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' REPLY MEMORANDUM
IN FURTHER SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

As Federal Defendants explained in their opening brief, the Secretary of Health and Human Services ("HHS"), acting through the Centers for Medicare & Medicaid Services ("CMS"), permissibly concluded in 2020 that Indiana's proposal to renew the Healthy Indiana Plan ("HIP") demonstration project was likely to assist in promoting the objectives of Medicaid. Based on the information available to the agency at the time, CMS rationally concluded that HIP was likely to expand coverage for eligible individuals through the State's proposal to cover benefits it was not required to cover and to reduce cost sharing requirements below what the State is permitted to charge under traditional Medicaid for those that elected to pay premiums, while offering a lower-tier plan for eligible beneficiaries with incomes at or below the poverty line and who did not pay premiums. CMS considered both the potential loss in coverage that might result from the waivers of Medicaid requirements Indiana requested and the projected benefits of the program, as well as the experimental results HIP was likely to generate.

Federal Defendants' opening brief also demonstrated that CMS's December 2023 letter reasonably explained why CMS would not now take action to withdraw any authority it had granted in its 2020 HIP approval. Despite expressing concern about premiums requirements in Medicaid demonstration projects, CMS reasonably explained that it had decided not to withdraw any authority to minimize any disruption to Indiana's Medicaid program.

Plaintiffs respond that CMS's analysis was impermissible under this Court's prior decisions, but they fail to account for the significant differences between Indiana's demonstration and the other State projects previously reviewed. Those cases primarily addressed distinct waiver authorities not at issue here. Nor do Plaintiffs adequately account for the serious disruptions that would attend withdrawing the authorities granted by CMS's 2020 approval now.

To the extent they are reviewable, both decisions at issue in the case were within the Secretary's statutory authority and were reasonably explained. For that reason, Plaintiffs' summary judgment motion should be denied, and Defendants' cross-motion should be granted.

ARGUMENT

I. Plaintiffs Lack Article III Standing

A. Plaintiffs Have Not Established That They Will Be Injured by CMS's Approval of HIP.

Plaintiffs lack standing to challenge CMS's 2020 approval of HIP because they have not provided a sufficient factual basis to support their claim of injury. Federal Defendants demonstrated in their opening brief that the three declarations Plaintiffs rely on do not adequately demonstrate that Plaintiffs are injured by any waiver of Medicaid requirements that CMS authorized in approving HIP. *See* Fed. Defs.' Mem. in Opp'n to Pls.' Mot. for Summ. J. 13-16, ECF No. 56 ("Fed. Br."). Instead of submitting supplemental declarations, Plaintiffs argue that the facts asserted in those declarations are already sufficient to establish that Plaintiffs are injured by three elements of the HIP approval. Pls.' Reply in Supp. of Pls.' Mot. for Summ. J. 4-6, ECF No. 59 ("Pls.' Reply"). Because Plaintiffs have not established a factual basis for injury on this record, however, they lack Article III standing.

Premium Requirements. Plaintiffs first argue that *any* person eligible for HIP is injured because he or she will either be forced to pay premiums or will be denied coverage for vision, dental, and chiropractic services. *See* Pls.' Reply at 4-5. As Federal Defendants have explained, however, the expanded benefits Indiana offers through HIP Plus are optional services that the Medicaid statute does not require States to provide. *See* Fed. Br. at 15. Plaintiffs do not dispute that the statute makes those coverages optional. Nor do they dispute that HIP Basic complies with the Medicaid Act's limits on cost sharing. *See* Pls.' Reply at 4. Indiana, therefore, did not require

a waiver to decline to cover vision, dental, and chiropractic services—it required a waiver only to impose premiums, and none of the portions of the record Plaintiffs cite establish otherwise. *See* Pls.' Reply at 4; SAR 1575 (waiver of statute to "the extent necessary to enable the state to charge monthly premiums"); SAR 1591, 1598-99 (describing different benefits available in HIP Basic and HIP Plus).

Plaintiffs thus misperceive Federal Defendants' argument. The argument is not that a plaintiff must show they risk "total loss of coverage" to establish injury-in-fact. Pls.' Reply at 4. Rather, Federal Defendants' argument is that these specific Plaintiffs have not clearly met their burden to show that they have been injured *at all* because their declarations do not clearly establish that they will be forced to pay premiums to obtain medical coverage that complies with the minimum requirements of Medicaid that Indiana could have offered without a waiver. *See* Fed. Br. at 13-15. If Indiana could remain in full compliance with the Medicaid statute without providing vision, dental, and chiropractic coverage, then a section 1115 waiver that permits the State to decline to offer those benefits for failure to pay premiums does no harm to those at or below 100% of the poverty line who decline to pay but nevertheless receive full Medicaid-compliant coverage.

Plaintiffs argue that one plaintiff establishes that she will be required to pay premiums or face disenrollment, *see* Pls.' Reply at 4-5, but her declaration does not clearly demonstrate that risk. Ms. Rames's declaration sets forth only her "gross income" but does not specify the size of her household to establish whether she is above the poverty line and therefore subject to disenrollment for failure to pay premiums. *See* Fed. Br. at 14-15. In response, Plaintiffs rely on two paragraphs of Ms. Rames's declaration. *See* Pls.' Reply at 5 (quoting Decl. of Emily Rames ¶¶ 10, 13, ECF No. 54-4 ("Rames Decl.")). The first of those paragraphs explains that "Indiana

re-approved" Ms. Rames "for Medicaid coverage in November or December of 2023," *id.* (citing Rames Decl. ¶ 10), but that paragraph does not illuminate whether Ms. Rames has income above the poverty line or the size of her household. The paragraph does say that Ms. Rames was notified she will have a monthly premium, but it is not clear whether the "monthly premium" cited is required for HIP coverage or only to obtain HIP Plus coverage. Rames Decl. ¶ 10.

