IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RONNIE MAURICE STEWART, et al., Plaintiffs, v. ALEX M. AZAR II, et al. Defendants.	Civil Action No. 1:18-cv-152 (JEB) (CORRECTED FILING)

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

INTRODUCTION

Kentucky's demonstration project is the culmination of a sixteen-month effort by the Commonwealth and the federal government to explore better ways to promote the health of Kentucky's poorest citizens. The project could not be more pressing for the Commonwealth. Kentucky residents are among the unhealthiest in the nation. And Kentucky is in the grips of a drug overdose epidemic—fueled by the opioid crisis—that costs more than a thousand lives every year. Through a time-limited demonstration project, KY HEALTH will test whether community engagement will help Kentuckians become healthier, whether replacing copayments with premiums will help them take greater control of their own healthcare decisions, and whether providing personal health care accounts will lead them to make more responsible health care decisions. In addition, through its substance-abuse component, KY HEALTH is substantially expanding the services available to combat drug overdose and addiction, including by covering residential treatment, methadone treatment for opioid dependence, and peer support.

Plaintiffs ask the Court to eliminate all of this, and return Kentucky to square one, on nothing more than misleading caricatures and political rhetoric. After spending nearly thirty pages assailing KY HEALTH for establishing a rigid "work requirement," plaintiffs finally acknowledge that KY HEALTH establishes a multi-faceted and flexible community engagement initiative. Plaintiffs also accuse the Secretary of seeking to "explode" the Affordable Care Act and the Medicaid expansion, and frame more than a year of careful analysis as an "assault on science." That political bombast fits neither the legal framework nor the record. The statute expressly authorizes the Secretary to waive the Medicaid requirements at issue, and the responsibility to determine whether more research on a given topic could be useful rests with the Secretary, not the plaintiffs.

In all events, plaintiffs lack standing to raise these challenges. Plaintiffs attack a straw man when they argue that pre-enforcement challenges are justiciable. The standing problem is not that

plaintiffs brought this case *too early*; it is that none of the plaintiffs is likely to be injured by the requirements. Plaintiffs' own declarations establish that some of them are currently complying with the community-engagement requirement and that many of them are likely to be exempt from the requirement. And plaintiffs' fears about losing access to coverage, to non-emergency medical transportation, and to use of the emergency room for non-emergencies are speculative. Plaintiffs fall far short of showing any injury that is certainly impending or even substantially likely to occur.

Even if plaintiffs had standing, judicial review would be unavailable. The statute grants discretion to the Secretary to decide whether a "demonstration project . . . is likely to assist in promoting the objectives of [Medicaid]," a decision that shall be made "in the judgment of the Secretary." That broad language forecloses judicial review or, at the least, requires an unusually deferential application of the arbitrary and capricious standard.

On the merits, plaintiffs present a mangled view of the objectives of the Medicaid Act. They insist that the appropriations provision sets forth the *only* "purpose" of the statute, even though the stated purpose explicitly applies only to the traditional Medicaid population (and not to the expansion population largely at issue here), and that provision itself expressly recognizes that Medicaid has other "purposes." The appropriations statute is informative but not exhaustive; it identifies *one* purpose of Medicaid but does not enumerate all of the "purposes of this subchapter." 42 U.S.C. § 1396-1. KY HEALTH is fully consistent both with the goal set forth in § 1396-1 and with those additional other purposes. Plaintiffs say that the government is arguing that the Secretary is "free to make [those other purposes] up," but that is another caricature. Medicaid's purposes can be discerned by examining the statutory text. For example, § 1396u-1(b)(3)(A) refutes plaintiffs' claim that "[e]ncouraging individuals to work . . . is manifestly *not* the goal of Medicaid." Pls.' Reply & Opp. 2, ECF No. 59 ("Pls.' Opp."). Under the express terms of that provision, States may terminate Medicaid eligibility for individuals who fail to meet the TANF work requirement. Thus, the text of the Medicaid Act itself makes crystal

clear that terminating coverage for individuals who are able but unwilling to work would *not* subvert the Act's purposes, as plaintiffs claim.

Without support in the statutory text, plaintiffs insist that Congress simply could not have intended to allow the Secretary to effect such a "restructuring" of the Medicaid program. But this case quite clearly does not implicate *King v. Burwell*'s analysis. *See* 135 S. Ct. 2480 (2015). Plaintiffs offer no persuasive reason to think that adopting a carefully crafted community-engagement initiative, with a flexible on-ramp back to coverage, is any more revolutionary than, for example, transforming Medicaid from fee-for-service to managed care. And even if KY HEALTH could be described as "transformative," Section 1115 authorizes the Secretary to waive "any" of the requirements of § 1396a, not just the ones that plaintiffs deem unimportant enough to waive. Plaintiffs' view would not only set courts on the unprincipled path of disregarding the statutory text to instead determine which provisions are "fundamental" and which are not, and which demonstration projects are "transformative" and which are not. It would also frustrate the purpose of Section 1115, which is to allow States to conduct experiments that can in turn inform national policy, including by providing the impetus for Congress to adapt the law to changing circumstances and incorporate best practices from the States. The Secretary's approval of KY HEALTH was a lawful exercise of his statutory authority and is fully consistent with both the letter and the spirit of Section 1115 and the Medicaid Act as a whole. It should be upheld.

ARGUMENT

I. PLAINTIFFS' CLAIMS CHALLENGING KY HEALTH ARE NON-JUSTICIABLE AND NON-REVIEWABLE.

A. Plaintiffs Fail to Show That They Have Standing to Challenge Kentucky's Demonstration.

Plaintiffs do not have standing to challenge KY HEALTH as a whole or its individual

components.[1] The federal defendants do not argue, as plaintiffs would have it, that it is impossible to challenge a program that has yet to take effect. *See* Pls.' Opp. 4. The point instead is that plaintiffs' asserted injuries depend on speculation as to future changes in their circumstances and the actions of Kentucky, which has latitude to (1) implement the various exemptions that CMS approved in the STCs, AR 17–81; and (2) decide in the first instance any administrative appeals from a decision to dis-enroll current recipients. *Cf. Amundson ex rel. Amundson v. Wis. Dep't of Health Servs.*, 721 F.3d 871, 873–74 (7th Cir. 2013). Indeed, the exemptions are designed to protect those most likely to be injured if KY HEALTH's new components applied to them.

Plaintiffs' citations, Pls.' Opp. 4–6, to *Village of Bensenville v. FAA*, 376 F.3d 1114 (D.C. Cir. 2004), and *Ass'n of Am. Physicians & Surgeons v. Sebelius*, 901 F. Supp. 2d 19 (D.D.C. 2012), *aff'd*, 746 F.3d 468 (D.C. Cir. 2014), simply establish the unexceptional proposition that standing may be based on a future injury that is "certainly impending," or imminent. *Vill. of Bensenville*, 376 F.3d at 1119. Here, however, plaintiffs do not demonstrate certainly impending future injuries from KY HEALTH, as explained in the federal defendants' opening brief and below.

Community-Engagement Initiative: Plaintiffs claim that "[w]hile it is possible that some plaintiffs may be able to prove that they qualify for an exemption, such possible changes are by no means certain, or even likely to occur." Pls.' Opp. 5–6 (citation omitted). But "changes" in plaintiffs' situations are not necessary, because each one has asserted facts strongly suggesting that he or she will be exempt or already in compliance. They assert, for example, that they have serious medical conditions, are primary caregivers of dependents, or are full-time students. *E.g.*, Bennett Decl. ¶ 8, ECF No. 33-7; Spears Decl. ¶ 9, ECF No 33-14; Penney Decl. ¶ 8, ECF No. 33-16.

[1] Plaintiffs assert that the federal defendants "concede" that plaintiffs "have standing to bring their APA claims challenging the Kentucky HEALTH waiver as a whole and their Take Care Clause claim." Pls.' Opp'n 3. The federal defendants do no such thing.

Plaintiffs miss the mark in asserting that they have "alleged facts indicating that it is substantially likely that they *may* be unable to meet" the community-engagement requirement. Pls.' Opp. 6 (emphasis added). That is not the test; plaintiffs must show a substantial likelihood that they *will* be injured. And plaintiffs' string citation proves the opposite point—that they are engaging in qualifying activities. *See* Penney Decl. ¶ 8 ("I am trying to find a job … ."); Radford Decl. ¶ 4–5, ECF No. 33-17 (engaging in caregiving services, volunteer work, and odd jobs); M. Woods Decl. ¶ 3, ECF No. 33-10 ("I own and operate … a service station for our repairs … ."); Bennett Del. ¶ 3 (working two part-time jobs and volunteering every week). Two plaintiffs also state that they suffer from medical conditions, which may medically exempt them from the community-engagement requirement altogether. *See* Penney Decl. ¶ 5–6; Bennett Decl. ¶ 6.

