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)

MEMORANDUM IN SUPPORT OF FEDERAL DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

In its prior decision in this case, this Court recognized that the Secretary of Health & Human Services ("HHS") "is afforded significant deference in his approval of pilot projects," also known as demonstration projects, under 42 U.S.C. § 1315. *Stewart v. Azar*, 313 F. Supp. 3d 237, 243 (D.D.C. 2018). This Court further noted that the Secretary may approve "demonstration projects that might adversely affect Medicaid enrollment or reduce healthcare coverage. After all, 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.* at 272.

This Court concluded, however, that the Secretary "never adequately considered whether Kentucky HEALTH," which was part of Kentucky's Medicaid demonstration project, KY HEALTH, "would in fact help the state furnish medical assistance to its citizens, a central objective of Medicaid." *Id.* at 243. The Court thus vacated HHS's approval of Kentucky HEALTH and remanded the matter to HHS for further review. *Id.* In light of the concerns raised by this Court, HHS opened a new comment period for stakeholders to comment on the issues raised in the litigation. After carefully considering those comments, HHS issued a new letter on November 20, 2018, that approved Kentucky HEALTH as a component of KY HEALTH and comprehensively explained why Kentucky's demonstration project will help the State furnish medical assistance to its citizens.

Kentucky HEALTH furthers the Medicaid statute's objective to furnish medical assistance because it allows Kentucky to experiment with ways to stretch limited Medicaid resources and thereby maximize coverage for its citizens through the broader KY HEALTH project. The Supreme Court and the D.C. Circuit have long recognized that "'considerable latitude' [] characterizes optional participation in a jointly financed benefit program" like Medicaid, *PhRMA v. Walsh*, 538 U.S. 644, 666 (2003), and that measures designed to stretch state resources further the objectives of Medicaid and

similar programs. *See id.*; *see also N.Y. State Dept. of Soc. Servs. v. Dublino*, 413 U.S. 405 (1973); *Pharm. Research & Mfrs. of Am. ("PhRMA") v. Thompson*, 362 F.3d 817 (D.C. Cir. 2004). States may "attempt to promote self-reliance and civic responsibility" in order "to assure that limited state welfare funds be spent on behalf of those genuinely incapacitated and most in need, and to cope with the fiscal hardships enveloping many state and local governments." *Walsh*, 538 U.S. at 666–67 (quoting *Dublino*). In accordance with these decisions, Kentucky HEALTH tests measures designed to help adults transition from Medicaid to greater financial independence and other forms of health coverage, including the subsidized coverage available through health exchanges. The community-engagement requirement is designed to enhance the financial independence of Medicaid recipients by requiring able-bodied adults to work, look for work, or engage in other activities that enhance their employability, such as job-skills training, education, and community service—and in turn to free up resources to provide medical assistance to others. Other components of Kentucky HEALTH—such as its premium provisions, waiver of retroactive coverage, and penalties for non-emergency use of the emergency room—encourage beneficiaries to become more engaged in their health care decisions and to rely more on preventive care, which both improves the health of beneficiaries and further conserves resources for the Medicaid program. Indeed, in 2012, HHS encouraged State initiatives that "encourage personal responsibility" and promote "healthier behaviors." Centers for Medicare & Medicaid Services ("CMS"), *Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid* ("FAQ") 15 (2012) ("2012 CMS Guidance").[1] And temporarily suspending eligibility for Medicaid recipients who fail to either complete annual Medicaid redetermination forms or report a change in circumstances that resulted in Medicaid ineligibility promote compliance with these important

[1] Available at https://www.cms.gov/CCIIO/Resources/Files/Downloads/exchanges-faqs-12-10-2012.pdf.

program requirements, and thus improves the fiscal sustainability of the Medicaid program.

Plaintiffs object that Kentucky HEALTH's community-engagement component is novel. But the central purpose of Section 1115 waiver authority is to foster innovation by allowing States to try new ideas, which may provide a template for new approaches at the federal level. For example, the work requirements in the Temporary Assistance for Needy Families ("TANF") program were informed by earlier demonstration projects such as the one upheld in *Aguayo v. Richardson*, 473 F.2d 1090 (2d Cir. 1973). Plaintiffs also predict that Kentucky HEALTH is doomed to fail. But evaluating such predictions is why Section 1115 demonstration projects exist—*to test* innovations that the Secretary finds are likely to assist in promoting the objectives of the program. Even demonstration projects that do not yield the anticipated results serve Section 1115's purpose by providing valuable data and experience to help shape future innovations. Moreover, Congress entrusted *the Secretary* with making the predictive judgments about which experiments are worthwhile, and here the Secretary made the considered determination that Kentucky HEALTH is likely to advance Medicaid's objectives. Plaintiffs' contrary conjecture is not a valid basis to overturn that considered judgment.

Plaintiffs emphasize some individuals might lose coverage for a period of time because some will not comply with various requirements contained in Kentucky HEALTH. But the same is true of any condition of eligibility—including the work requirements that preceded TANF. For example, an individual may have his Medicaid eligibility terminated for failing to report information requested by the State that could impact that eligibility, such as changes in income or residency status. 42 C.F.R. § 435.916. Medicaid eligibility is not a foregone conclusion, and requiring beneficiaries to provide information demonstrating that they continue to meet conditions of eligibility through a demonstration project is grounded in requirements established elsewhere in the Medicaid statute.

Plaintiffs' argument is especially weak because the individuals subject to Kentucky HEALTH

are predominately members of the new adult population, and Kentucky has the right to terminate that coverage *entirely*. That option flows from the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 575 (2012) ("*NFIB*"). Thus, in 2012, when many States were deciding whether to participate in the new adult expansion, HHS specifically assured them that States "have flexibility to start *or stop* the expansion." 2012 CMS Guidance at 11 (emphasis added). Plaintiffs' observation that the ACA describes this population "as a mandatory coverage group," Pls.' Mem. in Supp. of Mot. for Partial Summ. J., at 4, ECF No. 91-1 ("Pls.' Mem."), is simply irrelevant after *NFIB*'s contrary holding and the resulting 2012 CMS Guidance that encouraged States like Kentucky to expand coverage by assuring them they were free to later rescind that expansion. Here, hundreds of thousands of adults—including the sixteen plaintiffs themselves—are receiving coverage only because Kentucky made a discretionary decision to expand coverage to the new adult population in the first place. And now, Kentucky has "made clear that its continued expansion of coverage to the ACA expansion population is conditioned on implementation" of KY HEALTH. AR 6729. In considering the potential effect of Kentucky HEALTH on coverage, the Secretary properly took into account the Kentucky's prerogative to eliminate this optional coverage entirely.

In addition, Kentucky HEALTH is independently justified because the Secretary found that it is likely to improve the health of the Medicaid recipients receiving coverage under the demonstration. Plaintiffs argue it cannot be a freestanding objective of Medicaid to improve the health of the people that program covers, *see also Stewart*, 313 F. Supp. 3d at 266, but the Secretary emphatically disagrees. For the people who will receive coverage under Kentucky's demonstration, an important purpose of medical coverage is to maintain or improve their health—not just to provide emergency, *ad hoc* treatment of individual ailments after their health has already deteriorated. After all, as the Secretary's new approval letter explains, there is little value in paying for medical services if those

services are not advancing the health and wellness of the recipients. AR 6719. Plaintiffs' argument also rests on the false premise that measures designed to improve the health of the persons covered under Kentucky HEALTH have no bearing on the fiscal sustainability of Kentucky's Medicaid program. Quite the contrary. Policies that help these Medicaid recipients become healthier lower the cost of their care for the simple reason that healthy and productive people are less expensive to insure. Such policies thus may enhance the fiscal sustainability of Kentucky's overall Medicaid program and help preserve and expand the health-care safety net for those who need it the most.

Plaintiffs' remaining claims lack merit. Plaintiffs argue that the Secretary lacked the statutory authority to waive certain Medicaid provisions, but the text of the Social Security Act establishes otherwise. Their challenge to the letter that HHS sent to state Medicaid directors is not justiciable and is meritless in any event. And plaintiffs' extravagant claim that the Secretary's approval of Kentucky HEALTH violates the President's responsibility to take care that the laws be faithfully executed is unsupported. The Court should dismiss the amended complaint or, alternatively, grant summary judgment to the federal defendants and deny plaintiffs' motion for partial summary judgment.

BACKGROUND

Because this Court is already familiar with the central issues in this case, we focus the background discussion on the points most pertinent to the dispute.

I. STATUTORY BACKGROUND

The Medicaid program authorizes federal funding to States to assist certain individuals in obtaining medical care. 42 U.S.C. § 1396a(a)(10). To participate in the Medicaid program, a State must submit a plan for medical assistance (a "State plan") for approval by the Secretary. *Id.* § 1396a(b). A State plan defines the categories of individuals eligible for benefits and the specific kinds of medical services the State covers. *Id.* § 1396a(10), (17).

Under the traditional Medicaid program, States were required to cover only certain categories of needy individuals—pregnant women, children, needy families, the blind, the elderly, and the disabled. *See NFIB*, 567 U.S. at 575. There was no mandatory coverage for most able-bodied, childless adults, and the States typically did not offer any. *Id.*

As enacted, the ACA would have required States to expand their Medicaid programs by 2014 to cover all individuals under the age of 65 with incomes below 133 percent of the federal poverty line (the "new adult group" or the "expansion population") or else leave the program entirely. *Id.* at 576. But the Supreme Court ruled in *NFIB* that Congress could not condition a State's preexisting Medicaid funding on its compliance with the ACA's adult eligibility expansion requirement. The effect of that ruling was to separate the decision whether to provide coverage to the new adult population from the rest of a State's Medicaid program; to functionally make the expansion optional. Accordingly, in 2012, when many States were deciding whether to expand their Medicaid programs, HHS encouraged States to expand Medicaid by assuring them that they "have flexibility to start or stop the expansion." 2012 CMS Guidance at 11; *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."); Ex. A, Letter of Aug. 31, 2012 from CMS Administrator Cindy Mann to Arkansas Governor Mike Beebe (same).

