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)

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Legislative and Executive Material

Other Authorities

INTRODUCTION

The Secretary of Health & Human Services' (the "Secretary") recent approval of Kentucky HEALTH as a component of KY HEALTH directly and comprehensively addresses the concerns raised by this Court in its prior opinion. The Secretary has now expressly described how the demonstration will "in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid." *Stewart v. Azar*, 313 F. Supp. 3d 237, 243 (D.D.C. 2018). Specifically, Kentucky HEALTH allows the Commonwealth to experiment with ways to stretch limited Medicaid resources and thereby maximize the coverage it provides to its citizens through the broader KY HEALTH project. The demonstration is also justified because the Secretary concluded it is likely to improve the health of coverage recipients, which likewise furthers the objectives of Medicaid because healthier people utilize less medical services, thus preserving resources for those who need them most.

Plaintiffs' contrary arguments misunderstand relevant precedent, the record in this case, and the nature of a demonstration project. *First*, plaintiffs attempt to limit the Supreme Court's and D.C. Circuit's decisions recognizing that fiscal sustainability is an objective of Medicaid. But there is no meaningful basis for distinguishing those decisions, and their reasoning controls here. *Second*, plaintiffs wrongly argue that, despite the Supreme Court's ruling in *NFIB* and the consistent position of HHS concerning the effect of that decision, a State does *not* have the option of terminating coverage for the Medicaid expansion population. That is incorrect. *NFIB* invalidated the ACA-enacting Congress's attempt to mandate Medicaid expansion by decoupling federal funding for the Medicaid expansion from federal funding for the rest of a State's Medicaid program. Thus, as HHS has consistently told states like Kentucky since 2012, *NFIB* freed States to decide whether or not to expand Medicaid—or later rescind an expansion if they changed their minds—without their expansion decisions affecting the rest of their Medicaid funding. *Third*, plaintiffs assert the Secretary has not adequately considered the effects of the demonstration on coverage, even though the Secretary has expressly described how

the project is expected to promote coverage for beneficiaries. Plaintiffs' argument is premised on the assumption that a demonstration cannot result in any beneficiary ever losing coverage, even if just temporarily—a position fundamentally at odds with this Court's recognition that "demonstration projects [] might adversely affect Medicaid enrollment or reduce healthcare coverage." *Stewart*, 313 F. Supp. 3d at 272. Indeed, "the point of the [Section 1115] waivers is to give states flexibility in running their Medicaid programs, and experimental projects may . . . adversely affect healthcare access." *Id.*

Plaintiffs' other record-based arguments are equally meritless. The Secretary made a reasoned, predictive judgment that Kentucky HEALTH as a component of KY HEALTH is likely to promote Medicaid objectives, and that determination was not arbitrary or capricious. Plaintiffs predict that the demonstration will fail, but that is no reason to invalidate an experiment that, even if it fails, is still likely to provide data that is useful to policymakers. Plaintiffs ask this Court to substitute its judgment for that of the Secretary, to ignore the flexible and experimental nature of demonstration projects as set forth in 42 U.S.C. § 1315, and to prioritize plaintiffs' policy preferences. This Court should decline.

ARGUMENT

I. THE SECRETARY REASONABLY DETERMINED THAT THE DEMONSTRATION IS LIKELY TO ASSIST IN PROMOTING THE OBJECTIVES OF THE MEDICAID PROGRAM.

A. The Secretary's assessment is committed to agency discretion by law or, at a minimum, should be accorded great deference.

As explained in the federal defendants' opening brief, in Section 1115 Congress used language that committed to agency discretion the Secretary's judgment about whether a particular demonstration project is likely to assist in promoting the objectives of Medicaid. *See* Defs.' Mem. 14, ECF No. 107. Even if that judgment were reviewable, however, the Secretary's discretionary determinations are, at a minimum, entitled to the utmost deference. 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 1508, 1513 (D.C. Cir. 1989); *see also Stewart v. Azar*, 313 F. Supp. 3d 237, 243 (D.D.C. 2018) ("[T]he Secretary is afforded significant deference in his approval of pilot projects.").

Plaintiffs disagree and, indeed, argue that the Secretary's judgment is not even entitled to deference under *Chevron v. NRDC*, 467 U.S. 837 (1984), 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.' Reply 2, ECF No. 119 (citing *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015) and *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014)). But this Court has already given the Secretary deference in interpreting the objectives of the Medicaid statute in accordance with the *Chevron* doctrine. *See Stewart*, 313 F. Supp. 3d at 260, 270. Moreover, this case is about a time-limited demonstration project testing new approaches to Medicaid; this experimental project is not a "transformative" expansion of the Secretary's authority and is certainly not 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.

King is simply inapposite. There, 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 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). Congress conferred that authority precisely to ensure federal requirements do 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. Further, unlike the IRS in *King*, the Secretary *does* have expertise in health policy, including the specific expertise to determine whether various demonstration features are likely to help States furnish medical assistance to their citizens and to assist in promoting health and well-being.

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." *Util. Air*, 134 S. Ct. at 2442. Here, the Social Security Act *expressly permits* the Secretary to allow States to experiment with 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 2443–2444. Nothing remotely like that occurred here. Plaintiffs' rhetoric notwithstanding, the Secretary's approval of Kentucky HEALTH as a component of KY HEALTH does not "render the statute unrecognizable." On the contrary, it does precisely what the statute contemplates—authorize the Commonwealth to conduct an experimental demonstration that will test the hypothesis that the challenged requirements will ensure the overall fiscal sustainability of Kentucky's Medicaid program so the state can continue to provide medical assistance and will also improve the health of its residents. Allowing that demonstration is well within the express grant of authority to the Secretary in Section 1115.

B. Kentucky HEALTH is likely to assist in promoting Medicaid's core objective of furnishing medical assistance.

On remand, the Secretary was charged with considering whether Kentucky HEALTH would "help the state furnish medical assistance to its citizens"—in other words, would it "help or hurt [the] state[] in funding medical services for the needy?" *Stewart*, 313 F. Supp. 3d at 243, 262 (citation omitted). As explained in defendants' opening brief, *see* Defs.' Mem. 14–21, the Secretary has

considered that exact question and explained why the various components of Kentucky HEALTH are likely to "improve[]the sustainability of the safety net," and "allow[] the state to provide services to Medicaid beneficiaries that it could not otherwise provide." AR 6726. As just one example, the community engagement requirement is expected to help able-bodied adults transition from Medicaid to financial independence and potentially to other forms of health coverage, including the subsidized coverage that is available through the Exchanges. *Id* at 6733. The requirement will thus help "ensure the long-term fiscal sustainability of the [Medicaid] program, and ensure that the health care safety net is available to those Kentucky residents who need it most." *Id.* at 6726.

Plaintiffs disagree, arguing that no Medicaid purpose can be served by a demonstration project designed to stretch limited state resources by helping able-bodied adults transition out of Medicaid. They flatly deny that fiscal sustainability is a "legitimate objective under Section 1115," Pls.' Reply 9, and seek to conflate a purpose to preserve the safety net for those who need it with a purpose to save money for its own sake. *See id.* ("if the purpose of [a Section 1115] waiver application [i]s to save money, the application cannot meet the standards of Section 1115").

