UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ROSE, JR., *et al.*, Plaintiffs, v. XAVIER BECERRA, *et al.*, Defendants.	Civil Action No. 1:19-cv-2848 (JEB)

FEDERAL DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Federal Defendants Xavier Becerra, *et al.*, hereby move for summary judgment pursuant to Federal Rule of Civil Procedure 56 and Local Civil Rule 7(h). In support of this motion, Federal Defendants rely on the attached Memorandum in Opposition to Plaintiffs' Motion for Summary Judgment and in Support of Federal Defendants' Cross-Motion for Summary Judgment. A proposed order is also attached.

Dated: April 10, 2024

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FEDERAL DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF FEDERAL DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Since 2008, the State of Indiana has extended health-care benefits to certain groups of low-income adults by operation of a series of waivers to requirements of the Medicaid statute it obtained from the Secretary of Health and Human Services ("HHS"). Under section 1115(a) of the Social Security Act, the Secretary "may waive compliance" with those requirements "to the extent and for the period he finds necessary to enable" a State to operate "any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of" the Medicaid program. 42 U.S.C. § 1315(a)(1). Indiana's project has varied over time, expanding to cover additional groups and to offer additional coverage to existing groups and each time modifying the terms on which medical coverage was extended.

In 2020, the Secretary, acting through the Centers for Medicare & Medicaid Services ("CMS"), approved the current incarnation of Indiana's project for a ten-year period. That project differs from the ones this Court previously considered in other matters, as among other things it no longer contains any community-engagement requirement or lockout periods from coverage for failing to meet those requirements or others. Plaintiffs challenge that approval, but do not sufficiently establish that the program—which is the vehicle through which all three Plaintiffs obtain medical coverage—causes them harm. Even if they were harmed by the approval of Indiana's project, CMS's decision was reasonable at the time it was made, reasonably explained, and well within its statutory authority. As CMS reasonably concluded based on the evidence before it at the time, Indiana's project, when viewed as a whole, was likely to assist in expanding medical coverage by ensuring that those eligible for the project had access to optional services Medicaid does not require States to cover, and more basic coverage for the lowest-income adults who do not wish to pay for that additional coverage. Additionally, CMS reasonably concluded

that granting Indiana waivers to certain requirements of the Medicaid statute was necessary for the project to work after considering the potential downsides of granting those waivers.

Plaintiffs also challenge a letter CMS sent to Indiana in December 2023 declining to reconsider the waivers it had authorized in 2020, but Plaintiffs do not establish that vacating the letter—to the extent such a thing is possible—would independently grant them any relief. Even if it could, CMS's decision not to intervene mid-project while the State is focused on unwinding enhanced benefits and coverage that were in operation during the COVID-19 public health emergency was well supported and reasonably explained.

Plaintiffs therefore cannot succeed on their claims under the Administrative Procedure Act ("APA"). Their summary judgment motion should be denied, and Defendants' cross-motion should be granted.

BACKGROUND

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).

The Medicaid program outlines the populations and types of benefits that the State plan may or must cover. *See* 42 U.S.C. § 1396a(10)(A) (requiring a State plan to "provide for making medical assistance available, including at least the care and services listed in" specified paragraphs of 42 U.S.C. § 1396a(d)). As to populations, prior to 2014 States were required to cover only certain discrete categories of needy individuals—pregnant women, children, needy families, the blind, the elderly, and the disabled. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 575

(2012) ("*NFIB*"). There was no mandatory coverage for most non-disabled, childless adults, and the States typically did not offer any. *Id*.

As enacted, the Affordable Care Act ("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 level ("FPL") (the "new adult group" or the "expansion population"). *Id*. But the Supreme Court ruled in *NFIB* that Congress could not condition a State's preexisting Medicaid funding on the State's compliance with the ACA's adult eligibility expansion. *Id.* at 585. The effect of that ruling was to make coverage of the new adult population voluntary for States. Accordingly, in 2012, when many States were deciding whether to expand their Medicaid programs, HHS assured the States that they "have flexibility to start or stop the expansion." SAR 6116; *see also* SAR 6117 ("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.").

For those covered populations, Medicaid generally requires that a State plan must provide medical assistance that includes at least certain types of "care and services." 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(1)-(5), (13)(B), (17), (21), (28), (30); *see generally* Mandatory & Optional Medicaid Benefits, https://www.medicaid.gov/medicaid/benefits/mandatory-optional-medicaid-benefits/index.html (last visited Apr. 4, 2024). States may at their election provide additional optional benefits, such as prescription drug benefits, vision benefits, and dental benefits. 42 U.S.C. § 1396d(a)(10), (12). Among other requirements, the statute also limits the "premiums . . . deductions, cost sharing, or similar charges" a State may impose, *id.* § 1396a(a)(14); requires States to provide up to three months of retroactive coverage upon enrollment, *id.* § 1396a(a)(34); and requires States to "ensure necessary transportation for beneficiaries to and from providers," *id.* § 1396a(a)(4)(A); *see* 42 C.F.R. § 431.53.

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 1961 (1962) (Conf. Rep.).

"An application or renewal" of a demonstration project is subject to certain procedural requirements, including a process for notice and public comment at both the State and Federal level. 42 U.S.C. § 1315(d); 42 C.F.R. §§ 431.408, 431.416. Section 1115 provides alternate methods for the Secretary to approve the continuation of a demonstration project. As happened with Indiana's 2020 application, the Secretary may consider an application under the general provisions of section 1115(a). *See* 42 U.S.C. § 1315(a). As stated, the Secretary reviewing an application for a renewal of a demonstration project under that general provision may approve the project "for the period he finds necessary to enable" the State the carry out the project. *Id.* § 1315(a)(1).

Alternatively, a State operating a "State-wide comprehensive demonstration project

. . . may submit to the Secretary a written request for an extension[] of up to 3 years (5 years, in the case of a waiver" involving individuals eligible for both Medicare and Medicaid, who are also known as "dual eligibles"). 42 U.S.C. § 1315(e)(1), 2). An "extension of a waiver project under this subsection shall be on the same terms and conditions . . . that applied to the project before its extension under this subsection." 42 U.S.C. § 1315(e)(6). Further applications for an extension of a waiver project that is operating under an extension granted under subsection (e) "shall be submitted and approved or disapproved in accordance with subsection (f). *Id.* § 1315(f). Applications under that subsection are governed by unique timing requirements, and "a failure by the Secretary to approve or disapprove an application" within those time periods "shall be deemed to be an approval of the application." *Id.* § 1315(f)(B). Approvals under subsection (f) "shall be for a period not to exceed 3 years," or 5 years for projects involving dual eligibles. *Id.* § 1315(f)(6). As described below, Indiana's application under review here was approved under 42 U.S.C. § 1315(a). *See* SAR 1554.

II. Factual Background

In 2007, CMS approved a section 1115 demonstration project that expanded health care coverage to certain low-income adults in Indiana who were not then otherwise eligible for coverage under the Medicaid Act. *See* SAR 8239. That project, the Healthy Indiana Plan ("HIP"), coupled its optional provision of health care coverage with several features that required waivers of Medicaid requirements under section 1115, including a monthly premium requirement; termination of coverage and a 12-month lockout period for enrollees who did not pay their premiums; a lockout period for beneficiaries who did not complete the annual redetermination process by the deadline; elimination of retroactive coverage; and elimination of the assurance to provide non-emergency medical transportation ("NEMT"). *See* SAR 8264.

After the passage of the ACA, CMS approved a series of short-term extensions of the project while it negotiated with Indiana over coverage of the expansion population. Effective February 2015, CMS approved Indiana's proposal to conduct its demonstration as HIP 2.0. *See* SAR 8240. CMS's approval of HIP 2.0 permitted Indiana to construct a dual system of benefits that it offered to those eligible, which included the expansion population and low-income parents and caretaker relatives. As then approved, HIP 2.0 consisted of two tiers of benefits: HIP Basic and HIP Plus. Those beneficiaries who chose to make income-adjusted premium payments were enrolled in HIP Plus. Individuals with incomes at or below 100 percent of the FPL who did not make premium payments were enrolled in HIP Basic. Eligible individuals with incomes above 100 percent of the FPL were eligible only for HIP Plus, and therefore premiums were required for that group. Those individuals with incomes above 100 percent of the FPL who began, but subsequently ceased, making premium payments were disenrolled from coverage and subject to a six-month lockout.

HIP Basic required cost-sharing for enrollees that did not meet the definition of medically frail, and otherwise covered all mandatory Medicaid benefits except that it did not offer retroactive coverage and NEMT was offered only to pregnant women and the medically frail. HIP Plus covered all HIP Basic services plus the optional Medicaid benefits of vision and dental and did not require cost sharing.