Congress has also given the Secretary the authority to approve "any experimental, pilot, or demonstration project" proposed by a State that, "in the judgment of the Secretary, is likely to assist in promoting the objectives" of the Medicaid statute. 42 U.S.C. § 1315(a). For such projects, the Secretary may waive "compliance with any of the requirements of section … 1396a" in the Medicaid statute, and may approve waivers "to the extent and for the period he finds necessary to enable such State or States to carry out [the demonstration] project," *Id.* § 1315(a)(1). Separately, the Secretary may treat a State's expenditures for an approved demonstration project that otherwise would not qualify

for federal matching funds, *see id.* § 1396b, as expenditures under the State plan that are eligible for federal financial assistance to the "extent and for the period prescribed by the Secretary." *See id.* § 1315(a)(2)(A). Congress enacted Section 1115 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) (Conf. Rep.).

II. FACTUAL BACKGROUND

A. Background and Prior Proceedings

Effective January 1, 2014, the Commonwealth of Kentucky amended its state plan to include coverage of the ACA expansion population. AR 6720. As of September 2018, more than 454,000 individuals received medical assistance under the Kentucky state plan as a result of Kentucky's decision to participate in that expansion. *Id.* Kentucky's Medicaid expansion population includes not only childless adults but also many parents of dependent children, who otherwise are not eligible for coverage under the Kentucky state plan unless their household income is equal to or less than 24 percent of the federal poverty level ("FPL"). *Id.*

In August 2016, Kentucky submitted an application to the Secretary requesting waivers and expenditure authorities, pursuant to Section 1115(a), to implement a demonstration project called KY HEALTH. *See* AR 5432–33. The application proposed KY HEALTH as "an innovative, transformative healthcare program" that sought "to evaluate new policies and program elements designed to engage members in their healthcare and provide the necessary education and tools required to achieve long term health and an improved quality of life." AR 5440. The application emphasized the project's purposes of "improv[ing] health outcomes and overall quality of life" for all Kentucky Medicaid beneficiaries while ensuring "the long-term fiscal sustainability of the program," AR 5432, and strengthening Kentucky's behavioral health delivery system—which was "critical to

addressing Kentucky's substance abuse epidemic." *Id.*

Kentucky predicted that the increased costs of providing care to its expansion population would jeopardize its ability both to provide health care to traditional Medicaid populations and to fund essential services like education and pensions. AR 5432, 5439–40. Kentucky thus developed a comprehensive reform project to test innovative approaches to improve health and well-being in the State while also ensuring the Medicaid program's long-term sustainability and coverage of the expansion population. AR 5432–33, 5440. Before submitting its application, Kentucky conducted a public comment period and public hearings. AR 5475. Kentucky collected over 1,300 comments and provided in its waiver application a detailed summary of the comments, along with its responses and the changes it made to its project in light of the comments. AR 43–53, 5433, 5476, 5486, 5486–89.

On January 12, 2018, after conducting an additional public comment period, CMS approved Kentucky's application for KY HEALTH. AR. 1. Plaintiffs brought this lawsuit and, in June 2018, this Court granted Plaintiffs' motion for summary judgment in part. *Stewart*, 313 F. Supp. 3d. 237. Limiting its analysis to plaintiffs' challenge to Kentucky HEALTH as a whole, this Court concluded that the Secretary "failed to adequately analyze . . . whether the project would cause recipients to *lose* coverage" and "whether the project would help *promote* coverage." *Id.* at 262 (citation omitted). This Court accordingly vacated the Secretary's approval of Kentucky HEALTH, and remanded the application to the agency. *Id.* at 274.

B. The Secretary's November 20, 2018, Approval of Kentucky HEALTH

In light of this Court's decision, the Secretary re-opened the federal comment period for Kentucky HEALTH for an additional thirty days. AR 25,499. The Secretary received approximately 8,583 unique, substantive comments during this additional comment period. AR 6728. Upon reconsideration of Kentucky's proposal along with review of the new comments, the Secretary again

approved Kentucky HEALTH as a component of KY HEALTH on November 20, 2018, *see* AR 6718, for a five-year period beginning April 1, 2019,[2] *see* AR 6719. The Secretary concluded that "Kentucky HEALTH, working within the larger KY HEALTH demonstration program, is likely to assist in promoting the objectives of Medicaid," AR 6718, including the objective of furnishing medical assistance to Kentucky's citizens, *see* AR 6727–28, which this Court identified as an important Medicaid objective, *see Stewart*, 313 F. Supp. 3d at 265–66. As directly relevant to this Court's remand, the Secretary found that "KY HEALTH, including the Kentucky HEALTH program, is designed to lead to higher quality care at a sustainable cost." AR 6726. Improving the long-term sustainability of Kentucky's Medicaid program facilitates Kentucky's continued coverage of the adult expansion population and also allows Kentucky to provide optional services such as over-the-counter medications, vision care, dental care, and a new initiative to provide non-mandatory coverage for treatment of substance-use disorders through the broader KY HEALTH project. AR 6726–28. The components of Kentucky HEALTH at issue here are described below.

1. Community Engagement

As approved by the Secretary, Kentucky HEALTH includes a community engagement requirement as a condition of eligibility for adult beneficiaries ages 19 to 64 who do not qualify for Medicaid on the basis of disability. Generally, adults who are subject to Kentucky HEALTH will have to complete and report 80 hours of participation in community engagement activities, which can include (1) employment, (2) education, (3) caregiving, (4) job skills training, (5) job search activities, (6) participation in substance use disorder treatment, and (7) community service. AR 6721; *see also* AR

[2] On January 31, 2019, Kentucky delayed implementation of the community engagement component of Kentucky HEALTH until July 1, 2019. *See Kentucky Delays Start Time for Some New Medicaid Rules*, Associated Press (Jan. 31, 2019), https://www.apnews.com/7d47dd758d79495fabdec19592396c88.

6774. Various groups, however, are exempt from this requirement, including (1) beneficiaries who are considered medically frail, (2) beneficiaries who are diagnosed with an acute medical condition, (3) full-time students, (4) primary caregivers of a dependent, (5) pregnant women, (6) survivors of domestic violence, and (7) former foster care youth under the age of 26. AR 6721; *see also* AR 6774. In addition, the following individuals are deemed to satisfy the community engagement requirements and, thus, do not need to report their community engagement activities: beneficiaries who are working at least 120 hours per month, beneficiaries who meet or are exempt from the Supplemental Nutrition Assistance Program ("SNAP") and/or TANF employment initiatives, and beneficiaries who are enrolled in Kentucky's Medicaid employer premium assistance program. AR 6774–75.

If a beneficiary fails to comply with the community-engagement requirement in a given month, her eligibility for Medicaid will be suspended for the following month, unless she demonstrates good cause for not meeting or reporting her qualifying activities. AR 6775, 6777. But beneficiaries can re-activate their Medicaid eligibility at any time during their 12-month benefit period by simply completing 80 hours of community engagement in a 30-day period or by completing a state-approved health literacy or financial literacy course. AR 6777. Further, a beneficiary can re-activate her Medicaid eligibility even absent taking one of the steps above if she has been suspended from Medicaid eligibility and is then determined to be medically frail, is diagnosed with an acute medical condition, becomes the primary caregiver of a dependent, becomes pregnant, becomes a full-time student, or otherwise becomes exempt from the requirement or becomes eligible for Medicaid under an eligibility group that is not subject to the community engagement requirement. AR 6777. Kentucky must "[p]rovide full appeal rights as required under 42 C.F.R., Part 431, subpart E, prior to suspension and observe all requirements for due process for beneficiaries whose eligibility will be suspended, denied, or terminated for failing to meet the community engagement requirement." AR 6779. These

requirements include providing notice in advance of suspension, termination or reduction of an individual's Medicaid eligibility or services. *Id.*; *see also* 42 C.F.R. §§ 431.200–431.250.

2. Premiums and the My Rewards Account

Kentucky HEALTH also requires certain beneficiaries to pay monthly premiums in lieu of the copayments required under the existing state plan. AR 6722. The premiums are as low as one dollar per month and may not exceed four percent of a beneficiary's household income. AR 6768–69; AR 6766. If a beneficiary fails to pay her required premium amount and her income is above 100% of the FPL, she will be disenrolled from Kentucky HEALTH for up to six months, unless she completes the requirements for early re-enrollment. AR 6770.

But if the beneficiary's income is at or below 100% of the FPL or the beneficiary is eligible for transitional medical assistance, she will not be disenrolled for failure to pay premiums; instead, she will be required to make the usual copayments, and her *My Rewards Account* will be suspended. AR 6771. (Under the *My Rewards Account* component of Kentucky HEALTH, beneficiaries receive credits with a dollar value equivalent (but no monetary value) for engaging in healthy behavior and community engagement. Beneficiaries can use their *My Rewards* credits to obtain benefits that are not required under the Medicaid statute, such as vision care, dental care, and over-the-counter medications. AR 6721; *see also* AR 6763–66.)

If a beneficiary demonstrates good cause for her failure to pay her premium, she will be eligible to (1) re-enter Kentucky HEALTH without waiting through the full lockout period, if the beneficiary's income is above 100% of the FPL; or (2) resume premium payments instead of copayments and access her *My Rewards Account* by the next administratively feasible month, if her income is below 100% of the FPL. AR 6771. Medically frail individuals, former foster care youth, and survivors of domestic violence are not required to pay premiums or copayments. If they choose not to pay premiums, they

will not have access to a *My Rewards Account*, but they continue to receive vision care, dental care, and over-the-counter medications through Kentucky's state plan. AR 6721; *see also* AR 6762; AR 6772. Further, these categories of beneficiaries can reactivate their *My Rewards Account* by attending an early re-enrollment educational course and are not required to pay past-owed premiums to reactivate their account. AR 6772. Pregnant women are exempt from all Kentucky HEALTH premiums and continue to receive vision care, dental care, and over-the-counter medication through the state plan. AR 6773.

3. Non-eligibility Periods for Failure to Update Eligibility Information

Kentucky HEALTH also includes a six-month non-eligibility period for beneficiaries who fail to provide the necessary information to complete the annual Medicaid redetermination process or fail to report a change in circumstance resulting in Medicaid ineligibility. AR 6722; *see also* AR 6756–62. Medically frail individuals, pregnant women, survivors of domestic violence, and former foster care youth under age 26 are exempt; procedural protections, such as good-cause exemptions, are provided. AR 6722; *see also* AR 6757, 60. Kentucky must "[p]rovide full appeal rights prior to disenrollment and observe all requirements for due process for beneficiaries who will be disenrolled for failure to provide the necessary information to the state to complete their redetermination." AR 6759.

