Secretary's grant of waivers was amply supported by record evidence and was not arbitrary or capricious.

### A. The Claims Fail on Their Merits Because the Secretary's Evaluation of the Project as a Whole Complied With all APA Standards.

In Counts Two through Seven, plaintiffs splinter KY HEALTH into distinct components in an attempt to impose an atextual and unrealistic obligation on the Secretary. Plaintiffs would have the Secretary determine how each particular component of any demonstration project, standing alone, has independent experimental value in promoting Medicaid objectives. But that is not what the statute requires. Section 1115 directs the Secretary to evaluate the "experimental, pilot, or demonstration *project*" and to determine whether, "in the judgment of the Secretary, [it is] likely to assist in promoting the objectives" of the Medicaid Act. 42 U.S.C. § 1315(a) (emphasis added). The statute thus calls

upon the Secretary only to "reach an overall 'judgment'" as to the advisability of permitting a demonstration project. *Aguayo*, 473 F.2d at 1103. It does not require that each individual program component, standing alone, have experimental value and promote broader Medicaid goals.

For good reason. "Medicaid programs are complex and shaped by a diverse set of interconnected policies and components, including eligibility standards, benefit designs, reimbursement and payment policies, IT systems, and more." AR 3–4. The unavoidable result of plaintiffs' argument is that "any provision of a larger demonstration project could be challenged as not independently warranting approval under Section 1115, notwithstanding the provision's relationship to and interaction with the project as a whole." *Wood*, 922 F. Supp. 2d at 843. Here, the record makes clear that each component is interconnected with the demonstration's broader goals and design.[8] In evaluating the project as a whole, the Secretary carefully considered the utility of each challenged component in promoting the overall project goals. *See supra* Part II(C).

**B. Plaintiffs Lack Standing to Pursue Counts Two through Seven.**

Even if plaintiffs' challenges to the Secretary's individual *waivers* (as opposed to the approval of the project as a whole) were reviewable, plaintiffs would need to show that they have "suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical," and that is fairly traceable to the challenged action, with respect to each claim. *Sabre, Inc. v. U.S. Dep't of Transp.*, 429 F.3d 1113, 1117 (D.C. Cir. 2005). Plaintiffs fail to show that they will be harmed by any waiver that they challenge in Counts Two through Seven, because "[a]llegations of possible future injury do not satisfy the requirements of Art[icle] III …." *Whitmore v. Arkansas*, 495

[8] *See, e.g.*, AR 2 (explaining that the My Rewards Account, Deductible Account, and community-engagement requirement together serve to educate beneficiaries of and incentivize them to engage in healthy behaviors); *id.* at 5–6 (explaining that the My Rewards Account, waiver of retroactive eligibility, and non-eligibility period for failure to complete redetermination together will encourage beneficiaries' engagement in their personal health plan and incentivize better decision-making); *id.* at 6–8 (explaining the features that together will remove barriers to beneficiaries' transition to commercial coverage).

U.S. 149, 158 (1990); *see also Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014) (standing based on future harm only where the "threatened injury is certainly impending, or there is a 'substantial risk' that the harm will occur.") (internal citation omitted). Plaintiffs' fears of future injuries do not satisfy these standards but instead depend on "an attenuated chain of possibilities." *In re Sci. Applications Int'l Corp. Backup Tape Data Theft Litig. ("SAIC")*, 45 F. Supp. 3d 14, 24 (D.D.C. 2014).

*Community Engagement Requirements.* Plaintiffs assert that KY HEALTH's community-engagement component injures them because they "are at risk of losing their Medicaid coverage when they cannot find or maintain work." Pls.' Mem. 11. This assertion fails to consider (1) the different ways in which plaintiffs can fulfill the community-engagement requirement and (2) the various exemptions to the requirement.

First, Kentucky provides a non-exhaustive list of qualifying activities that can be performed in combination. They include job skills training, job search activities, education, training, community services, "[c]aregiving services for a non-dependent relative or other person[s] with a disabling medical condition," and participation in treatment for substance-abuse disorders. AR 42. Several of plaintiffs' declarations, on their face, show that those plaintiffs will easily meet the requirement. *E.g.*, Ballinger Decl. ¶ 4, ECF No. 33-5 ("I am a full-time student and caregiver to my children.").[9]

Second, the claims hinge on conjecture about Kentucky's future exemption determinations. The Commonwealth has not yet decided who qualifies as "medically frail" and is thus exempt from numerous project requirements. *See* AR 84. Indeed, multiple plaintiffs concede that they may receive

[9] *See* Hatcher Decl. ¶ 4, ECF No. 33-9 ("I am a full-time student …."); Allen Decl. ¶ 3, ECF No. 33-13 ("I recently started working full-time …."); Kobersmith Decl. ¶ 9, ECF No 33-6 ("Currently, I work 20 hours a week steadily."); Kasey Decl. ¶ 10 ("I am trying hard to find a job …."); Branham Decl. ¶ 9, ECF No. 33-4 ("spending many hours per week caring for my ill grandfather and attending outpatient substance abuse disorder services"); Radford Decl. ¶ 9, ECF No. 33-17 ("I might be able to count the hours I spend taking care of my grandmother and the volunteer work I do."); Woods Decl. ¶ 3, ECF No. 33-11 ("I work as a cleaning specialist" and "take care of [grandchild] full-time.").

such exemptions. *E.g.* Bennett Decl. ¶ 8 ("I might be able to have this waived if I can prove that I am medically frail …"); Spears Decl. ¶ 9, ECF No. 33-14 ("I may be able to get a medically frail exemption …"). Among others to be exempted are "former foster care youth, pregnant women, primary caregivers of a dependent," "beneficiaries diagnosed with an acute medical condition that would prevent them from complying with the requirements," and "full time students." AR 85, 42.

What is more, Kentucky will adjust, or exempt certain areas of the State from, the community-engagement requirement, where it finds "limited economies and/or educational opportunities" and "lack of public transportation … so that the community engagement requirements will not be impossible or unreasonably burdensome for beneficiaries to meet." AR 86. And individuals will "be deemed" to satisfy the community-engagement requirement if they (1) satisfy work requirements under Supplemental Nutrition Assistance Program (SNAP) or Temporary Assistance for Needy Families (TANF), or are exempt from those requirements; (2) are enrolled in the state's Medicaid employer premium assistance program, or are the spouse or dependent of someone who is enrolled in the program; or (3) are employed for 120 hours or more a month (for this final category, individuals need not "actively document their participation in qualifying activities"). AR 85.