The second paragraph on which Plaintiffs rely asserts that Ms. Rames will "lose [her] Medicaid coverage" if she does not make premium payments "[g]iven [her] income." *Id.* ¶ 13. But that is a legal conclusion about the applicability of HIP's premium requirement, not a factual statement about her income or size of her household, and it is unclear how or whether she has personal knowledge of HIP's disenrollment policies. *See Austin Inv. Fund, LLC v. United States*, No. 11-2300, 2015 WL 7303514, at *9-10 (D.D.C. Nov. 19, 2015) (concluding that a party could not rely on a declaration submitted for summary judgment because "the matters within the declaration are outside the scope of declarant's personal knowledge" and consist of "legal conclusions, which are outside of the scope of even expert testimony"). The declaration lays no foundation for Ms. Rames's personal knowledge of HIP's disenrollment policies or relevant income levels. At best, then, Ms. Rames's declaration reflects her understanding of HIP, but it does not clearly establish her income level or the size of her household in a way that would permit the Court to determine she is subject to disenrollment. *See Ecological Rts. Found. v. EPA*, 541 F. Supp. 3d 34, 52-53 (D.D.C. 2021). Plaintiffs could easily have supplemented Ms. Rames's declaration to establish that her income was at or below the poverty line by, for example, asserting that she is unmarried and has no dependent children. That they did not do so means that they have not met their burden to establish that Ms. Rames—or any other plaintiff—has been injured.

Waiver of NEMT. In their opening brief, Federal Defendants explained that none of the three plaintiffs submitted evidence to establish that CMS's waiver of the assurance of NEMT caused any injury. Fed. Br. at 15-16. In response, Plaintiffs rely only on the declaration of Mr. Rose, implicitly conceding that the other two declarations they submitted fail to meet Plaintiffs' evidentiary burden. *See* Pls.' Reply at 5-6. Mr. Rose's declaration, however, does not establish injury-in-fact because he currently receives NEMT "through [his] health plan." Decl. of Monte A. Rose ¶ 8, ECF No. 54-2 ("Rose Decl."); *see* Fed. Br. at 15. Thus, even if he is "virtually certain" to require NEMT as Plaintiffs argue, Pls.' Reply at 6, he has access to that transportation through his health plan's HIP coverage. In other words, Mr. Rose is currently receiving NEMT coverage despite CMS's waiver.

The fact that the NEMT provided by Mr. Rose's health plan has "sometimes fall[en] through" in the past, Rose Decl. ¶ 8, does not establish injury. Plaintiffs here seek only prospective relief, and sporadic past problems with NEMT do not prove future injury. *See City of L.A. v. Lyons*, 461 U.S. 95, 105 (1983). Plaintiffs do not demonstrate (or even argue) that Mr. Rose's NEMT services he receives through his health plan would be different in the absence of CMS's waiver of Indiana's obligation to provide it or that Mr. Rose's health plan is at risk of terminating that coverage. This case thus differs from the sole case Plaintiffs cite, which concluded not only that the plaintiff had pleaded that he would require ongoing prescription coverage but also that he would be erroneously denied coverage in the future. *See NB ex rel. Peacock v. Dist. of Columbia*, 682 F.3d 77, 83 (D.C. Cir. 2012); Pls.' Reply at 6. Leaving aside the difference in Plaintiffs' evidentiary burden in response to a summary judgment motion from a motion to dismiss, if Mr. Rose has access to NEMT that is consistent with what he would have in the absence of a waiver, he has not established Article III standing.

Waiver of Retroactive Coverage. Plaintiffs' sole argument that they are injured by CMS's approval of a waiver of retroactive coverage is that Ms. Rames is subject to disenrollment for nonpayment of premiums because her income exceeds 100% of the poverty line. *See* Pls.' Reply at 6. As an initial matter, Plaintiffs' argument stands or falls on the sufficiency of Ms. Rames's declaration, which for the reasons explained above fails to meet her evidentiary burden to demonstrate standing on summary judgment. Even assuming *arguendo* that Ms. Rames has demonstrated that her income exceeds the poverty line, Plaintiffs' argument remains reliant on a "chain of possibilities" that may never occur because a waiver of retroactive coverage would cause injury only if Ms. Rames (1) declined to pay premiums, (2) was disenrolled as a result of the nonpayment, and (3) experienced a need for coverage during any period of disenrollment. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 402 (2013) (Article III injury requirement not satisfied by "hypothetical future harm that is not certainly impending").

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

Plaintiffs also fail to establish Article III standing to mount an independent challenge to the December 2023 letter. That is so because vacating the 2023 letter would still leave the 2020 approval in place. Vacatur of that letter would net Plaintiffs nothing because the agency was not required to conduct its review in the first instance, and nothing would require it to issue a new letter after vacatur. *See* Fed. Br. 16-17. Plaintiffs argue that vacatur of the 2023 letter would "reopen the agency's review," Pls.' Reply at 8, but it is unclear how that would remedy any injury if the 2020 approval remained in place. While it is generally true that a court has authority to vacate an agency action for certain reasons even though the agency "'might later reach the same result for a different reason,'" *see* Pls.' Reply at 8-9 (quoting *Stewart v. Azar*, 313 F. Supp. 3d 237, 253 (D.D.C. 2018) ("*Stewart I*")), that logic does not apply here, where the original 2020 approval would remain independently in force.