4. Other Relevant Components

The approval also provides waivers of the Medicaid statutory and regulatory requirements that States provide (1) retroactive Medicaid eligibility to beneficiaries, AR 6722–23; and (2) non-emergency medical transportation for beneficiaries enrolled in the new adult group, AR 6723; *see also* AR 6765. Pregnant women and former foster care youth under age 26 are exempt from the former waiver. AR 6756. Medically frail individuals, certain 19- or 20-year-olds who are eligible for medical screening and treatment services, pregnant women, former foster care youth, and survivors of domestic violence are exempt from the latter waiver. AR 6765.

The project also reduces a beneficiary's *My Rewards Account* balance for each non-emergency visit to the emergency department. AR 6765. This reduction will be waived if the beneficiary contacts her managed care organization's nurse hotline prior to using the emergency department. AR 6765. The beneficiary must receive an appropriate medical screening examination before her *My Rewards Account* can be reduced, and Kentucky is required to ensure that hospitals educate beneficiaries about appropriate alternative settings for receiving medical care before deducting credits for non-emergency use of the emergency department. AR 6765; *see also* 42 C.F.R. § 477.54.

C. The Current Challenge

After the Secretary's November 20 approval of Kentucky HEALTH as a component of KY HEALTH, plaintiffs filed an amended complaint that raises the same nine claims they raised when they challenged the Secretary's prior approval. Count One seeks to challenge a letter that CMS sent to state Medicaid directors in January 2018, after Kentucky had applied for approval of KY HEALTH. . First Am. Compl., ECF No. 88, ¶¶ 372–78. Counts Two through Seven assert that the Secretary acted arbitrarily or unlawfully in approving various components of Kentucky HEALTH. *Id.* ¶¶ 379–417. Count Eight challenges the Secretary's approval of Kentucky HEALTH as a whole. *Id.* ¶¶ 418–23. Count Nine asserts a claim under the Take Care Clause of the U.S. Constitution, Art. II, § 3, cl. 5. *Id.* ¶¶ 424–41. Plaintiffs have moved for partial summary judgment on Counts One through Eight. ECF No. 91-1. This cross-motion addresses all counts of the amended complaint.

ARGUMENT

I. THE SECRETARY DID NOT ACT ARBITRARILY OR EXCEED HIS AUTHORITY BY APPROVING KENTUCKY HEALTH.

A. Legal Standards

The D.C. Circuit has held that, because "the Congress expressly conferred on the Secretary authority to review and approve" demonstration projects, and intended the "Secretary's

determinations" under the Medicaid statute to have "the force of law," his "interpretations of the Medicaid Act are therefore entitled to *Chevron* deference." *Thompson*, 362 F.3d at 822 (addressing the approval of state plan amendments). In addition, by authorizing the Secretary to approve a project that "in the judgment of the Secretary" is "likely to assist in promoting the objectives" of the program, and to waive requirements to the extent and for the period "he finds necessary to enable such State or States to carry out such project," Congress used the type of language that commits these determinations to the Secretary's discretion as a matter of law.[3] While this Court has determined that the Secretary's judgments under Section 1115 are judicially reviewable, *Stewart*, 313 F. Supp. 3d. at 256–57, at a minimum the Secretary's discretionary determinations are entitled to the utmost deference because they entail the exercise of policy and scientific expertise to make predictions about a project's likely research utility in furthering broad Medicaid goals. *See, e.g.*, *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 821 (D.C. Cir. 1983) ("[P]redictive judgments about areas that are within the agency's field of discretion and expertise" are entitled to "particularly deferential" treatment.).

B. The Secretary rationally decided that KY HEALTH promotes Medicaid objectives.

This Court vacated the Secretary's prior approval of Kentucky's demonstration project because it determined that HHS had not adequately explained how the project would "help the state furnish medical assistance to its citizens, a central objective of Medicaid." *Stewart*, 313 F. Supp. 3d at 243. The agency has now explained precisely that. *See* AR 6718–6737. The agency's new approval letter provides ample justification to uphold the Secretary's approval of Kentucky HEALTH as a component of KY HEALTH under the reasoning in the Court's decision.

In the approval letter, the Secretary explained that Kentucky HEALTH tests requirements

[3] *See, e.g.*, *Drake v. FAA*, 291 F.3d 59, 72 (D.C. Cir. 2002).

designed to "improve[]the sustainability of the safety net," which, in turn, "allows the state to provide services to Medicaid beneficiaries that it could not otherwise provide." AR 6726. The Secretary explained that the community-engagement requirement, which "helps individuals achieve financial independence and transition to commercial coverage," enable the State to "reduce dependency on public assistance" and thus efficiently use scarce Medicaid resources. AR 6727. Likewise, "[b]y incentivizing healthy behaviors and preventive care," premiums, the waiver of retroactive coverage, and penalties for the non-emergency use of the emergency room help "keep health care costs at sustainable levels." AR 6726. This "advance[s] the objectives of . . . Medicaid . . . by helping Kentucky stretch its limited Medicaid resources, ensure the long-term fiscal sustainability of the program, and ensure that the health care safety net is available to those . . . who need it most." *Id.*

By enabling Kentucky to stretch its finite resources, KY HEALTH facilitates the State's continued coverage of optional populations and optional benefits. AR 6726. Such optional populations include the ACA's new adult group itself. *Id.* And the optional benefits offered under KY HEALTH include over-the-counter medications, vision services, and dental services, as well as certain fitness related services and a new substance abuse disorder program that is of particular importance to Kentucky in light of the opioid crisis. *Id.*

The Secretary thus concluded that approving Kentucky HEALTH, is likely to "provide greater access to coverage for low-income individuals than would be available absent the demonstration." *Id.* The Secretary emphasized that "[i]t furthers the Medicaid program's objectives to allow states to experiment with innovative means of deploying their limited state resources in ways that may allow them to provide services beyond the statutory minimum." *Id.*

The Secretary's reasoning is well grounded in the governing precedent. The Supreme Court has long recognized that, in a cooperative federalism program like Medicaid, measures designed to

stretch limited state resources further the program's objectives. As the plurality put it in *Walsh*, States retain "the 'considerable latitude' that characterizes optional participation in a jointly financed benefit program." 538 U.S. at 666. Hence, in *Dublino*, 413 U.S. 405, the Supreme Court rejected a preemption challenge to a state statute that imposed work requirements as conditions for continued eligibility for benefits under the Aid to Families with Dependent Children ("AFDC") welfare program. *See Walsh*, 538 U.S. at 666–67 (plurality opinion). In so ruling, the Court instructed that a State may "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, and to cope with the fiscal hardships enveloping many state and local governments." *Id.* (discussing *Dublino*); *see also Aguayo*, 473 F.2d at 1103–04 (upholding a Section 1115 demonstration project that imposed employment requirements as conditions of AFDC eligibility because "Congress must have realized that extension of assistance to cases where parents, relatives or the child himself was capable of earning money would diminish the funds available for cases where they were not," and rejecting the argument "that the objective of federal participation in the AFDC program . . . is to assist the states 'to furnish financial assistance and rehabilitation and other services'. . . not to force their parents or relatives, or themselves, to work").

The Supreme Court and the D.C. Circuit applied the same reasoning in the context of Medicaid in *Walsh*, 538 U.S. 644, and *Thompson*, 362 F.3d 817. Those decisions recognized fluidity in Medicaid eligible populations, and that it is a legitimate objective of Medicaid to conserve state resources via measures that reduce the likelihood of borderline groups becoming Medicaid-eligible. The actions at issue in *Walsh* and *Thompson* imposed burdens on Medicaid recipients—requiring prior authorization for certain drugs—to encourage drug manufacturers to provide rebates for persons who were not Medicaid-eligible. In *Walsh*, 538 U.S. at 663, the Supreme Court agreed with the Secretary that Medicaid-related interests would be served if the rebates reduced costs enough to prevent their

recipients from becoming Medicaid-eligible. *See Thompson*, 362 F.3d at 824–25 (discussing *Walsh*).[4]

Similarly, the D.C. Circuit in *Thompson* accepted as rational the Secretary's determination that such measures "further the goals and objectives of the Medicaid program." *Thompson*, 362 F.3d at 825. There, the court relied on the Secretary's conclusion that "by making prescription drugs accessible to the [non-Medicaid] populations, which are closely related to Medicaid populations in terms of financial and medical need, it is reasonable to conclude that these populations . . . will maintain or improve their health status and be less likely to become Medicaid eligible." *Id.* The court explained that:

> [c]onversely, in the Secretary's view, the failure to implement the [measures] could require cuts in the two non-Medicaid programs that "will necessarily result in some individuals enrolling in Medicaid, and for others, lead to a decline in their health status and resources that will result in Medicaid eligibility or increased Medicaid expenses" and the "[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. The D.C. Circuit held that the "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." And it further held 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.* In other words, the D.C. Circuit concluded that a measure seeking to preserve the fiscal sustainability of the Medicaid program by conserving Medicaid resources plainly furthered the statute's goals.

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[4] Justice Stevens, joined by Justices Souter and Ginsburg, explained that "by enabling some borderline aged and infirm persons better access to prescription drugs earlier, Medicaid expenses will be reduced." *Walsh*, 538 U.S. at 663. "If members of this borderline group are not able to purchase necessary prescription medicine, their conditions may worsen, causing further financial hardship and thus making it more likely that they will end up in the Medicaid program and require more expensive treatment." *Id.* In a separate opinion, Justice O'Connor, joined by Chief Justice Rehnquist and Justice Kennedy, agreed that this rationale would be a basis to uphold the state law if supported by facts in the record. *Id.* at 689.

The logic of *Dublino*, *Aguayo*, *Walsh*, and *Thompson* extends to measures, like the features of Kentucky HEALTH, that facilitate the transition of Medicaid recipients out of Medicaid eligibility and, potentially, into employer or other coverage. When such transitions occur, the consequence is that "more resources will be available for existing Medicaid beneficiaries," which "further[s] the goals and objectives of the Medicaid program." *Thompson*, 362 F.3d at 825. KY HEALTH advances that objective and thus falls comfortably within the principle of these decisions.