Moreover, even assuming that plaintiffs will not be exempt from, or deemed to meet, the community-engagement requirement, they fail to show that they will not have a "good cause" in failing to comply. AR 44. Plaintiffs' asserted fears about losing Medicaid coverage would materialize, if at all, only if (1) they fail to engage in any of the wide array of qualifying activities for the required hours; (2) they fail to demonstrate good cause for their inability to meet the requirement; (3) Kentucky does not exempt them from the requirement (or deem them exempted); and (4) Kentucky does not find their geographic area to lack economic, educational, and public transportation opportunities that would warrant adjusting the requirement. Plaintiffs fail to show that a "substantial probability" that this confluence of events will occur, *Amer. Petroleum Inst. v. EPA*, 216 F.3d 50, 63 (D.C. Cir. 2000), and

the Court should not "endorse standing theories that rest on speculation about the decisions of independent actors." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013).

*Premium Requirements.* KY HEALTH's premium requirements do not apply to those who are medically frail, pregnant, or former foster care youth. AR 25–26. Only one plaintiff, David Roode, establishes that he is substantially likely not to be found exempt on the basis of medical frailty, but even he does not establish whether he would be exempt on another basis and therefore fails to establish with substantial certainty that he would be subject to the premium requirements.

*Non-Emergency Use of the Emergency Department.* Here, plaintiffs merely speculate that they *may* someday go to a hospital's emergency department for what Kentucky deems to be a non-emergency purpose. *E.g.*, Stewart Decl. ¶ 10, ECF No. 33-2 ("If I go to the emergency room, and Medicaid doesn't think it was an emergency, they will deduct $20 from my *My Rewards* account."); *see also* Kasey Decl. ¶ 11; Ballinger Decl. ¶ 15; Bennett Decl. ¶ 10. But (1) "[t]he beneficiary must receive an appropriate medical screening examination … before their *My Rewards* dollars can be deducted"; (2) Kentucky "will ensure that hospitals comply" with federal requirements to "educat[e] beneficiaries about appropriate alternative settings" before making *My Rewards* account deductions for non-emergency use of the emergency department; and, (3) the deductions from *My Rewards* accounts "will be waived for any beneficiary" who calls the "24-hour nurse hotline prior to utilizing the hospital emergency department." AR 34–35. Plaintiffs' feared deductions from *My Rewards* dollars—which plaintiffs have not even earned—are based on an attenuated and hypothetical chain of events.

*"Lockouts."* Again, plaintiffs merely speculate that they *may* be unable to complete their redetermination process by the end of their eligibility period or report changes in circumstances that affect their eligibility and, thus, be disenrolled from Medicaid. *See* Woods Decl. ¶ 8, ECF No 33-10 ("If we do not comply with this reporting requirement, or fail to recertify on time, we will lose Medicaid."); *see also* Allen Decl. ¶ 8; Spears Decl. ¶ 9. But there is no reason to suppose that plaintiffs

cannot comply with the requirement, and, in any event, plaintiffs would be exempt from the non-eligibility period if they are deemed medically frail, are pregnant, or are former foster care youth, or if Kentucky grants them a good-cause exception. AR 28–31; *see SAIC*, 45 F. Supp. 3d at 24.[10]

*Waivers of Retroactive Coverage.* Once more, plaintiffs present only attenuated possibilities. Each plaintiff is currently covered by Medicaid, so this waiver could only become an issue if their coverage were terminated. And any fears of disenrollment are speculative, as explained above. *See SAIC*, 45 F. Supp. 3d at 24; *e.g.*, Radford Decl. ¶ 9 ("If I get cut off, and have to reapply, there will be a gap in my coverage."); Penney Decl. ¶ 12, ECF No. 33-16; Roode Decl. ¶ 7.

*Waiver of Non-Emergency Medical Transportation.* Here, too, the only two plaintiffs who assert an injury fail to show with sufficient certainty that they (1) would be subject to the waiver—which applies to the "new adult group" and exempts the medically frail and pregnant women, among others, AR 32—and (2) would need to use non-emergency medical transportation. McComas Decl. ¶ 10, ECF No. 33-8; Spears Decl. ¶ 12; *see also Kansas Corp. Comm'n v. FERC*, 881 F.3d 924, 930 (D.C. Cir. 2018).

Because plaintiffs fail to show a cognizable injury from any of the individual waivers that they challenge, it follows that they lack standing to challenge the demonstration project as a whole.[11]

### C. The Secretary's Approval of KY HEALTH Was Not Arbitrary or Capricious.

Plaintiffs attempt to convert the grant of statutory authority in Section 1115(a)(1) into a

[10] Plaintiffs' assertions that they will need to report "any" changes in income within ten days appear incorrect. *See* Ballinger Decl. ¶ 5; Hatcher Decl. ¶ 12; Woods Decl. ¶ 8. They cite a Kentucky regulation requiring a recipient to report a change "*which may affect eligibility*," Pls.' Mem. 34 (citing 907 Ky. Admin. Regs 20:010 (emphasis added)), and Kentucky's plan notes that "[d]isenrollment will be limited to circumstances in which the failure to report a change affected eligibility," AR 30. But there is no reason to suppose that moderate fluctuations in income would constitute a change in circumstance necessarily triggering the reporting requirement.

[11] Kentucky has suggested that plaintiffs have a redressability problem because the Commonwealth will unwind its Medicaid expansion if KY HEALTH is invalidated. Indeed, Kentucky's approach presents redressability concerns because in the end, the federal courts cannot provide plaintiffs with relief from a state budget shortfall that results in the contraction of the Medicaid program.

stringent limitation—akin to a "least restrictive alternative" test. They also suggest that the Secretary must recite and refute every objection submitted in opposition to a proposed waiver—under which the courts may second-guess nearly every respect in which the demonstration project has effects that might have been lessened or prevented by a different design. But none of the cases cited by plaintiffs support such an approach, and indeed, no court has restricted the Secretary's waiver authority in that way. *See, e.g.*, *C.K.*, 92 F.3d at 185 ("[W]e … decline to find in *Beno v. Shalala* a rule that in all cases an administrative record is deficient and must be supplemented where it does not contain a specific recitation and refutation of objections submitted in opposition to a proposed section 1315(a) waiver."); *see also Aguayo*, 473 F.2d at 1107 (Section 1115 "does not require that, before the Secretary approves an experiment, every I must be dotted and every t crossed.").