Certain plaintiffs state that they do not know if they will be able to work for 80 hours each month, focusing on the risk of failing to meet this requirement. *E.g.*, M. Woods Decl. ¶ 8. But they do not explain why they would not be able to engage in other qualifying activities when they are not working. In all events, as this Court has explained, "Plaintiffs … do not have standing based on risk alone, even if their fears are rational." *In re SAIC Backup Tape Litig.*, 45 F. Supp. 3d 14, 26 (D.D.C. 2014). "After all, an *increased risk* or *credible threat* of impending harm is plainly different from *certainly impending* harm, and certainly impending harm is what the Constitution and *Clapper* require." *Id.* at 28 (emphasis in original) (citing *Clapper v. Amnesty Int'l*, 568 U.S. 398 (2013)).[2]

"Lockouts" and waiver of retroactive coverage: Plaintiffs' fears of being locked out are speculative, for at least five reasons. First, a change in circumstance would have to "affect ongoing eligibility for Medicaid" before it would potentially result in a lockout. AR 2027. Second, "normal fluctuations in

[2] For similar reasons, plaintiffs fail to explain how they would have standing to challenge the premium requirements. But even if they had standing to do so, they could not leverage that standing to challenge the project as a whole, or the other components of KY HEALTH that do *not* injure them (like the community-engagement initiative). *See Davis v. FEC*, 554 U.S. 724, 734 (2008).

income are not considered a change in circumstances," including "[a] change in work hours which will not exceed 30 days … ." *Id.* Third, there are "various methods to report changes, including by phone, through a [Department for Community Based Services] office, or online … ." *Id.* Fourth, Kentucky will implement good-cause exemptions from the reporting requirements. AR 30–31. Fifth, each plaintiff has a right to go through an administrative appeals process before coverage would be terminated. *Id.* Injury from the waiver of retroactive coverage for beneficiaries who are dis-enrolled and then re-enrolled in Medicaid, meanwhile, is one step even further removed. *See Nw. Airlines, Inc. v. FAA*, 795 F.2d 195, 201 (D.C. Cir. 1986) ("The injury requirement will not be satisfied simply because a chain of events can be hypothesized in which the action challenged eventually leads to actual injury.").

Non-emergency use of the emergency department: Plaintiffs allege that they have used emergency rooms in the past, but this does not show injury-in-fact here for two reasons. First, the allegations "relate[] to past injury rather than imminent future injury that is sought to be enjoined." *Summers v. Earth Island Inst.*, 555 U.S. 488, 495 (2009). Second, plaintiffs fail to show that they are likely to receive emergency room treatment for a *non-emergency* despite the procedural safeguards in place. Defs.' Mem. 30, ECF No. 51-1 (explaining the various safeguards, including the hospital's obligation to inform plaintiffs of alternative settings for their medical care); *see also* AR 34–35.

Non-emergency medical transportation: Finally, plaintiffs cursorily assert that they are likely to be injured by this waiver. Such injury could occur at some uncertain point in the future only if a plaintiff without his or her own means of transportation (1) is not exempted from this waiver as medically frail, (2) must travel to seek non-emergency medical treatment, (3) does not have a relative or friend who can drive him or her, and (4) cannot access public or private transportation. "When considering any chain of allegations for standing purposes, we may reject as overly speculative those links which are predictions of future events (especially future actions to be taken by third parties)," as well as

predictions of future injury that are not normally susceptible of labelling as 'true' or 'false.'" *Arpaio v. Obama*, 797 F.3d 11, 21 (D.C. Cir. 2015) (citation omitted).

B. Section 1115(a) and Section 1115(a)(1) Each Sets Forth a Separate Determination That Is Committed to Agency Discretion By Law.

Plaintiffs claim that the Secretary's Section 1115 decision is reviewable, but they do not quote the statutory text, let alone come to grips with it. Section 1115 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), (a)(1) (emphasis added). There is no meaningful difference between that language and the statute at issue in *Webster v. Doe*, 486 U.S. 592 (1988), which allowed the termination of an employee whenever the Director "shall deem such termination necessary or advisable in the interests of the United States." *Id.* at 592. If that statute "foreclose[d] the application of any meaningful judicial standard of review," *id.* at 600, 603, so too does Section 1115(a).

Plaintiffs say that "[u]nlike the bald grant of discretion in *Webster*," Section 1115 "is pegged to time-limited experiments that promote objectives set out in the Medicaid Act." Pls.' Opp. 11–12. But neither Section 1115 nor the Medicaid Act expressly defines the relevant statutory objectives, let alone specifies the objectives that apply to the expansion population. Without such definitions, whether a project is "likely to assist in promoting the objectives" of the Act—as with whether an agency is "'likely to succeed' in fulfilling its statutory mandate," *Lincoln v. Vigil*, 113 S. Ct. 2024, 2032 (1993)—is a consideration that involves complicated matters of policy judgment that are not fit for judicial review.[3]

[3] Other sections of the Social Security Act underscore the exceptional breadth of the Section 1115(a)(1) waiver authority. *See Lincoln v. Vigil*, 113 S. Ct. 2024, 2032 n.4 (1993). Section 402(a) of the Child Health Care Act of 1967 authorizes the Secretary "to develop and engage in experiments and

To the extent that the Ninth Circuit reached a contrary conclusion in *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994), that decision is nonbinding and unpersuasive. As plaintiffs acknowledge, Pls.' Opp. 11, *Beno* turned on the premise that Section 1115 "allows waivers only for the period and extent necessary to implement experimental projects which are 'likely to assist in promoting objectives' of the AFDC program." But Section 1115(a)(1) does not grant the Secretary the limited authority to "allow[] waivers *only for the period and extent necessary* to implement experimental projects," *Beno*, 30 F.3d at 1067 (emphasis added). Rather, it provides that "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." § 1315(a)(1) (emphasis added). What is more, *Beno* turned on the assumption that the statutory "objectives are set forth with some specificity" in the AFDC statute, 30 F.3d at 1067, which is not the case here. Congress's decision not to exhaustively define Medicaid's objectives further confirms that it drew the Secretary's authority under Section 1115(a) "in such broad terms that in a given case there is no law to apply," S. Rep. No. 79-752, at 212 (1945), and supports the conclusion that courts "have no meaningful standard against which to judge the agency's exercise of discretion" under Section 1115(a). *See Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

In all events, Section 1115 contains *two* separate commitments of discretion that are relevant here: first, Section 1115(a) commits to the "judgment of the Secretary" whether a project is likely to promote statutory objectives, § 1315(a); and second, Section 1115(a)(1) commits discretion to the Secretary to grant waivers for the scope and duration "he finds necessary" to permit the State to carry

---

demonstration projects" for eleven specifically enumerated purposes. 42 U.S.C. § 1395b-1(a). The statute also states that "the Secretary may waive compliance with the requirements" of certain sections "insofar as such requirements relate to" certain specifically enumerated matters. *Id.* § 1395b-1(b). This language stands in stark contrast to the Section 1115's broad grant of subjective discretion. *See id.* § 1315(a)(1) ("the Secretary may waive compliance" with the relevant statutes "to the extent and for the period *he finds necessary*" (emphasis added)).

out its project, § 1315(a)(1). Even if the Court could review whether a project promotes Medicaid objectives, the statute still precludes review of any challenge to the scope or duration of each waiver. *Cf. Portland Adventist Med. Ctr. v. Thompson*, 399 F. 3d 1091, 1098 (9th Cir. 2005) (Section 1115(a)(1) "identifies these as matters left to the Secretary"). Indeed, Plaintiffs do not dispute that Section 1115(a)(1) contains a separate commitment to agency discretion.

Nor can plaintiffs reasonably dispute that any review should be "unusually deferential," given the subjective, predictive judgments contemplated by Section 1115. *See* Defs.' Mem. 14. Where a statute "draw[s] a … distinction between the objective existence of certain conditions and the Secretary's determination that such conditions are present," judicial deference is at its maximum. *Kreis v. Sec'y of Air Force*, 866 F.2d 1513, 1514 (D.C. Cir. 1989). 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.

II. THE SECRETARY ACTED WITHIN THE SCOPE OF HIS SECTION 1115 AUTHORITY.

A. The Secretary's Interpretations of the Scope of His Authority Under Section 1115 Are Owed *Chevron* Deference.

Even if the Secretary's determinations were reviewable, his interpretations of his authority under Section 1115 are entitled to *Chevron* deference. *See Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 844 (1984). "Congress knows how to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion." *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013). Congress spoke "in capacious terms" in Section 1115 by providing 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*." 42 U.S.C. § 1315(a)(1), (a)(2) (emphases added). Congress also specified that Medicaid "[p]rogrammatic oversight [is] vested in the Secretary."