Plaintiffs' cases do not establish that vacatur of the 2023 letter would afford them any relief. The D.C. Circuit's decision in *National Parks Conservation Association v. Manson* addressed a federal agency's letter that had withdrawn a previous determination that a proposed power plant project would adversely affect the environment. 414 F.3d 1, 3-4, 6-7 (D.C. Cir. 2005). The Clean Air Act required federal officials to transmit findings as to the potential environmental effects of the proposed project, and also required the State permitting authority to explain any decision to disregard a federal adverse impact determination. *Id.* at 3. A conservation group alleged that building the power plant would result in environmental damage, injuring their conservation efforts and the interests of their members who make use of the lands. *Id.* At the time of the court's ruling, the permitting decision remained pending before State authorities, and therefore a district court order setting aside a letter withdrawing an adverse impact determination "would significantly affect these ongoing proceedings." *Id.* at 7. Setting aside the withdrawal would have reinstated the adverse impact determination and at a minimum triggered the State's obligation to explain its disagreement were it to nevertheless approve the project. *See id.* at 3. Here, however, the agency's approval of HIP is not an "ongoing proceeding." Setting aside the 2023 letter alone could not significantly affect the 2020 approval, which on its own terms extends through 2030. Unlike *Manson*, moreover, the CMS review at issue here was not part of an initial approval subject to specific procedural requirements.

The 2023 letter also imposes no barrier to Plaintiffs' challenge to CMS's HIP approval. *Contra* Pls.' Reply at 9-10. As Federal Defendants explained in their opening brief, the 2023 letter cannot retroactively save the 2020 approval. Fed. Br. at 17. Rather, to the extent Plaintiffs have standing to challenge it, the 2020 approval must rise or fall on its own terms based on the agency's analysis of HIP at the time of the decision. Plaintiffs' cases demonstrating that a plaintiff has

standing to remove barriers to obtaining relief from their ultimate injury are thus inapposite. *See* Pls.' Reply at 9-10.

II. The Secretary's 2020 Decision to Approve HIP Was Permissible.

A. CMS Permissibly Explained Its 2020 Determination That the Project as a Whole Was Likely To Assist in Promoting the Objectives of the Medicaid Program.

As Federal Defendants explained in their opening brief, CMS rationally concluded based on the evidence before it at the time that Indiana's proposed renewal of HIP, considering the project as a whole, was likely to assist in promoting the objectives of the Medicaid program. In doing so, CMS permissibly concluded that HIP was likely to be coverage promoting, and reasonably balanced the potential for coverage loss against the benefits of the project it then believed to be likely. *See* Fed. Br. at 22-26.

Even assuming those conclusions are subject to typical APA review, *but see id.* at 17-20, none of the arguments Plaintiffs raise in response establishes that CMS's 2020 decision was impermissible at the time it was made. First, Plaintiffs note that an analysis of prior HIP approval periods indicated that eligible individuals were not enrolled or lost coverage due to nonpayment of premiums. *See* Pls.' Reply at 13. CMS, however, acknowledged that prior evaluations had led to disenrollment and explained why it nevertheless decided to approve the project. *See* SAR 1570 (citing the "state's interim evaluation report" cited by Plaintiffs). As CMS explained, notwithstanding those losses, disenrollment "decreased over time," would not be a risk for individuals at or below the poverty line, and would be mitigated by limits on cost sharing and premiums. SAR 1570-71. Plaintiffs are simply incorrect that CMS's 2020 approval did not consider the potential loss in coverage that might result from premiums.

At most, Plaintiffs point to these same studies and weigh the implications of potential coverage loss differently. *See* Pls.' Reply at 14 (conceding that an evaluation noted "that

beneficiaries generally find HIP coverage affordable" but arguing that "the same evaluation noted that other members and providers interviewed were dissatisfied with HIP"). All that shows is that Plaintiffs would have weighed those concerns differently than CMS did at the time. *Cumberland Coal Res., LP v. Fed. Mine & Health Rev. Comm'n*, 717 F.3d 1020, 1028 (D.C. Cir. 2013) (stating that a court "may not reject reasonable findings and conclusions, even if [it] would have weighed the evidence differently").

The same is true of CMS's 2020 analysis of Indiana's application to waive the assurance of NEMT. As Federal Defendants have already explained, CMS relied on evaluations in the record that found beneficiaries without access to NEMT reported missing appointments at approximately the same rate as those who had access to NEMT services through their managed care plans. Fed. Br. 24-25. Plaintiffs again do no more than suggest that CMS relied on a flawed study, but do not dispute that the study actually supported CMS's conclusions. *See* Pls.' Reply at 15. An agency may rely on a study "[e]ven if that data is imperfect or inconclusive." *Pac. Shores Subdivision Cal. Water Dist. v. U.S. Army Corps of Eng'rs*, 538 F. Supp. 2d 242, 250 (D.D.C. 2008). Any conflict or "uncertainty" in the data in the record "is not fatal to" a rule because an agency is entitled to "'exercise its judgment in moving from the facts and possibilities on the record to a policy conclusion.'" *Am. Hosp. Ass'n v. Azar*, 468 F. Supp. 3d 372, 397 (D.D.C. 2020) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983)).