Moreover, plaintiffs' claims must be assessed in light of the fact that this is not a permanent program change but a *demonstration project* of limited duration. It is "critical" to consider the project's experimental nature, and the fact that the agency's decision involves a commitment to monitor the project's results. *See Consumer Fed'n of Am. v. Consumer Prod. Safety Comm'n*, 990 F.2d 1298, 1307 (D.C. Cir. 1993); *United Tel. Workers, AFL-CIO v. FCC*, 436 F.2d 920, 923–24 (D.C. Cir. 1970); *see also Aguayo*, 473 F.2d at 1103 (administrator may set "lower threshold for persuasion" when evaluating experimental project of limited duration). "The Secretary cannot be held to standards of scientific precision in that testing process. … While the conclusions he draws from such experiments may not stand the test of science, they nevertheless may be useful in making the decisions he is called upon to make." *CWRO*, 348 F. Supp. at 498. Only if objections to the project show such results "as to negate any appreciable possibility of success would the Secretary's approval be arbitrary and capricious." *Aguayo*, 473 F.2d at 1107.

Here, CMS reviewed all the comments it received in evaluating whether the project *as a whole* is likely to assist in promoting Medicaid objectives, and whether the waiver and expenditure authorities

sought were necessary and appropriate to implement the demonstration. AR 7–8. "To help determine whether the demonstration is meeting its goals of improving quality, accessibility, and health outcomes, Kentucky will submit, for CMS comment and approval, a draft evaluation design with implementation timeline." AR 9. Further, CMS noted that it would "work with Kentucky to ensure that the comments received also inform the monitoring and evaluation design and … provide for program adjustments when necessary." AR 9. CMS also reserved the right to modify or terminate the waivers "at any time it determines that continuing [them] would no longer be in the public interest or promote the [statutory] objectives." AR 24. *See Aguayo*, 473 F.2d at 1106 ("Secretary could properly give weight to the fact that the programs were of limited duration and would remain under the ongoing supervision (with the power to terminate approval) of [CMS]."). Plaintiffs' scattershot objections to CMS's conclusions all lose sight of the basic fact that this is a demonstration project, geared to assessing the efficacy of new approaches to health-policy issues. The evaluation whether the project succeeds in its aims is, itself, a legitimate objective. *See id.*

*State Assurances about Protections for Beneficiaries.* Plaintiffs insist that the Secretary failed to consider the impact of the demonstration on Medicaid beneficiaries. These claims have no basis in the record, which shows that the Secretary's approval of KY HEALTH was the product of lengthy negotiations with the Commonwealth on the efficacy of proposed program components. During its careful, 16-month-long evaluation, CMS requested multiple "guardrails" and "state assurances" to protect beneficiaries. AR 1536–41 (responses to CMS's concerns about lockouts, premiums, non-emergency medical transportation, and community engagement); AR 1754–56 (CMS's testing of lockout scenarios); AR 1777–79 (CMS's concerns or requests for state assurances regarding community-engagement, lockout, and premium requirements, including good-cause exemption for failure to pay premiums); AR 1794–95 (proposed guardrails and assurances regarding KY HEALTH's premium and lockout components). Further, although plaintiffs raise various concerns that potential

administrative costs and difficulties will prevent the project from improving beneficiaries' health, *see* Pls.' Mem. 23, 24 n.12, 32, 39, the Secretary considered such concerns and required that the Commonwealth "ensure the availability of adequate resources for implementation and monitoring of the demonstration," AR 24.

*Health Benefits of Community Engagement*. Plaintiffs *admit* that CMS's "evidence suggests a positive correlation between volunteering and health, and it indicates that certain gainful employment and increased earnings can improve health." Pls.' Mem. 24. But they nonetheless argue that the Secretary erred by concluding that the community-engagement requirement could promote Medicaid objectives. Plaintiffs' objections lose sight of the fact that the project is an experiment, whose exact results neither the Commonwealth nor the Secretary purports to know in advance. *See, e.g.*, Pls.' Mem. 25 (complaining that "CMS provides no evidence that work requirements *actually improve* income or long-term employment, much less that they do so in a manner that leads to improved health outcomes" (emphasis added)). Here, the Secretary made a factual conclusion, based on his predictive judgment and policy expertise, that the requirement would encourage activities that research has shown to lead to improved health and wellness, and would thus promote health, upward mobility, greater independence, and improved quality of life. AR 4. Further, he concluded that *requiring* community engagement was necessary to create an effective incentive, as voluntary referrals to employment services, which other states had already tested, had not been strong enough incentives to influence behavior. AR 4–5. And so he determined that suspending eligibility for individuals who fail to satisfy the community-engagement requirement, coupled with "on-ramps" to allow individuals to quickly regain access, could create sufficient incentives to generate the desired improvements to beneficiaries' health. AR 4. The Secretary thus concluded that these incentives will likely promote "Medicaid's objective of improving beneficiary health," AR 5, and the project will test multiple hypotheses to that end. AR 6. The extent to which these hypotheses are accurate will be addressed

in the evaluation of the experiment, but plaintiffs attempt to beg the question by assuming at the outset that recipients will not respond to the incentives by engaging in qualifying activities.[12]

*Incentives for Compliance with Program Requirements.* CMS concluded that evidence tying behaviors to health outcomes supports the rationale that the demonstration's various incentives—including rewards accounts, eligibility suspensions for failure to meet reporting requirements or comply with the redetermination process, and the waiver of retroactive eligibility—will promote Medicaid's objectives. AR 6. Further, the incentives could achieve the "additional goals" of encouraging responsive utilization of services, promoting continuity of care, and improving program integrity. AR 6. CMS noted that the impact of incentives, which include suspension, disenrollment, and on-ramps, "will be assessed through an evaluation designed to measure how the demonstration affects eligibility, behavior, and health outcomes over time for persons subject to the demonstration's policies." AR 5.