Id. § 1396(14). In the analogous context of state plan amendments, the D.C. Circuit has held that the comprehensive nature of the Secretary's authority "to review and approve state Medicaid plans" evidences a congressional "intent that the Secretary's determinations, based on interpretation of the relevant statutory provisions, should have the force of law." *See Pharm. Research & Mfrs. Am. v. Thompson*, 362 F.3d 817,822 (D.C. Cir. 2004) ("*PhRMA*"). The same is true here.

Plaintiffs respond that this case warrants an exception to *Chevron* because it presents a question of "deep economic and political significance" and would "bring about an enormous and transformative expansion" in the agency's authority. Pls.' Opp. 12 (citing *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015), and *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427 (2014)). But this case is nothing like the "extraordinary . . . case" where "there may be reason to hesitate before concluding that Congress has intended . . . an implicit delegation." *King*, 135 S. Ct. at 2488–89.

In *King*, the Supreme Court concluded that Congress did not *implicitly* delegate to the IRS the authority to determine whether tax credits created under the ACA were available for participants in the federally run health insurance exchange. 135 S. Ct. at 2489. The Court reasoned that Congress could not have intended to delegate that authority, given that the IRS had "no expertise in crafting health insurance policy of this sort" and that the issue had "deep economic and political significance." *Id.* (citation and internal punctuation omitted).

Here, by contrast, Congress *explicitly* delegated to "the Secretary broad power to authorize projects which do not fit within the permissible statutory guidelines of the standard public assistance programs." *Crane v. Mathews*, 417 F. Supp. 532, 539 (N.D. Ga. 1976). The very point of the authority is 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. Unlike in *King*, moreover, the Secretary *does* have expertise in the fields of public health and health policy, including the specific

expertise to determine whether community-engagement requirements are likely to assist in promoting health and well-being. The Secretary has experience evaluating the impacts of employment and other activities on health and well-being,[4] testing similar requirements in demonstrations under other programs like AFDC, AR 4761, 4767, 4768, 5090–91, assessing Medicaid policies impacting access to covered services and addressing preventive, acute, and long-term care, *see, e.g.*, § 1396(b)(5)(A), (B), and designing and overseeing social-science research relevant to Medicaid demonstration programs.[5]

Plaintiffs' reliance on *Utility Air* is even more misplaced. There, the challenged interpretation of the Clean Air Act would have "be[en] inconsistent with—in fact, would [have] overthrow[n]—the Act's structure and design." *Utility Air*, 134 S. Ct. at 2442. Here, the Social Security Act expressly *permits* the Secretary to allow States to adopt projects that would otherwise violate the Act. In *Utility Air*, moreover, the claimed interpretation would have "severely undermine[d] what Congress sought to accomplish" by allowing the agency to exercise "an extravagant statutory power over the national economy while at the same time strenuously asserting that the authority claimed would render the statute unrecognizable to the Congress that designed it." *Id.* at 2443–44. Nothing remotely like that occurred here. Plaintiffs' rhetoric notwithstanding, the Secretary's approval of Kentucky's demonstration project does not "render the statute unrecognizable." On the contrary, it implements precisely the statute that Congress designed by allowing Kentucky to test an innovative and experimental program to improve its residents' health, consistent with both the express grant of authority to the Secretary in Section 1115 and the limitations Congress imposed on that authority.

---

[4] *See, e.g.*, AR 91 ("CMS, in accordance with principles supported by the Medicaid statute, has long assisted state efforts to promote work and community engagement and provide incentives to disabled beneficiaries to increase their sense of purpose, build a healthy lifestyle, and further the positive physical and mental health benefits associated with work. . . . Optional Medicaid programs . . . allow workers with disabilities to have higher earnings and maintain their Medicaid coverage.").

[5] *See, e.g.*, 1115 Demonstration Evaluations, www.medicaid.gov/medicaid/section-1115-demo/evaluation-reports/index.html.

Indeed, Plaintiffs' argument that the Secretary has impermissibly "transform[ed]" the Medicaid statute entirely ignores the statutory language. In plaintiffs' view, the Secretary may never waive the "eligibility criteria" in "Section 1396a(a)(10)(A)" as part of a demonstration project, because doing so supposedly "restructure[s] the statute Congress has enacted." Pls.' Opp. 20. That position cannot be squared with Section 1115, which allows the Secretary to "waive compliance with *any* of the requirements" in § 1396a. § 1315(a)(1) (emphasis added). Nor do plaintiffs explain why § 1396a(a)(10)(A) is any more "fundamental" than any other provision of § 1396a, or how this Court is supposed to parse § 1396a in any principled way to determine which statutory requirements can or cannot be waived. *See Brogan v. United States*, 522 U.S. 398, 408 (1998) ("Courts may not create their own limitations on legislation, no matter how alluring the policy arguments for doing so.").

Without an argument based on the text, plaintiffs struggle to shoehorn this case into *MCI Telcomms. Corp. v. Am. Tel. & Tel. Co.*, where the Court held that the statutory grant of authority to "modify any requirement" did not give an agency the "authority to make . . . basic and fundamental changes" to the statutory scheme. 512 U.S. 218, 225 (1994). In *MCI* the challengers *did* have a textual hook, because the statute used the narrower term "modify" instead of "waive." Plaintiffs suggest that *MCI* rested on the Court's observation that Congress would never have left rate filings to agency discretion. Pls.' Opp. at 20. But Section 1115 *does* leave the question of waiver—of "*any* of the requirements of section . . . 1396a"—to the "judgment of the Secretary." 42 U.S.C. § 1315(a)(1).

Plaintiffs' position also sweeps too broadly, rendering the Secretary's indisputable authority to waive the comparability requirements of § 1396a(a)(10)(B) meaningless; indeed, plaintiffs do not dispute that the Secretary may waive comparability requirements "[t]o enable the state to offer different state plan benefits for different Kentucky HEALTH program beneficiaries" as necessary to implement a demonstration. AR 14. And plaintiffs' contention that "[o]ther waivers differ in kind from KY HEALTH" boils down to plaintiffs' own view, unadorned by any citation, that the agency

may not "authoriz[e] a state to provide Medicaid coverage only to a subset of the eligible population." Pls.' Opp. 22. Although plaintiffs prefer a different policy choice, Section 1115 plainly authorizes the Secretary to waive compliance with the eligibility requirements for a demonstration project so long as he is satisfied that doing so is likely to assist in promoting the objectives of Medicaid.

B. The Secretary Properly Interpreted the Statutory Objectives in Applying the "Purpose" in § 1396-1 and Weighing the Commonwealth's Goal to Continue to Provide Coverage to the Expansion Population.

Plaintiffs' reply fails to advance any coherent theory of Medicaid's objectives. On the one hand, they argue that § 1396-1 sets forth the Medicaid Act's *only* purpose. Pls.' Opp. 17–19. On the other hand, they ignore the plain language of § 1396-1, which by its terms applies only to Medicaid's *traditional* population. And although plaintiffs say that the ACA did not change Medicaid's purposes, Pls.' Opp. 2, they argue that Medicaid is meant to extend medical assistance to all low-income individuals, without considering the differing characteristics and needs of the traditional Medicaid population and the ACA expansion population.

Aside from its logical defects, this reasoning ignores the Supreme Court's ruling in *National Federation of Independent Business v. Sebelius* ("*NFIB*"), 567 U.S. 519, 534 (2012), which made a state's extension of coverage to the expansion population optional. Instead of eliminating coverage, Kentucky has addressed fiscal and public health concerns so as to allow it to continue to provide coverage to this population, and enable the Commonwealth to focus more of its finite resources on the traditional populations. Its approach, if successful, can serve as a model for other state governments that wish to cover the expansion population. This is exactly the sort of result that Section 1115 demonstrations are intended to accomplish.

Plaintiffs respond that the phrase "as far as practicable under the conditions in such State" in § 1396-1 actually means "as far as reasonably possible," thereby forbidding any consideration of a state's budgetary constraints in furnishing medical assistance to low-income populations. Pls.' Opp.