The logic of these decisions applies with special force to demonstrations that, like KY HEALTH, enable States to cover optional populations or benefits by ensuring the fiscal sustainability of the State's Medicaid program. By plaintiffs' own account, hundreds of thousands of adults—including plaintiffs themselves—are receiving health care coverage in Kentucky only because the State voluntarily chose to provide coverage for the new adult population. *See* Pls.' Mem. 6. The Secretary's approval properly took into account the State's discretion to terminate optional coverage *entirely*. Although Congress purported to make coverage of the new adult group mandatory, the Supreme Court held in *NFIB* that Congress could not constitutionally make a State's preexisting Medicaid funding contingent on coverage of this group. *NFIB*, 567 U.S. at 585. Thus, in 2012, when many States were considering whether to participate in the adult eligibility expansion, CMS assured the States that they would have "flexibility to start *or stop* the expansion." CMS FAQ at 11 (emphasis added).

In Kentucky, the risk of losing coverage for the expansion population is not theoretical. Kentucky explained in its application that it would soon be responsible for "approximately $1.2 billion in new spending for fiscal years 2017 through 2021" due to its decision to expand Medicaid, "an expense Kentucky cannot afford without jeopardizing funding for education, pension obligations, public safety and the traditional Medicaid program for [its] most vulnerable citizens." AR 25,500. Kentucky thus noted that the demonstration project is meant to "continue health coverage for [its]

existing Medicaid population while evaluating new policies designed to prepare individuals for self-sufficiency and private market coverage." AR 5432; *see also* AR 5440 ("Kentucky HEALTH's design saves taxpayer dollars, critical to ensuring the program's long-term financial viability."). The Secretary, in turn, recognized that Kentucky has repeatedly represented that if it cannot move forward with KY HEALTH, "it will discontinue coverage for the ACA expansion population, a choice it is entitled to make." AR 6726; *see also* Gov. Matthew G. Bevin, Exec. Order (Jan. 12, 2018), ECF No. 25-1.

Plaintiffs dismiss this possibility, but do so only by disregarding the explicit reasoning of *NFIB* and CMS's resulting assurance to the States. Plaintiffs assert that "once a state, like Kentucky, extends Medicaid coverage to include the expansion population, that state can no more choose to eliminate coverage for that group of Medicaid recipients than it could for pregnant women, individuals with disabilities, or any other mandatory-coverage population." Pls.' Mem. 16. But to support that remarkable assertion, they note only that "the expansion population remains a mandatory-coverage population" in the statute. Pls.' Mem. at 16 (citing 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII)). The cited provision is, of course, the adult eligibility expansion provision that was at issue in *NFIB*, which the Supreme Court held could *not* be a basis for terminating a State's preexisting Medicaid funding. *NFIB* made clear that the Secretary "cannot . . . withdraw existing Medicaid funds for failure to comply with the requirements set out in the expansion." *NFIB*, 567 U.S. at 585. In other words, as CMS explained to the States when encouraging them to expand coverage, States have "flexibility to start or stop the expansion." 2012 CMS Guidance at 11. There is thus no doubt that Kentucky can eliminate coverage of the new adult group without putting its entire Medicaid grant at risk.

It makes no difference whether Kentucky 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.' Mem. 17 (quoting *Stewart*, 313 F. Supp. 3d at 271). As a result of

NFIB, coverage of the adult expansion population is optional, which means that Kentucky is free to terminate that coverage. In this sense, the new adult population that is receiving coverage under the ACA expansion is not materially different from the adult population that was receiving coverage under the pre-ACA Oregon demonstration project in *Spry v. Thompson*, 487 F.3d 1272 (9th Cir. 2007). There, the Ninth Circuit explained that people in that expansion population were not "made worse off" by the requirements they challenged because, "without the demonstration project, they would not be eligible for Medicaid at all." *Id.* at 1276. Here, too, the new adult group that continues to receive coverage under Kentucky HEALTH will not be made worse off by the challenged requirements because, without the adult eligibility expansion, they would not be eligible for Medicaid at all.

In addition, the Secretary's approval of KY HEALTH is independently justified by the Secretary's finding that a number of its components, including within Kentucky HEALTH, are likely to improve the health of Medicaid recipients. Plaintiffs argue it is not a freestanding objective of Medicaid to improve the health of the people that program covers. Pls.' Mem. 13. But as the Secretary explained, "there is little intrinsic value in paying for services if those services are not advancing the health and wellness of the individual receiving them, or otherwise helping the individual attain independence." AR 6719. Indeed, the architect of Medicaid and other Great Society programs emphasized that the "aim is not only to relieve the symptom of poverty, but to cure it and, above all, to prevent it." Pres. Lyndon B. Johnson, Annual Message to Congress on the State of the Union (Jan. 8, 1964). The purpose of the Medicaid program is to improve the health and wellness of recipients so they can live happier, more independent lives; health care services are of greatest value if they advance those basic public-health objectives. AR 6719. That is why, in 2012, HHS explicitly encouraged States to develop initiatives "aimed at promoting healthy behaviors" and "individual ownership in health care decisions" as well as "accountability tied to improvement in health outcomes." 2012 CMS

Guidance at 15.

Further, plaintiffs' argument assumes that making people who receive Medicaid healthier will have no general impact on the Medicaid program. But as the Secretary explained, healthier people who are more engaged in their communities tend to consume fewer medical services and are generally less costly to cover. AR 6716. Measures that promote those objectives thus redound directly to Medicaid's benefit by conserving state resources, *id.*, at the same time that they improve quality of life for recipients.

C. Plaintiffs misread the record, the law, and this Court's prior opinion.

Plaintiffs raise a host of additional objections to the Secretary's approval; none are persuasive.

1. The Secretary adequately considered potential effects on coverage.

Notwithstanding the Secretary's comprehensive discussion of coverage effects in the November 20 approval, plaintiffs contend that the Secretary still has not sufficiently considered the effects of Kentucky HEALTH on coverage. Pls.' Mem. 19–22. In their view, nothing has changed since this Court's prior finding that the record was without "discussion about the effect of Kentucky HEALTH on health coverage." *Stewart*, 313 F. Supp. 3d at 263. That is simply incorrect. The Secretary's recent approval amply addresses Kentucky HEALTH's possible effects on coverage, including the issues raised in the Court's earlier decision.

As described above, the Secretary has now explained how KY HEALTH, including Kentucky HEALTH, is likely to promote coverage by ensuring the fiscal sustainability of the Medicaid program. AR 6726. The Secretary continues to recognize, of course, that "some individuals may choose not to comply with the conditions of eligibility imposed by the demonstration, and therefore may lose coverage." AR 6729; *see also* AR 6726. But "section 1115 of the [Medicaid] Act explicitly contemplates that demonstrations may 'result in an impact on eligibility.'" AR 6730 (quoting 42 U.S.C. § 1315(d)(1)).

Moreover, the Secretary considered the possibility of beneficiary noncompliance against the backdrop of the apparent alternative: that absent implementation of all of KY HEALTH, including Kentucky HEALTH, the State would "reconsider the ACA adult eligibility expansion." AR 6731. In other words, the Secretary recognized that the possibility of some coverage losses due to noncompliance would pale in comparison to the possibility of losing coverage for the more than 454,000 individuals covered by the ACA expansion in Kentucky, as well as other non-mandatory populations or benefits. AR 6731–32. In this way, the demonstration "is expected to provide greater access to coverage for low-income individuals than would be available absent the demonstration." AR 6726; *see also* AR 6729 ("[T]his demonstration is designed to *extend* coverage." (emphasis added)).

Plaintiffs insist that it was necessary for the Secretary to produce a "bottom-line" estimate of the number of people who would lose coverage over the course of the demonstration. Pls.' Mem. 19 (quoting *Stewart*, 313 F. Supp. 3d at 262). But plaintiffs cite no authority suggesting that such a precise estimate is a necessary precondition to a Section 1115 approval. Indeed, the demonstration does not even lend itself to an "estimate of how many people would lose Medicaid," Pls.' Mem. 19 (quoting *Stewart*, 313 F. Supp. 3d at 262), because a beneficiary may choose not to comply and thus lose coverage for a few months, but then come back into compliance and regain coverage once again. An estimate of the number of people who will lose coverage (the assumption being permanently) is therefore an inaccurate view of the effects of the demonstration on coverage.

In any event, because a demonstration project is an experiment, it is neither necessary nor practical for the Secretary to determine ex ante the exact number of individuals who may gain or lose coverage as a result of a project's features. Demonstration projects are designed to test innovations, and the actual impact on enrollment is not known in advance. That is particularly true here, where the State is testing whether individuals subject to a new incentive structure will comply with new

incentives—something that is inherently difficult to predict. Such "predictive calculations are a murky science in the best of circumstances," *Cablevision Sys. Corp. v. FCC*, 597 F.3d 1306, 1314 (D.C. Cir. 2010), and the Secretary is not required to quantify the expected outcome of an experiment in advance. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 519 (2009) ("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." (internal citation omitted)).

Indeed, the Secretary correctly—and at least reasonably—recognized that under Section 1115 "[i]t is not necessary for a state to show in advance that a proposed demonstration will in fact achieve particular outcomes" at all. AR 6730. "[T]he purpose of a demonstration is to test hypotheses and develop data that may inform future decision-making." *Id.* Even when a demonstration project does not succeed in achieving the desired results, the information it yields provides policymakers real-world data on the efficacy of such policies. *Id.* "That in itself promotes the objectives of the Medicaid statute," AR 6730, because Section 1115 "experiments are supposed to demonstrate the failings or success of such programs." *C.K. v. N.J. Dep't of Health & Human Servs.*, 92 F.3d 171, 187 (3d Cir. 1996); *see also Aguayo*, 473 F.2d at 1103 (explaining that the Administrator may set "lower threshold for persuasion" when evaluating experimental project of limited duration); *Cal. Welfare Rights Org. v. Richardson*, 348 F. Supp. 491, 498 (N.D. Cal. 1972) (holding that "project designed to collect data which may well be of significance both in the administration of the present Medicaid program and in the process of proposing legislative modifications to it" met "the requirements imposed by § 1115").