So, too, did CMS consider the coverage loss potential of waiving retroactive coverage. *See* Fed. Br. at 25-26; SAR 1564-65 & n.9 (noting only 10 percent of eligible members had made claims under Indiana's existing retroactive eligibility program). While waiver of retroactive coverage necessarily eliminates some coverage, *see* Fed. Br. at 25, CMS reviewed Indiana's

requests in the context of the demonstration's overall potential for coverage gains at the time of the approval, *see* SAR 1563-64, 1571-72.

As Federal Defendants have already explained, CMS balanced these risks against the potential benefits of HIP to coverage and explained its contemporaneous view that HIP was likely to assist in promoting the objectives of Medicaid because it provided additional services not required by the statute. *See* Fed. Br. at 22-26. Federal Defendants argument on this front is distinct from the one this Court rejected previously. *Contra* Pls.' Reply at 16-17 & n.3. "[F]ull compliance with the Medicaid Act" does not require Indiana to provide vision, dental, and chiropractic coverage because those are optional services under the Act. Pls.' Reply at 17 n.3; *see* Fed. Br. at 3. CMS could therefore rationally conclude that Indiana's proposal exceeded that baseline of full compliance by offering to cover non-required benefits and reduce cost sharing for certain populations if its requested waivers were granted. In that context, it was rational for CMS to have concluded that Indiana's proposal to offer those expanded benefits, but only to those who chose to pay premiums, was coverage expanding while still offering a lower-tier Medicaid-compliant plan for beneficiaries at or below the poverty line who determined their personal circumstances did not permit them to pay the income-limited premiums. *See* SAR 1561-64, 1570-71. And as already described, CMS adequately analyzed the burden on Medicaid recipients in granting the requested waivers against the potential benefits for coverage. *See* Fed. Br. at 21-26.

B. CMS Adequately Determined HIP Was an "Experimental, Pilot, or Demonstration Project" under Section 1115(a).

CMS's 2020 approval letter repeatedly cites the data it expected to collect from Indiana's proposed demonstration project and the limitations it perceived in evaluations of previous demonstrations with similar policies. *See, e.g.*, SAR 1558, 1562-65, 1571-73. Those portions of CMS's 2020 approval satisfy any minimal requirement section 1115(a) imposes on the Secretary

to determine that the proposed project is sufficiently experimental to be approved, especially in light of the evolution of HIP's elements over time and the short implementation periods reflected in prior approvals. *See* Fed. Br. at 26-28.

Plaintiffs contend several of the features of HIP have individually been studied in other contexts, but do not dispute that HIP's current incarnation contains differences from any demonstration project that has been previously approved. *See* Pls.' Reply at 23. Recognizing that HIP has changed over time does not "read[] the experimental requirement out of the statute." *Id.* Even small tweaks might lead to additional information about the implementation of certain policies, or at least CMS could rationally make that determination though other conclusions could also be rational. *See Air Transport Ass'n of Am., Inc. v. Nat'l Mediation Bd.*, 719 F. Supp. 2d 26, 44 (D.D.C. 2010) (upholding agency decision "[a]lthough reasonable minds could disagree").

Plaintiffs' out-of-circuit citations are not to the contrary. In *Newton-Nations v. Betlach*, the Ninth Circuit rejected the Secretary's sparse statement in a letter that "Arizona's demonstration project 'will continue to ensure wider health benefit coverage to low-income populations'" and concluded that the real "purpose of Arizona's waiver application was to save money." 660 F.3d 370, 381 (9th Cir. 2011). Those conclusions do not apply here, where CMS identified changed authorities and explained the data it believed would be generated from the project. Plaintiffs also point to "the evidence cited in [CMS's] December 2023 [letter]" as establishing that "premiums have no experimental foundation." Pls.' Reply at 24 n.4. But at least some of that evidence post-dates the relevant 2020 approval and is therefore not properly considered for this purpose. SAR 4-5; *see Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971). Even if it were true that the Secretary might make a different determination now with additional evidence,

what matters is what CMS reasonably determined based on the information in the record at the time of the decision.

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

1. Sections 1115(e) and (f) Do Not Restrict CMS's Authority to Approve Demonstrations under Section 1115(a).

Plaintiffs argue that sections 1115(e) and (f) place temporal limits on any extension to a state-wide comprehensive demonstration project. *See* Pls.' Reply at 27-28. Even if that were correct, however, that would not prohibit the Secretary from approving the HIP demonstration in 2020, which was approved under the alternate procedures of section 1115(a).

Plaintiffs simply assume without analysis that HIP qualifies as an "extension" within the meaning of section 1115(e). *See id.* at 27. Even on Plaintiffs' reading, section 1115(e) applies only to extensions, not new projects. *See id.* But Plaintiffs nowhere provide any definition of the term "extension" for purposes of determining whether that subsection applies.

For purposes of section 1115(e), the statute makes clear that extensions are to "be on the same terms and conditions . . . that applied to the" demonstration before the extension. 42 U.S.C. § 1315(e)(6). As a result, a State's application for a continued demonstration project is not subject to any limitations of section 1115(e) when it proposes to modify the terms and conditions of the project. *See* Vikki Wachino, CMS, *CMCS Informational Bulletin* 3 (July 24, 2015), https://perma.cc/TQ5K-4H6S ("Section 1115(e) extensions are available to states with comprehensive demonstrations proposing no program changes."). Such projects must be approved under section 1115(a).