Plaintiffs are wrong on each count. Decisions of both the Supreme Court and the D.C. Circuit recognize that Medicaid eligibility is fluid, and that the long-term objectives of the program are obviously served by reducing the need for borderline populations to receive Medicaid. For example, the state Medicaid programs at issue in *PhRMA v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004), and *PhRMA v. Walsh*, 538 U.S. 644 (2003), imposed burdens on Medicaid recipients (prior authorization for certain drugs) in order to induce drug manufacturers to provide benefits to persons who were not Medicaid-eligible (reduced drug prices). The plaintiffs there argued that those provisions were not in "the best interests of Medicaid recipients" because they burdened Medicaid recipients in order to benefit others. *Thompson*, 362 F.3d at 824 (quoting 42 U.S.C. § 1396a(a)(19)). The D.C. Circuit disagreed, accepting the Secretary's conclusion that such provisions "will further the goals and

objectives of the Medicaid program." *Id.* at 825 (quoting a September 2002 HHS Letter to State Medicaid Directors). "Specifically, the Secretary concluded that 'by making prescription drugs accessible to [borderline] populations,' it is 'reasonable to conclude that these populations . . . will maintain or improve their health status and *be less likely to become Medicaid eligible*.'" *Id.* (quoting the approval letter) (emphasis added). "Conversely, in the Secretary's view, the failure to implement" the provision for these populations could "lead to a decline in their health status and resources that will *result in Medicaid eligibility or increased Medicaid expenses*." *Id.* (quoting same) (emphasis added). Such "[i]ncreased Medicaid enrollments and expenditures for newly qualified Medicaid recipients will strain already scarce Medicaid resources in a time of State budgetary shortfalls." *Id.* (quoting same).

The D.C. Circuit held that "[t]he Secretary's conclusion that a prior authorization program that serves Medicaid goals in this way can be consistent with Medicaid recipients' best interests, as required by section 1396a(a)(19), is reasonable on its face." *Id.* The court explained that "[i]f the prior authorization program prevents borderline populations in Non-Medicaid programs from being displaced into a state's Medicaid program, more resources will be available for existing Medicaid beneficiaries." *Id.* The court also noted that "[s]ix Justices in *Walsh* acknowledged that such an effect can be in the best interests of Medicaid beneficiaries." *Id.* (describing the plurality and concurring opinions in *Walsh*). More generally, *Walsh* reaffirmed the point that the Supreme Court had recognized decades earlier in *N.Y. State Dept. of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973): the objectives of a welfare program are served by measures that "attempt to promote self-reliance and civic responsibility, to assure that limited state welfare funds be spent on behalf of those genuinely incapacitated and most in need." *Walsh*, 538 U.S. at 666-67 (discussing *Dublino*).

These decisions foreclose plaintiffs' assertion that fiscal sustainability is not "a legitimate objective under Section 1115." Pls.' Reply 9. The decisions were not about "saving money" in the abstract, *id.*, but were making the basic point that states are entitled to—indeed, they often must—

conserve "scarce Medicaid resources" to preserve the benefits of Medicaid for those who need it most. *Thompson*, 362 F.3d at 825. The fisc is not infinite and helping borderline Medicaid recipients become self-sustaining enough to afford private healthcare is obviously in the long-term interest of the program and its recipients. *See also 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 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." (citations omitted)); *Crane v. Mathews*, 417 F. Supp. 532, 540 (N.D. Ga. 1976). ("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.").

Plaintiffs note that *Walsh* was a preemption challenge, *see id.*, but its reasoning, relied on in *Thompson*, applies equally to the Section 1115 project at issue here. In *Thompson*, 362 F.3d at 825, the D.C. Circuit upheld the Secretary's conclusion that the challenged provision would "further the goals and objectives of the Medicaid program"—language which parallels the language of Section 1115. *See* 42 U.S.C. § 1315(a) (authorizing the Secretary to approve a demonstration project that, in the judgment of the Secretary, "is likely to assist in promoting the objectives" of Medicaid). The fact that *Thompson* and *Walsh* did not involve demonstration projects makes no difference to the question here—whether the Secretary's approval furthers the objectives of Medicaid. And plaintiffs' assertion that no deference is owed to the Secretary's understanding of the Medicaid statute's objectives, *see* Pls.' Reply 2, is foreclosed by *Thompson*'s contrary holding, *see* 362 F.3d at 822, 825.

The Secretary's consideration of fiscal sustainability as an objective of Medicaid is also properly viewed in the context of Kentucky's prerogative to end the adult eligibility expansion entirely. As of September 2018, more than 454,000 individuals in Kentucky received Medicaid coverage through its ACA expansion. AR 6720. Although Congress intended to make coverage of this group mandatory

when it enacted the ACA, the Supreme Court held in *NFIB* that Congress could not condition coverage of the adult expansion population on the State's preexisting Medicaid funding. The Supreme Court thus ruled that the Secretary "cannot . . . withdraw existing Medicaid funds for failure to comply with the requirements set out in the expansion." *NFIB v. Sebelius*, 567 U.S. 519, 585 (2012). In accordance with that decision's decoupling of federal funds for expansion from federal funds for Medicaid generally, CMS assured States in 2012 that they would have "flexibility to start *or stop* the expansion." Centers for Medicare & Medicaid Services (CMS), *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* (2012 CMS Guidance) at 11 (2012) (emphasis added);[1] *see also id.* at 12 ("A state may choose whether and when to expand, and, if a state covers the expansion group, it may decide later to drop the coverage."); Letter to Arkansas Governor Mike Beebe, ECF No. 107-1 (same).

Plaintiffs insist that *NFIB* "established only whether requiring coverage of the expansion population *without a state's opt-in* was coercive," and that, once a state has chosen to expand, the state cannot reverse the expansion without placing all of its Medicaid funding at risk. Pls.' Reply 11. But that conclusion ignores the reasoning of *NFIB* and CMS's longstanding interpretation of that decision. *NFIB* held that the expansion constitutes a new program altogether—"a shift in kind, not merely degree." 567 U.S. at 583. Thus, forcing a state to maintain the expansion under threat of a wholesale loss of Medicaid funding is not analogous to "requiring" coverage of traditional categories such as "pregnant women and children," Pls.' Reply 11, and is just as coercive as forcing a state to accept the expansion in the first place. CMS's explicit assurances to States in 2012, which were made to encourage States to participate in the expansion, are entitled to deference. Contrary to plaintiffs' assertion, the "bargain" presented to States was that if they chose to cover the expansion population, they could later eliminate that coverage without risking the rest of their Medicaid funding. *Id.*

[1] Available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/exchanges-faqs-12-10-2012.pdf (last visited March 1, 2019).

Nor are plaintiffs correct that under defendants' reasoning "any proposed project that cuts spending" would be permissible under Section 1115, "so long as the state continued to cover some populations and/or services." Pls.' Reply 12. Under the plain terms of Section 1115, the Secretary must determine that a demonstration has a "research or experimental goal." *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994). Moreover, the Secretary must determine that the project is likely to advance the objectives of the Medicaid program. Here, the project plainly has a research purpose, *see* Section I.E., *infra*, and although plaintiffs assert that some individuals could lose coverage as a result of the project, their asserted coverage figures are "likely dwarfed by the 454,000 newly eligible adults who stand to lose coverage if Kentucky elects to terminate the non-mandatory ACA expansion." AR 6732.

Plaintiffs' attempts to distinguish *Spry v. Thompson* fare no better. 487 F.3d 1272 (9th Cir. 2007); Pls.' Reply 13–14. Kentucky's new adult population is receiving coverage only because the State has voluntarily chosen to provide it and is thus similar to the adult population receiving coverage under the pre-ACA Oregon demonstration project in *Spry*. There, the Ninth Circuit explained that people in a demonstration-only population were not "made worse off" by the challenged requirements because, "without the demonstration project, they would not be eligible for Medicaid at all." *Id.* at 1276. Contrary to plaintiffs' arguments, Pls.' Reply 13–14, the circumstances here are similar: the members of Kentucky's new adult group are not "made worse off" by the challenged requirements because without Kentucky's voluntary expansion—an expansion it has said it will discontinue if it cannot implement the challenged requirements—those adults "would not be eligible for Medicaid at all."

Finally, it makes no difference whether the Commonwealth is "'actually at risk' of financial collapse," nor does Kentucky need to show that ending coverage of the adult expansion population "would be the best remedy for any budget woes." Pls.' Reply 14 (quoting *Stewart*, 313 F. Supp. 3d at 270–71). *NFIB* and the assurances CMS provided to Kentucky before the State expanded Medicaid are categorical; they make clear that Kentucky has the authority to eliminate coverage of the new adult

group without putting the entirety of its Medicaid funding at risk, and, again, the State has made clear it will do just that in the event that Kentucky HEALTH is not implemented. *See* Gov. Matthew G. Bevin, Exec. Order 2018-040 (Jan. 12, 2018), ECF No. 25-1.