17 (emphasis omitted). But Congress did not say that states are required to extend coverage to all low-income individuals "as far as reasonably possible." It instead appropriated funds "[f]or the purpose of enabling each State, as far as practicable under the conditions in such State," to furnish medical assistance, rehabilitation, and other services to the traditional populations identified in § 1396-1. Congress meant what it said when it provided that the "conditions in such State" and practicability necessarily inform how the State is to administer its Medicaid program.[6]

Moreover, § 1396-1 expressly recognizes that other statutory purposes exist, leaving an interpretive gap for the Secretary to fill. That is, Congress implicitly delegated authority to the Secretary to interpret the Act's objectives in light of the statute as a whole. Plaintiffs take issue with the conclusion that the Medicaid Act has purposes other than the one specifically outlined in the appropriations provision, asserting that the provision's reference to "the purposes of this subchapter" refers back to the earlier stated "purpose" of the appropriation. Pls.' Opp. 17–18. Plaintiffs' argument ignores that there are two sets of statutory "purposes" mentioned in § 1396-1. The first reference is to the "purpose" (singular) of "enabling each State" to furnish medical assistance, rehabilitation, and other services to the traditional Medicaid population. The second reference is to the sufficiency of the "sum" required to "carry out the purposes"—plural—"of this subchapter," that is, the Medicaid Act. Section 1396-1 thus makes clear that the statute has purposes in addition to enabling States to

[6] *See Wood v. Betlach*, 922 F. Supp. 2d 836, 849 (D. Ariz. 2013) ("Here, the cost-saving measures are identified as a means to continue providing medical benefits [to the demonstration population receiving those benefits pursuant to a Section 1115(a)(2) authority] that the state would otherwise have to cut due to budgetary concerns. This is relevant to whether the project as a whole furthers the goals of the Medicaid Act." (internal citations omitted)); *Cal. Welfare Rights Org. v. Richardson, ("CWRO")*, 348 F. Supp. 491, 497 (N.D. Cal. 1972) (considering the "serious fiscal problems over the years since the Medicaid program was initiated" and approving state experiment "to see how imposition of some cost-sharing will decrease utilization of the program benefits, and, consequently, costs"); *Crane*, 417 F. Supp. at 540 ("It is clear that the Medicaid program has important cost considerations. The incurring of excess costs with respect to one phase of the Medicaid program may very well mean a reduction of the program in another area. The public purse, both that of the state and even of the United States, is not absolutely unlimited.").

furnish medical assistance and services to the traditional Medicaid population. Those purposes can be discerned by examining the statute's provisions individually and as a whole. *See Rapanos v. United States*, 547 U.S. 715, 752 (2006) ("[N]o law pursues its purpose at all costs, and . . . the textual limitations upon a law's scope are no less a part of its 'purpose' than its substantive authorizations.").

Regardless, the Secretary's approval of KY HEALTH is consistent with the "purpose" stated in § 1396-1.[7] The federal defendants did not "dismiss[] Section 1396-1," Pls.' Opp. 17, as plaintiffs contend. Quite the opposite, we explained in detail why the approval of KY HEALTH is consistent with § 1396-1's stated purpose. Defs.' Mem. 20–25. Further, contrary to plaintiffs' characterization, the Secretary did not purport to rely *exclusively* on § 1396-1 to conclude that community engagement is appropriate for the expansion population.[8] It is true that, in approving KY HEALTH, the Secretary did not cite the hundreds of provisions of the Medicaid Act that collectively illustrate the Act's purposes. But he did not have to. *See Nat'l R.R. Passenger Corp. v. Bos. & Me. Corp.*, 503 U.S. 407, 420 (1992) (that agency's "interpretation" was implicit "does not mean that we may not defer to that interpretation"); *Sherley v. Sebelius*, 644 F.3d 388, 395 (D.C. Cir. 2011).

Plaintiffs claim that the Secretary is trying to "dramatically expand[]" his waiver authority, in contravention of Congress's supposed decision to impose "substantive limits" on the Secretary's

[7] Plaintiffs also challenge the Secretary's interpretation of the word "independence" in § 1396-1. Pls.' Opp. 19. Both the Second and Third Circuits interpreted nearly identical language in the pre-amended version of the AFDC statute as authorizing the Secretary to approve incentives for independence to increase self-support or self-care of welfare recipients. *See Aguayo v. Richardson*, 473 F.2d 1090, 1105–06 (2nd Cir. 1973); *C.K. v. N.J. Dep't of Health & Human Servs.*, 92 F.3d 171,184–85 (3rd Cir. 1996). *Compare* 42 U.S.C. § 1396-1, *with* 42 U.S.C. § 601 (1994) (AFDC appropriation provision) (calling for the furnishing of "financial assistance and rehabilitation and other services" for the purpose of "retain[ing] the capability for self-support and personal independence").

[8] In the SMD letter, the Secretary cited § 1396-1 in a footnote to support the independent and alternative rationale that "[s]uch programs may also, separately, be designed to help individuals and families rise out of poverty and attain independence, also in furtherance of Medicaid program objectives." AR 90. But the Secretary described the objectives of Medicaid as "promot[ing] better mental, physical, and emotional health" *without* tying those objectives to § 1396-1, AR 90.

waiver authority under the ACA. Not so. The ACA merely added procedural, not substantive limits on the Secretary's authority, Defs.' Mem. 7 (discussing § 1315(d)), and even when it did so, Congress recognized the waiver authority as broad enough to approve "State-wide comprehensive demonstration project[s]." 42 U.S.C. § 1315(e).

Finally, contrary to plaintiffs' assertion, federal defendants do not contend that the Secretary's discretion is "limitless." The statute itself specifies several important checks. First, the Secretary must define the extent and period when approving a project; the Secretary thus cannot approve a project of boundless scope or duration. *See* Defs.' Mem. 26. Second, the Secretary may approve only projects that, in his judgment, are likely to assist in promoting the objectives of the Medicaid Act. As discussed, the Secretary is not free to "make up" those objectives; they are ascertainable from the statutory text. Third, Section 1115(d)(3) instructs the Secretary to report, *to Congress*, all actions he takes with respect to state demonstration project applications. 42 U.S.C. § 1315(d)(3). Congress thus designed the statutory scheme to ensure that it (rather than the courts) could play an important role in policing the Secretary's Section 1115(a) decisions.[9]

C. The Community-Engagement Requirement Is Consistent with the Secretary's Section 1115 Authority and with the Design and Structure of the Medicaid Act.

Plaintiffs argue that the community-engagement initiative cannot be squared with Medicaid's purposes because the "Medicaid Act, by its plain terms, aims to provide medical assistance to those individuals who cannot afford it. Period." Pls.' Opp. 27. The statute's plain terms prove otherwise. When Congress replaced AFDC with TANF, it amended § 1396u of the Medicaid Act to give States

[9] Plaintiffs miss the mark in asserting that the federal government's position raises constitutional questions under the non-delegation doctrine. As the limits discussed above illustrate, the statute guides the Secretary's exercise of his discretion by specifying an "area" in which, and a "purpose" for which, he should act. *Detroit Int'l Bridge Co. v. Gov't of Canada*, 883 F.3d 895, 902–03 (D.C. Cir. 2018). That easily satisfies the "intelligible principle" requirement. That an intelligible principle exists, however, does not mean that a court should police it. *See id.*; *Nat'l Fed'n of Fed. Emps. v. United States*, 905 F.2d 400, 405 (D.C. Cir. 1990).

the "option to terminate medical assistance for failure to meet [the TANF] work requirement." 42 U.S.C. § 1396u-1(b)(3)(A). Under that section, when an individual receiving TANF benefits "has the cash assistance under [TANF] terminated … because of refusing to work, the State may terminate such individual's eligibility for medical assistance under [Medicaid]." *Id.* If the purpose of Medicaid were solely to provide medical assistance as plaintiffs claim, this provision would not exist. But it does exist, and it shows that permitting a State to terminate Medicaid coverage for individuals who are able but unwilling to work is consistent with the purposes of the Medicaid Act.

In any event, plaintiffs err in supposing that community-engagement requirements are no different in effect from "employment requirements" in other statutory programs. Pls.' Opp. 28 (conflating "employment status" with a requirement to "participate in 80 hours of non-voluntary activities per month"). Community-engagement requirements approved in the context of Medicaid differ in nature and in purpose from the "work requirements" that plaintiffs themselves recognize were adopted in programs "created to achieve different ends." Pls.' Opp. 29 (discussing AFDC). Thus, whether Congress "intend[ed] for Medicaid to be a work program," Pls.' Opp. 29, is not the pertinent question. Rather, the question under Section 1115 is whether the Secretary has the authority to approve community-engagement requirements on an experimental basis, if he finds that such requirements would likely assist in promoting the statutory objectives by, for example, encouraging activities that improve health and wellness. 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.