On February 1, 2018, CMS approved the State's request to amend HIP and extend the demonstration through December 31, 2020. That approval allowed Indiana to maintain many of the prior elements of HIP 2.0, including its two-tiered benefit plan. The approval also authorized Indiana to make several changes to HIP. CMS authorized Indiana to "apply a premium surcharge for HIP Plus beneficiaries who use tobacco, and who do not participate in tobacco cessation

activities." Letter from Demetrios L. Kouzoukas, Principal Deputy Adm'r, CMS, to Allison Taylor, Medicaid Dir., Ind. Fam. & Soc. Servs. Admin. 1 (Feb 1, 2018). The 2018 approval also changed the way Indiana calculated required premiums for enrollment in HIP Plus, added chiropractic benefits to HIP Plus, reimposed a lockout period to apply to beneficiaries who did not complete the annual redetermination process by the deadline, and created a program to address substance use disorders for all Medicaid beneficiaries. *Id.* at 2. That approval also authorized Indiana to impose a community engagement requirement for continued eligibility for Medicaid for those in the expansion population who did not meet specified exemptions, *Id.* at 1-2, but the penalties associated with that requirement never went into effect.[1]

In January 2020, Indiana again applied for section 1115 waivers to allow it to continue operating HIP. SAR 8234. The State's application maintained many of the same features HIP had previously offered, including the two-tiered benefits scheme, a premium requirement for access to HIP Plus and vision, dental, and chiropractic benefits, HIP Basic for eligible individuals at or below the FPL who did not pay premiums, and a community-engagement requirement for certain eligible HIP participants. *See* SAR 8238-39. That application also requested new authority for Indiana to periodically modify without seeking a waiver amendment from CMS the premiums it charged for HIP Plus and the copayments it charged to HIP Basic members so long as the premiums remained below three percent of member income and the copayment amounts remained within the allowable limits of traditional Medicaid. *See* SAR 8263.

[1] Plaintiffs' original complaint, filed on September 23, 2019, challenged CMS's 2018 approval of HIP. *See* Compl. For Declaratory & Injunctive Relief, ECF No. 1. At that point, the D.C. Circuit was considering an appeal from a decision of this Court vacating an Arkansas demonstration project, which was ultimately decided on February 14, 2020. *See Gresham v. Azar*, 950 F.3d 93 (D.C. Cir. 2020), *vacated & remanded sub nom.*, *Becerra v. Gresham*, 142 S. Ct. 1665 (2022) (Mem.). Shortly thereafter, this case was stayed during the pendency of the COVID-19 public health emergency. *See* Minute Order (Apr. 6, 2020).

Indiana also requested that the demonstration be approved for a 10-year period. As justification for this period, Indiana argued that "[t]hree-year renewal cycles create administrative complexity" because programs "may only be in effect for 12-18 months before drafting of the renewal must begin." SAR 8265. According to the State, that "short approval period prohibits the ability to provide meaningful data on progress and results of demonstration policies." *Id.*

CMS approved the requested waiver on October 26, 2020, "in accordance with section 1115(a) of the" Social Security Act. SAR 1554. Through that approval, which is the one at issue here, CMS authorized Indiana to continue offering HIP Basic and HIP Plus. As CMS explained, "Beneficiaries who consistently make required monthly contributions to their POWER Account maintain access to an enhanced benefit plan, known as 'HIP Plus,' which includes enhanced benefits such as dental, vision, and chiropractic coverage." SAR 1558. The approval meant that Indiana will "continue to charge HIP Plus beneficiaries premiums based on income bands" that are "capped at three percent of household income." SAR 1559. As with prior approvals, "beneficiaries with incomes above 100 percent of the [FPL] who do not pay the premium will be disenrolled from the HIP Plus program," but those at or below the FPL would be placed in HIP Basic. SAR 1559, 1591. CMS approved those authorities for a ten-year period, through December 31, 2030. CMS's letter also approved an extension of the State's substance use disorder program and a serious mental illness program for five years. SAR 1560.

The approval letter identified several changes to the prior HIP program. *See* SAR 1557-58. Those changes included "allowing the state flexibility to change premium and copayment amounts within the parameters described in the" accompanying special terms and conditions without seeking an amendment of the demonstration. SAR 1557; *see* SAR 1559 (noting that

Indiana "will have the flexibility to change the premium amounts" up to a cap of three percent of household income "without submitting an amendment to CMS").[2]

CMS's approval letter explained the basis for its decision and responded to comments it had received during the comment period. CMS first identified the objectives of the Medicaid statute that HIP was "likely to assist in promoting." SAR 1555. As relevant here, CMS concluded based on the available evidence that "this demonstration would" advance the "important objective" of "furnish[ing] medical assistance and other services to vulnerable populations" by "expanding the scope of coverage." SAR 1555. CMS also explained that section 1115 demonstration projects could "also provide an opportunity for states to test policies that ensure the fiscal sustainability of the Medicaid program," which could "enable states to stretch their scarce Medicaid dollars" and make "it more viable for states to furnish medical assistance to a broader range of persons in need or providing additional benefits to existing beneficiaries." SAR 1556.

CMS likewise explained why the HIP demonstration was likely to assist in promoting those objectives. For example, the demonstration would test how HIP's waiver of NEMT would enable the state "to better contain Medicaid costs and more efficiently focus resources" and improve "the fiscal sustainability of the Medicaid program." SAR 1561-62. That would, in turn, "help Indiana to continue to cover non-mandatory benefits and eligibility groups (such as the . . . expansion population and dental and vision benefits)." SAR 1561-62; *see* SAR 1562 ("Enhancing fiscal sustainability allows the state to provide services to Medicaid beneficiaries that it could not

[2] For certain other of the State's requests, CMS's approval was "contingent on the Supreme Court issuing a decision in *Azar v. Gresham*, No. 20-37 that legally authorizes these elements." SAR 1554. Specifically, CMS only conditionally approved Indiana's request to continue the community engagement requirement, eligibility lockout periods for nonpayment of premiums, and lockout periods for failure to complete the redetermination process. *See* SAR 1559-60. Because the Supreme Court did not issue any decision authorizing those elements, the condition never triggered, and those elements are not part of HIP.

otherwise provide."); SAR 1572 ("Indiana's demonstration is expected to improve the fiscal sustainability of the state's safety net and contribute to the provision of additional services offered through HIP."). Similarly, CMS explained that the demonstration would test how HIP's premiums and cost-sharing requirements allowed beneficiaries "to determine if it is more cost efficient and practical" to enroll in HIP Plus, "an enhanced health package" with "vision and dental benefits" that also required premiums, or for those with incomes at or below the FPL, to enroll in HIP Basic and forego those added benefits in exchange for not paying premiums. SAR 1563. CMS also concluded that HIP was likely to assist in promoting coverage because it allowed Indiana to test "whether waiving retroactive eligibility for certain groups of Medicaid beneficiaries will encourage them to obtain and maintain health coverage, even when healthy." SAR 1564. CMS noted that it "expected [that waiver] to help promote Medicaid's objectives by improving uptake of preventive services" which would, in theory, lead to "continuity of coverage" and also "improv[e] beneficiary health." SAR 1564.

As to the ten-year duration of the approval, CMS explained that "[s]ome of these policies have been long-standing features of the HIP demonstration" but "have been challenging to evaluate due to relatively short implementation periods within each approval period and programmatic changes with each extension." SAR 1572. CMS authorized the ten-year period to "facilitate certain aspects of the rigor of the demonstration's evaluation" and "enable the state to conduct well-designed longitudinal beneficiary surveys to track beneficiary outcome over time." SAR 1572.

In February 2021, CMS notified Indiana that it had "preliminarily determined that allowing work and other community engagement requirements to take effect in Indiana would not promote the objectives of the Medicaid program." SAR 1076. Although those requirements had not yet

fully gone into effect in Indiana, CMS informed Indiana that it was commencing a process of determining whether to withdraw the State's conditional authority. SAR 1076. CMS also informed the state that it would review "various other authorities that CMS approved in the demonstration." SAR 1076.

On June 24, 2021, CMS notified Indiana that it was "withdrawing the conditional approval of the community engagement requirement in the October 26, 2020 extension of HIP." SAR 838. At that time, CMS informed Indiana that its review of "the other authorities CMS previously approved in the HIP demonstration . . . remains ongoing." SAR 860.

In December 2023, CMS notified Indiana that it would not "tak[e] any action now on" any authorities "in the approved HIP demonstration because, given the totality of the circumstances, [CMS] concluded that withdrawing those authorities at this time is too disruptive" in the context of unwinding from the COVID-19 public health emergency. SAR 1. In reaching that conclusion, CMS noted that it had "concerns with premium requirements in section 1115 demonstrations generally based on the large body of evidence suggesting that premiums beyond those authorized under the Medicaid statute reduce access to coverage and care among populations that Medicaid is designed to serve." SAR 1. CMS also explained that circumstances had changed in the affordability of other routes to medical coverage. Specifically, Congress extended COVID-era subsidies for premiums for health plans obtained through the ACA's marketplace through 2025, meaning that individuals up to 150 percent of the FPL who obtain coverage through that route would have their premium requirements fully subsidized. SAR 3. Those subsidies, however, are not available to individuals eligible for Medicaid. SAR 3.