C. The Secretary concluded that Kentucky HEALTH is likely to assist in improving beneficiary health, another important goal of the Medicaid program.

As the Secretary explained in his recent approval, Kentucky HEALTH is also designed to "improve the health of Medicaid beneficiaries." AR 6723. The Secretary emphasized the validity of this goal, sensibly noting that furnishing medical assistance to individuals who cannot afford necessary medical services has "little intrinsic value" if that assistance does not "advance[e] the health and wellness of the individual[s] receiving" it. AR 6719. Plaintiffs respond that "the Secretary cannot avoid the express language of Section 1396-1 by simply proclaiming that Kentucky HEALTH may improve health outcomes," Pls.' Reply 15, but that is not what the Secretary did. To the contrary, the Secretary explained that improving health makes beneficiaries "less costly for Kentucky to care for, thus further advancing the objectives of the Medicaid program by helping Kentucky stretch its limited Medicaid resources." AR 6726. Accordingly, by focusing on beneficiary health, the Secretary described how Kentucky HEALTH in fact *promotes* the goal of furnishing medical assistance.[2]

D. The community-engagement requirement is neither a "benefits cut" nor a "work requirement."

Plaintiffs also mischaracterize the terms of the community-engagement requirement. Plaintiffs repeatedly liken the community-engagement requirement to the demonstration project that was at issue in *Beno*, 30 F.3d 1057, but the two projects have nothing relevant in common. The California demonstration project in *Beno* imposed an across-the-board reduction in AFDC benefits, with the aim of giving recipients an incentive to look for work. *See id.* at 1060–61. By its terms, the project was a

[2] For the reasons explained in defendants opening brief, Defs.' Mem. 40–41, the Secretary's conclusion that Kentucky HEALTH is likely to promote health and financial independence was also rational. *See also* Defs.' Reply 17–20, *Gresham v. Azar*, 18-cv-01900-JEB (D.D.C.), ECF No. 52.

benefits cut: California simply reduced AFDC spending to 11% below 1992 levels. *See id.* at 1062–63. In that context, the Ninth Circuit declared that a "simple benefits cut, which might save money, but has no research or experimental goal," does not satisfy the requirement that a demonstration project "test out new ideas and ways of dealing with the problems of public welfare recipients." *Id.* at 1069.

That reasoning does not apply to the community-engagement requirement here. First, while the demonstration project in *Beno* imposed an across-the-board reduction in state spending on AFDC, the community-engagement requirement does not, by its terms, cut benefits for anyone. Everyone who complies with the requirement will continue to receive the same Medicaid benefits they would receive absent the demonstration, and numerous safeguards are in place to make compliance achievable for all who are subject to the community engagement requirement. Second, while the California demonstration project purported to establish a "work incentive" for people who were unable to work—such as persons with disabilities and children—the community-engagement requirement is limited to able-bodied adults, exempting (among others) those who are medically frail. Furthermore, although plaintiffs label it a "work requirement," the adults who are subject to the community-engagement requirement can fulfill it through a wide array of activities other than working. And third, there is no doubt that Kentucky HEALTH's community-engagement component has experimental value, which the Commonwealth will evaluate on a statewide basis. *Beno* is thus inapplicable to the community-engagement requirement here, which is, indeed, considerably more flexible than the state work requirements upheld by the Supreme Court in *Dublino* and the Second Circuit in *Aguayo v. Richardson*, 473 F.2d 1090 (2d Cir. 1973).

E. KY HEALTH is an "experimental, pilot, or demonstration project."

In his recent approval of Kentucky HEALTH as a component of KY HEALTH, the Secretary explained that the project as a whole was designed "to determine whether there is a more effective way to furnish medical assistance to the extent practicable under the conditions in Kentucky." AR

6729. For example, the purpose of the community-engagement requirement is to "test" whether its incentive structure will help beneficiaries attain "financial independence" and "improve[] health outcomes," thereby "further[ing] Medicaid's objectives." AR 6733. Likewise, the waiver of retroactive eligibility seeks to determine whether the requirement will reduce gaps in coverage by encouraging eligible beneficiaries to obtain coverage when healthy, thus "improv[ing] uptake of preventive services" and "improve[ing] beneficiary health." AR 6736. And the premium requirement seeks to test whether beneficiaries who pay premiums "are more likely to obtain primary care and preventive care, have better drug adherence, and rely less on the emergency room for treatment compared to those who do not"—outcomes which promote coverage by lowering costs and ensuring the fiscal sustainability of the program.[3] AR 6734–35. These and other statements in the approval letter leave no doubt that the project has research and experimental goals, and that the Secretary determined the demonstration was likely to yield useful information furthering those goals.

Plaintiffs, for their part, concede that the community-engagement requirement is novel in the context of Medicaid, but nonetheless object that the Secretary has previously waived retroactive eligibility and imposed premiums as part of demonstrations in other states. Pls.' Reply 23. Plaintiffs fail to recognize, however, that the Secretary is testing *the particular combination of features* that make up Kentucky HEALTH (as well as KY HEALTH), so the data to be collected will be both original and useful. *See, e.g.*, AR 6735 ("[P]remiums . . . merit additional research and evaluation when viewed in conjunction with other demonstration features . . . ."). In any case, Section 1115 nowhere states that a demonstration or the data it provides cannot be similar to that of prior experiments. Indeed, each State and State Medicaid program is different, and data from a range of States is useful to policymakers,

[3] Indeed, the existing literature on premiums indicates that more evidence is needed to determine whether they will have the desired effect; Indiana's demonstration provides some initial evidence, and CMS is seeking more evidence through KY HEALTH. *See* AR 6734–35 & n.11.

especially if Congress might ultimately consider applying a demonstration-tested Medicaid policy nationwide, through legislation. What the statute requires is only that the project be "experimental," a "pilot," or a "demonstration"—not that it be unprecedented or even novel. 42 U.S.C. § 1315(a). Kentucky's demonstration satisfies this standard, and the Secretary reasonably determined it to do so.

F. The Secretary properly evaluated the demonstration as a whole.

Defendants maintain their position that the several parts of KY HEALTH, including both the SUD program and Kentucky HEALTH, should be evaluated as a whole, in accordance with the Secretary's consistent approach in this case. AR 2, 6718. In its 2018 ruling, this Court agreed with defendants that demonstrations must be viewed as a whole. *See Stewart*, 313 F. Supp. 3d at 257 (citing *Wood v. Betlach*, 922 F. Supp. 2d 843).[4] At the time, the Court concluded that Kentucky HEALTH constituted a separate demonstration. *See id.* at 258. Defendants respectfully submit that the Secretary's November 20, 2018 approval letter clarifies that this is not so. In that letter, the Secretary repeatedly makes clear that he views Kentucky HEALTH as a component of the larger demonstration program known as KY HEALTH, and that the Secretary concluded that KY HEALTH, incorporating Kentucky HEALTH, is likely to advance the objectives of Medicaid. *See, e.g.*, AR 6723. And while plaintiffs make much of the fact that Kentucky HEALTH and the SUD program "apply to different population groups, have different effective dates, and serve different purposes," Pls.' Reply 21, ECF No. 119, they cite to no precedent for their proposition that to qualify as a single demonstration, a project must apply in its entirety to the exact same population, and that each component must have the exact same effective date and the exact same purpose. Such a proposition conflicts with past practices across administrations, as CMS has repeatedly approved demonstrations with components that apply to different population groups, have different effective dates, and/or serve different

[4] Plaintiffs, too, have agreed that the ultimate legal inquiry is whether the state's application as a whole is for "an 'experimental, pilot, or demonstration project' that is likely to promote Medicaid's objectives." Pls.' Reply Br. 24, ECF No. 59.

purposes. In light of the Secretary's November 20, 2018 approval letter, this Court should evaluate the demonstration as considered and approved by the Secretary—that is, KY HEALTH as a whole, including both Kentucky HEALTH and the SUD program.