Section 1115(e)(6) is as mandatory as section 1115(e)(1) in that both use the word "shall," yet Plaintiffs' argument does not account for the former statutory provision. Plaintiffs concede that a State application to extend a state-wide comprehensive project that proposes sufficiently

"substantial" modifications could be exempt from section 1115(e), but they provide no statutory basis for how to determine when modifications are substantial or merely "minimal." Pls.' Reply at 27. In the very next paragraph, Plaintiffs appear to concede that section 1115(e) "requir[es] an extension to operate under the existing terms and conditions." *Id.* at 28. If Plaintiffs' argument that section 1115(e) applies to all applications to continue state-wide comprehensive demonstration projects were correct, then the Secretary could never approve a continuation of a project with modified terms, a result even Plaintiffs disclaim. *See id.* at 28 n.6.[1]

The Secretary's reading of the statute contains no such inconsistencies. Under that reading, a State may apply for additional time to operate its comprehensive demonstration through section 1115(e) with "no program changes." Vikki Wachino, CMS, *CMCS Informational Bulletin* 3 (July 24, 2015). When receiving that application, "[b]y statute, CMS can only consider an extension period of up to three years." *Id.* The Secretary must respond to the request within 6 months of its submission, or "the request is deemed to have been granted." 42 U.S.C. § 1315(e)(3). When a State elects to seek to continue a demonstration with modifications, in contrast, different procedures apply. Those applications are considered under section 1115(a) and are subject to a different application timeline. *See* 42 C.F.R. § 431.412(c) (requiring applications under 1115(e) to be submitted "at least 12 months prior to the expiration date of the demonstration" and applications under 1115(a) to be submitted "6 months prior to the expiration date of the

[1] Plaintiffs cite dicta from *California Welfare Rights Organization v. Richardson* in which that court concluded that it would be an abuse of discretion for the Secretary to approve a hypothetical demonstration project "for an unreasonably long period." 482 F. Supp. 491, 498 (N.D. Cal. 1972). That case did not address section 1115(e), as that provision was not adopted until decades later. *See* Fed. Def. Br. at 29 (citing 1997 Conference Report accompanying enactment of section 1115(e)).

demonstration"). Section 1115(a), moreover, contains no provision for default approval of the application. *See* 42 U.S.C. § 1315(a). The Secretary must respond for the project to be approved.

The Secretary's reading of the statute thus gives due effect "to every clause and word of a statute" by providing two tracks to approve continuations of demonstration projects. *See Duncan v. Walker*, 533 U.S. 167, 174 (2001). Extensions under 1115(e) are limited to three years, but are on the same terms and conditions that the Secretary previously approved. *See* 42 U.S.C. § 1315(e)(2), (6). Applications for demonstration projects that request modifications are considered under section 1115(a), and are limited "to the extent and for the period [the Secretary] finds necessary to enable [the State] to carry out such project." *Id.* § 1315(a)(1). Plaintiffs reading, by contrast, gives no effect to section 1115(e)(6).

Interpreting section 1115(e) to apply only to unmodified extensions is also consistent with legislative history. *See* Fed. Br. at 29-30. Plaintiffs argue that the Court need not consider legislative history because "the statutory language is unambiguous," Pls.' Reply at 28, but fail to so demonstrate. At a minimum, the statute does not clearly demarcate when a statewide comprehensive demonstration application is an "extension" subject to any limits imposed by section 1115(e) and when it may be approved under section 1115(a). And while it may be true in the abstract that "Congress could at once provide for a simplified renewal or extension process and place limits on the length of extensions," Pls.' Reply at 28, the legislative history provides congressional support for only the former of those goals, *see* Fed. Br. at 29-30.

Plaintiffs do not dispute that CMS's 2020 approval at issue here was "in accordance with section 1115(a)" rather than the more streamlined provisions of subsections 1115(e) or (f). SAR 1554. Notably, Plaintiffs concede that the Secretary retains authority to approve projects under section 1115(a) even if the State obtained approval for a prior demonstration. *See* Pls.' Reply at

27. If CMS's 2020 approval was permissible under section 1115(a) as a renewed project with experimental value, then it is unclear why section 1115(e) would bar that approval. Plaintiffs provide no answer.

2. CMS Permissibly Approved HIP for Ten Years.

Based on the information before it at the time of the decision, CMS permissibly concluded that approving HIP for ten years would aid Indiana and the Secretary in evaluating the effectiveness of certain policies that had previously been difficult to evaluate during shorter approval periods. *See* Fed. Br. at 30-31.[2] In response, Plaintiffs appear to fault the Secretary for not using the word "necessary." *See* Pls.' Reply at 25-26. But CMS's contemporaneous analysis of the ten-year duration it was approving was sufficient to "discern the agency's analytical path." *Van Hollen, Jr. v. Fed. Election Comm'n*, 811 F.3d 486, 497 (D.C. Cir. 2016). As the agency explained in 2020, prior, "relatively short implementation periods" had made policies "challenging to evaluate." SAR 1558. That analysis was sufficient to support CMS's approval of HIP for ten years. *See* Fed. Br. at 30-32.