In Count Five, plaintiffs challenge the Secretary's waivers to permit the Commonwealth to impose "lockouts"—that is, disenrollment with a specified non-eligibility period, as a penalty for beneficiaries who fail to timely comply with program requirements for reporting material changes in circumstances and completing the re-determination process. *See* Pls.' Mem. 34–36. But, tellingly, plaintiffs neglect to address the program's "on-ramp" that enables individuals "to regain eligibility and successfully access all of the benefits, resources, and tools of the KY HEALTH program, without

[12] For example, plaintiffs contend that evidence about *voluntary* employment and community service does not prove that the same benefits would necessarily be realized from *requiring* those activities in order to receive Medicaid benefits. Pls.' Mem. 24. This supposed distinction is illusory; after all, many people work because they are required to do so in order to achieve a desired end (such as a paycheck). Although plaintiffs cite an article that they contend has found that community-engagement requirements are harmful., Pls.' Mem. 24 n.13 (citing article at AR 5112–5368), that article's actual conclusion is that "Overall, the beneficial effects of work outweigh the risks of work, and are greater than the harmful effects of long-term unemployment or prolonged sickness absence." AR 5119. In any event, the Secretary acted well within his discretion in allowing Kentucky to test whether those who respond to the incentive for community engagement will enjoy similar health benefits.

waiting until the end of the non-eligibility period." AR 7. Nor do they discuss the program's good-cause exemptions, or the exemptions for the medically frail and other vulnerable populations. AR 7.

Further, plaintiffs are wrong to argue that "[n]othing in the record" indicates that CMS considered evidence that these policies would reduce coverage and access to health services. Pls.' Mem. 35; AR 9 (noting that CMS and Kentucky responded to those comments by including on-ramps for affected beneficiaries); AR 5487–89 (listing the changes Kentucky made to its original proposal in response to public comments). And, although plaintiffs brush off the goal of preserving "program integrity," the Secretary acted reasonably in crediting the Commonwealth's explanation why incentives are needed to "dissuade members from failing to timely report changes." AR 5413; *id.* at 7 (concluding that the non-eligibility period "ensures that resources are preserved for individuals who meet eligibility requirements" and that the timely completion of redeterminations and reporting requirements are "fundamental safeguards for purposes of program integrity"). Similarly, plaintiffs' arguments challenging the premium requirements merely expound on their fears that premiums will deter enrollment in KY HEALTH. Pls.' Mem. 30–33. These arguments presume what they set out to prove—that the KY HEALTH experiment will fail—and are outside of this Court's review.

In Count Seven, plaintiffs take issue with the Secretary's waiver to permit the Commonwealth to limit non-emergency medical transportation ("NEMT"). *See id.* at 39–41. But this waiver was based on the Secretary's evaluation of the Commonwealth's conclusion that the expansion population, unlike the traditional population, did not need or use NEMT. AR 5478. Plaintiffs' claims amount to nothing more than their disagreement with the Secretary's factual conclusions and predictive judgments concerning the potential efficacy of the program's incentives. *See, e.g.*, *id.* at 36 ("E]ven assuming that Medicaid enrollees do need help preparing for commercial insurance, the lockouts would not provide that preparation."); *id.* ("Nothing suggests that Kentucky has a particular problem with program integrity or that the lockouts would remedy such a problem."). Ascertainment by actual demonstration

whether these claims are true is itself a legitimate objective. *See Aguayo*, 473 F.2d at 1106.

*Results of Prior Demonstrations.* The approval of these incentives hardly represents a sea change in the Administration's position, as plaintiffs suggest. In its waiver application, the Commonwealth noted that "most of the features of Kentucky HEALTH" had been approved in other State demonstrations, AR 5433, 5437, and the results of the other demonstrations informed Kentucky's project design. For example, during the last Administration, CMS approved a provision for suspension of coverage for Indiana's demonstration known as HIP 2.0. Ex. F. That project permitted the State to impose disenrollment and a non-eligibility period for beneficiaries with income over the federal poverty level who fail to pay their premiums, as an incentive to promote program compliance. *See also* Ex. E, Montana Health and Economic Livelihood Partnership (HELP) Program (adopting provisions permitting disenrollment for failure to pay premiums for beneficiaries with incomes up to 150 percent of the federal poverty level through § 1315(a)(2) authority); Ex. H, Wisconsin Badger Care (adopting a three-month disenrollment period). Waivers of retroactive coverage, too, have been approved, across Administrations.[13] And Indiana's HIP 2.0 demonstration, among other State demonstrations, included a waiver of NEMT for the new expansion population. *See also* Ex. K, Healthy Michigan; Ex. P, Iowa Wellness Plan.

The Secretary reasonably concluded that these policies were worth testing and were likely to assist in promoting the objectives of the Medicaid program. The Court should decline plaintiffs' invitation to substitute their judgment—or the Court's—for that of the Secretary.

[13] *See* Indiana HIP 2.0 (Ex. F); Delaware Diamond State Health Plan (Ex. I); Montana Basic Medicaid for Able-Bodied Adults (Ex. E); Oklahoma SoonerCare (Ex. J); Healthy Michigan (Ex. K); Arkansas Safety Net Benefit Program (Ex. L); New Hampshire Health Protection Program Premium Assistance (Ex. M); Tennessee TennCare II (Ex. N); Oregon Health Plan (Ex. O).

### D. Each Challenged Element of the KY HEALTH Demonstration Is Consistent With the Secretary's Section 1115(a)(1) Waiver Authority.

Plaintiffs argue that the Secretary acted beyond his statutory authority by "waiv[ing] requirements *not* found in § 1396a" in approving KY HEALTH—specifically, requirements concerning premiums, NEMT, retroactive coverage, and cost-sharing for non-emergency use of hospital emergency departments. Pls.' Mem. 13. But the Secretary's determination that the waivers fall within his authority is correct, and at a minimum is entitled to *Chevron* deference.

#### 1. The Secretary's Waiver of Premium Requirements Is Consistent with His Authority to Waive "Any of the Requirements" of 42 U.S.C. § 1396a.

Section 1396a specifies numerous requirements with which State Medicaid plans must comply, including the conditions specified in 83 separate provisions of subsection (a). *See* 42 U.S.C. §§ 1396a(a)(1)–(83). As relevant here, subsection (a)(14) requires that a State plan "provide that *enrollment fees, premiums, or similar charges*, and deductions, cost sharing, or similar charges, may be imposed only as provided in section 1396o …." § 1396(a)(14) (emphasis added). Section 1396o, in turn, sets forth the requirements for the two categories of charges identified in § 1396a(a)(14)—that is, "enrollment fees, premiums, or similar charges," and "deductions, cost sharing, or similar charges." Section 1396o-1 describes certain exceptions to § 1396o.