II. PLAINTIFFS' STATUTORY AND RECORD-BASED ARGUMENTS FAIL.

A. The Secretary adequately considered potential effects on coverage.

Plaintiffs repeat their argument that the Secretary has not adequately considered the effects of Kentucky HEALTH on coverage. Pls.' Reply 24–28. But plaintiffs do not dispute that in his recent approval letter, the Secretary explained how KY HEALTH, including Kentucky HEALTH, is likely to promote coverage by ensuring the fiscal sustainability of the Medicaid program. AR 6726; *see also* AR 6729 ("[T]his demonstration is designed to *extend* coverage"). Nor do they dispute that Section 1115 permits "demonstration projects that might adversely affect Medicaid enrollment or reduce healthcare coverage." *Stewart*, 313 F. Supp. 3d at 272. They do not try to argue that the 95,000 figure calculated by commenters actually predicts the number of beneficiaries who will lose coverage and not regain it. They do not contest that a beneficiary who chooses not to comply with the community-engagement requirement and accordingly loses coverage for one or more months may simply complete 80 hours of community engagement in a 30-day period or complete a state-approved health literacy or financial literacy course and regain coverage once again. AR 6777. They do not dispute that the Secretary considered possible effects on coverage against the baseline of the State's choice to participate in the Medicaid expansion, AR 6731, or that the Governor of Kentucky has issued an executive order directing the State Cabinet for Health and Family Services to "terminate Kentucky's Medicaid expansion program" in the event KY Health is not implemented. Gov. Matthew G. Bevin, Exec. Order 2018-040 (Jan. 12, 2018), ECF No. 25-1. And they do not point to any authority for the proposition that the Secretary in all cases must "quantify" *ex ante* the number of beneficiaries who will lose coverage under a demonstration. Pls.' Reply 26.

Rather than contest any of these points, plaintiffs' arguments reduce to little more than the assertion that because commenters predicted some beneficiaries will lose coverage at least temporarily under the project, and because the Secretary did not specifically recite and refute each of these comments, his approval was inconsistent with the APA. But again, it is permissible for demonstrations to have an adverse impact on coverage for some individuals. *See Stewart*, 313 F. Supp. 3d at 272. And although the Secretary reviewed all of the comments submitted and did not "ignore" any of them, Pls.' Reply 38, he was not required to respond in writing *at all*, let alone respond to every single comment submitted in opposition to the proposed demonstration. Defs.' Mem. 40; *see also Stewart*, 313 F. Supp. 3d at 263. Nor is it practical or even useful to attempt to predict precisely what effect a demonstration will have. The entire purpose of a *demonstration* project is to *test* the effects of a temporary change in policy. *See Cal. Welfare Rights Org. v. Richardson*, 348 F. Supp. 491, 498 (N.D. Cal. 1972). 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.[5]

Plaintiffs may disagree with KY HEALTH as a policy matter. And as a predictive matter, they may think the project will fail. But those are not reasons to disregard the fact that the Secretary considered the issue of effects on coverage, and rationally determined that the demonstration would promote coverage.

[5] *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 … .").

B. The Secretary has the authority to approve a community engagement requirement.

Pursuant to the Section 1115 waiver provision,[6] the Secretary possesses the authority to approve a community-engagement requirement on an experimental basis if he finds that the requirement, in combination with the other features of a particular demonstration, would likely assist in promoting Medicaid's statutory objectives. 42 U.S.C. § 1315(a). That is precisely what the Secretary did here. Plaintiffs object that the Medicaid statute does not itself include a community engagement requirement, and that Congress has in recent terms rejected bills that would impose work requirements as a condition of Medicaid. Pls.' Reply 39–40. But as defendants have already explained, *see* Defs.' Mem. 28–30, plaintiffs confuse a temporary demonstration with a statutory amendment. The purpose of Section 1115 is to empower the Secretary to waive statutory requirements that would otherwise "stand in the way" of temporarily testing out new policy ideas. S. Rep. at 19. At any rate, Congress's failure to amend the Medicaid statute says little about how to interpret that statute, let alone how to interpret a waiver provision lying elsewhere in the Social Security Act. *See Mich. v. Bay Mills Indian Cmty.*, 572 U.S. 782, 826 (2014) ("We walk on quicksand when we try to find in the absence of corrective legislation a controlling legal principle" (quoting *Helvering v. Hallock,* 309 U.S. 106, 121 (1940)).

Nor does it matter that CMS previously took the position that the Secretary could not lawfully approve work requirements for Medicaid. Pls.' Reply 40. There is nothing unusual about an agency exercising its discretion to change its interpretation of a statute, and doing so "is not a basis for declining to analyze the agency's interpretation under the *Chevron* framework." *Nat'l Cable & Telecom. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005). Indeed, "change is not invalidating, since the whole point of *Chevron* is to leave the discretion provided by the ambiguities of a statute with the implementing agency." *Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 742 (1996).

[6] Contrary to plaintiffs' assertion, to the extent they interpret the waiver provision to bar approval of a community engagement requirement, defendants *do* contest plaintiffs' reading of the term "waive." Pls.' Reply 39.

C. Premiums were lawfully approved and adequately explained.

Although it is not necessary for premiums independently and in isolation to advance the objectives of Medicaid, the premium requirement here is expected to improve beneficiary health because those who pay premiums are more engaged in their personal healthcare plans, and more likely to obtain primary and preventive care and take medications as prescribed. AR 6734–35. In turn, these "health-promoting behaviors" reduce healthcare costs and stretch Medicaid resources to cover more needy individuals. AR 6735. Plaintiffs may find it "implausible" that premiums would improve health, or that better health would help the State stretch its resources, Pls.' Reply 32, but such determinations are "primarily of a judgmental or predictive nature" and thus fall squarely within the Secretary's discretion and expertise. *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 813 (1978).

The premium requirements are also on solid legal footing. The Secretary correctly—and, at least, reasonably—concluded that Section 1115(a) permitted him to waive § 1396a(a)(14), "insofar as" that condition "incorporates" §§ 1396o or 1396o-1. AR 6741. 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.

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.' Reply 42 n.9. 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 the reality that § 1396o(f), far from refuting the Secretary's authority to waive § 1396o's premium requirements, expressly confirms it. As defendants have explained, *see* Defs.' Mem. 33, § 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 (via § 1396a) and *restricts* the exercise of that authority with respect to § 1396o's cost-sharing requirements but *not* its premium requirements.

Nor do plaintiffs have any response to the plain text of § 1396o-1(b)(6)(B), which expressly recognizes "the authority of the Secretary through waiver to modify limitations on premiums and cost sharing under [§ 1396o-1]." This provision 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.

Unable to answer the statute's text and structure, plaintiffs retreat to the statutory and legislative history. Pls.' Reply 41–43. Plaintiffs concede that the history they cite concerned cost-sharing, not premiums, so it is unclear what relevance it has here. *Id.* at 41–42. Nor is there any merit to plaintiffs' theory that Congress has "consistently confirmed that the flexibilities available to states with respect to premiums and cost sharing must come from Congress," not the Secretary. *Id.* at 42. This is a non sequitur; Congress's decision to amend 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 short, the Secretary's reading of the various provisions at issue is correct or, at the least, is permissible and merits *Chevron* deference. Plaintiffs' contrary reading should be rejected.