It is of course true that some able-bodied individuals who are capable of working or performing community service may choose not to do so and lose coverage as a result. But the Secretary reasonably weighed that result against the predicted health benefits that would accrue to the beneficiaries who *do* respond to the community-engagement initiative. Those health benefits, in turn, would make providing care less expensive, freeing resources that the Commonwealth could then

spend providing medical assistance to the traditional Medicaid population. *See* § 1396-1. The Secretary was careful, moreover, to ensure that any locked-out beneficiaries have a flexible on-ramp back to coverage. Such trade-offs arise with *any* demonstration project that changes Medicaid's eligibility rules or imposes penalties for failure to comply with certain requirements. The responsibility to weigh these issues rests with the Secretary, not with plaintiffs or the Court.

III. THE SECRETARY COMPLIED WITH ALL APA STANDARDS.

A. Plaintiffs' Claims Challenging the Sufficiency of the Secretary's Explanation Ignore the Relevant Legal Standards.

Plaintiffs raise several claims based on their erroneous assertion that the Secretary was required "to respond to significant comments and consider alternatives." Pls.' Opp. 24. They mistakenly conflate the APA's rulemaking standards with the distinct procedures that govern the public process for a Section 1115 demonstration application.[10] While the APA generally requires an agency to respond to significant comments received in a rulemaking, the Secretary has no duty to provide a written response to any comment when approving a demonstration project under Section 1115.

The APA requires an agency to respond to significant comments only when conducting a *rulemaking*, and Congress separately specified what the Secretary must do when approving a demonstration project. In 2010, Congress added a provision to Section 1115 directing the Secretary to "promulgate regulations relating to applications for … a demonstration project that provide for … a process for providing public notice and comment after the application is received by the Secretary, that is sufficient to ensure a meaningful level of public input." 42 U.S.C. § 1315(d)(2)(C). The procedural obligations imposed on the Secretary under that provision are less restrictive than what is

[10] Plaintiffs' suggestion that *Aguayo*, 473 F.2d 1090 and *CK*, 92 F.3d 171, conflict with Supreme Court and D.C. Circuit precedent, Pls.' Opp. 27 n.10, fails for the same reason. In any event, those cases expressly relied on Supreme Court precedent, and plaintiffs specify no way in which they conflict with D.C. Circuit precedent.

required under a general rulemaking under the APA, which requires the agency to permit members of the public to submit "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. 5 U.S.C. § 553(c). Significantly, Section 1115(d)(2) imposes no obligation on the Secretary to provide any statement concerning his decision on a Section 1115 demonstration application.

In accordance with Section 1115(d)(2)'s directive to "promulgate regulations," the Secretary issued a regulation establishing the administrative procedures for federal public notice and approval. 42 C.F.R. § 431.416. The regulation provides that "CMS will review and consider all comments received by the deadline, *but will not provide written responses to public comments*." § 431.416(d)(2) (emphasis added). That regulation—which implements express statutory authority delegated to the Secretary by Congress, and which plaintiffs do not challenge—is binding law. It supersedes any obligation the Secretary otherwise might have to respond to comments under the APA. And it means that the Secretary's approval of a demonstration project under Section 1115 cannot be set aside based on the Secretary's alleged failure to respond adequately to comments.

Here, CMS reviewed all the comments it received in evaluating whether KY HEALTH as a whole is likely to assist in promoting Medicaid objectives, and whether the waiver and expenditure authorities sought were needed to implement the demonstration. AR 7–8. CMS did more than was required when it issued a letter detailing its findings and conclusions, and summarizing the major objections in the public comments it received. Plaintiffs' attempt to impose additional procedural requirements under Section 1115 thus should be rejected. *Cf. Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524 (1978); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 246 (D.C. Cir. 2008).

Second, plaintiffs contend that "[t]here is nothing in the record to suggest that compelled work will promote health outcomes, particularly for the people who will lose health care coverage as a result of the requirements." Pls.' Opp. 27. But whether the project "will" achieve its objectives is not the

question. A demonstration project is a research experiment, and the results cannot be known in advance: "Given the lack of experience with work-related requirements in Medicaid, there is no solid information on what impacts they might have in the program." AR 4725. Indeed, several of the research articles considered by the Secretary expressly conclude that *more research is needed* to establish the very findings that plaintiffs insist are a prerequisite to a Section 1115 determination.[11] "It is one thing to set aside agency action under the [APA] because of failure to adduce empirical data that can readily be obtained. It is something else to insist upon obtaining the unobtainable." *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 519 (2009) (internal citation omitted); *see also Cablevision Sys. Corp. v. FCC*, 597 F.3d 1306, 1314 (D.C. Cir. 2010).

Finally, plaintiffs accuse the Secretary of failing to consider the impact of the demonstration on Medicaid beneficiaries. To the contrary, the record shows that, during its careful, 16-month-long evaluation, CMS requested multiple "guardrails" and "state assurances" to protect beneficiaries. *See* Defs.' Mem. 33–34 (citing AR 1536–41; AR 1754–56; AR 1777–79; AR 1794–95). Further, plaintiffs are wrong to argue that "[n]othing in the record" indicates that CMS considered how the project might reduce coverage and access to health services, Pls.' Opp. 27. *See* 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). While plaintiffs contend that the Secretary "disregarded" a "mountain of evidence in the record," Pls.' Opp. 26, plaintiffs in fact invite the Court to substitute its judgment for that of the Secretary on numerous

[11] *See, e.g.*, AR 4731 ("To answer [] questions about the purpose, expected outcomes, and practical implementation, and associated costs of work requirements, *additional information is needed*." (emphasis added)); AR 4731 ("[I]nformation on the effectiveness of current work requirement policies is outdated or insufficient … . *More study is needed* to determine whether and how work requirements have the intended effects and produce any negative unintended consequence." (emphasis added)); AR 5405 ("Better understanding of how volunteer work fosters personal well-being would offer a positive theoretical complement to stress theory … .").

predictive judgments falling squarely within the Secretary's technical and policy expertise. As explained below, there is no basis for the Court to do so.

B. The Record Amply Supports the Secretary's Determination That KY HEALTH Is "Likely to Assist in Promoting" Medicaid Objectives.

Section 1115(a) vests the Secretary with the broad discretion to make a determination that is "primarily of a judgmental or predictive nature," *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 813 (1978): whether a proposed demonstration project, in his judgment, is likely to assist in promoting Medicaid objectives. Here, the Secretary made a reasoned predictive judgment that KY HEALTH would be likely to promote Medicaid objectives, and his determination was not arbitrary or capricious. The Secretary rationally explained his conclusions in the approval letter, and the record amply supports those conclusions. *See also* Defs.' Mem. 31–37.

1. The Approval of Community-Engagement Requirements Entailed a Reasoned, Predictive Judgment Requiring the Secretary's Expertise.

Plaintiffs argue that the Secretary's decision to approve community-engagement requirements was based on "a selective and inaccurate reading of the relevant research." Pls.' Opp. 36. But as plaintiffs themselves have conceded, the record evidence both (1) "suggests a positive correlation between volunteering and health," Pls.' Mem. 24, ECF No. 33-1, and (2) "indicates that certain gainful employment and increased earnings can improve health," *id.* Nonetheless, Plaintiffs argue that the record shows merely a positive *correlation* between community-engagement and health. Pls.' Opp. 36–37. Even if evidence of "actual causation" were somehow required (and it is not, under Section 1115 or any principle of administrative law), the record is replete with evidence that employment and volunteering actually *lead to* positive health outcomes:

- "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 5121.

- "A good-paying job makes it easier for workers to live in healthier neighborhoods, provide quality education for their children, secure child care services, and buy more nutritious food—all of which affect health … . Higher earning also translates to a longer lifespan … ." AR 5072.

- "[E]mployment significantly reduces the risk of depression … ." AR 5052; *see also* AR 5098 ("volunteering leads to lower rates of depression for individuals 65 and older").

- "Several studies have . . . looked specifically at the effects of volunteering on those with chronic or serious illness. These studies have found that when these patients volunteer, they receive benefits beyond what can be achieved through medical care." AR 5102.

- Volunteering improves access to psychological and social resources, which are found to have a positive effect on health; increases physical and cognitive activity; and releases hormones that regulate stress and inflammation. AR 4825.

- "[V]olunteers had a 20 percent lower risk of death than their peers who did not volunteer. The study also found that volunteers had lower levels of depression, increased life satisfaction and enhanced well-being." AR 5045.

The record also supports the conclusion that requiring community engagement as a condition of continued eligibility, rather than making it voluntary, is more likely to lead to positive health outcomes. Defs.' Mem. 34–35 (citing AR 4–5 (explaining that voluntary referrals to employment services, which other states had already tested, had not been strong enough incentives to influence behavior)); *see also* AR 4836 (An "optional, nonenforceable work requirement on medical care provided to nonworking ABAWDs"—that is, able-bodied adults without dependents—is "empty symbolism that will accomplish nothing."). The Secretary reasonably relied on evidence supporting the conclusion that work and volunteering promote health. "[I]t is not [this Court's] job to referee battles among experts; [it] is only to evaluate the rationality of the agency's decision." *Mississippi v. EPA*, 744 F.3d 1334, 1348 (D.C. Cir. 2013).