Here, the Secretary exercised his authority to waive § 1396a(a)(14), "insofar as" that condition "incorporates" §§ 1396o or 1396o-1, "[t]o the extent necessary to enable Kentucky to require monthly premium payments …." AR 14. Plaintiffs contend that the Secretary's authorization of premium requirements is outside the scope of his authority. Pls.' Mem. 26–29. Plaintiffs concede, as they must, that the Secretary has the authority to waive § 1396a(a)(14), Pls.' Mem. 26, but argue that this authority does not extend to waiving the premium requirements of §§ 1396o and 1396o-1, *id.* at 26–29. But no plausible reading of the statutory text, context, or history supports, let alone compels, this conclusion.

To begin, the Secretary indisputably has authority to waive § 1396a(a)(14), which requires State

plans to comply with § 1396o.[14] Such a waiver necessarily means that a State plan need *not* comply with § 1396o—the authority to waive § 1396a(a)(14) would be meaningless if State plans were still required to comply with § 1396o despite the Secretary's waiver. By placing the requirement to comply with § 1396o in § 1396a(a)(14) and authorizing the Secretary to waive "any of the requirements of … 1396a," Congress clearly authorized the Secretary to waive compliance with § 1396o. Plaintiffs' interpretation would strip § 1396a(a)(14) from the scope of Section 1115's waiver authority.[15]

Moreover, contrary to plaintiffs' contention, § 1396o(f) *confirms* that the Secretary has authority to waive compliance with premium requirements in § 1396o by virtue of his authority to waive § 1396a(a)(14). Plaintiffs argue that the waiver provision in § 1396o(f) for cost-sharing charges would be superfluous "if the Secretary could use Section 1115 to waive the requirements in Section 1396o," and they contend that the inclusion of § 1396o(f) demonstrates Congress's intent to exclude any comparable authority to waive § 1396o's distinct premium requirements. Pls.' Mem. 27.

Both arguments fail for the same basic reason: they are based on the erroneous premise that § 1396o(f) contains a specific grant of authority to waive § 1396o's cost-sharing requirements. In fact, § 1396o(f) does not *grant* any waiver authority; it *limits* the Secretary's Section 1115 waiver authority with respect to cost-sharing charges, and in so doing *presumes* that Section 1115's waiver authority

[14] Plaintiffs acknowledge that courts have upheld the Secretary's authority to waive premium requirements of § 1396a(a)(14). Pls.' Mem. 28–29 (citing *Crane*, 417 F. Supp. at 538–40; *CWRO*, 348 F. Supp. 491. But plaintiffs attempt to distinguish those cases by pointing to the subsequent legislative enactments that added §§ 1396o and 1396o-1. These cases are still good law, however, and no court has held them to be superseded. Plaintiffs' reliance on dicta in *Pharmaceutical Research & Manufacturers of America v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001), is likewise misplaced. There, the court read 42 U.S.C. § 1396r-8 not to authorize the Secretary to approve a demonstration in which manufacturers would pay rebates for drugs purchased by non-Medicaid beneficiaries. The court did not address the distinct question, presented here, whether the Secretary can permit a state to impose premiums on certain beneficiaries through a waiver of § 1396a(a)(14).

[15] Plaintiffs contend that § 1396a(a)(14)'s use of the phrase "only as provided in 1396o" somehow shows that Congress intended to place all premiums outside the Secretary's Section 1115 authority. Pls.' Mem. 27. But this ignores that Congress authorized the Secretary to waive *any* of the provisions in § 1396a, including § 1396a(a)(14)'s "only as provided in" language.

extends to § 1396o. Section 1396o(f) does not say that the Secretary "may waive" § 1396o's requirements for cost-sharing charges. Instead, its language is prohibitory, providing that "no [such] charge may be imposed under any waiver authority … unless such waiver" complies with specified conditions. 42 U.S.C. § 1396o(f). This prohibitory language would be unnecessary if the Secretary's Section 1115 waiver authority did not extend to § 1396o in the first place, as plaintiffs contend.

Furthermore, § 1396o(f) does not limit the waiver authority with respect to State plan requirements for "enrollment fees, premiums, or similar charges"—which are the only charges at issue here. By its terms, § 1396o(f) only restricts the waiver authority with respect to the requirements for the *other* category of charges addressed in § 1396a(a)(14): "deductions, cost sharing, or similar charges." Thus, § 1396o(f) shows that (1) Congress recognized that the Secretary's Section 1115 waiver authority extends to § 1396o, and (2) Congress knew how to limit that authority but did not do so for § 1396o's *premium* requirements (as opposed to the cost-sharing requirements).

The Secretary's waiver authority also extends to § 1396o-1. Although, as plaintiffs note, § 1396a(a)(14) does not expressly reference § 1396o-1, there was no need for Congress to include such a reference because § 1396o-1 is simply an *exception* to § 1396o. *See* § 1396o-1(a)(1) ("Notwithstanding sections 1396*o* and 1396a(a)(10)(B) of this title … a State … may impose premiums and cost sharing …"). The Secretary's authority to waive compliance with § 1396o thus necessarily includes the authority to waive compliance with § 1396o-1. Any doubt on that score is dispelled by § 1396o-1(b)(6)(B), which provides that "[n]othing in this section shall be construed … as affecting the authority of the Secretary through waiver to modify limitations on premium and cost sharing under this section." Congress thus expressly provided in the text of § 1396o-1 itself that the Secretary has

authority "through waiver to modify limitations on premium and cost sharing under [§ 1396o-1]."[16]

Nor does the statutory or legislative history support plaintiffs' interpretation. Contrary to plaintiffs' telling, *see* Pls.' Mem. 28–29, §§ 1396o and 1396o-1 were not targeted at restricting the Secretary's waiver authority in any respect; rather, they were primarily intended to provide another way by which States can "exceed the normal limitations" on Medicaid cost-sharing. *See Newton-Nations*, 660 F.3d at 375. Indeed, the House Committee Report cited by plaintiffs shows that the 1982 amendments adding § 1396o were designed primarily to provide *greater* flexibility to the States to impose cost-sharing, in light of the increased State interest in doing so. H.R. Rep. 97-757, pt. 1, at 6 (1982) (noting that "a large number of States have sought" Section 1115 waivers to impose cost-sharing, and that the bill would "give[] States sufficient flexibility" to impose cost-sharing even in the absence of a Section 1115 waiver). And § 1396o-1, which provides exceptions to § 1396o, "further relaxes the normal cost-sharing restrictions." *Newton-Nations*, 660 F.3d at 375.