D. Plaintiffs' challenges to the remaining features of Kentucky HEALTH are non-justiciable and meritless.

At the outset, plaintiffs lack standing to challenge the remaining components of Kentucky HEALTH. With respect to the waiver of retroactive eligibility, every plaintiff is currently covered by Medicaid, so the waiver would not affect them unless they happened to lose coverage in the future. *See, e.g.*, McComas Decl. ¶ 19, ECF No. 91-4. Whether that will occur is entirely speculative. *See Nw. Airlines, Inc. v. FAA*, 795 F.2d 195, 201 (D.C. Cir. 1986). Thus, the fact that some plaintiffs may "suffer from chronic conditions that require regular visits to specialists and prescription medication," Pls.' Reply 5, does not grant them standing to challenge the retroactive eligibility waiver.

Likewise, no plaintiff has alleged a "certainly impending" injury from the non-eligibility period. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 401 (2013). Before a plaintiff could be affected by the period, that plaintiff would have to fail to report a change in income or not comply with the redetermination process—obligations already required of beneficiaries as a condition of Medicaid eligibility. AR 6722, 6756–62. Plaintiffs point to only one plaintiff who has previously lost coverage for failing to comply with these requirements, Pls.' Reply 6 (citing Segovia Declaration), and there is no allegation that this plaintiff intends not to comply again. And even if there were, a party "cannot manufacture standing merely by inflicting harm on themselves." *Clapper*, 568 U.S. at 416.

With respect to *My Rewards Account* deductions for non-emergency use of the emergency department, the fact that some plaintiffs have received emergency care for non-emergency conditions in the past, *see* Pls.' Reply 7, does not mean it will happen again in the future, and plaintiffs' predictions to the contrary are speculative. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 556 (1992). Similarly, although some plaintiffs allege they have relied on non-emergency medical transportation ("NEMT") in the past, *see* Pls.' Reply 7, none have shown that they will need to do so in the future, or that they do not come within one of the project's exceptions to the NEMT waiver, AR 6763–65.

On the merits, plaintiffs' challenges to these features continue to miss the mark. To start with, the Secretary's explanation for the waiver of retroactive coverage was not "conclusory." Pls.' Reply 34 (quoting *Stewart*, 313 F. Supp. 3d at 265). In analysis amounting to far more than a "single sentence," *Stewart*, 313 F. Supp. 3d at 265, the Secretary explained that he was targeting a recurring problem among Medicaid programs: when individuals who are Medicaid eligible and can enroll when healthy "wait until they are sick" to enroll. AR 6724. To address this persistent and costly problem, the Secretary sought to test whether reducing retroactive eligibility will encourage these individuals "to obtain and maintain health coverage, even when healthy, and whether there will be a reduction in gaps in coverage when beneficiaries churn on and off Medicaid or sign up for Medicaid only when sick." *Id.* Of course, "restricting retroactive eligibility will, by definition, reduce coverage" for those who churn on and off of Medicaid. *Stewart*, 313 F. Supp. 3d at 265. But the Secretary is *testing* whether the waiver will nonetheless promote coverage *overall* by deterring that churn in the first place. Beneficiaries who enroll early and stay enrolled are, in turn, more likely to "obtain preventive health services," which improves health, "better contain[s] Medicaid costs and more efficiently focus[es] resources on providing accessible and high-quality health care, thereby promoting the sustainability of [the] Medicaid program." AR 6727. Plaintiffs simply ignore this explanation. Instead, they insist that the Secretary produce evidence of the waiver's success before the experiment has even begun—a demand inconsistent with the purpose of Section 1115. Pls.' Reply 34–35.

Equally meritless is Plaintiffs' challenge to the periods of non-eligibility. They again ignore the explanation offered by the Secretary: that "incentiviz[ing] program compliance" with the premium, redetermination, and change-in-income reporting requirements is likely to "improv[e] the financial sustainability of Kentucky's Medicaid program." AR 6736. Instead, they focus on the baseless allegation that the Secretary has somehow changed position, even though the Indiana demonstration to which they point *involved a non-eligibility period*. *See* Indiana HIP 2.0, ECF No. 51-8;

Pls.' Reply 33–34. To be sure, the Secretary initially rejected a proposed expansion of Indiana's non-eligibility period to cover noncompliance with its redetermination requirement, AR 239–40, but in February 2018 the Secretary approved just such an expansion of Indiana's non-eligibility period, *see* Exhibit A at 2–3. In any event, even if the non-eligibility period here could be characterized as a change in position, Kentucky has submitted new data that plainly justifies any such change. *See* AR 6727; Defs.' Mem. 38).

Nor should the Court credit plaintiffs' objections to the waiver of non-emergency medical transportation. The Secretary expressly recognized that by waiving NEMT for the able-bodied individuals in the new adult group, Kentucky could "better contain Medicaid costs and more efficiently focus resources on providing accessible and high-quality health care," AR 6727, thus "improve[ing] the fiscal sustainability of the state's safety net and contribut[ing] to the provision of additional services offered through Kentucky HEALTH and KY HEALTH," AR 6735. Plaintiffs predict this aspect of the demonstration will fail, Pls.' Reply 35, but that is no reason to override the Secretary's considered judgment. Plaintiffs also ignore the fact that waiving NEMT helps to align Kentucky HEALTH with the commercial insurance market, "where [NEMT] is not typically available," AR 6725. This alignment could make it easier for beneficiaries to eventually transition to commercial insurance, thus stretching Medicaid resources for those who need it. *Id.*

Finally, the Court should reject plaintiffs' attempt to conflate the deduction of virtual-dollar credits from a *My Rewards Account* with "cost-sharing" charges subject to statutory cost-sharing limits. Pls.' Reply 43–45. "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 do not dispute that beneficiaries pay no actual money when the State makes a deduction from their *My Rewards Account*, nor is there any actual beneficiary-deposited money in those accounts. Plaintiffs likewise do not dispute that the Commonwealth assigns *non-monetary* dollar values to the credits, which can be

redeemed only for *optional or demonstration-only* benefits that the State could have otherwise opted not to provide. AR 6721. Thus, even if plaintiffs were correct that *My Rewards Account* credits have financial importance for beneficiaries, Pls.' Reply 44, Kentucky making virtual deductions from a *My Rewards Account* that it funds with virtual currency is plainly different than cash payments from beneficiaries for a particular service. The Secretary thus acted reasonably in concluding that the cost-sharing limits cited by plaintiffs do not apply to Kentucky's treatment of its *My Rewards Accounts*.

III. ANY RELIEF SHOULD BE LIMITED TO THE SIXTEEN PLAINTIFFS.

Should this Court issue relief against defendants, any such relief should be limited in scope to the plaintiffs before the Court. Although plaintiffs may be willing to take the risk that Kentucky will end the optional adult expansion, other members of that population may reject that risk. *See* Defs.' Mem. 42. More fundamentally, neither Article III nor principles of equity permit relief "more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979); *see Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018) ("A plaintiff's remedy must be tailored to redress the plaintiff's particular injury."). "This rule applies with special force where," as here, "there is no class certification." *L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664 (9th Cir. 2011). Indeed, plaintiffs pled this case as a putative class action and had an opportunity to seek class certification, *see* Fed. R. Civ. P. 23, but chose not to do so. That was their choice to make, but, their having made it, any injunction must "be limited to the inadequacy that produced the injury in fact" with respect to the plaintiffs. *See Lewis v. Casey*, 518 U.S. 343, 357 (1996).

The fact that plaintiffs have raised claims under the APA does not change this result, as the APA preserves all ordinary principles of equity. *See* 5 U.S.C. § 702(1) ("Nothing herein affects . . . the power or duty of the court to . . . deny relief on any other appropriate legal or equitable ground[.]"); *see also id.* § 703. Nor does the APA's text permit, let alone require, relief beyond what is necessary to redress a plaintiff's own cognizable injuries. *Cf. Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas,

J., concurring) ("No statute expressly grants district courts the power to issue universal injunctions."); *see also Los Angeles Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664-65 (9th Cir. 2011) (vacating district court's grant of nationwide injunction in APA case); *Virginia Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 383 (4th Cir. 2001) (same).