Although this Court previously described the Secretary's lack of a bottom-line estimate as a "glaring" "oversight." *Stewart*, 313 F. Supp. 3d at 262, that description was based on the record as it then existed. In particular, the Court determined that the Secretary had not addressed the 95,000 figure that plaintiffs derived from estimates submitted by Kentucky. *Id.* at 262; Pls.' Mem. 19. The Secretary

has now expressly stated that he considered Kentucky's estimated coverage effects and plaintiffs' interpretation of those figures, and he has explained why approval of the project is nonetheless warranted. AR 6730–31. For example, he explained that, contrary to plaintiffs' assertions, the study submitted by Kentucky does not estimate that 95,000 beneficiaries will become uninsured under the project. Rather, plaintiffs and other commenters calculated that figure by taking Kentucky's own estimate of the aggregate number of fewer "member months" expected to be covered over the lifetime of the demonstration and dividing that figure by twelve. AR 6730–31, 16708; *see* AR 6731 ("One member month is equal to one member enrolled for one month."). In other words, Plaintiffs incorrectly assume, with no foundation for doing so, that every member month of coverage lost under the demonstration is part of a full year of coverage for a person who never regains coverage over the lifetime of the demonstration (despite the demonstration's opportunities for regaining coverage). Simply put, the study submitted by Kentucky presents only an estimated decrease in covered member months, not covered years. And the Secretary adequately considered this information. As the Secretary explained, Kentucky's estimate amounted to only a five percent decrease in total member months, and is "likely attributable to a number of factors, including beneficiaries transitioning to commercial coverage, as well as the elimination of retroactive eligibility and beneficiaries who are temporarily suspended or otherwise lose eligibility for part of the year due to their noncompliance with program requirements." AR 6731. The Secretary also noted that Kentucky's figure did not take into account "changes made to the demonstration at approval," including the addition of certain "guardrails expected to help beneficiaries maintain enrollment." *Id.*

More fundamentally, the Secretary emphasized that even the 95,000 figure (like various other coverage estimates offered by commenters) is "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.

This observation underscores why it was reasonable for the Secretary to approve KY HEALTH without a precise estimate of coverage losses. Aside from the inherent difficulty in predicting such a figure, there is no evidence that losses would amount to the size of the State's new adult group.

Although the Secretary was not obligated to produce an estimate of the number of people who would lose coverage under the demonstration, as described above, he nonetheless considered the prospect that some individuals might lose coverage, even if just temporarily. Thus, both the Secretary and Kentucky sought to minimize effects on coverage by making compliance "achievable." AR 6727. And rather than "limit[ing] his review to only 'vulnerable individuals,'" as plaintiffs assert, Pls.' Mem. 20 (quoting *Stewart*, 313 F. Supp. 3d at 263–64), the Secretary considered the demonstration's impact on all beneficiaries subject to its requirements, and concluded that the demonstration as a whole seeks to make compliance with these requirements achievable for all beneficiaries subject to them.

The demonstration does this through a combination of exemptions and other provisions that are designed to accommodate a wide range of circumstances that beneficiaries subject to the demonstration's policies might face. For example, the demonstration exempts certain categories of individuals—such as the medically frail, pregnant women, former foster care youth, or survivors of domestic violence—who may face barriers to compliance with the program's requirements. *See, e.g.*, AR 6755, 6757, 6760, 6762, 6774.[5] Such categories of individuals are likewise exempt from certain penalties, such as the non-eligibility period for failure to report a change in circumstance or submit redetermination paperwork. AR 6757, 6760. With respect to those individuals who are not exempt, the demonstration is designed to make compliance readily attainable. AR 6727. For instance, the

[5] Indeed, at least one plaintiff was informed in June 2018 that he was exempt from the community-engagement requirement. *E.g.*, Decl. of Stewart, R. ¶ 11, ECF No. 89-2.

community engagement requirement may be satisfied not just by working (as plaintiffs still appear to suggest), but through community service, job skills training, or a number of other activities. AR 6774. Indeed, several plaintiffs state that they are currently meeting this requirement.[6] Others indicate that they are working or engaging in other activities that may total, or nearly total, that amount, such that those plaintiffs either already meet the 80-hour monthly requirement or may meet it by engaging in a few additional hours of qualifying activities.[7] Likewise, the premium requirement may not exceed four percent of household income. AR 6769. And the State is obligated to engage in outreach and education regarding the project's requirements, as well as to provide beneficiaries with sufficient notice of the project's requirements and their own status under it. AR 6758–59, 6761–62, 6766–69, 6777–78.

Further, should an individual choose not to comply with the project's requirements, there are guardrails in place to limit any impact on coverage, including opportunities to avoid adverse actions stemming from noncompliance by demonstrating that there was good cause for the noncompliance, AR 6757–58, 6760, 6776, 6768; full appeal rights prior to any loss of eligibility, AR 6759–61, 6769, 6779; no loss of eligibility for failure to pay premiums when the beneficiary's household income is at

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[6] *See, e.g.*, Supp. Decl. of McComas, S. ¶ 4, ECF No. 89-4 (currently works 40 hours per week); Supp. Decl. of Roode, D. ¶ 4, ECF No. 89-6 (currently works between 20 to 30 hours per week); Decl. of Keith, L. ¶ 2, ECF No. 89-8 (currently works approximately 28 hours per week); Decl. of Malone, H. ¶ 5, ECF No. 89-10 (currently a full-time student); Decl. of Segovia, D. ¶ 4, ECF No. 89-13 (currently works 30 hours per week); Decl. of Lee, R. ¶ 2, ECF No. 89-17 (currently works 20 hours per week).

[7] *See, e.g.*, Stewart Decl. ¶¶ 4, 11 (received a determination in June 2018 that he was not subject to the community engagement requirement and currently is working 15 hours per week); Decl. of Spears-Lojek, M. ¶ 7, ECF No. 89- 5 (expects to work 19 hours/week); Decl. of Kobersmith, K. ¶¶ 2, 3. ECF No. 89-3 (currently working between 10 to 12 hours per week and home-schooling and is caring for her children); Decl. of Wittig, D. ¶ 2, ECF No. 89-9 (currently works 12 to 14 hours per week); Decl. of Yates, R. ¶ 5, ECF No. 89-12 (has helped to take care of the elderly, has worked in home care, and does odd jobs); Decl. of Martin, S. ¶ 3, ECF No. 89-15 (currently a part-time student).

or below 100 percent of the federal poverty line, AR 6770–71, 6773; and the opportunity to regain coverage by coming back into compliance with the program's requirements. And if unexpected coverage losses do occur in significant numbers, CMS has reserved the right "to withdraw waivers or expenditure authorities" or to "require the state to submit a corrective action plan," AR 6728.

In light of these design features and the Secretary's new explanations, the deficiencies this Court perceived have been corrected. It cannot now be said that the Secretary "neglected" to address coverage concerns. *Stewart*, 313 F. Supp. 3d at 264. Nor is the Court being asked to "credit . . . speculations" or infer "reasoning from mere silence." *Id.* at 264. The Secretary has grappled with coverage-effect estimates, and explained why the demonstration is ultimately expected to promote coverage—easily demonstrating a "rational connection between the facts found and the choice made" and satisfying arbitrary and capricious review. *Kisser v. Cisneros*, 14 F.3d 615, 619 (D.C. Cir. 1994).

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

In an attempt to evade the deference owed to the Secretary's "overall judgment" under Section 1115(a), plaintiffs not only seek to separate Kentucky HEALTH from KY HEALTH, but they also separate Kentucky HEALTH into individual components in Counts Two through Seven. But as this Court recognized, demonstrations must be judged based on whether the project *as a whole* would promote the objectives of Medicaid, and not whether each component in isolation would do so. *Stewart*, 313 F. Supp. 3d at 257. This Court concluded that Kentucky HEALTH is "wholly distinct from other pieces of KY HEALTH," and that the Secretary "effectively treated the SUD program and Kentucky HEALTH as two separate demonstration projects." *Stewart*, 313 F. Supp. 3d at 257. But as the Secretary explained in its November 20, 2018, approval, these are not separate demonstration projects. Rather, "Kentucky HEALTH, working within the larger KY HEALTH demonstration program, is likely to assist in promoting the objectives of the Medicaid program." AR 6723.

Demonstrations often involve a package of tradeoffs and compromises, and it would be inappropriate for this Court to cobble together portions of KY HEALTH to create a new project the Secretary never even considered, much less determined likely to advance Medicaid's objectives.

In any event, Counts Two through Seven fail on their merits as they are founded on the erroneous premise that each component of the project independently must merit approval under Section 1115 standards. The statute simply does not countenance such a "myopic analysis." *Wood*, 922 F. Supp. 2d at 843; *see also Stewart*, 313 F. Supp. 3d at 257 ("To the extent Plaintiffs mean to argue that none" of the individual components of Kentucky HEALTH "is *independently* likely to further the Act's objectives, such focus would be misplaced. . . . While it may be relevant to the Secretary's determination whether any given component is consistent with the Act's objectives, he must ultimately determine whether, on balance, the project as a whole passes muster.").

Viewing the project as a whole, the Secretary's grant of waivers was amply supported by record evidence and was not arbitrary or capricious. And even if the components of Kentucky HEALTH were to be considered separately, the Secretary adequately explained why each component, on its own, is likely to further the objectives of Medicaid, as described below.

3. The community-engagement requirement does not "comprehensively transform Medicaid."

Plaintiffs assert that the Secretary lacks authority to "comprehensively transform Medicaid" through a community-engagement requirement. Pls.' Mem. 34. But that assertion confuses a demonstration project with a statutory amendment. The decision whether to amend the Medicaid statute to include a community engagement requirement is, of course, for Congress to make, just as the decision to include a work requirement in the TANF legislation was a matter for Congress. But the decision to allow States to *test* community-engagement requirements as part of a Section 1115 project is well within the Secretary's authority. The very purpose of Section 1115 is to ensure that

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." Conf. Rep. at 19. And unlike a statutory amendment, which is typically permanent, a demonstration project is for a limited term—here only 5 years. AR 6718. There is nothing unlawful about the Secretary exercising his waiver authority to temporarily approve a new component to gather data useful to policymakers.

This approach is the ordinary course. HHS has long recognized that demonstration projects of this kind can "influence policy making at the [s]tate and Federal level, by testing new approaches that can be models for programmatic changes nationwide or in other States." Medicaid Program; Review and Approval Process for Section 1115 Demonstrations; Application, Review, and Reporting Process for Waivers for State Innovation; Final Rules, 77 Fed. Reg. 11678, 11680 (Feb. 27, 2012). Indeed, many States tested innovative welfare-reform initiatives through demonstration projects under AFDC, leading Congress to incorporate these policies into the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, the legislation that replaced AFDC with the TANF program. Likewise, demonstration projects that allowed States to implement managed care and benchmark plans informed Congress's addition of Section 1932 of the Social Security Act in the Balanced Budget Act of 1997. *See* Pub. L. 105-33, 111 Stat. 251 (permitting States to implement managed care and benchmark plans through the State plan amendment process without having to seek waivers of Medicaid rules). And after demonstration projects tested the efficacy of family-planning services, the ACA incorporated these into an optional eligibility group that States can include in their plans, *see* 42 U.S.C. § 1396a(a)(10)(A)(ii)(XXI).