The Secretary reads §§ 1396a(a)(14), 1396o, and 1396o-1 together as part of a comprehensive, coherent, and consistent regulatory scheme that achieves Congress's purposes with respect to State flexibility to impose premiums while preserving the Secretary's authority to waive premium requirements. This reading is correct or, at the least, is a permissible one that merits *Chevron* deference. *See City of Arlington*, 569 U.S. at 296 n.4. At most, plaintiffs' alternative reading points to "internal tension" among different provisions in the Act that point "in divergent ways"—but in such a case, "*Chevron* dictates that a court defer . . . to the agency's expert judgment about which interpretation fits best with, and makes the most sense of, the statutory scheme." *Scialabba v. Cuellar de Osorio*, 134 S. Ct. 2191, 2203 (2014) (plurality); *accord id.* at 2219–20 & n.3 (Sotomayor, J., dissenting).

[16] Because the Secretary has authority to waive compliance with both § 1396o and § 1396o-1, there is no "absurd result" under the Secretary's interpretation. Pls.' Mem. 29. If anything, plaintiffs' worry about an "absurd result" further supports the Secretary's authority to waive compliance with § 1396o-1 despite the absence of an express reference to § 1396o-1 in § 1396a(a)(14).

**2. The Secretary Properly Construed Other § 1396a Requirements.**

Plaintiffs' statutory challenges to other individual waivers also fall short of the showing needed to overcome the deference owed to the Secretary's interpretations.

*Non-Emergency Use of the Emergency Room.* Count Four turns on plaintiffs' assertion that "deductions" from rewards account balances should be deemed "cost-sharing" charges subject to statutory cost-sharing limits. This argument is inconsistent with the definition of "cost-sharing," which refers to payments made as a condition for receiving particular services or benefits. *See* 42 C.F.R. §§ 447.51–447.54. The *My Rewards* account permits beneficiaries to "earn incentives" in the form of non-monetary credits to access demonstration-specific benefits funded through the Section 1115(a)(2) expenditure authority, or optional benefits that the state could have opted not to provide even if KY HEALTH were not approved, *see* AR 33. KY HEALTH does not impose a charge on beneficiaries to access those benefits, but specifies the terms on which the project itself will advance earned incentives to the beneficiaries. And the credits have no cash value; rather an arbitrary dollar value is assigned to the credits that beneficiaries may redeem to receive certain optional or demonstration-only benefits, *see* AR 33. Indeed, in a paragraph titled "No Actual Charges to Beneficiaries," the STCs cite the State's assurance that "at no time would a beneficiary be required to make a monetary payment to the state as a result of having a negative dollar balance in his or her My Rewards Account," AR 35. The Secretary's interpretation of what might constitute a "deduction" or "co-payment" within the meaning of the statute, as well as his interpretation of his own regulations, are entitled to deference. *See* AR 34 ("As the My Rewards Account deduction is not a copayment, the amount is not subject to the limitations in 42 C.F.R. § 447.54(b).").

*Waiver of Retroactive Coverage.* In Count Six, plaintiffs assert a puzzling challenge to the Secretary's waiver of the retroactive-coverage requirement. It is not clear how their assertion that the Secretary "lacks authority to waive retroactive coverage" can be squared with their admission that the

Secretary has authority to waive § 1396a(a)(34)'s retroactive-coverage requirement. *See* Pls.' Mem. 37. They appear to argue that the authority to waive this provision is at odds with other Medicaid requirements, which plaintiffs contend cannot be waived. This argument would nullify the Secretary's authority to waive § 1396a(a)(34), and Section 1115(a)(1)'s textual commitment of discretion to the Secretary to waive "any of the requirements" of § 1396a that *he* believes necessary means that it is not up to plaintiffs to say which provisions should or should not have been waived.[17] But even if there were "internal tension" because different provisions point "in divergent ways," as plaintiffs seem to contend, the Secretary's interpretation warrants deference. *See Scialabba*, 134 S. Ct. at 2203 (plurality).

## IV. THE CHALLENGE TO THE SMD LETTER IS NON-JUSTICIABLE AND OUTSIDE THE SCOPE OF REVIEW UNDER THE APA, AND FAILS ON ITS MERITS IN ANY EVENT.

In Count One, plaintiffs seek extraordinarily broad relief with respect to "practices" purportedly "authorized" in the SMD letter. This claim fails for multiple reasons. To begin, plaintiffs cannot show that the letter caused them any redressable injury-in-fact. Second, the letter is not a final agency action subject to APA review; rather, it merely announced CMS's policy position concerning community-engagement requirements, and sought to provide guidelines for States considering applying for approval of a demonstration project.[18] In all events, Count One fails on its merits.

To begin, Plaintiffs cannot show an injury that is fairly traceable to the letter. Their asserted injuries stem from CMS's approval of Kentucky's demonstration project, not the letter. *See Util. Air Regulatory Grp. v. EPA*, 320 F.3d 272, 278 (D.C. Cir. 2003). Nor would the relief they request—a declaration that the letter violated the APA—redress those asserted injuries, because they cannot show

[17] In any event, plaintiffs' argument is beside the point because the Secretary indisputably has authority to waive § 1396a(a)(10) to the extent it requires retroactive coverage, and the other provision they cite, § 1396d(a), is merely definitional and sets forth no obligation to provide retroactive coverage.

[18] Plaintiffs' request for broad injunctive relief preventing defendants from carrying out any conceivable version of the practices discussed in the letter is also unreviewable under the APA, which provides no relief for the "broad, programmatic" attack upon which plaintiffs' claim is based. *See Norton v. Southern Utah Wilderness All.*, 542 U.S. 55, 64 (2004).

that, in the absence of the letter, CMS would not have approved Kentucky's demonstration project. *See, e.g.*, *Nat'l Multi Hous. Council v. Jackson*, 539 F. Supp. 2d 425, 431–32 (D.D.C. 2008) (because the challenged guidance "by its own terms does not create any new obligations … the relief plaintiffs seek would not redress their claimed injury"). Plaintiffs thus lack standing to bring Count One.