The text of 5 U.S.C. § 706(2) also does not support plaintiffs' position that the Secretary's approval, if found deficient and meriting vacatur, should be "set aside" *on its face* rather than *as applied to the plaintiffs*. To the contrary, absent a statutory provision specifically authorizing review of the entire program, the application of the program to the plaintiffs would be the only proper ripe subject of review, *see Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990), and thus the outer limit of any relief. Likewise, in the absence of a clear and unequivocal statement in the APA that it displaces traditional rules of equity, the Court should construe the "set aside" language in section 706(2) as applying only to the Plaintiffs to this lawsuit. Moreover, the historical backdrop to the APA's enactment bolsters this reading. The absence of nationwide injunctions before Congress's enactment of the APA in 1946 (and for over fifteen years thereafter), *see Hawaii*, 138 S. Ct. at 2426 (Thomas, J., concurring), suggests that the APA was not originally understood to authorize courts to issue such broad relief. Plaintiffs' citations to non-binding district court decisions, *see* Pls.' Reply 49, and to a D.C. Circuit opinion that predates more recent Supreme Court jurisprudence on the matter, *see Harmon v. Thornburgh*, 878 F.2d 484, 495 (D.C. Cir. 1989), do not change this conclusion.[7]

[7] Alternatively, defendants maintain their position that if this Court concludes that a specific portion of KY HEALTH is invalid, it should remand the whole demonstration project back to the Secretary so that the Secretary and Kentucky may decide whether to proceed with the rest of the project. Any such remand, should it occur, should be without vacatur.

IV. PLAINTIFFS' CHALLENGE TO CMS'S LETTER TO STATE MEDICAID DIRECTORS IS NON-JUSTICIABLE AND MERITLESS.

The State Medicaid letter challenged by plaintiffs had no legal effect; the Secretary's approval of KY HEALTH, including Kentucky HEALTH, did not turn on the letter; and plaintiffs cannot show that the letter caused their asserted injuries. Indeed, plaintiffs concede that the Secretary's recent approval does not cite the State Medicaid letter at all. Pls.' Reply 47. Thus, plaintiffs cannot challenge the letter even in the context of the instant challenge.

The letter is also not final agency action. 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 92–93. 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) (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 Min. 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).

Finally, even if the letter could be deemed final agency action, it easily satisfies review on the merits. As a general statement of policy exempt from notice-and-comment procedures, 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" 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 253. Moreover, the letter offered a "reasoned explanation" for the agency's policy shift towards supporting Medicaid demonstration projects with community-engagement components, thus plainly surviving arbitrary-and-capricious review. *See FCC v. Fox Television Stations*, 556 U.S. 502, 515–16 (2009). The letter describes the agency's policy view that it would be better to support demonstrations that will help it determine whether community-engagement programs lead to better health outcomes, and provides reasoning to support this conclusion, including by relying on multiple studies that demonstrate a correlation between work and community engagement and positive health outcomes. *See* AR 91. 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 1032, 1038 (D.C. Cir. 2012).

V. 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. The Clause applies to the President alone, and not to anyone else. Both *Printz v. United States*, 521 U.S. 898, 922 (1997), and *Util. Air*, 134 S. Ct. at 2446, 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.

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: March 1, 2019

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

JAMES BURNHAM
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Matthew Skurnik
VINITA ANDRAPALLIYAL
MATTHEW SKURNIK
Trial Attorneys
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, D.C. 20005
(202) 616-8188
Matthew.Skurnik@usdoj.gov

Counsel for the Federal Defendants

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services

Deputy Administrator
Washington, DC 20201

FEB - 1 2018

Allison Taylor
Medicaid Director
Indiana Family and Social Services Administration
402 W. Washington Street, Room W461, MS25
Indianapolis, IN 46204

Dear Ms. Taylor:

The Centers for Medicare & Medicaid Services (CMS) is approving Indiana's request for CMS approval of its Medicaid demonstration entitled, "Healthy Indiana Plan (HIP)" (Project Number 11-W-00296/5) in accordance with section 1115(a) of the Social Security Act (the Act).

This approval is effective February 1, 2018, through December 31, 2020, upon which date, unless reauthorized or otherwise noted, all authorities granted to operate this demonstration will expire. CMS's approval is subject to the limitations specified in the attached expenditure authorities, waivers, and special terms and conditions (STC). The state may deviate from Medicaid state plan requirements only to the extent those requirements have been listed as waived or as not applicable to expenditures.

Extent and Scope of Demonstration

The current HIP section 1115 demonstration was implemented by the State of Indiana ("state") on February 1, 2015. The HIP program provides beneficiaries with a consumer-driven plan with required monthly contributions, supported by the Personal Wellness and Responsibility ("POWER") account, which is similar to a health savings account. With this approval, the state is authorized to make several changes to HIP, which the state has indicated are designed to improve member outcomes by targeting tobacco cessation, substance use disorder (SUD), chronic disease management, and community engagement. HIP also aims to help prepare beneficiaries for participation in the commercial insurance marketplace. The state's approach is designed to prepare beneficiaries for the personal responsibility required to maintain coverage and continuity of care they will experience when they seek commercial insurance coverage.

Indiana is making a change to how HIP Plus beneficiaries will be charged premiums. The state will apply a premium surcharge for HIP Plus beneficiaries who use tobacco, and who do not participate in tobacco cessation activities. This increased premium will be applied after the first year of enrollment, during which beneficiaries are encouraged to use the various state plan options available to cease tobacco use. By charging beneficiaries a surcharge related to a specific behavior (i.e., tobacco use), the state will test whether incentivizing beneficiaries to change behavior and engage in their own healthcare will achieve better health outcomes.

In addition, the state will be moving from charging HIP Plus beneficiaries a premium that is exactly two percent of household income to assessing premiums based on income bands, in which most beneficiaries will pay no more than two percent of household income.

In addition, beginning in 2019, Indiana will implement a community engagement requirement as a condition of continued coverage and eligibility for adult beneficiaries enrolled in HIP who are not exempt. The terms and conditions of Indiana's community engagement requirement that accompany this approval are aligned with the guidance provided to states through State Medicaid Director's Letter (SMD 18-0002), Opportunities to Promote Work and Community Engagement Among Medicaid Beneficiaries, issued on January 11, 2018.

Certain groups, including pregnant women, beneficiaries identified as medically frail, students, some caregivers of dependents, and beneficiaries in active SUD treatment will be exempt from this requirement. To maintain coverage, non-exempt members will be required to participate in community engagement activities that may include (but are not limited to) employment, education, job skills training, or volunteer work for a weekly hours requirement that will phase in over the life of the demonstration to eventually become a requirement of 20 hours per week. Compliance will be required for eight months of the 12-month calendar year (for a non-exempt beneficiary that participates for the full year). Beneficiaries will have four months (within a 12-month calendar year) in which they do not have to meet the community engagement requirement. Beneficiaries who fail to meet their required community engagement hours in the preceding calendar year will have their eligibility suspended in the new calendar year until the month following notification to the state that they have completed a calendar month of required hours. If a suspended beneficiary does not complete the one month of community engagement hours to reactivate coverage by their redetermination date, and does not qualify for an exemption, or qualify for another eligibility category that is not subject to the community engagement requirement in the month of redetermination, the individual will be disenrolled from Medicaid at that time, and will have to reapply to reenroll in Medicaid. When an individual whose enrollment was terminated during redetermination reapplies, their previous noncompliance with the community engagement requirement will not be factored into the state's determination of their eligibility for reenrollment into HIP. Indiana will allow good cause exemptions in certain circumstances for beneficiaries who cannot meet their requirement. With this policy, the state will test whether requiring some beneficiaries to engage in community engagement requirements will lead to improved health outcomes.