Federal Defendants did not "misconstrue" Plaintiffs' argument related to the authority for Indiana to vary the premiums it charged within a certain range without seeking amendment. *Contra* Pls.' Reply at 26. Permitting Indiana to vary premium levels is itself a "programmatic change" subject to CMS evaluation in the current approval period. It was, therefore, permissible for CMS in 2020 to determine that there was evaluative potential in granting Indiana that dynamic

[2] Contrary to Plaintiffs' assertion, Pls.' Reply at 26 n.5, the evaluation of the HIP demonstration is not limited to a single longitudinal member survey. Under the CMS approved evaluation, Indiana is required to submit multiple Interim Evaluation reports, a Summative Evaluation Report, and Quarterly and Annual Monitoring Reports. SAR 417-18; *see also* SAR 1573 (describing "comprehensive requirements for monitoring and evaluating the demonstration"); SAR 1630-31. That one portion of the evaluation is set to occur after one year of the demonstration does not undermine the importance and necessity of other forms of monitoring and evaluation provided for in the authorization.

authority, rather than requiring it to adhere to a static premium level. Plaintiffs' other arguments against the ten-year approval period largely reassert their view that the substance of the HIP demonstration is unlikely to promote the objectives of Medicaid. *See* Pls.' Mem. in Supp. of Mot. for Summ. J. at 33, ECF No. 54-1 ("Pls.' Mem."); Pls.' Reply at 26. Those arguments do not independently undermine the time-period authorized.

D. The Secretary Has Authority to Waive Limitations on Premium Requirements in Connection with a Demonstration Project.

Section 1115(a)(1) authorizes the Secretary to "waive compliance with any of the requirements of section . . . 1396a" in connection with an approved demonstration project. 42 U.S.C. § 1315(a)(1). One of the requirements in section 1396a requires State plans to "provide that enrollment fees, premiums, or similar charges . . . may be imposed only as provided in section 1396o." *Id.* § 1396a(a)(14). Exercising his section 1115(a)(1) waiver authority, the Secretary waived section 1396a(a)(14) "insofar as it incorporates" sections 1396o and 1396o-1 to "the extent necessary to enable" Indiana "to charge monthly premiums." SAR 1575. The natural result of that waiver is that Indiana was no longer required to "impose[]" premiums "only as provided in section 1396o." *See* Fed. Br. at 32-36.

Plaintiffs' arguments in response do not undercut this straightforward reading of the statutory text. Initially, Plaintiffs rely on legislative and statutory history. Pls.' Reply at 29-30. But none of those arguments overcome the language of the statute, which plainly permits waiver of section 1396a(a)(14). Fed. Br. at 33 & n.8; *see Azar v. Allina Health Servs.*, 587 U.S. 566, 579-80 (2019). Even if there were ambiguity in the statute that would permit resort to legislative history, Federal Defendants have already explained why that legislative history supports the Secretary's reading. *See* Fed. Br. at 35-36.

The Secretary's reading of the statute also accounts for section 1396o(f). *Contra* Pls.' Reply at 30. As Federal Defendants have explained, that provision expressly limits "any waiver authority of the Secretary" with respect to "deduction, cost sharing, or similar charge[s]." 42 U.S.C. § 1396o(f). None of those charges are at issue here because the Secretary did not waive any cost-sharing requirements. In contrast, that section does not restrict the Secretary's waiver authority with respect to premiums. *See* 42 U.S.C. § 1396a(a)(14) (distinguishing between "enrollment fees, premiums, or similar charges" and "deductions, cost sharing, or similar charges"). It is, therefore, perfectly consistent for the Secretary to maintain authority to waive section 1396o's limits on premiums in connection with a demonstration project he determines is likely to assist in promoting the objectives of Medicaid while placing other limits on the Secretary's authority to waive cost-sharing requirements.

Plaintiffs' argument that the Secretary's waiver authority does not extend to section 1396o-1 similarly fails in the face of statutory text. "Nothing in [that] section shall be construed . . . as affecting the authority of the Secretary through waiver to modify limitations on premiums and cost sharing." 42 U.S.C. § 1396o-1(b)(6)(B). Plaintiffs interpret this provision as "preserv[ing] Section 1396o(f)'s limits on the Secretary's waiver authority." Pls.' Reply at 31. That cannot be correct because, as just explained, section 1396o(f) imposes limits only on the Secretary's ability to waive limits on cost sharing, not premiums. That difference in language indicates section 1396o-1(b)(6)(B)'s reference to the "authority of the Secretary through waiver to modify limitations on premiums" refers to section 1115(a), which remains unaffected as to premiums.

III. The December 2023 Letter Is Not Reviewable Final Agency Action and Was in Any Event Reasonable.

A. The December 2023 Letter Is Not Final Agency Action.

CMS's December 2023 letter declined to rescind any authorities that had been previously granted in CMS's original 2020 approval of HIP. *See* SAR 1. As that letter explained, however, CMS's letter was subject to "ongoing oversight and monitoring of the HIP demonstration." *Id.* In addition, nothing about the letter purported to approve Indiana's demonstration project. Rather, Indiana's authority to implement HIP flows from CMS's 2020 approval. *See* Fed. Br. at 37-38. The letter was neither the consummation of the agency's decision-making process nor a decision by which legal consequences will flow—it was not final agency action. *See Bennett v. Spear*, 520 U.S. 154, 178 (1997).

Plaintiffs respond that this argument would mean that "no Section 1115 approval is final agency action," Pls.' Reply at 32. That is not so. The original approval marks the consummation of the Secretary's statutorily granted waiver authority. *See* 42 U.S.C. § 1315(a). That process is governed by detailed statutory and regulatory requirements, including detailed requirements for State applications, provision for two periods of public comment, and an ultimate approval decision by the Secretary. *See* 42 U.S.C. § 1315(d); 42 C.F.R. § 431.412. The 2023 letter, by contrast, bears none of those hallmarks of formality and finality.