Nor does Count One challenge any final agency action, as would be required under 5 U.S.C. § 704. A final agency action is one (1) that marks the "consummation of the agency's decisionmaking process" and (2) by which "rights or obligations have been determined, or from which "legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citation omitted). The D.C. Circuit also looks to factors such as whether the "agency had taken a definitive legal position concerning its statutory authority," whether "the case presented a purely legal question of statutory interpretation," and whether "the agency's letter imposed an immediate and significant practical burden" on the agency. *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011) (citation omitted). General statements of policy are, categorically, not final agency actions that are subject to review under the APA. *See Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). A general statement of policy is defined as "[a]n agency action that merely explains how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion or permitting discretion under some extant statute or rule …." *Id.* at 252.

The SMD letter does not mark either the "consummation" of the agency's decisionmaking process, nor is it a decision from which "legal consequences flow." Rather, as a general statement of policy, the letter merely (1) "announc[ed] a new policy" to "support state efforts to test incentives that make participating in … community engagement a requirement for continued Medicaid eligibility or coverage for certain adult Medicaid beneficiaries in demonstration projects authorized under section 1115 of the Social Security Act," and (2) "describe[d] considerations for states that may be interested in pursuing demonstration projects" that seek for "Medicaid beneficiaries to participate in work and

community engagement activities." AR 90. *See Nat'l Min. Ass'n*, 758 F.3d at 251.

Rather than "consummat[ing]" the decision-making process through the letter, CMS will evaluate a specific state's proposal before any changes may go into effect. As the letter notes, "[e]ach state is different," and "CMS will evaluate each demonstration project application on its own merits" and respond to the comments submitted during each demonstration project's required notice and comment period. AR 93. In this case, no final agency action was taken until Kentucky's demonstration plan was approved, and that action can be evaluated through plaintiffs' several claims attacking that decision. The D.C. Circuit's "long-standing practice in circumstances like this is to require the complaining party to challenge the specific implementation of the broader agency policy." *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 22 (D.C. Cir. 2006).

Nor does the letter impose any legal consequences on, or require any action of, the States, let alone on plaintiffs. Rather, the letter guides States that wish to prepare demonstration projects with community-engagement components. *See Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 732 (D.C. Cir. 2003) ("No legal consequences flow from the agency's conduct …, for there has been no order compelling [the regulated party] to do anything."). When "the practical effect of the agency action is not a certain change in the legal obligations of a party, the action is non-final for the purposes of judicial review." *Nat'l Ass'n of Home Builders v. Norton*, 415 F.3d 8, 15 (D.C. Cir. 2005).

Plaintiffs cite portions of the letter that purportedly set forth binding criteria. But the cited statements do not impose new legal obligations on States; rather, they simply remind States to comply with existing laws or requirements. *E.g.*, AR 95 ("States are required … to comply with all applicable federal civil rights laws …."); AR 97 ("States will be subject to other monitoring and reporting requirements, consistent with regulations ….").

The excerpts in which CMS states what it is looking for in a successful demonstration project

do not describe legal obligations. Rather, they describe the agency's policy views on the kinds of demonstration projects that may further the aims of Medicaid. *See* AR 94 ("Individuals enrolled in and compliant with a TANF or SNAP work requirement, as well as individuals exempt from [those] requirement[s], must automatically be considered to be complying with the Medicaid work requirements."); AR 94–95 ("States must also create exemptions for individuals determined by the state to be medically frail and should also exempt … any individuals with acute medical conditions … that would prevent them from complying with the requirements."). This statement does not, in any event, detract from the precatory nature of the letter as a whole. *Compare with Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (guidance document was final agency action where "[t]he entire Guidance, from beginning to end—except the last paragraph—reads like a ukase.").

Moreover, the letter did not bind the agency in its subsequent approval of Kentucky's demonstration project. *See Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1057 n.4 (D.C. Cir. 1987). First, CMS characterizes the letter as nonbinding guidance. AR 90. *See Nat'l Min. Ass'n*, 758 F.3d at 252. Second, CMS did not cite the letter as the source of legal authority for its approval of Kentucky's demonstration project, but rather permissibly referred back to its guidance in explaining the reasoning behind its policy decision to allow for States to submit proposed demonstration projects with community-engagement requirements.[19] *See id.* The Secretary's approvals of the Kentucky project, and of other States' projects, are supported "just as if the [SMD letter] had never been issued," because

[19] Plaintiffs' reliance on CMS's approval of Arkansas's and Indiana's demonstration projects is misplaced. In both cases, the approvals noted in passing that each State's demonstration project conformed with the guidance provided in the SMD letter before delving into pages of analysis on how each State's project was specifically likely to assist in promoting Medicaid's objectives, in accordance with Section 1115. *See* (Ex. Q, Letter from Seema Verma, Admin., Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health and Human Servs., to Cindy Gillespie, Dir., Ark. Dep't of Human Servs. (Mar. 5, 2018); Ex. R, Letter from Demetrios Kouzoukas, Dep. Admin., Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health and Human Servs., to Allison Taylor, Medicaid Dir., Ind. Family and Social Servs. Admin. (Feb. 1, 2018).

the agency specifically analyzes each state's demonstration project to determine whether approval under section 1115 is proper. *See Nat'l Mining Ass'n*, 758 F.3d at 253.

To be sure, it is possible for documents styled as letter guidance to amount to final agency action if they have independently binding and legally consequential effect. *See Barrick Goldstrike Mines Inc. v. Browner*, 215 F.3d 45, 48 (D.C. Cir. 2000). Here, however, "there has been no "'order compelling the regulated entity to do anything."' *Nat'l Min. Ass'n* , 758 F.3d at 253 (quoting *Indep. Equip. Dealers Ass'n v. EPA,* 372 F.3d 420, 428 (D.C. Cir. 2004)). "[T]he document itself would [not] be given any weight at all in [subsequent] proceedings." *Molycorp, Inc. v. EPA*, 197 F.3d 543, 546 (D.C. Cir. 1999), because the authority for the demonstration project flows from Section 1115, not the letter.

Even if the letter amounted to final agency action and plaintiffs' asserted injuries could be properly redressed by the relief they seek, Count One fails on the merits. First, for the same reasons that the letter was not final agency action, it was not a legislative rule, and did not need to go through notice and comment. "General statements of policy" are exempt from notice-and-comment unless another statute provides otherwise, 5 U.S.C. § 553(b)(3)(A), and no statute does so here. The letter "compels action by neither the recipient nor the agency" and thus cannot be a legislative rule. *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012). Indeed, CMS's actions would not bind a State unless and until the State submitted a proposed demonstration project, which *is* subject to certain public notice procedures, further demonstrating why the preceding letter announcing a policy shift is not subject to those procedures. *See* 42 C.F.R. §§ 431.408(a)(1), (3).