Even so, CMS determined based on several factors that withdrawing those authorities with respect to this particular demonstration was too disruptive at that time. *See* SAR 2 (noting that

CMS's position "concerns only the HIP demonstration" and that similar authorities in other demonstrations "must be assessed on a case-by-case basis"). Those factors included the possibility of "beneficiary loss of coverage" from inadvertent errors during the eligibility determination process due to the "added complexity" of changes to the demonstration's operational system, SAR 2; the "[e]vidence on the effects of premiums in the HIP demonstration" was "preliminary and was interrupted due to the" COVID-19 pandemic, SAR 2; demonstrations are generally approved for a fixed term, SAR 2; and the demonstration "evaluation requirements were also substantially fortified in the HIP demonstration with its most recent extension," SAR 11; *see* SAR 2. CMS's decision aimed "to minimize any unintended disruptions for the state's Medicaid beneficiaries." SAR 1.

STANDARD OF REVIEW

Under Rule 56, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In the context of an APA claim, "[s]ummary judgment . . . serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Zevallos v. Obama*, 10 F. Supp. 3d 111, 117 (D.D.C. 2014) (quoting *Kadi v. Geithner*, 42 F. Supp. 3d 1, 9 (D.D.C. 2012)), *aff'd*, 793 F.3d 106 (D.C. Cir. 2015); *see also id.* (noting the court's "limited role . . . in reviewing the administrative record" (citations omitted)).

ARGUMENT

I. Plaintiffs Lack Article III Standing to Challenge Either the 2020 Approval or the December 2023 Letter.

Plaintiffs' claims fail at the outset for lack of Article III standing. To demonstrate Article III standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete,

particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). "Standing is not dispensed in gross. Rather, a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought." *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008) (cleaned up). Here, Plaintiffs lack standing to challenge CMS's 2020 approval of HIP because they have not met their burden of establishing injury-in-fact, where none of the declarations they have submitted establish for summary judgment purposes that they will be affected by any relevant section 1115 waiver. Plaintiffs lack standing to challenge the December 2023 letter because they fail to show that the remedy they request in their summary judgment papers—vacatur of that letter—would afford them any relief.

A. Plaintiffs Lack Article III Standing Because They Have Not Established That They Will Be Injured by CMS's Approval of HIP.

Plaintiffs attempt to establish injury by pointing to three elements of HIP: (1) "HIP Premiums and associated consequences for inability to pay," Suppl. Compl. For Declaratory & Injunctive Relief ¶ 152, ECF No. 50-1 ("Compl."); Pls.' Mem. in Supp. of Mot. for Summ. J. at 13, ECF No. 54-1 ("Pls.' Mem."); (2) the elimination of NEMT, Compl. ¶ 152; and (3) the "elimination of retroactive coverage", *id.* At the summary judgment stage, however, a plaintiff "must set forth by affidavit or other evidence specific facts" to support their claim of injury. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (cleaned up). Plaintiffs here have attempted to meet that burden by submitting three declarations, but those declarations do not establish that they are harmed by CMS's 2020 HIP approval.

Premiums. Plaintiffs assert that they are concerned that they will be required to pay premiums. *See* Decl. of Monte A. Rose, Jr. ¶ 16, ECF No. 54-2 ("Rose Decl."); Decl. of Chelsey Lang ¶¶ 6, 14, ECF No. 54-3 ("Lang Decl."); Decl. of Emily Rames ¶ 13, ECF No. 54-5 ("Rames

Decl."). In *Stewart v. Azar*, this Court concluded that any increase in premiums would be sufficient injury-in-fact for purposes of Article III standing. 313 F. Supp. 3d 237, 251 (D.D.C. 2018) ("*Stewart I*"). Here, however, none of Plaintiffs' declarations establish that they will be required to pay premiums to obtain Medicaid coverage under HIP.

Under CMS's 2020 approval, "[b]eneficiaries with income at or below 100 percent of the [FPL] who do not make monthly POWER Account contributions will be defaulted to a more limited benefit plan meeting alternative benefit plan requirements (known as 'HIP Basic')." SAR 1581. Crucially, those individuals "would not be disenrolled for nonpayment of premiums." SAR 1570. Beneficiaries below the FPL need not make any premium payments at all—upon enrollment or otherwise—to obtain coverage. *See* SAR 1589. Coverage for such individuals "will be effective the first day of the month in which the 60-day payment period expires." *Id.*; *see also* SAR 1603.

It is true that the terms of HIP permit the state to terminate coverage for beneficiaries with incomes above the FPL for nonpayment of premiums. *See* SAR 1602.[3] But none of Plaintiffs' declarations clearly establish that their incomes exceed the FPL, which in 2024 is $15,060 for a single-person household and $20,440 for a two-person household, *see* Annual Update of the HHS Poverty Guidelines, 89 Fed. Reg. 2961, 2962 (Jan. 17, 2024). Plaintiffs Rose and Lang plainly fall below that level. Mr. Rose asserts that he does "not currently have paid work or any income." Rose Decl. ¶ 4. Ms. Lang does not convey her annual income for any year, but she asserts that she works "10-12 hours per week, on average, . . . making $17.00/hour." Lang Decl. ¶ 15. Assuming 12 hours per week for a full year (with no time off) at that salary would equate to an income of

[3] CMS also conditionally approved the state's request to impose a six-month non-eligibility period for certain beneficiaries with incomes above the FPL who did not pay required premiums. SAR 1602. But because the triggering condition was never satisfied, that element of HIP is no longer approved or part of the demonstration.

$10,608, which falls below the FPL. Ms. Rames asserts that her "gross income in 2023 was approximately $17,790." Rames Decl. ¶ 2. That income would exceed the FPL, but Ms. Rames's declaration does not establish the size of her household. *See id.* ¶ 1 (noting that Ms. Rames lives with a "partner"). None of these declarations clearly establish that any Plaintiff has income at or above the FPL, nor state that any Plaintiff expects his or her income to fluctuate over time such that it may reasonably be expected to surpass the FPL, which would trigger a premium requirement to maintain HIP coverage.

To be sure, those who pay premiums are enrolled in HIP Plus, obtain vision, dental, and chiropractic benefits, and are relieved of the obligation to make most copayments. SAR 1591; *see* SAR 1604. But the expanded benefits are optional services that states are not required to provide under Medicaid. *See* 42 U.S.C. §§ 1396a(10)(A), 1396d(a)(10), (12). And the cost-sharing requirement for HIP Basic members mirrors that of traditional Medicaid. 42 C.F.R. § 447.52(b); SAR 1604.

Waiver of NEMT. Similarly, Plaintiffs' assertions that the waiver of NEMT will cause them harm rest on attenuated and hypothetical chains of events. For example, Ms. Rames notes that "[i]f [her] car breaks down" at a time that overlaps with a medical appointment she may need NEMT. Rames Decl. ¶ 9. But that mere possibility falls far short of a "certainly impending" injury. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted). Similarly, Mr. Rose notes that he has "transportation services available through his health plan" but that his "arranged transportation" through those services "sometimes falls through on the day of the appointment." Rose Decl. ¶ 8. But if Mr. Rose has NEMT provided to him by his current health plan under the HIP demonstration, then it is not clear from Mr. Rose's declaration that any missed appointment resulted from CMS's waiver of NEMT requirements. In any event, that past

experience does not establish any "certainly impending" future harm. *Clapper*, 568 U.S. at 409; *see City of L.A. v. Lyons*, 461 U.S. 95, 105 (1983).

Waiver of Retroactive Coverage. Plaintiffs allege that they are "harmed" by the "elimination of retroactive coverage," Compl. ¶ 152, but they do not explain how any such harm could arise. Each Plaintiff currently has medical coverage through HIP. *See* Rose Decl. ¶ 12; Lang Decl. ¶¶ 6-8, 11; Rames Decl. ¶ 6-7, 10. Thus, any waiver of retroactive coverage could only harm Plaintiffs if their coverage were terminated and they experienced a medical need before re-enrolling in HIP. But Plaintiffs have not demonstrated this is likely to occur because, as noted above, none of the Plaintiffs have established that they are above the FPL and therefore at risk of having their coverage terminated for nonpayment of premiums. Nor have Plaintiffs otherwise established that they are likely to lose coverage. Plaintiffs thus have not established that any threat of losing retroactive coverage is "certainly impending" as required to establish injury-in-fact. *Clapper*, 568 U.S. at 409 (citation omitted).

B. Plaintiffs Lack Article III Standing to Challenge the December 2023 Letter.

As to the December 2023 letter, Plaintiffs fail to establish that the relief they seek through their summary judgment motion is likely to redress their claimed injuries. Plaintiffs' motion seeks only vacatur of the December 2023 letter, *see* Pls.' Mem. at 43, but they nowhere explain how independently vacating that letter would help them. It would not. Vacatur of that letter alone would still leave CMS's 2020 approval in place. The agency was under no obligation to reassess its HIP approval, so simply undoing the December 2023 letter would not require CMS to reevaluate the project anew. That being so, it is simply speculative to assume that CMS would both voluntarily reevaluate and then rescind demonstration authorities should Plaintiffs prevail on their request for the Court to vacate the letter. *See Lujan*, 504 U.S. at 561 ("[I]t must be 'likely,' as

opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" (quoting *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 38, 43 (1976)).