Plaintiffs also fault the Secretary for supposedly failing to respond to commentators' concerns that individuals who fail to satisfy the community-engagement requirements will lose health coverage. Pls.' Opp. 37. Even assuming that the Secretary was required to do so (which he is not), *see supra* Part III(A), the Secretary directly addressed those concerns. Suspended beneficiaries can reactivate their

enrollment by completing 80 hours of community engagement in a given month or by completing a health literacy or financial literacy course. AR 2–3. Only if they fail to do so by the redetermination date will enrollment be terminated, but that too only if the beneficiary fails to show good cause for the failure to meet the requirements. Defs.' Mem. 30–31. In addition, the Secretary ensured "important protections for vulnerable individuals," AR 8, including exemptions that are tailored to address many of the potential barriers to compliance cited by commentators. *Cf.* AR 4725.

Finally, plaintiffs argue that the Secretary ignored "uncontroverted evidence from SNAP and TANF demonstrating" that many individuals will lose coverage, and that Kentucky "expects at least 95,000 low-income individuals to lose Medicaid coverage." Pls.' Opp. 38. But the Commonwealth never posited that 95,000 individuals would lose coverage for failing to meet the community-engagement requirement; rather, it predicted that the demonstration would help a large number of individuals transition to employer-sponsored or commercial coverage. In any event, evidence in the record suggests that while "[t]he experiences with TANF and SNAP work requirements offer some useful insights, [] the populations served by TANF and SNAP differ from each other and from the populations served by Medicaid …." AR 4731. It was thus entirely reasonable for the Secretary to "allow states to test the implementation of community engagement requirements in Medicaid," AR 9. Plaintiffs may not agree with these conclusions, but nothing required the Secretary to give dispositive weight to their views.

2. The Secretary Considered the Relevant Factors and Rationally Explained His Approval of KY HEALTH's Other Components.

The record similarly supports the Secretary's decision to approve the other challenged components of KY HEALTH as a permissible exercise of his predictive judgment.

Ensuring continuity of care. The Secretary determined that the combination of a premium requirement, a non-eligibility period for certain beneficiaries who do not comply with requirements, and other components not challenged here had the potential to "empower individuals to improve

their health and well-being." AR 7. If successful, the project would "increase individual engagement in health care decisions[] and prepare individuals who transition to commercial health insurance coverage to be successful in this transition." *Id.* Contrary to plaintiffs' contention, facilitating a smooth transition to commercial coverage helps ensure continuity of care—which is particularly important for members of the expansion population, whose Medicaid eligibility may fluctuate with their income—and thus promotes the objectives of the Medicaid Act.

At the same time, KY HEALTH ensured that "vulnerable individuals like people with disabilities and pregnant women continue to receive medical assistance" by: exempting "certain vulnerable populations, such as pregnant women and individuals who are medically frail," from the premium requirements and non-eligibility periods; allowing "temporary good cause exemptions" for those who fail to meet the requirements; and providing an "on-ramp" for individuals to quickly regain eligibility. AR 7. Thus, the Secretary's decision balanced the empowering aspects of the project against the needs of vulnerable populations and "articulated a rational connection between the facts found and the choice made." *Kisser v. Cisneros*, 14 F.3d 615, 619 (D.C. Cir. 1994) (citation omitted).

Plaintiffs argue that the Secretary failed to respond to public comments about the potential negative impact of the premium requirement. They dismiss the exemptions and the "on-ramp" protections by arguing that Kentucky included those features in its original plan. Pls.' Opp. 41; *see also* AR 5466–67. But CMS added a flexible good cause exemption to the premium requirement, a significant guardrail that is not limited to the blanket exemptions specifically listed. *See* AR 37; AR 1540. CMS also required Kentucky to (1) "[c]onduct outreach and education to beneficiaries to ensure that they understand . . . how premium payments should be made," AR 36–37; (2) "monitor that beneficiaries do not incur household cost sharing and premiums that, combined, exceed [five] percent of the aggregate household income," AR 36; and (3) "[p]rovide beneficiaries written notice of specific activities that would qualify them for early re-enrollment during a non-eligibility period" and "assure

these activities are available during a range of times and through a variety of means (e.g., online, in person) at no cost to the beneficiary." AR 37, 1538–40. Further, CMS made the on-ramp more accessible to those who do not pay their premiums and do not receive an exemption, facilitating a quicker return to coverage. *See* AR 31.

Strengthening beneficiary engagement in personal health care. The Secretary approved KY HEALTH's beneficiary accounts, in conjunction with "redetermination and reporting requirements" and the waiver of retroactive eligibility, to "strengthen beneficiary engagement in their personal health care plan and provide an incentive structure to support responsible consumer decision-making." AR 5–6. The Secretary relied on "[p]rior evaluations of demonstration projects with beneficiary engagement components," which suggest, in the Secretary's predictive judgment, that these components may "have a positive impact on beneficiary behavior." AR 5. Thus, the Secretary allowed Kentucky to test whether a waiver of retroactive eligibility "encourages beneficiaries to obtain and maintain health coverage, even when healthy," AR 6, and whether redetermination and reporting requirements "encourage[] individuals to maintain compliance with longstanding beneficiary responsibilities." *Id.* The Secretary engaged with public comments on the reporting requirements by limiting the noneligibility period to "only where the unreported change in circumstances would have resulted in loss of eligibility for Medicaid," and he noted that individuals will have access to the "on-ramp" to quickly return to eligibility. AR 9. The Secretary's approval of these components is thus rationally connected to evidence from prior demonstration projects, responsive to public concerns, and tailored in scope to mitigate harsh effects.[12] *See Kisser*, 14 F.3d at 619.

[12] Plaintiffs accuse the Secretary of failing to explain a shift in policy when he approved strengthened redetermination requirements, pointing to the agency's 2016 rejection of a similar proposal by Indiana. Pls.' Opp. 44. But the Secretary explained this shift, noting that he now "believes that this policy should be evaluated and is likely to support the objectives of Medicaid to the extent that it prepares individual for a smooth transition to commercial health insurance coverage and ensures that resources are preserved for individuals who meet eligibility requirements," AR 7. *See Nat'l Ass'n of Home Builders*,

Further, there are meaningful differences between Indiana's 2016 proposal and what the Secretary approved here, and the Secretary addressed the substance of the agency's prior concerns about the challenges that low-income individuals face in completing the redetermination procedures. AR 239. To mitigate "language access issues, as well as frequent moves and other difficulties obtaining their mail," AR 239, the Kentucky plan provides, in accordance with 42 C.F.R. § 436.916(a)(3)(iii), an extra 90 days for individuals to submit their redetermination paperwork, AR 27. The plan further ensures that Kentucky would "[p]rovide beneficiary education and outreach that supports compliance with redetermination requirements." AR 29. To prevent low-income individuals from being locked out of coverage due to "disabling conditions … or … homelessness," AR 239–40, the Secretary included blanket good cause exemptions for beneficiaries with disabilities who lacked "reasonable modifications" to complete their paperwork and for beneficiaries who were "evicted from home or experienced homelessness during the redetermination reporting period." AR 28–29. And KY HEALTH's medically frail and good-cause exemptions, *see* AR 28, address any concerns that an individual may be prevented from completing the redetermination process due to an "acute health event," AR 240.

Plaintiffs next posit that the Secretary's waiver of retroactive eligibility will reduce continuity of coverage. Pls.' Opp. 45–46. But the Secretary predicted that the waiver of retroactive eligibility would "strengthen beneficiary engagement in their personal health care plan." AR 5; *cf.* AR 5066 ("Engaged people make better health care decisions. Better health care decisions result in better health."). KY HEALTH's medically frail and good-cause exemptions for failure to complete the community engagement, redetermination, reporting, and premium requirements, meanwhile, mitigate

682 F.3d at 1038 (agency need only provide a "reasoned explanation of its action" that displays "awareness that it *is* changing position," in reevaluating a policy).

the risk of sick beneficiaries being subject to a gap in their coverage due to the retroactive eligibility waiver. *See* AR 27–31, 35–38.

Non-emergency medical transportation. Finally, the Secretary approved the waiver of non-emergency medical transportation ("NEMT") for the expansion population to offer "a commercial health insurance market experience."[13] AR 5525. Plaintiffs argue that the waiver "will reduce access to medically necessary services." Pls.' Opp. 47. But the waiver for the expansion population does not apply to "children, pregnant woman, medically frail individuals, and any individuals eligible for Medicaid prior to the passage of the Affordable Care Act." AR 5477–78. Further, Kentucky indicated that the service was used by a small proportion of the more than 400,000 individuals in the expansion population (and that there were few public comments about this component). *Id.*

The Secretary "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43. His determination that KY HEALTH is likely to assist in promoting Medicaid objectives was proper.