Plaintiffs are correct that Congress has not adopted a community engagement requirement in the Medicaid statute, Pls.' Mem. 36–38, but that is just the point: the Secretary is temporarily testing a requirement not contained in the statute to inform future policymaking efforts. Nor does it matter

that "during the 50-plus years of Medicaid" CMS has not previously approved a community engagement requirement as a condition of Medicaid eligibility. Pls.' Mem. 37. The purpose of Section 1115 is to allow for this sort of experiment, and every experiment has a first time. Moreover, as a result of the ACA's adult eligibility expansion that began in 2014, many able-bodied adults are now covered by Medicaid—a stark departure from the 50-plus years of Medicaid in which eligibility was confined to vulnerable populations such as children and persons with disabilities.

4. Premiums were lawfully approved and adequately explained.

Plaintiffs present a pair of arguments concerning the premium requirement, both of which fall short. First, they point to comments which they allege show that some individuals will not pay the premiums and will accordingly lose coverage. Pls.' Mem. 23–25. As with any conditional benefit, noncompliance is of course a possibility. But the premiums here were designed to minimize effects on coverage by making compliance feasible: the premium varies based on household income; a failure to pay only affects coverage for those with household income above 100% of the federal poverty line; and there is an opportunity to avoid adverse consequences for missed payments by demonstrating good cause to miss them. AR 6766, 6768–69, 6773.

More fundamentally, the premiums themselves are expected to promote coverage. HHS has previously encouraged demonstration projects that "encourage personal responsibility" and "individual ownership in health care decisions." 2012 CMS Guidance at 15. Indeed, the prior administration previously approved projects that contained premium requirements. *See, e.g.*, Montana HELP, ECF No. 51-7; Indiana HIP 2.0, ECF No. 51-8; Healthy Michigan, ECF No. 51-13. And in approving Kentucky HEALTH, the Secretary explained that interim evidence from the Indiana project showed that those who paid premiums were "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." AR 6734–35. Such "health-promoting behaviors" and increased "engagement by beneficiaries in their personal health care plans" reduce healthcare costs and allow the state to stretch resources to cover more beneficiaries. AR 6735. Plaintiffs quibble that the data from Indiana is not perfect, Pls.' Mem. 31, but the Secretary is under no obligation to obtain incontrovertible evidence before approving an experiment *meant to obtain more evidence*. Nor do plaintiffs explain why premiums cannot have research value both independently and in conjunction with the other features of Kentucky HEALTH. *See* Pls.' Mem. 24; AR 6735.

Second, plaintiffs argue that the Secretary lacks the Section 1115 authority to approve a premium requirement in the first place—a contention that would call into question demonstrations approved across multiple administrations and that is wrong on several counts. Pls.' Mem. 38–42. Section 1115 authorizes the Secretary to waive compliance with Section 1396a. Section 1396a specifies numerous requirements with which State Medicaid plans must comply, including the conditions specified in 83 separate provisions of subsection (a). *See* 42 U.S.C. §§ 1396a(a)(1)–(83). As relevant here, subsection (a)(14) requires that a State plan "provide that *enrollment fees, premiums, or similar charges*, and deductions, cost sharing, or similar charges, may be imposed only as provided in section 1396o …." § 1396(a)(14) (emphasis added). Section 1396o, in turn, sets forth the requirements for the two categories of charges identified in § 1396a(a)(14)—that is, "enrollment fees, premiums, or similar charges," and "deductions, cost sharing, or similar charges." Section 1396o-1 describes certain exceptions to § 1396o. Here, the Secretary exercised his authority to waive § 1396a(a)(14), "insofar as" that condition "incorporates" §§ 1396o or 1396o-1, "[t]o the extent necessary to enable Kentucky to require monthly premium payments …." AR 6741.

Plaintiffs concede, as they must, that the Secretary has the authority to waive § 1396a(a)(14), but argue that this authority does not extend to waiving the premium requirements of §§ 1396o and

1396o-1. Pls.' Mem. 38–39. However, no plausible reading of the statutory text, context, or history supports, let alone compels, this conclusion. The Secretary's conceded authority to waive § 1396a(a)(14), which is what requires State plans to comply with § 1396o, necessarily means that a State that is granted a waiver need *not* comply with § 1396o. The authority to waive § 1396a(a)(14) would be meaningless if State plans were still required to comply with § 1396o despite the Secretary's waiver. By placing the requirement to comply with § 1396o in § 1396a(a)(14) and authorizing the Secretary to waive "any of the requirements of … 1396a," Congress expressly authorized the Secretary to waive compliance with § 1396o. Plaintiffs' interpretation otherwise would strip § 1396a(a)(14) from the scope of Section 1115's waiver authority.[8]

Contrary to Plaintiffs' contention, § 1396o(f) *confirms* that the Secretary has authority to waive compliance with premium requirements in § 1396o by virtue of his authority to waive § 1396a(a)(14). Plaintiffs argue that the waiver provision in § 1396o(f) for cost-sharing charges would be superfluous "if the Secretary could use Section 1115 to waive the requirements in Section 1396o," and they contend that the inclusion of § 1396o(f) demonstrates Congress's intent to exclude any comparable authority to waive § 1396o's distinct premium requirements. Pls.' Mem. 39. Both arguments fail for the same

[8] Plaintiffs contend that § 1396a(a)(14)'s use of the phrase "only as provided in section 1396o" shows that Congress intended to place all premiums outside the Secretary's Section 1115 authority. Pls.' Mem. 39–40. But this assertion ignores the fact that Congress authorized the Secretary to waive *any* of the provisions in § 1396a, including § 1396a(a)(14)'s "only as provided in" language. Plaintiffs acknowledge that courts have upheld the Secretary's authority to waive the requirements of § 1396a(a)(14), *see* Pls.' Mem. 40 (citing *Crane v. Mathews*, 417 F. Supp. 532, 538–40 (N.D. Ga. 1976); *CWRO*, 348 F. Supp. 491), but attempt to distinguish those cases by pointing to the subsequent legislative enactments that added §§ 1396o and 1396o-1. These cases are good law and no court has held them to be superseded. Plaintiffs' reliance on dicta in *Pharm Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, 222 (D.C. Cir. 2001), is likewise misplaced. Pls.' Mem. 38. There, the court read 42 U.S.C. § 1396r-8 not to authorize the Secretary to approve a demonstration in which manufacturers would pay rebates for drugs purchased by non-Medicaid beneficiaries. The court did not address the distinct question, presented here, whether the Secretary can permit a state to impose premiums on certain beneficiaries through a waiver of § 1396a(a)(14).

basic reason: they are based on the erroneous premise that § 1396o(f) contains a specific grant of authority to waive § 1396o's cost-sharing requirements. In fact, § 1396o(f) does not *grant* any waiver authority; it *limits* the Secretary's Section 1115 waiver authority with respect to cost-sharing charges, and in so doing *presumes* that Section 1115's waiver authority extends to § 1396o. Section 1396o(f) does not say that the Secretary "may waive" § 1396o's requirements for cost-sharing charges. Instead, its language is prohibitory, providing that "no [such] . . . charge may be imposed under any waiver authority . . . unless such waiver" complies with specified conditions. 42 U.S.C. § 1396o(f). This prohibitory language would be unnecessary if the Secretary's Section 1115 waiver authority did not extend to § 1396o in the first place, as plaintiffs contend.

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

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

authority of the Secretary through waiver to modify limitations on premium and cost sharing under this section." Congress thus expressly provided in the text of § 1396o-1 itself that the Secretary has authority "through waiver to modify limitations on premium and cost sharing under [§ 1396o-1]."

Nor does the statutory or legislative history support Plaintiffs' interpretation. Contrary to Plaintiffs' telling, *see* Pls.' Mem. 40–42, §§ 1396o and 1396o-1 do not restrict the Secretary's waiver authority in any respect; rather, they were primarily intended to provide another way by which States can "exceed the normal limitations" on Medicaid cost-sharing. *Newton-Nations v. Betlach*, 660 F.3d 370, 375 (9th Cir. 2011). Indeed, the House Committee Report cited by plaintiffs shows that § 1396o was designed primarily to provide *greater* flexibility to the States to impose cost-sharing, in light of the increased State interest in doing so. H.R. Rep. 97-757, pt. 1, at 6 (1982) (noting that "a large number of States have sought" Section 1115 waivers to impose cost- sharing, and that the bill would "give[] States sufficient flexibility" to impose cost-sharing even in the absence of a § 1115 waiver). And § 1396o-1, which provides exceptions to § 1396o, "further relaxes the normal cost-sharing restrictions." *Newton-Nations*, 660 F.3d at 375. At most, the legislative history suggests that Congress anticipated the Secretary might need to use his waiver authority to approve cost-sharing infrequently—not that it somehow *eliminated* that authority, let alone the authority to approve premiums.

The Secretary reads §§ 1396a(a)(14), 1396o, and 1396o-1 together as part of a comprehensive, coherent, and consistent regulatory scheme that achieves Congress's purposes with respect to State flexibility to impose premiums while preserving the Secretary's authority to waive premium requirements. This reading is correct or, at the least, is a permissible one that merits *Chevron* deference. *See City of Arlington v. FCC*, 569 U.S. 290, 296–97 (2013); *Thompson*, 362 F.3d at 822 (holding that the "Secretary's interpretations of the Medicaid Act" are "entitled to *Chevron* deference"). At best, Plaintiffs' alternative reading points to "internal tension" among different provisions in the Act that

point "in divergent ways"—but in such a case, "*Chevron* dictates that a court defer . . . to the agency's expert judgment about which interpretation fits best with, and makes the most sense of, the statutory scheme." *Scialabba v. Cuellar de Osorio*, 573 U.S. 41, 57 (2014) (plurality).