The cases cited by Plaintiffs do not establish that the December 2023 letter is the consummation of the agency's decision-making process. Pls.' Reply at 32. The agency in *United States Army Corps of Engineers v. Hawkes Co.* did "not dispute that an approved [jurisdictional determination] satisfies the first *Bennett* condition." 578 U.S. 590, 597 (2016). As the Court explained, those determinations were issued "after extensive factfinding" guided by internal agency policy manuals, were "typically not revisited," and were defined by regulation as final

agency action. *Id.* at 597-98. None of those factors apply to the December 2023 letter. Similarly, the court in *Young v. United States Department of Labor* rejected the government's argument that an agency policy was nonfinal because it was only one part of a process. No. 17-2428, 2020 WL 1557170, at *12 (D.D.C. Apr. 1, 2020). No party here contends that the December 2023 letter is a necessary predicate of some future decision. Rather, Federal Defendants argument is that CMS's non-recission of waivers of certain Medicaid requirements is non-final because it is subject to further review and analysis. *See* Fed. Br. at 37.

As to the second part of the *Bennett* test, any legal consequences on Plaintiffs flow from the original 2020 approval of HIP. Contrary to Plaintiffs' argument, the December 2023 letter did not "authoriz[e] Indiana to resume premium requirements." Pls.' Reply at 33. That authority was granted by the original 2020 approval. Plaintiffs argue that courts sometime "review circumstances where agencies decline to reverse course from a prior decision." *Id.* (citing *Berry v. U.S. Dep't of Lab.*, 832 F.3d 627, 634 (6th Cir. 2016)). The *Berry* case, however, came to the court on review from a denial of a request to reopen an agency's claim decision, which was permitted by the agency's processes. *See Berry*, 832 F.3d at 630-31. As Indiana correctly notes, Mem. of Intervenor-Def. Indiana Family & Social Services Admin. In Supp. of its Mot. to Dismiss at 38, ECF No. 58, the Secretary's regulations permitting withdrawal of waivers do not require the agency to re-approve demonstration authorities at any point, *see* 42 C.F.R. § 431.420(d)(2).

B. The December 2023 Letter Reasonably Concluded That Rescinding Indiana's Demonstration Authorities Would Be Too Disruptive.

As explained in Federal Defendants' opening brief, CMS reasonably concluded that intervening mid-demonstration to withdraw authority for Indiana to charge premiums had the potential to be too disruptive under the circumstances and might lead to the very coverage loss

Plaintiffs seek to avoid. Fed. Br. at 38-41. That decision was both reasonable and reasonably explained.

Notably, CMS did not ignore evidence suggesting that imposing premiums could itself cause coverage disruptions. As Plaintiffs concede, CMS extensively analyzed evidence suggesting negative coverage effects of premiums from other States and prior Indiana demonstration periods and noted its continuing "concerns with premium requirements in section 1115 demonstrations." *See* SAR 4-11; Pls.' Reply at 36. CMS also explained why it was "not taking any action now." SAR 1. Those reasons included the default fixed term for which demonstrations are approved, "operational concerns with the time and resources of phasing out such policies from eligibility systems and managed care plan contracts," potential for mistakes to eligibility redetermination during unwinding of the COVID-19 public health emergency, and the "complexity of providing beneficiary communication on such changes during the unwinding period." SAR 1-2. Although Plaintiffs take issue with these conclusions and the weight given to them by the agency, the fact remains that these are predictive determinations about the effect of withdrawing authorities that the agency is entitled to make. *See Oceana, Inc. v. Gutierrez*, 488 F.3d 1020, 1025 (D.C. Cir. 2007). And Plaintiffs can hardly argue that CMS did not consider the downsides of its proposed approach, given the pages of analysis it undertook explaining its concerns with premiums in other iterations of HIP and in other demonstration projects. *See* SAR 2-10.

Nor does the upcoming conclusion of the unwinding process undermine CMS's decision. *Contra* Pls.' Reply at 36. As CMS explained, the December 2023 letter reflected its view "at this time" and was intended to "minimize disruptions to the state's unwinding efforts." SAR 11. CMS expressly reserved "its authority to take appropriate action in the future" if circumstances later suggested that premium requirements were leading to coverage loss in practice that outweighed

any benefits of the demonstration and that those authorities could be withdrawn with minimal disruption. SAR 1. CMS simply took no position on whether that might occur in the future.

Plaintiffs suggest that CMS's decision is arbitrary because there can be no "disruption-based justification" to maintain "a policy that has not been in place for four years." Pls.' Reply at 37. That premise is incorrect. The December 2023 letter does not "introduce[] a change to the status quo." *Id.* CMS approved Indiana's demonstration project and granted a waiver that would allow Indiana to charge premiums in 2020. The December 2023 letter does not alter that authority. While it is true that Indiana did not charge premiums during the COVID-19 pandemic, *see* Pls.' Mem. at 9, the relevant HIP approval has remained unchanged, *see* SAR 1575. Withdrawing that authority now would be a change to the status quo, and the disruptive effects of that change on coverage determinations supported CMS's decision not to intervene. *See* SAR 1-2. CMS's December 2023 letter "aim[ed] to minimize" those "unintended disruptions." SAR 1. At a minimum, withdrawing those authorities would require Indiana to change what it had been telling beneficiaries about HIP coverage. SAR 2. And CMS was also concerned that it would require alterations to the State's operational and eligibility systems, errors that could cause unintended coverage loss. *Id.* It is, therefore, no response for Plaintiffs to say that premiums had not been charged during the COVID-19 pandemic. *See* Pls.' Reply at 37. CMS reasonably concluded that withdrawing Indiana's *authority* to charge premiums at the last moment, while the State was simultaneously unwinding from the COVID-19 public health emergency, could have serious disruptive effects.