Second, the letter plainly survives arbitrary-and-capricious review. Contrary to plaintiffs' argument, Pls.' Mem. 43–44, the letter extensively explains why community-engagement provisions promote the Medicaid Act's purposes. Plaintiffs contend that CMS's "complete repudiation of its longstanding position" on community engagement shows that the agency did not engage in reasoned decisionmaking. Pls.' Mem. 45–46 (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502 (2009)). But

*Fox* held that a change in agency policy is not subject to "more searching review" than a policy that is adopted in the first instance. *Id.* at 515. Rather, it is generally enough for the agency to "display awareness that it *is* changing its position" and that "there are good reasons for the new policy." *Id.* The letter does both; it communicates up front that CMS's acceptance of State demonstration projects with community-engagement components is a "shift from prior agency policy regarding work and other community engagement as a condition of Medicaid eligibility or coverage," AR 92, and relies on multiple studies demonstrating a relationship between productive work and community engagement and positive health outcomes, AR 91.

An agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, and there are good reasons for it, and that the agency *believes* it to be better." *Fox*, 556 U.S. at 514 (emphasis in original); *see also Otsuka Pharm. Co. v. Price*, 869 F.3d 987, 1001 (D.C. Cir. 2017) ("Agencies . . . can change their interpretations provided that they acknowledge and explain the change and the new position is otherwise permissible."). Here, the letter describes the agency's policy view that it would be better to support demonstration projects that will help it determine whether community-engagement programs lead to better health outcomes, and provides reasoning to support this conclusion.[20] *See N. America's Bldg. Trades Unions v. OSHA*, 878 F.3d 271, 303 (D.C. Cir. 2017). CMS's reasoning is detailed and goes beyond what *Fox* requires. AR 92.

[20] Plaintiffs rely on *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117 (2016), for the proposition that CMS "failed to discharge [its] duty to explain why [it] deemed it necessary to overrule their previous position on work requirements." Pls.' Mem. 45 (quoting *id.* at 2126). But in *Encino*, "decades of industry reliance on the Department [of Labor]'s prior policy" and the fact that the agency "said almost nothing" about the "'good reasons for the new policy'" led the Court to find the agency's explanation for its new rule insufficient. *Encino*, 136 S. Ct. 2127 (quoting *Fox*, 556 U.S. at 515). Here, however, the ACA's creation of the Medicaid expansion population went into effect only in 2014, which means that any relevant reliance interests—and it is by no means clear that there are any such interests here—are much shorter-lived than those in *Encino*. More to the point, CMS explained the "good reasons for the new policy" in substantive detail. *See Fox*, 556 U.S. at 515.

Finally, it was not arbitrary for the letter to cite studies that predated past CMS decisions denying certain components of demonstration projects that sought to impose work requirements. *See Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1037–38 (D.C. Cir. 2012) (policy shift permissible where agency "did not rely on new facts, but rather on a reevaluation of which policy would be better in light of the facts …." because "'[a]n agency's view of what is in the public interest may change, either with or without a change in circumstances.'") (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 57 (1983)). Further, those past CMS decisions were issued very recently, in 2015 and 2016, and do not indicate a long-established agency finding that community-engagement programs could never further the aims of Medicaid. After all, the ACA's creation of the expansion population went into effect only in 2014, was only adopted by some States, and significantly changed the demographics of the Medicaid populations in those States. The possibility of demonstration projects involving the Medicaid expansion population, then, is new.

## V. THE TAKE CARE CLAUSE PROVIDES NO BASIS FOR RELIEF.

The Take Care Clause states that the President "shall take care that the laws be faithfully executed." U.S. Const. Art. II, § 3. By its terms, it applies to the President—who is not a party here—not to his subordinates. *Id.* And the Supreme Court has held that "the duty of the President in the exercise of the power to see that the laws are faithfully executed" is not judicially enforceable. *Mississippi v. Johnson*, 71 U.S. (4 Wall.) 475, 499 (1866). Of course, "[r]eview of the legality of Presidential action can ordinarily be obtained in a suit seeking to enjoin the officers who attempt to enforce the President's directive" through other mechanisms, including the APA, under which plaintiffs bring their other claims. *Franklin v. Massachusetts*, 505 U.S. 788, 828 (1992) (Scalia, J., concurring in the judgment). But the Take Care Clause provides no means for courts to review the actions of subordinate Executive officials. A court cannot direct the actions of subordinate officers on the basis of the Take Care Clause without exercising authority that the Clause commits to the

President himself rather than to courts. Count Nine, accordingly, should be dismissed.

## VI. PLAINTIFFS' REQUESTED RELIEF IS IMPROPER.

Plaintiffs seek to enjoin defendants from implementing both the policies announced in the SMD guidance and "the approval" of the KY HEALTH waiver application, Compl., Prayer for Relief ¶ 4, and they ask the Court to vacate both the letter and the approval. But it is black-letter law that, if the record does not support the agency's decision, "the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985). Even if the Court finds error in the approval of the demonstration project, it may not "devise a specific remedy for the Secretary to follow," but must instead remand to the agency. *Cty. of L.A. v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999). And under the two-part analysis required in the D.C. Circuit, any remand should be without vacatur.[21] Vacatur would be significantly disruptive: among other consequences, Kentucky has indicated that its Medicaid expansion population of over 428,000 individuals, *see* AR 5437, would face the prospect of having their coverage terminated. *See* AR 5 (Kentucky leaders have expressed the importance of the demonstration in preserving coverage); AR 5440; ECF No. 25-1, Gov. Matthew G. Bevin, Exec. Order (Jan. 12, 2018).

## CONCLUSION

For the foregoing reasons, the Court should dismiss Plaintiffs' Complaint, or, in the alternative, grant summary judgment to the federal defendants and deny plaintiffs' motion.

Dated: April 25, 2018

Respectfully submitted,

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[21] The court must evaluate (1) "how likely it is the [agency] will be able to justify its decision on remand; and (2) the disruptive consequences of vacatur." *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 197 (D.C. Cir. 2009) (citations omitted).

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