Conversely, if CMS's 2020 approval of the HIP demonstration were set aside as unlawful (and it should not be), the December 2023 letter would not save the project. In either event, solely vacating the letter would afford Plaintiffs no relief.

II. The Secretary's Determination That a Particular Demonstration Project is Likely to Assist in Promoting the Objectives of Medicaid is Reviewable, if at all, under a Standard that is Highly Deferential to the Agency's Decision.

Section 1115 authorizes HHS to approve a demonstration project which, "in the judgment of the Secretary, is likely to assist in promoting the objectives" of the Medicaid statute, 42 U.S.C. § 1315(a). This broad grant of discretion reflects the nature and purpose of demonstration projects. The projects are time-limited experiments that can "influence policy making at the State and Federal level, by testing new approaches that can be models for programmatic changes nationwide or in other States." *Medicaid Program; Review and Approval Process for Section 1115 Demonstrations*, 77 Fed. Reg. 11,678, 11,680 (Feb. 27, 2012). The point of these experiments is to test hypotheses, and either validate a hypothesis that might lead to new innovations or else refute the hypothesis and help Congress and HHS avoid mistaken policies in the future. The costs of trying out new approaches in state-level experiments are vastly lower than the alternative of testing out new provisions nationwide through statutory or regulatory amendments, and even unsuccessful experiments can provide useful information.[4]

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

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

Consistent with the broad grant of discretion and the nature of a demonstration project, section 1115 does not require that HHS provide an explanation for its decisions. Nor does the APA: a demonstration project is not the product of rulemaking, and it "does not involve 'adjudication required by statute to be determined on the record after opportunity for an agency hearing,' 5 U.S.C. § 554(a), to which alone the [APA's] requirement of findings, 5 U.S.C. § 557(c), applies." *Aguayo*, 473 F.2d at 1107. Accordingly, the regulations that implement section 1115 indicate that HHS "will review and consider all comments received by the deadline, but will not provide written responses to public comments." 42 C.F.R. § 431.416(d)(2).

The purpose of demonstration approval letters is not to facilitate judicial review, which, as the terms of the statute make clear, is extremely limited to the extent it is available at all. Section 1115 authorizes HHS to approve a demonstration project that, "*in the judgment of the Secretary*, is likely to assist in promoting the objectives" of the Medicaid program, and to "waive compliance with any of the requirements" of 42 U.S.C. § 1396a "to the extent and for the period *he finds necessary* to enable such State or States to carry out" the project, 42 U.S.C. § 1315(a) (emphases added). This is the type of language that Congress uses when it commits determinations to an agency's discretion, *see* 5 U.S.C. § 701(a)(2)—language that sets out "a subjective standard (whether the agency thinks that a condition has been met)" rather than "an objective one (whether

the condition in fact has been met)." *Drake v. FAA*, 291 F.3d 59, 72 (D.C. Cir. 2002). In *Drake,* for example, the D.C. Circuit held that "[a] provision that allows the Administrator to act when she '*is of the opinion* that the complaint does not state facts that warrant an investigation,' gives the FAA virtually unbridled discretion over such decisions" because the "only statutory reference point is the Administrator's own beliefs." The Court explained that "[w]hat may be *thought* necessary may not in fact *be* necessary, but a court may pass judgment only on the latter, not the former." *Id*. Similarly, in *Claybrook v. Slater*, 111 F.3d 904 (D.C. Cir. 1997), the Court concluded that the applicable statute's "plain language reinforces the conclusion that the decision whether to adjourn is committed to agency discretion." *Id*. at 909. "Rather than allowing adjournment when it is in the public interest, section 10(e) authorizes the agency representative to *determine* whether adjournment is in the public interest." *Id*.

Section 1115 similarly commits to the Secretary's discretion—and thus makes unreviewable—the judgment that a demonstration project is likely to promote the Medicaid program's purposes, and that waiving particular requirements is necessary to facilitate the project. That conclusion is reinforced by "the nature of the administrative action at issue," *Drake*, 291 F.3d at 70, which is a time-limited experiment intended to inform future policy. Section 1115 thus does not direct the Secretary to determine whether an experiment "will promote" the Medicaid program's objectives, but only whether it is "likely to assist" in doing so. Although the Government recognizes that this Court has previously concluded that the Secretary's approval of a section 1115 demonstration is judicially reviewable, *see, e.g., Stewart I*, 313 F. Supp. 3d at 254-56, Defendants hereby preserve that issue for appellate review.[5]

[5] The Government also acknowledges that the D.C. Circuit "reject[ed] the government's contention that" the Secretary's "considerable discretion to grant a waiver . . . renders his waiver

Assuming, however, that CMS's determination that a demonstration project is "likely to assist" in promoting program objectives is reviewable, "[t]he 'arbitrary and capricious' standard is particularly deferential in matters implicating predictive judgments." *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009). "[P]redictive judgments about areas that are within the agency's field of discretion and expertise" are entitled to "particularly deferential" treatment. *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 821 (D.C. Cir. 1983); *see FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 813 (1978). That is especially true when, as in section 1115, the statute offers no standards by which to measure the reasonableness of the agency's judgment. Likewise, even assuming that the "substantial evidence" requirement were applicable, "the threshold for such evidentiary sufficiency is not high." *Biestek v. Berryhill*, 139 S. Ct. 1148, 1154 (2019). "Substantial evidence" means "more than a mere scintilla." *Id*. (citation omitted). "It means—and means only—'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion,'" a standard the Supreme Court has likened to "the deferential clearly-erroneous standard." *Id*. (citation omitted).

CMS's 2020 determination that the demonstration project at issue here was likely to promote the Medicaid program's objectives at the time of the approval satisfies any minimal requirements imposed by the APA in this context.

III. The Secretary's 2020 Decision Reasonably Concluded that the Proposed HIP Demonstration Was Likely to Assist in Promoting the Objectives of the Medicaid Program.

"Section 1115(a) asks whether a '*project*' would promote the Act's objectives, not whether each component, 'viewed in isolation,' would." *Stewart I*, 313 F. Supp. 3d at 257 (quoting *Wood v. Betlach*, 922 F. Supp. 2d 836, 843 (D. Ariz. 2013)). In its 2020 approval, CMS considered

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decisions unreviewable." *Gresham v. Azar*, 950 F.3d 93, 98 (D.C. Cir. 2020), *vacated & remanded sub nom.*, *Becerra v. Gresham*, 142 S. Ct. 1665 (2022) (Mem.).

Indiana's proposed demonstration as a whole and specifically concluded based on the evidence available to it at that time that the demonstration was likely to assist in promoting two objectives of the Medicaid Act previously authorized by this Court: coverage promotion and the fiscal sustainability of the social safety net. *See Stewart v. Azar*, 366 F. Supp. 3d 125, 138-39, 148-49 (D.D.C. 2019) ("*Stewart II*"). Plaintiffs assert that CMS also identified several other Medicaid objectives that the demonstration was likely to assist in advancing. *See* Pls.' Mem. at 16-17. But even if those other objectives are not "independent objective[s] of the Act," *Stewart II*, 366 F. Supp. 3d at 145, CMS's approval permissibly relied on the objectives the Court has previously approved.

A. CMS Permissibly Explained How the Project as a Whole was Likely to Assist in Promoting the Objectives of the Medicaid Program.

An agency's decision is reviewed based on the record before the agency at the time the decision was made. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971). Based on the circumstances that existed at the time it made its decision, CMS determined, viewing the project as a whole, that the HIP demonstration was likely to assist in promoting the objectives of the Medicaid program. First, CMS specifically determined that HIP was likely to assist in promoting coverage. Citing the substance use disorder and serious mental illness components of HIP, CMS explained that those elements would improve "access to high-quality services" and "expand[] covered services" that would "otherwise be excluded from federal reimbursement." SAR 1561. But CMS's coverage determinations were not limited to those components. CMS also determined that the HIP demonstration created "incentives for individuals to enroll as soon as possible and to obtain preventive services," "enable[d] states to expand or maintain coverage for needy individuals," promoted "continuity of coverage and care," and provided certain beneficiaries

with "an enriched benefit package" through HIP Plus. SAR 1556, 1561, 1563-64. Those are coverage-promotion rationales.

Second, CMS also permissibly determined that the demonstration would enable "the state to better contain Medicaid costs and more efficiently focus resources on providing accessible and high-quality health coverage" and "provide services to Medicaid beneficiaries that it could not otherwise provide." SAR 1561-62. Plaintiffs argue that CMS's fiscal sustainability rationale was based on a "false premise" that Indiana could "terminate coverage for the mandatory expansion population." Pls.' Mem. at 18. But CMS's analysis was not based solely on the concern that Indiana would withdraw coverage from any population. Rather, the approval letter stated a determination that HIP was likely to make "it more viable for states to furnish medical assistance to a broader range of persons in need" or provide "*additional benefits to existing beneficiaries*." SAR 1556 (emphasis added). In other words, HIP's cost savings meant that Indiana could provide "additional benefits" through HIP Plus that were "non-mandatory," such as "dental" and "vision benefits," and that Indiana could provide those benefits to more people. SAR 1561-62; *see also* SAR 1572 (noting that certain waivers were "expected to improve the fiscal sustainability of the state's safety net and contribute to the provision of additional services offered through HIP").