IV. THE SECRETARY PROPERLY EXERCISED HIS SECTION 1115(a)(1) WAIVER AUTHORITY.

Plaintiffs assert that the Secretary exceeded his statutory authority to "waive compliance with any of the requirements of" § 1396a by (1) approving the community-engagement requirement, Pls.' Opp. 27–31; (2) approving the program's premiums, *id.* at 31–34; and (3) permitting Kentucky to deduct rewards from the *MyRewards* accounts of beneficiaries who use hospital emergency departments for non-emergencies, *id.* at 34–36. The Secretary reasonably interpreted Section 1115 to permit these waivers; his reading, at a minimum, is owed *Chevron* deference. The community-

[13] The Secretary also separately waived NEMT for methadone treatment services to permit Kentucky to provide methadone treatment benefits without excessively increasing costs. *See* AR 32. Plaintiffs do not specifically contest this waiver. *See* Compl. ¶¶ 143–46.

engagement waivers are addressed in Part III(C) above. Here, we discuss the two other claims.

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

The Secretary correctly—and, at a minimum, reasonably—concluded that Section 1115(a) permitted him to waive § 1396a(a)(14), "insofar as" that condition "incorporates" §§ 1396o or 1396o-1. AR 14. Section 1115(a) expressly authorizes the Secretary to waive "any" of § 1396a's requirements, and § 1396a(a)(14) requires, in relevant part, that a State plan "provide that enrollment fees, premiums, or similar charges … may be imposed only as provided in section 1396o." By virtue of his authority to waive § 1396a(a)(14), the Secretary has authority to waive compliance with the premium requirements in § 1396o and § 1396o-1. As we showed, this conclusion is compelled by the statute's text and structure. Defs.' Mem. 38–41.

In response, plaintiffs have remarkably little to say about the statute's text and structure. They fail to explain how their theory can be squared with Congress's placement of the requirement to comply with § 1396o in § 1396a. Their only response is that this "ensured that Section 1396a remained an exhaustive list of all required state plan elements." Pls.' Opp. 32 n.11. But it also ensured that the requirement to comply with § 1396o, like the other required state plan elements, remained subject to the Secretary's authority to waive "any of the requirements of section … 1396a." Had Congress intended to carve out § 1396a(a)(14) from the Secretary's waiver authority, it would have said so.

Plaintiffs also ignore our showing that § 1396o(f), far from refuting the Secretary's authority to waive § 1396o's premium requirements, expressly confirms it. Defs.' Mem. 39–40. Plaintiffs persist in baldly asserting that § 1396o(f) "allows the Secretary to waive the limits on cost sharing, but not the limits on premiums." Pls.' Opp. 33. But as we showed, § 1396o(f) does not *provide* the Secretary any waiver authority. Rather, it *recognizes* that the Secretary has authority under Section 1115 to waive § 1396o's requirements and *restricts* the exercise of that authority with respect to § 1396o's cost-sharing

requirements but *not* its premium requirements. Plaintiffs have no response to this dispositive point.

Nor do plaintiffs' have any persuasive response to the plain text of § 1396o-1(b)(6)(B), which expressly recognizes "the authority of the Secretary through waiver to modify the limitations on premiums and cost sharing under [§ 1396o-1]." Plaintiffs relegate this provision to a footnote, asserting "*this argument* assumes that the Secretary had the authority to waive Section 1396o-1(b)(1)(A)'s restrictions in the first place." Pls.' Opp. 34 n.13 (emphasis added). This is nonsense. Section 1396o-1(b)(6)(B) shows that *Congress* assumed the Secretary has authority to waive compliance with § 1396o-1. Congress would not have provided that "nothing in this section shall be construed" to affect "the authority" to waive § 1396o-1's limitations if the Secretary did not have that authority in the first place. This too decisively refutes plaintiffs' view of the Secretary's waiver authority.

Unable to answer the statute's text and structure, plaintiffs rely principally on their telling of the statutory and legislative history. Pls.' Opp. 31. Plaintiffs concede that their cited history concerned cost-sharing, not premiums, so it is unclear what relevance it has here. *See id.* ("the cases Congress was responding to [in enacting § 1396o] only concerned cost sharing"); *id.* at 32 (the "legislative history only mentions cost sharing and not premiums"). But to the extent it is relevant at all, it too undermines plaintiffs' theory. Plaintiffs quote a committee report stating that "this bill gives the States sufficient flexibility in this regard to make further exercise of the Secretary's demonstration authority unnecessary." *Id.* (quoting H.R. Rep. No. 97-757, pt. 1, at 6 (1982)). But this snippet of legislative history at most shows that Congress anticipated that the Secretary would not so frequently need to use his waiver authority to approve cost-sharing. It obviously does not show that Congress *eliminated* that authority, because as plaintiffs concede—and § 1396o(f) makes plain—the Secretary retains the authority to waive § 1396o's cost-sharing requirements, subject to the limitations set forth in § 1396o(f). And Congress's *limitation* of the Secretary's authority to waive *cost-sharing* requirements in no way shows that Congress *eliminated* the Secretary's authority to waive *premium* requirements.

Finally, there is no merit to the new theory plaintiffs advance in their reply: that Congress, over "decades," has "consistently confirmed that the flexibilities available to states with respect to premiums and cost sharing must come from Congress, not a federal agency." Pls.' Opp. 32. This is a non sequitur; that Congress amended the Medicaid Act to afford states *greater flexibilities* to impose cost-sharing and premiums under §§ 1396o and 1396o-1 in no way compels the inference that Congress intended to eliminate the Secretary's authority to *waive* cost-sharing and premium requirements for demonstration projects. In fact, this new theory is flatly contradicted by the text of Section 1115 itself. Section 1115(d)(1), which Congress added in the ACA, provides certain new procedural requirements for the Secretary's consideration of any Section 1115(a) demonstration projects "that would result in an impact on eligibility, *enrollment*, benefits, *cost-sharing*, or financing with respect to a State program" under the Medicaid Act. 42 U.S.C. § 1315(d)(1) (emphasis added). That is, as recently as the passage of the ACA, Congress recognized that the Secretary's Section 1115(a) waiver authority extends to demonstrations seeking to impose enrollment-related charges like premiums, or cost-sharing charges. Plaintiffs' argument that Congress intended "to isolate" premiums and cost-sharing from the Secretary's waiver authority cannot be squared with Section 1115(d)(1), any more than it can be squared with the rest of the statute's text and structure.

B. The Deduction of Virtual-Dollar Credits from a Rewards Account Is Not "Heightened Cost Sharing" Under Any Statutory or Regulatory Definition.

"Cost-sharing" refers to payments made *by the beneficiary* as a condition for receiving particular services or benefits. *See* 42 C.F.R. §§ 447.51–447.54. Plaintiffs concede that beneficiaries pay no "actual money" for non-emergency use of the emergency room and that no "actual money" is deducted from beneficiaries' *MyRewards* accounts. Pls.' Opp. 35. Nonetheless, they argue that the program's deductions of virtual-dollar *MyRewards* credits for non-emergency use of the ER "function as" financial charges and thus should be subject to cost-sharing limits. Pls.' Opp. 34–36. This makes little sense, as plaintiffs do not dispute that the Commonwealth assigns *arbitrary* dollar values to the

credits, which can be redeemed only for *optional or demonstration-only* benefits. Defs.' Mem. 42 (citing AR 33). Thus, even if plaintiffs were correct that *MyRewards* credits have financial importance for beneficiaries, Pls.' Opp. 35, the demonstration *program* provides the thing of financial value (*i.e.*, the virtual-dollar credits) *to beneficiaries*—not the other way around—to access other optional services and benefits that the Commonwealth could have opted not to provide. Because virtual deductions for non-emergency use of the emergency room from an account created by the program itself are not the same, in practice or effect, as a financial payment by a beneficiary for that service, the Secretary acted reasonably in concluding that the cost-sharing limits cited by plaintiffs do not apply. *See* AR 33–34.