HIP enrollees have their eligibility reconfirmed through a redetermination period, which begins 45 days prior to the end of the beneficiary's eligibility period. Beneficiaries who do not provide requested information to confirm eligibility during this period will be subject to disenrollment, unless otherwise exempted. However, beneficiaries subject to disenrollment will have an "on-ramp" back into coverage during an additional 90-day reconsideration period, consistent with Medicaid regulations. During the 45-day redetermination period, the state and plans will conduct outreach to ensure understanding of paperwork requirements and encourage compliance. If an individual subject to disenrollment does not take advantage of the on-ramp and cannot show good cause for non-compliance, he or she will not be able to re-enroll in HIP for three months following the reconsideration period. With this policy, the state will test whether

incentivizing beneficiaries to follow established procedures and engage in maintaining their healthcare coverage will lead to improved health outcomes.

This HIP demonstration will also include a SUD program to ensure that a broad continuum of care is available to Indiana Medicaid beneficiaries with a SUD, which will help improve the quality, care, and health outcomes for those Medicaid beneficiaries. The SUD program contributes to a comprehensive statewide strategy to combat prescription drug abuse and opioid use disorders, and expands the SUD benefits package to cover short-term residential services for all Medicaid enrollees.

Determination that the demonstration project is likely to assist in promoting Medicaid's objectives

Demonstration projects under section 1115 of the Act offer a way to give states more freedom to test and evaluate innovative solutions to improve quality, accessibility and health outcomes in a budget-neutral manner, provided that, in the judgment of the Secretary, the demonstrations are likely to assist in promoting the objectives of Medicaid.

While CMS believes that states are in the best position to design solutions that address the unique needs of their Medicaid-eligible populations, the agency has an obligation to ensure that proposed demonstration programs are likely to better enable states to serve their low-income populations, through measures designed to improve health and wellness and help individuals and families attain or retain capability for independence or self-care. Medicaid programs are complex and shaped by a diverse set of interconnected policies and components, including eligibility standards, benefit designs, reimbursement and payment policies, information technology (IT) systems, and more. Therefore, in making this determination, CMS considers the proposed demonstration as a whole.

In its consideration of the proposed changes to HIP, CMS examined whether the demonstration was likely to assist in improving health outcomes; whether it would improve access to high-quality, person-centered services; whether it would address behavioral and social factors that influence health outcomes; whether it would incentivize beneficiaries to engage in their own healthcare and achieve better health outcomes; and whether it would familiarize beneficiaries with a benefit design that is typical of what they may encounter in the commercial market and thereby facilitate smoother beneficiary transition to commercial coverage. CMS has determined that the HIP demonstration is likely to promote Medicaid objectives, and that the waivers and expenditure authorities sought are appropriate to carry out the demonstration.

1. **The demonstration is likely to assist in improving health outcomes through strategies that promote community engagement and address certain health determinants.**

HIP is a consumer-driven health plan that provides a combination of complementary incentives and disincentives that are intended to address certain health determinants, and promote increased upward mobility, greater independence, and improved quality of life. Indiana's community engagement requirement, an evolution of the state's existing Gateway to Work program, is an

incentive for beneficiaries to obtain employment or engage in other community activities that are correlated with improved health and wellness. As Indiana informed CMS in the request for approval of the community engagement program, Gateway to Work, the state's work referral program, did not prove to provide a sufficient incentive to influence many Medicaid beneficiaries to participate in employment. Despite the fact that around 244,000 HIP beneficiaries were unemployed and an additional 58,000 worked fewer than 20 hours per week, only 580 beneficiaries attended Gateway to Work orientations during the first 15 months of the program. By making participation in community engagement a requirement to receive benefits for most non-pregnant, non-medically frail beneficiaries who are not eligible for Medicaid on the basis of a disability, Indiana is incentivizing certain beneficiaries to participate in employment, volunteer work, education, or training. As noted in CMS' SMDL: 18-002, these activities have been shown to lead to healthier individuals.

Approving a range of community engagement incentive structures in various states is likely to give CMS and the states helpful information about how different incentive structures function; the evidence generated by a range of incentive structures designed around work and community engagement requirements will inform future agency decisions about which program features best promote the objectives of Medicaid. CMS has determined that the Indiana demonstration includes a meaningful incentive by requiring affected beneficiaries to demonstrate compliance with the community engagement requirements during the prior calendar year, or face a suspension in the next calendar year. CMS considered Indiana's experience in the existing Gateway to Work program and has determined that the proposal has been informed by this experience as the state seeks to strengthen the incentives for community engagement. Indiana has tailored the incentive structure to include beneficiary protections, such as the opportunity to reactivate suspended eligibility in the month following notification to the state that the beneficiary has completed a calendar month of required hours, as well as the opportunity to begin a new period of eligibility at the beneficiary's next redetermination date. The impact of this incentive, as well as other aspects of the demonstration, 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.

2. **The demonstration is likely to improve health outcomes for beneficiaries with substance use disorder.**

The SUD program directly supports Medicaid's objectives by improving access to high-quality services, and it is critical to addressing Indiana's substance use epidemic. All Medicaid beneficiaries in Indiana will continue to have access to all current mental health and SUD benefits. In addition, all beneficiaries, ages 21 through 64, will have access to expanded covered services provided while residing in an Institution for Mental Diseases (IMD) for SUD short-term residential stays. The SUD program will allow beneficiaries with SUD to access benefits that include SUD residential treatment, crisis stabilization and withdrawal management services provided in IMDs, which would otherwise be excluded from federal reimbursement.

3. The demonstration is expected to strengthen beneficiary engagement in their personal health care, and provide incentives for responsible decision-making.

Indiana expects that requirements related to redetermination and reporting will also strengthen beneficiary engagement in their personal health care plan, and provide an incentive structure to support responsible consumer decision-making.

Indiana's previous HIP evaluation has indicated that some of the demonstration's prior features had a positive impact on beneficiary behavior.[1] For example, a majority of HIP beneficiaries opt into paying premiums in order to receive an enhanced benefit package. Therefore, the state is retaining this requirement, but adjusting the premium structure for administrative simplification so any slight fluctuation in a beneficiary's income will no longer always change the amount of the premium due. In a program enhancement, to encourage individuals to take advantage of the tobacco cessation options available through the state plan, beneficiaries who do not use tobacco will be charged a lower premium; beneficiaries who do identify as tobacco users will be given a year to stop using tobacco before paying the surcharge.

The waiver of retroactive eligibility encourages beneficiaries to obtain and maintain health coverage, even when healthy. This demonstration is intended to increase continuity of care by reducing gaps in coverage when beneficiaries churn on and off Medicaid or sign up for Medicaid only when sick.

Imposition of a non-eligibility period for failing to complete timely redetermination encourages individuals to maintain compliance with longstanding beneficiary responsibilities, as described in regulation, and helps to ensure Medicaid is covering only those individuals who are eligible for the program.

4. The demonstration will remove potential obstacles to a successful beneficiary transition to commercial coverage.

Indiana anticipates many Medicaid beneficiaries will transition to commercial health insurance since the demonstration seeks to provide members the tools to successfully utilize commercial market health insurance, thereby removing potential obstacles to a successful transition from Medicaid to commercial coverage. The demonstration includes several features that align with common features of commercial market plans. For instance, the demonstration includes premium payment requirements (with a non-eligibility period for non-payment for certain populations), limited managed care enrollment windows, and limited time periods to switch between managed care plans. The HIP Plus benefit package also provides enhanced medical benefits (e.g., vision and dental) above Medicaid state plan benefits, requires monthly member premiums, and initiates benefits prospectively from the initial premium payment.