B. CMS Balanced the Potential for Coverage Loss Against the Benefits of the HIP Demonstration.

CMS also specifically considered the "consequences for coverage" of Indiana's requested waivers as to premiums, NEMT, and retroactive coverage. *Stewart II*, 366 F. Supp. 3d at 150.

Premiums. CMS addressed what it viewed as the potential benefits and drawbacks that charging premiums would cause to Medicaid coverage based on the information available to the agency at the time. First, CMS observed that HIP's premiums were designed in such a way to permit beneficiaries to "determine if it is more cost efficient and practical for them to enroll in an

enhanced health package to receive vision and dental benefits." SAR 1563. For individuals at or below the FPL, beneficiaries could choose to pay premiums to enroll in HIP Plus and obtain expanded, optional coverages. *See* SAR 1563. Or they could choose not to pay premiums and still maintain the mandatory benefits covered by Medicaid (other than NEMT and retroactive coverage) and be responsible for copayments permitted under traditional Medicaid. *See* SAR 1563; 1604-05; *see also* 42 U.S.C. § 1396a(a)(10)(A) (identifying mandatory benefits). Importantly, CMS noted that "beneficiaries with household income at or below 100 percent of the FPL would not be disenrolled for nonpayment of premiums." SAR 1570. CMS also cited evidence that people in HIP Plus showed "higher participation and utilization rates for preventive services, primary care, and specialty services," and thereby used their medical coverage more effectively. SAR 1563-64.

CMS also considered the potential for coverage loss from any premium requirement, as Plaintiffs implicitly recognize. *See* Pls.' Mem. at 21 (citing CMS's responses to concerns about premiums and coverage loss). Specifically, CMS cited the state's interim evaluation report, which "noted that beneficiaries generally found premiums and copayments affordable" but also observed a "disenrollment rate due to non-payment" of premiums. SAR 1570. Nevertheless, CMS relied on that report's findings that "showed that the number and proportion of individuals disenrolled due to non-payment decreased over time." SAR 1570; *see* SAR 4755. Thus, contrary to Plaintiffs' argument, Pls.' Mem. at 21-22, CMS's decision did expressly consider the potential for coverage loss and explained why that potential did not override the agency's determination that the project was likely to assist in promoting the objectives of the Medicaid program.

Plaintiffs, moreover, focus narrowly on CMS's consideration of the potential for coverage loss without analyzing the coverage gains CMS expected at the time from its demonstration

approval. *See* Pls.' Mem. at 20-25. HIP Plus provides optional benefits not required under the Medicaid statute for beneficiaries that pay premiums. Compared with a "baseline" of full "compliance with the statute's requirements," *Stewart II*, 366 F. Supp. 3d at 154, it was lawful for CMS to conclude at the time that HIP was likely to compare favorably because it provided benefits the statute does not strictly require.

NEMT. Similarly, CMS explained how it believed that restricting NEMT to certain populations helped expand coverage of non-mandatory benefits and eligibility groups. *See* SAR 1561-62; SAR 1572. As to the potential for coverage loss, CMS relied on evidence that "found that beneficiaries without" access to "NEMT services did not appear to be more likely to report missing an appointment and to report transportation as a reason for a missed appointment." SAR 1562; *see* SAR 6049 (noting "no statistically significant difference" between the proportion of members with and without NEMT provided by a managed care entity who missed a medical appointment). Because the "evaluation findings for this policy did not indicate evidence of adverse effects on beneficiaries," CMS concluded that "the benefit of offering NEMT to the new adult group is outweighed by enhancements to programmatic sustainability and the value of the optional services Indiana offers." SAR 1572. In other words, CMS relied on evidence in the record before it at the time of decision to determine that waiving NEMT requirements had little downside to coverage but could enable Indiana to offer enhanced, optional coverages like vision, dental, and chiropractic benefits through HIP Plus. *See* SAR 1561-62; SAR 1572. That analysis satisfied any requirement that CMS balance potential loss of coverage against the expected gains. *See Stewart II*, 366 F. Supp. at 150.

Plaintiffs contend that the evaluation CMS relied on contained flaws, Pls.' Mem. at 23, but an agency decision is not arbitrary or capricious simply because a plaintiff "would have weighed

the evidence differently." *Cumberland Coal Res., LP v. Fed. Mine & Health Rev. Comm'n*, 717 F.3d 1020, 1028 (D.C. Cir. 2013).[6] Even in the absence of perfect evidence, the APA leaves it to the agency to apply its expert judgment subject only to deferential review. *See EarthLink, Inc. v. FCC*, 462 F.3d 1, 12 (D.C. Cir. 2006).

Waiver of Retroactive Coverage. CMS explained how it "expected" the waiver of retroactive coverage "to help promote Medicaid's objectives by improving the uptake of preventive services." SAR 1564. It also explained that Indiana was "testing whether waiving retroactive eligibility for certain groups of Medicaid beneficiaries will encourage them to obtain and maintain health coverage, even when healthy, or to obtain health coverage as soon as possible after becoming eligible, rather than potentially waiting until they are sick." SAR 1564; *see* SAR 1571-72. As CMS concluded at the time, that waiver would reasonably be predicted to increase "continuity of coverage and care." SAR 1564.

Plaintiffs argue that CMS's analysis of the waiver of retroactive coverage was a "'conclusory reference'" akin to the one rejected in *Stewart*. Pls.' Mem. at 24 (citing *Stewart II*, 366 F. Supp. 3d at 143). But even if that is so, CMS's coverage analysis was sufficient because it considered coverage gains and losses for the project as a whole. The government, moreover, respectfully disagrees that anything more was required of CMS in approving HIP. Although waiving retroactive coverage by necessity eliminates some coverage, CMS explained how it initially expected the project to promote coverage overall. Plaintiffs may believe that any harms

[6] Plaintiffs also note that the study on which CMS relied contains data that some beneficiaries cited a "lack of transportation" as a reason that they "miss[ed] scheduled appointments." Pls.' Mem. at 23 (citing SAR 6050-56). CMS did not "ignore[]" that data. *Id.* Rather, CMS concluded that the proportion of beneficiaries who indicated that lack of transportation was a reason they missed a medical appointment was not significantly different between beneficiary groups with access to NEMT and those groups without access. SAR 1562.

from lost retroactive coverage will outweigh the benefits of coverage gains from earlier sign-ups, a more healthy population, additional optional benefits like vision and dental, and a more sustainable Medicaid program. But such weighing of costs and benefits was a decision for CMS, not Plaintiffs, and approving a test to gather more information on the question is well within CMS's discretion and expertise. *See Sec. Indus. & Fin. Markets 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").

C. CMS Adequately Determined that the HIP Demonstration was Experimental.

"Section 1115 of the Social Security Act . . . vests in the Secretary broad power to authorize projects which do not fit within the permissible statutory guidelines of the standard public assistance programs." *Crane v. Mathews*, 417 F. Supp. 552, 539 (N.D. Ga. 1976). Using this authority, the Secretary has authorized waivers for wide-ranging purposes. In the half-century since Medicaid's enactment, States have used demonstrations to expand coverage, change delivery systems, alter eligibility and benefits, impose cost-sharing, and modify provider payments.

In its approval here, CMS reasonably determined that Indiana's proposal fit within the definition of an "experimental, pilot, or demonstration project" within the scope of section 1115. 42 U.S.C. § 1315(a). The special terms and conditions CMS approved set forth the "several demonstration goals" Indiana sought to achieve through the project, which included improving "health care access, appropriate utilization, and health outcomes," among other goals. SAR 1582. Those goals informed "the state's evaluation design hypotheses," which CMS required to be evaluated by an independent party. SAR 1582; *see* SAR 1642-43. CMS also explained its view of Indiana's experiment, noting that it was "testing" various "requirements that are designed to promote the provision of healthcare coverage." SAR 1555-58. The entire project, moreover, was subject to "comprehensive requirements for monitoring and evaluating the demonstration" so that

CMS could "understand the performance and effectiveness of the demonstration in a timely fashion and eventually garner conclusive evidence on the impact of demonstration policies." SAR 1573. All this reasonably establishes that CMS had determined the HIP demonstration was likely to yield data that could be used to inform healthcare delivery policy.

Plaintiffs' main argument that the HIP demonstration was insufficiently experimental is that there was already substantial data about premiums, the elimination of NEMT, and the elimination of retroactive coverage in Indiana. *See* Pls.' Mem. at 29. Section 1115, however, does not demand that the program be experimental in the "scientific" sense, only that it be "designed to collect data which may well be of significance." *Cal. Welfare Rts. Org. v. Richardson*, 348 F. Supp. 491, 498 (N.D. Cal. 1972). And CMS here explained why the duration the policies had been in place did not deprive HIP of experimental potential. CMS stated that "long-standing policy features" had "evolved in design over time" and therefore this precise configuration of policies had yet to be robustly tested. SAR 1558. The 2020 approval also added to the evaluative potential of the project because prior "relatively short implementation periods" had made prior policies "challenging to evaluate." SAR 1558.