5. Plaintiffs' challenge to the waiver of retroactive eligibility is non-justiciable and meritless.

Although plaintiffs purport to challenge the waiver of retroactive eligibility, none established standing to do so. *See Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008) ("Standing is not dispensed in gross."). Each plaintiff is currently covered by Medicaid, and any fears of future disenrollment (and re-enrollment subject to the waiver) are speculative. *See, e.g.*, McComas Decl. ¶ 19; Supp. Decl. of Penney, S. ¶ 16, ECF No. 89-7; Roode Decl. ¶ 13; Keith Decl. ¶ 13; Wittig Decl. ¶ 13; Malone Decl. ¶ 10. Article III's "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." *Nw. Airlines, Inc. v. FAA*, 795 F.2d 195, 201 (D.C. Cir. 1986).

In any event, Plaintiffs' contentions regarding the waiver of retroactive eligibility are meritless. They assert the Secretary has not sufficiently explained how the waiver promotes coverage, Pls.' Mem 25–26, but the Secretary has done just that: he explained that this feature of the demonstration (which has been approved across administrations[9]) is designed to test whether beneficiaries "will be encouraged to obtain and maintain health coverage, even when healthy," and "whether there will be

[9] *See* Indiana HIP 2.0 (2015), ECF No. 51-8; Delaware Diamond State Health Plan (2012), ECF No. 51-11; Montana HELP (2016), ECF No. 51-7; Oklahoma SoonerCare (2010), ECF No. 51-12; Healthy Michigan (2013), ECF No. 51-13; Arkansas Safety Net Benefit Program (2011), ECF No. 51-14; New Hampshire Health Protection Program Premium Assistance (2015), ECF No. 51-15; Tennessee TennCare II (2012), ECF No. 51-16; Oregon Health Plan (2002), ECF No. 51-17.

a reduction in gaps in coverage when beneficiaries churn on and off Medicaid or sign up for Medicaid only when sick." AR 6724. Studies bear out that such churn occurs.[10] And the Secretary recognized that gaps in coverage matter because when people who can enroll in Medicaid when they are healthy "wait until they are sick" to do so they "may be less likely to obtain preventive health services during periods when they are not enrolled." *Id.* This is of particular concern in Kentucky, where, in the first year of the state's Medicaid expansion, "fewer than l0 percent of beneficiaries in the ACA expansion population received an annual wellness or physical exam." *Id.* By encouraging eligible individuals to enroll in Medicaid while they are healthy, the waiver seeks to enable Kentucky to "better contain Medicaid costs and more efficiently focus resources on providing accessible and high-quality health care, thereby promoting the sustainability of its Medicaid program." AR 6727. This promotes coverage by "help[ing] to permit Kentucky to continue to provide Medicaid to the ACA expansion population, and to continue to cover non-mandatory benefits and eligibility groups." AR 6736.

Plaintiffs cannot dismiss the Secretary's explanation as "conclusory." Pls.' Mem. 25 (quoting *Stewart*, 313 F. Supp. 3d at 265). Although waiving retroactive coverage by necessity eliminates some coverage, the Secretary has fully explained how he expects the waiver to promote coverage overall. Plaintiffs may believe that lost retroactive coverage will outweigh coverage gains from earlier sign-ups, a more healthy population, and a more sustainable Medicaid program. But such weighing of costs and benefits is a decision for the Secretary, not Plaintiffs, and approving a test to gather more information on the question is well within the Secretary's discretion and expertise. *See Sec. Indus. & Fin. Markets*

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[10] *See, e.g.*, *Profile of the Medicaid Expansion Population* (Jan. 2018), at 3 https://www.antheminc.com/cs/groups/wellpoint/documents/wlp_assets/d19n/mzmw/~edisp/pw_g330411.pdf ("Across plans and states, the expansion population experienced high disenrollment rates, indicating that, as in other Medicaid eligibility groups, there is substantial churn in this population.").

Ass'n v. CFTC, 67 F. Supp. 3d 373, 430 (D.D.C. 2014) (the weighing of costs and benefits "epitomize[s] the types of decisions that are most appropriately entrusted to the expertise of an agency").

6. Plaintiffs' challenge to the non-eligibility periods is non-justiciable and meritless.

Plaintiffs argue that the non-eligibility periods will "by definition, reduce coverage." Pls.' Mem. 26–27. Again, Plaintiffs fail to establish standing to challenge this particular aspect of Kentucky HEALTH. Plaintiffs merely speculate that they may be unable to complete their redetermination process by the end of their eligibility period or report changes in circumstances that affect their eligibility and, thus, may be disenrolled from Medicaid. *See* Decl. of Humber, A. ¶ 12, ECF No. 89-11; Decl. of Ritter, R. ¶ 15, ECF No. 89-14; Wittig Decl. ¶ 13. But there is no reason to suppose that plaintiffs cannot comply with the requirement, especially since there are "various methods to report changes, including by phone, through a [Department for Community Based Services] office, or online . . . ." AR 2027. Moreover, plaintiffs would be exempt from the non-eligibility period if they are medically frail, pregnant, former foster care youth, or survivors of domestic violence, or if Kentucky grants them a good-cause exception. AR 6757, 6760; *see In re Sci. Applications Int'l Corp. Backup Tape Data Theft Litig.*, 45 F. Supp. 3d 14, 24 (D.D.C. 2014).

As to the merits, the Secretary acknowledged that temporary suspensions of eligibility may affect coverage levels, AR 6726, but explained that the suspensions are expected nonetheless to "incentivize program compliance," thereby "improving the financial sustainability of Kentucky's Medicaid program." AR 6736. Although plaintiffs assume the non-eligibility period will fail in this regard, Pls.' Mem. 27, 31–32, that is exactly what the demonstration sets out to test—whether the additional incentive of a temporary suspension of eligibility will promote compliance with the premium, redetermination, and change in circumstance requirements. Tellingly, plaintiffs neglect to address the program's "on-ramp" that enables individuals, by attending a health or financial literacy

course, "to regain eligibility and successfully access all of the benefits, resources, and tools of the Kentucky HEALTH program, without waiting until the end of the non-eligibility period." AR 6725. Nor do they discuss the program's good-cause exemptions, or the exemptions for the medically frail and other vulnerable populations. AR 6725–26.

Furthermore, contrary to plaintiffs' assertion, Pls.' Mem. 27, the Secretary has not changed positions on whether a demonstration can include a non-eligibility period. Although CMS previously rejected some aspects of Indiana's proposed non-eligibility period, *see* AR 239–40, 6725, the Secretary ultimately permitted the State to impose disenrollment and a six-month suspension of eligibility for beneficiaries with income over the federal poverty level who failed to pay their premiums. *See* Indiana HIP 2.0, ECF No. 51-8; *see also* Wisconsin Badger Care, ECF No. 51-10 (adopting a three-month disenrollment period). In any event, even if the instant approval could be viewed as a change in position, the Secretary adequately justified any such change with his recognition that new evidence—state-level data from 2017—showed that only 37 percent of people who were required to submit redetermination paperwork in fact did so. AR 6727. This new evidence indicates that current approaches to incentivizing beneficiaries to meet redetermination requirements are not working, and that it is necessary and appropriate to test new measures.

7. Plaintiffs' challenge to the waiver of non-emergency medical transportation is non-justiciable and meritless.

Plaintiffs challenge the NEMT waiver, but here too, they lack standing. The only plaintiffs who assert a purported injury stemming from this waiver fail to show with sufficient certainty that they (1) would be subject to the waiver, which applies to the new adult group and exempts the medically frail and pregnant women, among others, AR 32; and (2) would need to use non-emergency medical transportation in the future. *See, e.g.*, McComas Decl. ¶ 18; Yates Decl. ¶ 8. One plaintiff says that she has never used NEMT but plans to do so for future appointments, Spears-Lojek Decl. ¶ 11,

but she does not show that she is not exempted from this waiver or lacks other means of transport.

Moreover, although plaintiffs assert that the Secretary limited his review of NEMT to only "vulnerable individuals," Pls.' Mem. 28 (quoting *Stewart*, 313 F. Supp. 3d at 263–64), that is not the case. Rather, 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, thereby promoting the sustainability of its Medicaid program." AR 6727; *see also* AR 6735–36. Plaintiffs' prediction that waiving NEMT for the new adult group may cause Kentucky to lose money is thus beside the point, Pls.' Mem. 28, as a central purpose of the demonstration is to test that exact question—whether the waiver will "more efficiently focus resources" for Kentucky Medicaid, AR 6727. For the same reason, the waiver is also not a "simple benefits cut," Pls.' Mem. 28 (quoting *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994)); it has research value, distinguishing this waiver from the project in *Beno*. *See* 30 F.3d at 1069 & n.30. Indeed, the Secretary explained that the waiver of NEMT is aligned with the commercial insurance market, where this benefit is not typically available, and the waiver thus helps familiarize beneficiaries with a constraint they will face if they transition to commercial coverage. AR 6725.

8. Plaintiffs' challenge to deductions from the My Rewards Accounts is non-justiciable and meritless.

Plaintiffs next assert that "deductions" from their *My Rewards* account for non-emergency use of the emergency room should be deemed "cost-sharing" charges subject to statutory cost-sharing limits. Pls.' Mem. 42–43. Here again, they lack standing to raise this claim. Plaintiffs merely speculate that they *may* someday go to a hospital's emergency department for a non-emergency purpose. *E.g.*, Segovia Decl. ¶ 12; Humber Decl. ¶ 10; Keith Decl. ¶ 11. Some plaintiffs explain that they have used the emergency room in the past, *e.g.*, Keith Decl. ¶ 11, but it is well-established that past injuries cannot sustain a claim of future harm, *Summers v. Earth Island Inst.*, 555 U.S. 488, 497 (2009).

On the merits, plaintiffs' argument is flatly inconsistent with the definition of "cost-sharing," which refers to payments made as a condition for receiving particular services or benefits. *See* 42 C.F.R. §§ 447.51–447.54. The *My Rewards Account*, in contrast to that definition, permits beneficiaries to "receive incentives" in the form of credits possessing "no actual monetary value." AR 6721. These incentives may then be used to access certain demonstration-specific benefits, as well as optional benefits that the state could have chosen not to provide even if Kentucky HEALTH were not approved. *Id.* The project does not impose a charge on beneficiaries to access those benefits, but instead specifies the terms on which the project itself will advance earned incentives to the beneficiaries. And, as discussed above, the credits have no cash value; rather an arbitrary dollar value is assigned to the credits that beneficiaries may redeem to receive certain optional or demonstration-only benefits. *Id.* Indeed, in a paragraph titled "No Actual Charges to Beneficiaries," the STCs cite the State's assurance that "at no time would a beneficiary be required to make a monetary payment to the state as a result of having a negative dollar balance in his or her My Rewards Account." AR 6765.