V. 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.

A. Plaintiffs Lack Standing to Challenge the SMD Letter.

Plaintiffs lack standing to challenge the SMD letter, because their asserted injuries are not traceable to that letter and would not be redressed if it were set aside. Plaintiffs have "introduced no evidence into the record—as [they] must at summary judgment—establishing that[,] if [the Court] were to vacate the Guidance," HHS would have to withdraw its approval of KY HEALTH. *Scenic Am., Inc. v. U.S. Dep't of Transp.*, 836 F.3d 42, 51 (D.C. Cir. 2016), *cert. denied*, 138 S. Ct. 2 (2017). That is because the SMD letter "is 'merely an announcement to the public of the policy which the agency hopes to implement in future rulemakings or adjudications,' and does not injure [plaintiffs] in any imminent or redressable manner." *Util. Air Regulatory Grp. v. EPA*, 320 F.3d 272, 278 (D.C. Cir. 2003) (quoting *Pac. Gas & Elec. Co. v. Fed. Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974)).

Plaintiffs assert that their "injuries flow" from the SMD letter, Pls.' Opp. 10, but that is incorrect. Plaintiffs' asserted injuries are entirely independent of the SMD letter: If that letter existed but the letter approving Kentucky's project did not, plaintiffs would have no injury; and if the approval letter existed but the SMD letter did not, their asserted injuries would be precisely the same. Any

injuries plaintiffs might suffer are thus traceable to the approval letter, not the SMD letter.

Likewise, plaintiffs cannot establish redressability. If the Court were to set aside the SMD letter but not the approval letter, the judgment would do nothing to redress plaintiffs' asserted injuries. Plaintiffs cite *Scenic American, Inc. v. United States Department of Transportation*, 983 F. Supp. 2d 170, 181 (D.D.C. 2013), for the proposition that "redressability is satisfied where vacating guidance would prevent the plaintiff from having to challenge the same guidance in reference to future agency decisions." Pls.' Opp. 10. But the D.C. Circuit reversed this holding in *Scenic American*, 836 F.3d at 51, and plaintiffs cannot establish redressability for their asserted injuries by invoking a hypothetical future injury from a hypothetical future demonstration project.[14]

B. The SMD Letter Is Not Final Agency Action, Let Alone a Legislative Rule.

Nor do plaintiffs respond to our showing that the SMD letter is not final agency action. Rather, they cursorily quote *Ark Initiative v. Tidwell*, 64 F. Supp. 3d 81, 96 (D.D.C. 2014), *aff'd*, 816 F.3d 119 (D.C. Cir. 2016), for the proposition that "such 'as applied' challenges are appropriate means by which a party may challenge a broad agency policy document." *Id.* at 96. Presumably, they mean to suggest that they are challenging the SMD letter as applied to CMS's approval of KY HEALTH. *Arkansas Initiative*, however, examined whether the plaintiffs had standing to raise their claim, not whether the underlying "policy document"—there, a regulation—constituted final agency action under the APA. 64 F. Supp. 3d at 96.

Further, *Ohio Forestry Association, Inc. v. Sierra Club*, 523 U.S. 726, 734 (1998), the decision on which *Arkansas Initiative* relied, specifically states that any as-applied challenge may include a challenge

[14] Nor does *Ark. Initiative v. Tidwell*, 64 F. Supp. 3d 81, 96 (D.D.C. 2014), *aff'd*, 816 F.3d 119 (D.C. Cir. 2016), help plaintiffs. There, the court permitted the plaintiff to challenge a "regulation—and have it invalidated as unlawful—in the context of a challenge to one of the [regulation's] specific applications." *Id.* Here, however, plaintiffs challenge a policy letter that has no legal effect and, thus, unlike the regulation in *Tidwell*, its rescission would work no change in the law.

to the lawfulness of the underlying policy "if (but only if)" the policy document "then matters," in other words, if the policy document "plays a causal role with respect to the . . . harm" asserted. As explained earlier, the SMD letter had no legal effect, CMS's approval of KY HEALTH did not turn on the SMD letter, and plaintiffs cannot show that the SMD letter caused their asserted injuries. Thus, they cannot challenge the letter even in the context of a challenge to KY HEALTH.

Nor does the letter qualify as a legislative rule. *See* Pls.' Opp. 50. Far from creating a binding rule, the letter announces CMS's support for demonstration projects with community-engagement components, stating that "a spectrum of additional work incentives, including those discussed in this letter," could further the aims of Medicaid, that "applications will be reviewed on a case by case basis," and that CMS "will evaluate each demonstration project application on its own merits." AR 91–93. This is a textbook example of non-final guidance in the form of "statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 666 (D.C. Cir. 1978) (internal citation omitted). Nor does the letter bind the agency. Nowhere does the letter state that certain projects will certainly be approved, and CMS remains free to approve or reject demonstration projects that propose work requirements on a case-by-case basis. *See* AR 90–99. *See also Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 253 (D.C. Cir. 2014) (no binding effect where "States and permit applicants may ignore the Final Guidance without suffering any legal penalties or disabilities, and permit applicants ultimately may be able to obtain permits even if they do not meet the recommendations" in the guidance) (internal citations omitted).

Finally, even if the letter could be deemed final agency action, it was not arbitrary or capricious. It offered a "reasoned explanation" for the agency's policy shift, which is all the law requires. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009). Plaintiffs also set forth a laundry list of steps the agency did not take, Pls.' Opp. 49, but those steps are not required by law. Plaintiffs blithely

state that "the Letter's citation to a handful of studies does not make up for this deficiency," *id.*, without explaining *why* the letter's reliance on multiple scientific studies that support further exploration of the link between community engagement and positive health outcomes was in any way improper. The agency's "reevaluation" of its policy, as supported by these scientific studies, "is well within [its] discretion." *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d at 1038.

VI. THE TAKE CARE CLAUSE PROVIDES NO BASIS FOR RELIEF.

Nothing in the Take Care Clause authorizes a court to manage how federal officers implement the law or carry out Presidential directives, if those officers' actions are otherwise lawful, as they are here for all the reasons discussed above. Both *Printz v. United States*, 521 U.S. 898, 922 (1997), and *Utility Air Regulatory Group v. EPA*, 134 S. Ct. 2427, 2446 (2014), stand for the unremarkable proposition that the President at times discharges his Take Care Clause duties by instructing his subordinates as to how they should perform their statutory responsibilities. Neither case, however, supports the notion that the Clause creates a cause of action against federal officers, or that such a cause of action would add anything to the remedies that plaintiffs already have against federal officers.

VII. PLAINTIFFS' REQUESTED RELIEF IS IMPROPER.

If the Court finds any error in the Secretary's approval of the demonstration project, the proper remedy is remand without vacatur. As plaintiffs acknowledge, this Court evaluates two factors in deciding whether to vacate agency action: (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) (internal citation omitted). Although the precise analysis of the first factor would depend on which part of the Secretary's decision is found to be infirm, most of the alleged errors could easily be cured on remand by providing further explanation. And vacatur would be highly disruptive for Kentucky residents, including those Medicaid beneficiaries in the Commonwealth who critically need the project's new programs for the treatment of substance use

disorders. AR 5432. Given the scope of the opioid epidemic, this program is vitally important to the Commonwealth. That consideration, and the possibility that Kentucky would seek to terminate its Medicaid expansion absent the project, weigh heavily against vacatur. *See Wood v. Betlach*, 922 F. Supp. 2d 836, 851 (D. Ariz. 2013) ("Vacating the entire demonstration project would, of course, deny Plaintiffs and the class the very health benefits they claim to require.").

If the Court were to vacate any part of the approval order, it should set aside only those "findings … and conclusions found to be" arbitrary and capricious or contrary to law. 5 U.S.C. § 706(2). If the Court concluded that the project as a whole is not likely to assist in promoting the objectives of the Medicaid Act, the Court should attempt to preserve as much of the project as possible by vacating the approval order only to the extent necessary to sever the offending provision or provisions. In addition, the Court can invalidate a particular provision only if a plaintiff has standing to challenge that provision. *See Davis v. FEC*, 554 U.S. 724, 734 (2008). If, for example, the Court concluded that plaintiffs have standing to challenge only the premiums, the relief would be limited to invalidating only that component of KY HEALTH.[15]

CONCLUSION

For the reasons set forth above and in the federal defendants' opening brief, the Court should dismiss plaintiffs' Complaint, or, in the alternative, grant summary judgment to the federal defendants and deny plaintiffs' motion.

Dated: May 24, 2018

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General

ETHAN P. DAVIS
Deputy Assistant Attorney General

[15] In the event that the Court concludes that the approval contained any error, federal defendants respectfully request the opportunity to submit supplemental briefing as to what remedy would be appropriate to address any such error.

JOEL McELVAIN
Assistant Branch Director
Federal Programs Branch

/s/ Deepthy Kishore
DEEPTHY KISHORE
VINITA ANDRAPALLIYAL
Trial Attorneys
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue, N.W.
Washington, D.C. 20530
(202) 616–4448 (telephone)
deepthy.c.kishore@usdoj.gov

Counsel for the Federal Defendants