Plaintiffs argue that Indiana has had authority to impose premiums "since 2008." Pls.' Mem. at 29. Those premiums in place in 2008, however, differed somewhat from the ones adopted in HIP 2.0 in 2015 in that they were not tied to the two-tiered plans Indiana subsequently adopted. *See* SAR 8253 (explaining the difference in premiums between HIP 1.0 and HIP 2.0). As to HIP 2.0, evidence of the impact of premiums in that project was interrupted by COVID-19 when those policies were suspended. *See* SAR 2, 5. Far from the 13-year period of evidence of premiums Plaintiffs cite, CMS later noted that "[e]vidence from HIP comes from the period from 2015

through 2019," SAR 5, and that the data was "preliminary" and prior to "strengthened requirements for demonstration monitoring and evaluation." SAR 2.

Moreover, Indiana had never previously operated HIP under this precise configuration of policies. *See* SAR 1557 (explaining the changes to the demonstration CMS was approving); SAR 8239-41 (explaining the historical narrative of the evolution of HIP). It was reasonable for CMS to conclude that Indiana's program contained unique features that were likely to yield valuable data.

D. The Ten-Year Demonstration Period Was Permissible under Section 1115.

1. Sections 1115(e) and (f) Do Not Restrict CMS's Ability to Authorize Continuations of Demonstrations with Modified Terms under Section 1115(a)

Section 1115(a)(1) permits the Secretary to authorize a demonstration project "to the extent and for the period he finds necessary to enable such State . . . to carry out such project." 42 U.S.C. § 1315(a). So long as the Secretary makes the relevant determination, that statutory language places no outer temporal limit on the length of a demonstration project. Plaintiffs contend that subsection (e) limits the time period that the Secretary may authorize for an initial extension of a "State-wide comprehensive" Medicaid demonstration, but that provision does not operate the way Plaintiffs suggest.

Starting with the statutory text, subsection (e) simply does not apply to the continuation of a demonstration project that changes its terms and conditions and is expressly approved by the Secretary. Specifically, that subsection provides that a State "may submit to the Secretary a written request for an extension" of up to three or five years. 42 U.S.C. § 1315(e)(2). "If the Secretary does not respond to the request within 6 months after the date it is submitted, the request is deemed to have been granted." *Id.* § 1315(e)(3). Paragraph (6) of that subsection further provides that "the extension of a waiver project under this subsection shall be on the same terms and conditions

. . . that applied to the project before its extension under this subsection." *Id.* § 1315(e)(6). Read together, these provisions do not limit the authority of the Secretary to authorize demonstration projects under section 1115(a). Rather, they establish an expedited process for the default approval of the extension of a demonstration project on the same terms and conditions previously approved if the Secretary does not timely respond to the State's request for an extension. Put another way, a request to continue a demonstration project is not an "extension" under subsection (e) when that request includes modifications to the terms and conditions of the project.

That construction makes sense. After all, the Secretary could simply consider an extension request as an application for a new demonstration project. *See* 42 C.F.R. § 431.412(c)(1). Plaintiffs' argument would lead to one of two absurd results. If subsection (e) applies any time a State requests a second statewide waiver, then paragraph (6) would prohibit that State from ever requesting a modification of the terms and conditions of its demonstration project. If, instead, a State may request modifications in connection with an extension, an "extension" would be limited to three years, but the same request submitted as a new demonstration could be approved for as long a period as the Secretary finds is necessary so long as the other statutory requirements are met. There is no reason to rely on such untenable distinctions. *Kaseman v. Dist. of Columbia*, 444 F.3d 637, 642 (D.C. Cir. 2006) ("When possible, statutes should be interpreted to avoid untenable distinctions, unreasonable results, or unjust or absurd consequences." (citation omitted)).

Reading subsection (e) not to limit the Secretary's approval authority under subsection (a) is also consistent with its legislative history. The conference report that accompanied the addition of subsection (e) to the statute explained that "States [had] objected to the waiver process as unnecessarily complex and lengthy." H.R. Conf. Rep. No. 105-217, at 895 (1997), *as reprinted in* 1997 U.S.C.C.A.N. 176, 516. Congress therefore enacted subsection (e) "to provide for a

simplified renewal or extension process" where the "extension would be on the same terms and conditions that applied to the project before the extension." *Id.* Plaintiffs' argument turns this history on its head by converting a provision designed to ease extensions of demonstration projects into a new limit on the Secretary's ability to authorize demonstrations consistent with subsection (a).

Each time Indiana sought to continue its HIP 2.0 project, it requested some modifications to the terms and conditions of its project. *See* SAR 1557 (describing the "changes" that "have been . . . made to the demonstration"); SAR 8240-41 (describing history of HIP changes); SAR 8263 (describing requested changes in 2020 approval). The Secretary's consideration of that application was, therefore, constrained only by section 1115(a)'s requirement that a demonstration project must be limited to "the period" the Secretary "finds necessary to enable" the State "to carry out such project." 42 U.S.C. § 1315(a).[7]

2. CMS Permissibly Concluded that the Ten-Year Period was Appropriate.

In determining whether to approve Indiana's request to operate certain "long-standing features of the HIP demonstration" for a ten-year period, CMS concluded that those policies previously had been "challenging to evaluate due to relatively short implementation periods within each approval period and programmatic changes with each" renewal. SAR 1558. CMS explained that the ten-year approval period "will enable the state to conduct well-designed longitudinal beneficiary surveys to track beneficiary outcome[s] over time, including after separation from the

[7] Because subsection (e) did not apply to any of Indiana's requests for approval to operate its HIP demonstrations, subsection (f) also did not apply. *See* 42 U.S.C. § 1315(f) (setting forth requirements for an "application . . . for an extension of a waiver project the State is operating under an extension under subsection (e)"). Even if it did, that provision was also designed to "[s]treamline[] approval of continued state-wide 1115 Medicaid waivers," not substantively limit what the Secretary could approve under section 1115(a). *See* H.R. Conf. Rep. 106-1033, 906-07 (2000).

demonstration and the Medicaid program, and evaluate the program's longer-term effects on beneficiary health insurance/coverage" and other metrics. SAR 1572-73. In addition, CMS noted that it expected strengthened monitoring requirements "will enable [it] to understand the performance and effectiveness of the demonstration in a timely fashion and eventually garner conclusive evidence on the impact of the demonstration policies." SAR 1573. CMS also "considered factors such as policy complexity, implementation status, Indiana's objectives and consideration for pursuing the demonstration policies, and evidence on the performance of the demonstration and specific policies, where available." SAR 1572. That reasoning satisfies section 1115(a). *See* 42 U.S.C. § 1315(a); *Beno v. Shalala*, 30 F.3d 1057, 1070 (9th Cir. 1994); *Stewart I*, 313 F. Supp. 3d at 256.

Plaintiffs argue that CMS "did not consider whether an additional 10-year period was necessary," Pls.' Mem. at 33, but that argument ignores the pages of analysis the approval letter devoted to the "[e]xtent and [s]cope of [the d]emonstration." SAR 1557-60; SAR 1572-73.

Plaintiffs' remaining arguments regarding the duration of the approval are not so much an APA challenge as they are a disagreement with CMS's policy conclusions. First, Plaintiffs disagree with CMS's evaluation of the evidence of the effect of certain elements of the HIP demonstration. But this again focuses on the individual elements of the program and not "whether, on balance, the project as a whole passes muster." *Stewart*, 313 F. Supp. 3d at 257. As to that issue, CMS reasonably concluded that some elements of the demonstration had "evolved in design over time" and thus their effect had not been adequately studied in this configuration. SAR 1558. CMS, moreover, reasonably supported its conclusion that prior iterations of those elements were successful based on the information before the agency. *See* SAR 1570 (explaining that the state's

interim evaluation report "noted that beneficiaries generally found premiums and copayments affordable"); SAR 1571-72; *cf.* SAR 4797 (interim evaluation report).

Second, Plaintiffs argue that CMS's approval of a waiver that would permit Indiana to vary its level of premiums without amendment deprives the demonstration of evaluative rigor. *See* Pls.' Mem. at 33. It was reasonable for CMS to predict based on the record before it, however, that changes in the level of premiums could lead to "additional data" the state could use "to determine whether" HIP's tiered structure "encourages beneficiaries to choose to pay for premiums in order to receive an enriched benefit package." SAR 1563.

Third, Plaintiffs argue that the ten-year approval period is inconsistent with CMS's policy under which it may grant a 10-year approval of "'routine, successful, non-complex' waivers." Pls.' Mem. at 33 (quoting CMS, CMCS Informational Bulletin: Section 1115 Demonstration Process Improvements (Nov. 6, 2017), https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib110617.pdf). But CMS concluded that, in its view at the time, there was "initial promising evidence" to support authorization of the HIP demonstration for a ten-year period. SAR 1558; *see* SAR 1564-65 (discussing evidence); SAR 1570-72 (same). Though Plaintiffs obviously disagree with CMS's conclusions, at a minimum the agency reasonably addressed all relevant factors. Even though CMS does not grant waivers of such extended duration for complex and untested programs as a policy matter, it was within CMS's legal authority to approve this waiver for the reasons given when it was initially granted.