This approval also gives Indiana additional tools to encourage HIP beneficiaries to complete the annual redetermination process (with a non-eligibility period for non-compliance for certain populations), which will help educate beneficiaries on the need to timely complete enrollment requirements. CMS notes that in the state's HIP 1.0 demonstration, Indiana successfully applied

[1] https://www.in.gov/fssa/files/Lewin_IN%20HIP%202%200%20Interim%20Evaluation%20Report_FINAL.pdf

a policy of non-eligibility for a small population of individuals who were in the expansion group who did not complete the redetermination process. CMS later did not allow the state to impose this policy on the new adult population as part of HIP 2.0, in part due to concerns about the impact of the policy on access to affordable coverage. CMS has reconsidered its earlier position and believes the state should be given the opportunity to test the efficacy of this policy in HIP , with the appropriate assurances of safeguards for individuals who may need an exception for good cause (such as hospitalization, domestic violence, or the death of a family member) or who have a disability. The state expects this policy will build on the successes of the redetermination and open enrollment policy in the original HIP program and, with continued beneficiary outreach efforts by the state and managed care entities, will result in improved compliance with redetermination requirements. CMS is approving the state's request to apply this policy to non-pregnant and non-medically frail HIP beneficiaries. Incentivizing beneficiaries to complete the annual redetermination process is likely to help educate beneficiaries on the need to timely complete enrollment requirements because of limited opportunities to enroll in coverage. Thus, in addition to the opportunity to enhance program integrity noted above, approval of this policy is likely to support the objectives of Medicaid to the extent that it prepares individuals for a smooth transition to commercial health insurance coverage and ensures that resources are preserved for individuals who meet eligibility requirements.

Similar to how commercial coverage operates, coverage eligibility will continue to be impacted under this approval for certain HIP Plus beneficiaries with income over 100 percent of the FPL for non-payment of premiums. Unless exempt, such beneficiaries will be disenrolled and have a six month non-eligibility period. The demonstration includes special exemptions for those that lose private insurance coverage or are the victim of domestic violence. CMS also notes that Indiana has taken steps to minimize beneficiary harm by exempting certain vulnerable populations, such as pregnant women and individuals who are medically frail, from disenrollment for non-payment of premiums.

Overall, CMS believes that HIP has been designed to empower individuals to improve their health and well-being. If successful in its objectives, HIP will improve health outcomes, promote increased upward mobility and improve quality of life, increase individual engagement in health care decisions, and prepare individuals who transition to commercial health insurance coverage to be successful in this transition. At the same time, HIP ensures vulnerable individuals, like people with disabilities and pregnant women, continue to receive medical assistance.

Consideration of Public Comments

Both Indiana and CMS received a large volume of comments during the state and federal public comment periods. Consistent with federal transparency requirements, CMS reviewed all of the materials submitted by the state, as well as all the public comments it received, when evaluating whether the demonstration project as a whole was likely to promote the objectives of the Medicaid program, and whether the waiver and expenditure authorities sought were necessary and appropriate to implement the demonstration. In addition, CMS took public comments submitted during the federal comment period into account as it worked with Indiana to develop the STCs that accompany this approval, and that will bolster beneficiary protections, including specific state assurances around these protections to further support beneficiaries.

In both the state and federal comment periods, there were comments in support of the application, specifically the state's efforts to promote beneficiary responsibility and accountability, and enhance sustainability of the program in the long-term. Supporters noted that the demonstration has provided them with affordable, accessible, and comprehensive health coverage, while others agreed with the state's move to realigning POWER account contributions to a simpler income-band approach. Some supporters also noted their agreement with the principle that working-age adults who are not eligible for Medicaid on the basis of a disability must meet community engagement requirements as a condition of eligibility. Many commenters supported the state's efforts to expand services for substance use disorder by requesting expenditure authority for residential SUD services in an IMD and by incentivizing tobacco cessation.

In the state and federal comment periods, opposing commenters expressed general disagreement with the continued efforts of the state to utilize non-traditional means to expand Medicaid. Commenters indicated they would rather the state expand through the state plan, without an accompanying section 1115 demonstration, because they found the enrollment process confusing and a barrier to care. Some offered more specific feedback regarding individual elements of the demonstrations or the impact of certain provisions on distinct populations. In addition, some commenters were concerned that the qualifying activities and list of exemptions were not broad enough.

Some commenters asserted that the premium provisions in the HIP 2.0 demonstration had resulted in a higher rate of disenrollment due to nonpayment, citing the state's independent evaluation on this project. We continue to believe that the demonstration's premium provisions are appropriate to prepare beneficiaries to participate in the commercial market. We note that the independent evaluation has reported several positive impacts from the demonstration to date, namely that HIP 2.0 has reduced the number of uninsured low-income Indiana residents, many of whom were previously uninsured or underinsured, and that at least a portion of those who disenrolled showed the primary reason was a change in income or having secured insurance from another source.

Other commenters expressed concerns that the community engagement requirements, or that the requirements for beneficiaries to cooperate with the redetermination process, would be burdensome on families or create barriers to coverage for non-exempt people who might have trouble accessing care. We believe that the community engagement requirements create appropriate incentives for beneficiaries to gain employment. Given that employment is positively correlated with health outcomes, it serves the purposes of the Medicaid statute to impose these requirements, both to improve beneficiaries' health and to encourage beneficiaries to gain independence and to transition to private coverage.

Additional comments characterized the provisions to lock beneficiaries out of coverage for failure to participate in the redetermination process as "punitive," and characterized the state's paperwork requirements as confusing and complicated. We disagree with these characterizations. We believe that it is appropriate to protect the integrity of the program by expecting beneficiaries to cooperate with the state in providing necessary documentation to determine their eligibility. Far from a "punitive" process, the demonstration calls for the state to

assist individuals over a 45-day period in completing redetermination, and an individual is disenrolled, for a limited three-month period, only if that individual has not cooperated with the state before the end of the expiration of the reconsideration period.

In response to the comments submitted to the state, the state added participation in accredited English as a Second Language courses to the list of qualifying activities; beneficiaries who meet the Supplemental Nutrition Assistance Program (SNAP) work requirements were added to the list of those who would be considered to have met the community engagement requirement. Responding to the comments to expand the list of exemptions for community engagement requirements, the state added beneficiaries who are homeless or receiving Temporary Assistance for Needy Families (TANF) to the exemption list. Some commenters requested that the state exclude former foster care youth under age 26 from the community engagement requirement; however, this population is not covered under the demonstration and therefore, not subject to the community engagement requirement. The state also assures that it will make good faith efforts to connect beneficiaries to existing community supports that are available to assist beneficiaries in meeting community engagement requirements, such as available non-Medicaid assistance with transportation and child care.

To help determine whether the demonstration is meeting its goals of improving quality, accessibility, and health outcomes, Indiana will submit, for CMS comment and approval, a draft evaluation design with implementation timeline, no later than 180 days after demonstration approval. CMS will work with Indiana to ensure that the comments received also inform the monitoring and evaluation design and the necessary oversight is in place to provide for program adjustments when necessary.

The CMS' approval of this demonstration is conditioned upon compliance with the enclosed list of waiver and expenditure authorities and STCs defining the nature, character and extent of anticipated federal involvement in the project. The award is subject to our receiving your written acknowledgement of the award and acceptance of these STCs within 30 days of the date of this letter.

Your project officer for this demonstration is Ms. Shanna Janu. She is available to answer any questions concerning your section 1115 demonstration. Ms. Janu's contact information is as follows:

Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
Mail Stop: S2-03-17
7500 Security Boulevard
Baltimore, MD 21244-1850
E-mail: Shanna.Janu@cms.hhs.gov

Official communications regarding program matters should be sent simultaneously to your project officer and Ms. Ruth Hughes, Associate Regional Administrator in our Chicago Regional Office. Ms. Hughes's contact information is as follows:

Ms. Ruth Hughes
Associate Regional Administrator
Centers for Medicare & Medicaid Services
Division of Medicaid and Children Health Operations
233 N. Michigan Avenue, Suite 600
Chicago, IL 60601-5519
Email: Ruth.Hughes@cms.hhs.gov

If you have questions regarding this approval, please contact Ms. Judith Cash, Acting Director, State Demonstrations Group, Center for Medicaid and CHIP Services, at (410) 786-9686.

Thank you for all your work with us, as well as stakeholders in Indiana, over the past months to reach approval.

Sincerely,

[redacted]

Demetrios Kouzoukas
Principal Deputy Administrator

Enclosures