Plaintiffs' remaining arguments about premiums ignore both the difference between an initial approval and a mid-demonstration withdrawal and apply the wrong standard. As CMS explained, demonstrations are generally approved "for a fixed term." SAR 2. Therefore, there is

a difference between CMS's consideration of a waiver authority in connection with a new demonstration or renewal, on the one hand, and a mid-stream demonstration on the other. It is completely rational for CMS to conclude that withdrawing a demonstration authority mid-stream would have more disruptive effects than declining to authorize that same waiver in the context of an initial application or renewal. While CMS retains authority to withdraw a waiver mid-stream, it reasonably applied its discretion in declining to do so here. *See* SAR 1. Plaintiffs argue the distinction between an initial application or renewal and mid-stream review does not affect whether "*these waiver authorities* are unlikely to promote Medicaid's core purpose." Pls.' Reply at 38 (emphasis added). But that asks the wrong question. The statute and implementing regulations require the Secretary to consider whether the "demonstration *project* . . . is likely to assist in promoting the objectives" of the Medicaid program, not any particular waiver included in that project. 42 U.S.C. § 1315(a) (emphasis added); 42 C.F.R. § 431.420(d)(2) ("The Secretary may also withdraw waivers or expenditure authorities based on a finding that the demonstration project is not likely to achieve the statutory purposes."); *see Stewart I*, 313 F. Supp. 3d at 257. Plaintiffs cannot evade the requirement that demonstration projects must be considered as a whole by casting their claim as against the Secretary's decision not to withdraw a specific authority.

Finally, Plaintiffs fault CMS for not independently discussing whether to withdraw its waiver of retroactive coverage and NEMT. *See* Pls.' Reply at 39. But if the original 2020 approval is permissible, then that authority would extend until it terminates according to its terms, and no review was required. In any event, CMS explained that in addition to its decision not to withdraw its waiver of Medicaid's limits on premiums, it was not withdrawing "any other authority[] in the approved HIP demonstration because, given the totality of the circumstances," it had "concluded that withdrawing those authorities at this time is too disruptive." SAR 1. In context, those "other

authorities" necessarily included the authority to waive retroactive coverage and the assurance to provide NEMT. *See id.* Even were CMS required to re-analyze those authorities in this context, its concern about the disruptive effects of withdrawing any demonstration authorities amply explains its decision not to withdraw those related to NEMT and waiver of retroactive coverage. *See* SAR 1-2.

IV. Any Remedy Should Be Limited.

Even if the Court concludes that the Secretary's 2020 approval or the December 2023 letter were unlawful agency action, any remand should be without vacatur under the two-factor test set forth in *Allied-Signal, Inc. v. United States Nuclear Regulatory Commission*, 988 F.2d 146 (D.C. Cir. 1993). *See* Fed. Br. at 42. Plaintiffs argue that the agency's approval cannot be rehabilitated, but for the reasons already stated, CMS's approval was within the Secretary's statutory authority. To the extent the Court determines the agency's decision was inadequately explained, further analysis on remand could remedy that error. As to whether vacatur would cause disruption, Plaintiffs rely heavily on this Court's prior rulings in *Stewart I* and *II*, *Gresham*, and *Philbrick*, but fail to account for the significant differences presented by HIP. Those cases primarily addressed work requirements and lockout periods, neither of which are elements that are approved portions of HIP today. *See Gresham v. Azar*, 363 F. Supp. 3d 165, 183-84 (D.D.C. 2019), *vacated by Arkansas v. Gresham*, 142 S. Ct. 1665 (2022); *Stewart v. Azar*, 366 F. Supp. 3d 125, 130 (D.D.C. 2019) ("*Stewart II*"); *Philbrick v. Azar*, 397 F. Supp. 3d 11, 31 (D.D.C. 2019), *vacated by Arkansas v. Gresham*, 142 S. Ct. 1665 (2022). Those demonstrations were also either not in effect or only partially in effect, whereas here Indiana residents have been participating in HIP's current approval for nearly 3.5 years. These circumstances present an increased risk of disruption for the path by which those beneficiaries have been obtaining coverage.

As CMS explained in its December 2023 letter, the risk of disruption in altering authorities is particularly acute at this time, as Indiana continues its unwinding process. Plaintiffs maintain that "disruption could only come from the State starting [premiums] back up," Pls.' Reply at 42, but that ignores the significant operational challenges the State may face in making changes to its operations and messaging. CMS credited Indiana's "operational concerns with the time and resources of phasing out such policies from eligibility systems and managed care plan contracts," SAR 2, and Plaintiffs offer no reason why those concerns would be less in the context of a court-ordered vacatur of the HIP demonstration.

Finally, Federal Defendants renew their argument that any remedy should be limited to "redress the plaintiff[s'] particular injury." *Gill v. Whitford*, 585 U.S. 48, 73 (2018). Federal Defendants acknowledge that this Court has ruled against the government on this argument in prior cases, *see* Pls.' Reply at 40 (citing cases), but nevertheless assert it here for preservation purposes.

CONCLUSION

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

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