9. Kentucky HEALTH is likely to promote health and financial independence.

Finally, plaintiffs cite comments in the record which they claim show that Kentucky HEALTH will not actually promote health and financial independence. Pls.' Mem. 28–34. As an initial matter, plaintiffs' argument displays a fundamental misunderstanding about the nature of a demonstration project—which is, again, a temporary experiment rather than a permanent revamp of Medicaid, and which does not require definitive results before the experiment has even begun. AR 6730. Plaintiffs' position also presumes an impossibly high standard for approval, whereby the Secretary's conclusions on matters within his technical expertise are unreasonable unless every contrary comment has been described and refuted. But that is not the law. As this Court has already recognized, "the Secretary was not required to address each comment in writing." *Stewart*, 313 F. Supp. 3d at 263. Moreover, "it

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). Indeed, only if objections to the project show such results "as to negate any appreciable possibility of success would the Secretary's approval be arbitrary and capricious." *Aguayo*, 473 F.2d at 1107; *see also C.K.*, 92 F.3d at 185 ("[W]e … decline to find . . . a rule that in all cases an administrative record is deficient and must be supplemented where it does not contain a specific recitation and refutation of objections submitted in opposition to a proposed section 1315(a) waiver.").

Here, the Secretary's conclusion that Kentucky HEALTH would likely promote health and independence was plainly rational in light of evidence from past demonstrations bearing similarities to Kentucky HEALTH, AR 4837, 4962, 4970, and studies showing a correlation between work and/or community engagement and improved health outcomes, AR 4824, 4840, 5112, 5047, 5054, 5061, 5074, 6733 n.10. Plaintiffs may not agree with the Secretary's conclusions, but nothing required the Secretary to give dispositive weight to their views.

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

Plaintiffs ask this Court to enjoin the implementation of Kentucky HEALTH. Am. Compl., Prayer for Relief ¶ 4. Even assuming that relief should be granted, there is no basis for such sweeping relief. On the contrary, any relief should be tailored to the sixteen individuals before the Court. As the Supreme Court recently reaffirmed, a court's "constitutionally prescribed role is to vindicate the individual rights of the people appearing before it," and "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1933, 1934 (2018). Moreover, the APA's equitable remedies are discretionary. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967) ("injunctive and declaratory judgment remedies are discretionary"). There is no equitable reason to disrupt the statewide implementation of Kentucky HEALTH and thus jeopardize the expansion

coverage for hundreds of thousands of individuals who are not before this Court.

To the extent that any of the sixteen plaintiffs will experience injury, it will be as a result of the application of particular Kentucky HEALTH requirements *to them*—not a result of the Secretary's approval of the State's program, or the program's application to third parties not before the Court. That application of the program to particular plaintiffs would be the only proper subject of review and thus the outer limit of any relief. *Cf. Lujan* v. *Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990). And while the amended complaint was styled as a class action, Plaintiffs did not move for class certification and thus forfeited the ability to do so. *See Am. Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 546 (1974) (explaining that Rule 23's requirement of a prompt class certification order prevents the unfairness of waiting until the merits are deciding before addressing class certification).

Nor is there reason to believe that other members of the new adult group share plaintiffs' desire to take the risk that Kentucky will terminate the expansion if the demonstration project is enjoined. We assume that plaintiffs were informed of that risk and knowingly accepted it, although their declarations suggest otherwise. *See*, *e.g.*, Stewart Decl. ¶ 16 (stating that it is "important to keep Medicaid for anyone who qualifies for it"). But even if those sixteen individuals are prepared to put their own coverage at risk, their views should not be imposed on the expansion population at large.[11]

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

Plaintiffs also purport to challenge a January 11, 2018, letter that CMS sent to state Medicaid directors, but that letter was not final agency action subject to judicial review. The letter did not mark

[11] Alternatively, 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 HHS and Kentucky may decide whether to proceed with the rest of the project. Further, any such remand should be without vacatur. *See, e.g., Defs. of Wildlife v. Jackson*, 791 F. Supp. 2d 96, 118–19 (D.D.C. 2011).

the "consummation of the agency's decisionmaking process" nor did it determine "rights or obligations." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citation omitted).

Instead, the letter simply provided guidance for state Medicaid directors and indicated that CMS was prepared to assist States in their efforts to encourage work and community engagement among non-elderly, non-pregnant adult Medicaid beneficiaries who are eligible for Medicaid on a basis other than disability. AR 90. The letter explained that CMS would "support state efforts to test incentives that make participation in work or other community engagement a requirement for continued Medicaid eligibility or coverage for certain adult Medicaid beneficiaries in demonstration projects." *Id.* The letter indicated that demonstration projects are intended to give States "more freedom to test and evaluate approaches to improving quality, accessibility, and health outcomes in the most cost-effective manner." AR 92. The letter provided "a number of issues for states to consider" in developing such demonstration projects, such as the project's alignment with other state welfare programs, the population that would be subject to any community-engagement requirements, and considerations of budget neutrality, monitoring, and evaluation. AR 91–98. And it provided guidance to assist the States in developing successful demonstration projects. *See, e.g.*, AR 78. 94–95.

Guidance of this sort is commonplace for CMS, and it neither commits CMS to a course of action nor requires state Medicaid directors to act. For example, in 2012 guidance, CMS explained that it was "interested in working with states to promote better health and health care at lower costs and [had] been supporting, under a demonstration established by the Affordable Care Act, state initiatives that are specifically aimed at promoting healthy behaviors." 2012 CMS Guidance at 14. CMS "invite[d] states to continue to come to us with their ideas, including those that promote value and individual ownership in health care decisions as well as accountability tied to improvement in health outcomes," and noted that "states have considerable flexibility under the law to design benefits for the new adult

group and to impose cost-sharing, particularly for those individuals above 100%" of the FPL. *Id.*

Such CMS guidance does not constitute final agency action. "No legal consequences flow from the agency's conduct …, for there has been no order compelling [the regulated party] to do anything." *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 732 (D.C. Cir. 2003). The "long-standing practice in circumstances like this is to require the complaining party to challenge the specific implementation of the broader agency policy." *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 22 (D.C. Cir. 2006). Here, of course, plaintiffs have done exactly that by challenging the requirements of Kentucky HEALTH.

There is thus no reason or authority to adjudicate a freestanding challenge to the letter. CMS itself characterizes the letter as nonbinding guidance. *See* AR 90. Moreover, CMS did not cite the letter as the legal authority for its approval of Kentucky HEALTH (or any other State's project); indeed, the Secretary's approval did not cite the SMD letter at all. AR 6718–34. The Secretary's approval of the Kentucky demonstration project is supported "just as if the [letter] had never been issued," because the agency considered the specifics of the project and supporting record in deciding to approve the amendments. *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 253 (D.C. Cir. 2014).

In any event, plaintiffs' challenge to the letter has no merit. For largely the same reasons that the letter is not final agency action, it is also not a legislative rule subject to the APA's notice-and-comment requirement. "General statements of policy" are exempt from notice-and-comment unless another statute provides otherwise, 5 U.S.C. § 553(b)(3)(A), and no statute does so here. The letter "compels action by neither the recipient nor the agency" and thus cannot be a legislative rule. *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 944 (D.C. Cir. 2012). By contrast, a State's submission of a proposed demonstration project *is* subject to specified public notice procedures, further demonstrating why the earlier letter is not subject to such procedures. *See* 42 C.F.R.

§§ 431.408(a)(1), (3). Plaintiffs' contention that the Secretary lacks authority to approve demonstration projects with community-engagement requirements, or that he has failed adequately to explain the reasons for doing so, is meritless for reasons discussed above.

IV. THE CLAIM UNDER THE "TAKE CARE CLAUSE" SHOULD BE DISMISSED.

Plaintiffs offer no argument in support of their allegation that the Secretary's approval violates the President's responsibility to "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3. This is not a suit against the President; it is an APA action against an agency and its officials. Plaintiffs do not meaningfully explain how the Secretary's approval of the amendments to Kentucky HEALTH could be regarded as a violation of the President's duty to take care that the laws be faithfully executed. *See* First. Am. Compl. ¶¶ 424–41. Moreover, even assuming *arguendo* that the Clause applies directly to the Secretary, separate from its application to the President, the Supreme Court has held that "the duty" the Clause imposes "in the exercise of the [President's] power to see that the laws are faithfully executed" is not judicially enforceable. *Mississippi v. Johnson*, 71 U.S. (4 Wall.) 475, 499 (1866). Nor do plaintiffs have a cause of action to raise that constitutional claim, because neither the APA nor the Take Care Clause itself furnishes a right to sue the President. *See Franklin v. Massachusetts*, 505 U.S. 788, 796 (1992); *cf. Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1383-1384 (2015). Count Nine, accordingly, should be dismissed.

CONCLUSION

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

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Dated: February 4, 2019

Respectfully submitted,

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Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Center for Medicaid and CHIP Services

August 31, 2012

The Honorable Mike Beebe
Governor of Arkansas
Little Rock, AR 72201

Dear Governor Beebe:

I am writing to follow up on our discussion and to respond to the question you have asked about the Medicaid low-income adult eligibility expansion in light of the Supreme Court's decision in *NFIB v. Sebelius*. As you know, beginning in 2014, the Affordable Care Act provides for the expansion of Medicaid eligibility to adults under the age of 65 with incomes up to 133 percent of the federal poverty level who were not previously eligible for Medicaid. Pursuant to the Court's decision, a state may choose not to undertake this expansion without losing federal funding for its existing Medicaid program. The Court's decision did not affect other provisions of the law.

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. The federal financial support for this coverage established under the Affordable Care Act is 100 percent in 2014, 2015, and 2016, gradually declining to 90 percent by 2020 and remaining at that level thereafter. While states have flexibility with respect to whether and when to start or stop the expansion, the match rates that are available are tied by law to the specific calendar years noted. Ultimately, I am hopeful that state leaders will take advantage of the opportunity provided to insure their poorest families with these unusually generous federal resources while dramatically reducing the burden of uncompensated care on their hospitals and other health care providers.

I hope this information is helpful and look forward to continuing to work with you and others in Arkansas on ensuring the Arkansas Medicaid program is as strong and effective as it can be.

Sincerely,

Cindy Mann
Director