E. The Secretary has Authority to Waive Section 1396a to the Extent Necessary to Permit States to Include Premium Requirements in Demonstration Projects that Are Likely to Assist in Promoting the Objectives of the Medicaid Program.

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." *Id.* § 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 provision "incorporates" §§ 1396o or 1396o-1, "[t]o the extent necessary to enable" Indiana "to charge monthly premium payments." SAR 1575. Plaintiffs contend that the Secretary's waiver of the title XIX limitations on premiums is outside the scope of his authority. Pls.' Mem. at 39-43. But no plausible reading of the statutory text, context, or history supports, let alone compels, this conclusion.

To begin, the Secretary indisputably has authority to waive § 1396a(a)(14), which requires State plans to comply with § 1396o.[8] Such a waiver necessarily means that a State plan need *not* comply with § 1396o—the authority to waive § 1396a(a)(14) would be meaningless if State plans were still required to comply with § 1396o despite the Secretary's waiver. By placing the requirement to comply with § 1396o in § 1396a(a)(14) and authorizing the Secretary to waive "any of the requirements of . . . 1396a," Congress clearly authorized the Secretary to waive compliance

[8] Plaintiffs acknowledge that courts have upheld the Secretary's authority to waive premium requirements of § 1396a(a)(14). Pls.' Mem. at 41 (citing *Crane*, 417 F. Supp. at 538-40; *CWRO*, 348 F. Supp. 491). But Plaintiffs attempt to distinguish those cases by pointing to the subsequent legislative enactments that added §§ 1396o and 1396o-1. These cases are still good law, however, and no court has held them to be superseded. Plaintiffs' reliance on dicta in *Pharmaceutical Research & Manufacturers of America v. Thompson*, 251 F.3d 219 (D.C. Cir. 2001), is likewise misplaced. There, the court read 42 U.S.C. § 1396r-8 not to authorize the Secretary to approve a demonstration in which manufacturers would pay rebates for drugs purchased by non-Medicaid beneficiaries. The court did not address the distinct question, presented here, whether the Secretary can permit a state to impose premiums on certain beneficiaries through a waiver of § 1396a(a)(14).

with § 1396o. Plaintiffs' interpretation would strip § 1396a(a)(14) from the scope of section 1115's waiver authority.[9]

Moreover, contrary to Plaintiffs' contention, § 1396o(f) *confirms* that the Secretary has authority to waive compliance with premium requirements in § 1396o by virtue of his authority to waive § 1396a(a)(14). Plaintiffs argue that the waiver provision in § 1396o(f) for cost-sharing charges would be superfluous "if the Secretary could use Section 1115 to waive the requirements in Section 1396o," and they contend that the inclusion of § 1396o(f) demonstrates Congress's intent to exclude any comparable authority to waive § 1396o's distinct premium requirements. Pls.' Mem. 40.

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

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[9] Plaintiffs contend that § 1396a(a)(14)'s use of the phrase "only as provided in 1396o" somehow shows that Congress intended to place all premiums outside the Secretary's Section 1115 authority. Pls.' Mem. at 40. But this ignores that Congress authorized the Secretary to waive *any* of the provisions in § 1396a, including § 1396a(a)(14)'s "only as provided in" language.

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 *alternative* to § 1396o. *See* § 1396o-1(a)(1) ("Notwithstanding sections 1396*o* and 1396a(a)(10)(B) of this title . . . a State . . . may impose premiums and cost sharing . . . ."). The Secretary's authority to waive compliance with § 1396o thus necessarily includes the authority to waive compliance with § 1396o-1. Any doubt on that score is dispelled by § 1396o-1(b)(6)(B), which provides that "[n]othing in this section shall be construed . . . as affecting the authority of the Secretary through waiver to modify limitations on premium and cost sharing under this section." Congress thus expressly provided in the text of § 1396o-1 itself that the Secretary has authority "through waiver to modify limitations on premium and cost sharing under [§ 1396o-1]."

Nor does the statutory or legislative history support Plaintiffs' interpretation. Contrary to Plaintiffs' telling, *see* Pls.' Mem. at 41-42, §§ 1396o and 1396o-1 were not targeted at restricting the Secretary's waiver authority in any respect; rather, they were primarily intended to provide another way by which States can "exceed the normal limitations" on Medicaid cost-sharing. *See*

Newton-Nations v. Betlach, 660 F.3d 370, 375 (9th Cir. 2011). Indeed, the House Committee Report cited by Plaintiffs shows that the 1982 amendments adding § 1396o were designed primarily to provide *greater* flexibility to the States to impose cost-sharing, in light of the increased State interest in doing so. H.R. Rep. 97-757, pt. 1, at 6 (1982) (noting that "a large number of States have sought" section 1115 waivers to impose cost-sharing, and that the bill would "give[] States sufficient flexibility" to impose cost-sharing even in the absence of a section 1115 waiver). And § 1396o-1, which provides exceptions to § 1396o, "further relaxes the normal cost-sharing restrictions." *Newton-Nations*, 660 F.3d at 375.

The Secretary reads §§ 1396a(a)(14), 1396o, and 1396o-1 together as part of a comprehensive, coherent, and consistent regulatory scheme that achieves Congress's purposes with respect to State flexibility to impose premiums while preserving the Secretary's authority to waive premium requirements. This reading is correct or, at the least, is a permissible one that merits *Chevron* deference. *See City of Arlington, Tex. v. FCC*, 569 U.S. 290, 296 n.4 (2013). At most, Plaintiffs' alternative reading points to "internal tension" among different provisions in the Act that point "in divergent ways"—but in such a case, "*Chevron* dictates that a court defer . . . to the agency's expert judgment about which interpretation fits best with, and makes the most sense of, the statutory scheme." *Scialabba v. Cuellar de Osorio*, 134 S. Ct. 2191, 2203 (2014) (plurality); *accord id*. at 2219-20 & n.3 (Sotomayor, J., dissenting).

IV. The December 2023 Letter is Not Reviewable Final Agency Action and Was in any Event Reasonable.

In December 2023, CMS informed Indiana by letter that it had concluded review of the authorities it had previously approved in the HIP demonstration and was "not taking action now" to withdraw any such authority. SAR 1. Even if Plaintiffs could establish standing as to this portion of their claim, *see supra* Part I.B, that letter is not reviewable final agency action under the

APA. And, even if it were reviewable, CMS reasonably declined to rescind Indiana's demonstration authorities given the disruption it would cause.

A. The December 2023 Letter is not Final Agency Action.

The APA expressly limits judicial review to "final agency action." 5 U.S.C. § 704. Courts "have long recognized" that the term "agency action," while "expansive," "is not so all encompassing as to authorize . . . judicial review over everything done" by an agency. *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 19 (D.C. Cir. 2006). A final agency action is one (1) that marks the "consummation of the agency's decisionmaking process" and (2) by which "rights or obligations have been determined, or from which "legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citation omitted). Both prongs of this test "must be satisfied independently." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1271 (D.C. Cir. 2018).

The December 2023 letter fails both elements of that test. First, the letter is not the "consummation" of CMS's decision-making process because it is subject to further review. CMS repeatedly explained in the letter that CMS's inaction was subject to further review "as part of its ongoing oversight and monitoring of the HIP demonstration." SAR 1; *see also* SAR 2 ("CMS may suspend implementation of the demonstration or withdraw an authority . . . ."); SAR 11 (explaining that continued "systematic monitoring and comprehensive evaluation of the effects of the demonstration" may " support undertaking future actions"). CMS also explained that the available evidence was "preliminary" and that the demonstration had been "interrupted due to the COVID-19" public health emergency. SAR 2. The letter's conclusion that CMS would "not tak[e] any action now" was therefore explicitly subject to further review. SAR 1.

Second, any "legal consequences" Plaintiffs face flow from CMS's approval of HIP in 2020, not from the December 2023 letter. "Indeed, the letter did nothing more than leave

[Plaintiffs] in the same position [they] were in after" HIP was authorized in 2020. *Aerosource, Inc. v. Slater*, 142 F.2d 572, 580 (3d Cir. 1998); *see also Hormel Foods Corp. v. U.S. Dep't of Agric.*, 808 F. Supp. 2d 234, 246 (D.D.C. 2011) (holding that agency letter declining to rescind approval of certain labels was not final agency action). For that reason, the letter does not "impose[] an obligation, den[y] a right, or fix[] some legal relationship" and is not reviewable final agency action. *Reliable Automatic Sprinkler Co. v. Consumer Product Safety Comm'n*, 324 F.3d 726, 731 (D.C. Cir. 2003).

B. Even assuming Reviewability, the December 2020 Letter Reasonably Concluded that Rescinding Indiana's Demonstration Authorities Would Be Too Disruptive.

Even if the December 2023 letter were a reviewable action, CMS's decision was both "reasonable and reasonably explained." *Nat'l Tel. Co-Op. v. FCC*, 563 F.3d 536, 541 (D.C. Cir. 2009). Though CMS acknowledged its concerns with premiums in Medicaid demonstrations, it ultimately concluded that withdrawing authority to charge premiums mid-demonstration had the potential to be "too disruptive" under the circumstances. SAR 1. CMS cited several factors in support of that conclusion, including that (1) demonstrations are "[i]n general" approved "for a fixed term"; (2) the "added complexity" of unwinding of the COVID-19 public health emergency and related beneficiary eligibility determinations "may lead to inaccuracies . . . and result in beneficiaries being inadvertently disenrolled and delays to new beneficiary enrollment" and other "operational concerns"; and (3) the "[e]vidence on the effects of premiums in the HIP demonstration" in particular "is preliminary and was interrupted due to the COVID-19" public health emergency. SAR 1-2. Those factors coalesced around the conclusion that forcing a last-minute change to Indiana's waiver authorities, mid-stream, could possibly cause more confusion and coverage loss than maintaining the previously approved authorities.

In response to these factors, Plaintiffs mainly rely on their own "[c]ommon sense" notion about what would be less disruptive. Pls.' Mem. at 35. But other than that conclusory argument, they nowhere dispute that there were "operational concerns" about the eligibility effects of "phasing out" demonstration policies mid-stream, or the added "complexity of providing beneficiary communication on such changes during the unwinding period." SAR 2. CMS is the federal agency devoted to administering Medicaid with its State partners. As the expert agency, it has substantial experience in projecting the disruptive effects of mid-stream operational changes to a State Medicaid program. *See Oceana, Inc. v. Gutierrez*, 488 F.3d 1020, 1025 (D.C. Cir. 2007) (upholding an agency's predictive determination that rested "on the agency's evaluation of past performance and its expert judgment about how the measures it implemented will operate in the future"). It is not Plaintiffs' "common sense," but CMS's expertise and reasonable discretion that control.

Plaintiffs also point to CMS's treatment of premium requirements in several other demonstrations, Pls.' Mem. at 35-36, but fail to explain that each of those decisions was made in connection with a State's application either for a new demonstration approval or to renew an otherwise expiring existing demonstration project, *see* Letter from Daniel Tsai, Deputy Admin. and Dir. CMCS, to Jamie Kuhn, State Medicaid Dir., Wis Dep't of Health Servs. (Nov. 17, 2023), https://www.medicaid.gov/sites/default/files/2023-11/wi-badgercare-reform-cms-tmpry-extns-amndmt-aprvl.pdf (approving a "temporary extension" to "allow the state and CMS to continue negotiations over the state's extension application"); Letter from Chiquita Brooks-LaSure, Adm'r, CMS, to Dawn Stehle, Deputy Dir. For Health & Medicaid, Ark. Dep't of Hum Servs. 1 (Dec. 21, 2021), https://www.medicaid.gov/sites/default/files/2021-12/ar-arhome-ca.pdf (approving "Arkansas's request for a new section 1115(a) demonstration"); Letter from Chiquita Brooks-

LaSure, Adm'r, CMS, to Marie Matthews, Medicaid Dir., Mont. Dep't of Pub. Health & Hum. Servs. 1 (Dec. 21, 2021), https://www.medicaid.gov/sites/default/files/2021-12/mt-HELP-program-ca.pdf (approving "one-year temporary extension of Montana's section 1115 demonstration). Those decisions, therefore, lacked at least one of the crucial factors CMS cited here: that Indiana's demonstration project was in the middle of its fixed approval term.

In any event, CMS's determination in 2023 not to disrupt the HIP demonstration mid-approval is consistent with its disapproval of premium requirements in other demonstration applications. As CMS noted in its 2023 letter with respect to Indiana's demonstration, it "has concerns with premium requirements in section 1115 demonstrations generally based on the large body of evidence suggesting that premiums beyond those authorized under the Medicaid statute reduce access to coverage and care among populations that Medicaid is designed to serve." SAR 1. CMS cited evidence supporting those concerns, including evidence that was not available at the time of the 2020 approval. *See* SAR 2 n.7; SAR 3 n.5. Notwithstanding those concerns, CMS "aim[ed] to minimize any unintended disruptions" that could result from withdrawing approvals mid-stream. SAR 1. In other words, CMS balanced the potential harms of withdrawing its approval and determined that, on balance, the risk to coverage of doing so was too great at this time but that balance may change in the future. That reasoning was well within CMS's reasonable discretion.

Plaintiffs also argue that CMS arbitrarily declined to require "Indiana to wind down the premiums after the" COVID-19 public health emergency "unwinding process ends this summer." Pls.' Mem. at 36. At this point, however, CMS has only announced that it was "not taking any action now"—as of December 22, 2024—"on the premium authority." SAR 1. CMS was clear

that it may "take appropriate action in the future, as part of its ongoing oversight and monitoring of the HIP demonstration." SAR 1.

Nor was CMS required to re-analyze any other waiver authority, including waivers of retroactive coverage and NEMT. *But see* Pls.' Mem. at 38. As CMS explained, the HIP approval was for a "fixed" ten-year "term." SAR 2. Nothing required CMS to reconsider its original approval. The only effect of the December 2023 letter is that the 2020 approval continues as originally planned. Plaintiffs' quarrel is with that approval. *See Aerosource*, 142 F.2d at 580.

V. Any Remedy Should be Limited to the Plaintiffs.

To the extent the Court concludes that CMS's approval of HIP was deficient under the APA, it should issue an appropriately limited remedy. 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*, 585 U.S. 48, 73 (2018).

To the extent that any of the Plaintiffs will experience injury, it would result from the application of particular demonstration waivers to them. That application of the program to a specific plaintiff would be the only proper subject of review and thus the outer limit of any relief. *Cf. Lujan*, 497 U.S. at 891. The Court could readily craft a remedy that would fully redress Plaintiffs' own injuries without exceeding the proper limits on remedies. *See Whitford*, 585 U.S. at 73.

Plaintiffs instead ask this Court to vacate the entire HIP demonstration, but there is no reason to grant that expansive relief. As an initial matter, the APA's remedies are discretionary. *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967). And here there is no reason to disrupt the implementation of HIP. Unlike the Kentucky demonstration at issue in *Stewart II*, coverage under the HIP demonstration is no longer contingent on completion of community-engagement requirements and no lockout period is imposed on those who are disenrolled for nonpayment of

premiums. *See* 366 F. Supp. 3d at 132-34 (summarizing proposed Kentucky HEALTH demonstration); Pls.' Mem. at 14 (acknowledging these elements are no longer "approved components of the project"). The "great deal of harm" that concerned the Court in *Stewart II* from those provisions are not at issue here. 366 F. Supp. 3d at 155. Also, unlike *Stewart II*, the HIP demonstration is currently in operation, albeit in a modified form without implementation of certain authorized policies. *See id.* at 156 (noting that "Kentucky HEALTH has yet to take effect"). Plaintiffs focus solely on the premium requirement, Pls.' Mem. at 44, but the other portions of the HIP demonstration have been ongoing while the premium policy has been suspended during the COVID-19 public health emergency.

Although "vacatur is the normal remedy" under the APA in this Circuit, courts "sometimes decline to vacate an agency's action" depending on "the 'seriousness of the order's deficiencies' and the likely 'disruptive consequences' of vacatur."[10] *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014) (quoting *Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). The disruptive consequences of vacatur of the HIP demonstration approval at this late stage would be immense, as evidenced by CMS's December 2023 letter. *See* SAR 1-2; 11. As that letter explained, any changes to the State's operating authorities runs the risk of "inaccuracies in beneficiary eligibility determinations during unwinding" and could "result in beneficiaries being inadvertently disenrolled and delays to new beneficiary enrollment." SAR 2. If CMS withdrawing demonstration authorities would cause disruption, the Court vacating the entire HIP approval would be chaos. And, as CMS explained, the resulting confusion could lead to loss of enrollment—the very harm the Plaintiffs seek to avoid. *Id.*

[10] The Government notes for preservation purposes its position that the APA does not authorize courts to universally vacate unlawful agency action. *See United States v. Texas*, 599 U.S. 670, 693-99 (2023) (Gorsuch, J., concurring).

As of CMS's 2020 approval, HIP provided "coverage to more than 400,000 Hoosiers each year." SAR 8234. Beneficiaries have been participating in HIP in its current form for more than three years. Vacating the approval now would, at a minimum, change the path by which those beneficiaries have been receiving medical coverage, and the resulting confusion would be great. The better course would be to remand without vacatur and permit CMS and Indiana to address any potential deficiencies in the HIP authorization.

CONCLUSION

For the foregoing reasons, Federal Defendants' Cross-Motion for Summary Judgment should be granted, and Plaintiffs' Motion for Summary Judgment should be denied.

Dated: April 10, 2024

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ROSE, JR., *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 1:19-cv-2848 (JEB)

[PROPOSED] ORDER

Upon consideration of Plaintiffs' Motion for Summary Judgment, Federal Defendants' Cross-Motion for Summary Judgment, and the oppositions and replies thereto, it is hereby

ORDERED that the Federal Defendants' Cross-Motion for Summary Judgment is **GRANTED**, and the Plaintiffs' Motion for Summary Judgment is **DENIED**.

Dated: _____, 2024

_____
James E. Boasberg
Chief Judge