

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF GEORGIA
BRUNSWICK DIVISION**

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| THE STATE OF GEORGIA, et al. |) | |
| |) | |
| Plaintiffs, |) | |
| |) | |
| v. |) | |
| |) | Case No. 2:24-cv-16-LGW-BWC |
| CHIQUITA BROOKS-LASURE in her official capacity as Administrator of the Centers for Medicare and Medicaid Services; et al. |) | |
| |) | |
| |) | |
| Defendants. |) | |

**DEFENDANTS’ MEMORANDUM IN OPPOSITION TO
PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF
DEFENDANTS’ CROSS-MOTION FOR SUMMARY JUDGMENT**

INTRODUCTION

Medicaid is a cooperative federal-state endeavor. Defendant Centers for Medicare & Medicaid Services (“CMS”) has statutory authority to authorize experimental or demonstration projects. In 2019, Plaintiff, the State of Georgia, sought such a demonstration project; and in 2020, CMS granted the demonstration request for the period from October 15, 2020 to September 30, 2025. In July 2023, Georgia began enrolling residents in the Pathways to Coverage (“Pathways”) project. Georgia seeks to extend the duration of this project beyond the end date specified in CMS’s approval. Federal law provides a mechanism to extend demonstration projects such as Pathways. And in multiple successive communications, CMS has explained to Georgia how to comply with these requirements. Bypassing those requirements, Georgia now asks this Court to unilaterally extend the Pathways project, and create for Georgia an exception to the application and notice procedures that are required by law and that apply to every other demonstration project.

This Court should reject Georgia’s request. First, Georgia’s arguments hinge on several incorrect characterizations: of the authorization for Pathways set forth in CMS’s approval letter, of

the accompanying Expenditure Authority document, and of the special terms and conditions (“STCs”) that govern the project. These documents are unequivocal: the project is authorized until September 30, 2025, whereupon, absent an extension, the relevant authorization will expire. Georgia was not guaranteed five years to operate Pathways; the state was guaranteed a demonstration until the specified end date. Second, and sensibly, any effort by Georgia to change the end date of Pathways constitutes an extension of the demonstration, not an amendment. To extend Pathways, Georgia must submit application materials as outlined in federal regulations. Until the state does so, CMS cannot evaluate such an extension request. For this reason, CMS has yet to make a substantive decision about whether it is appropriate to extend Pathways beyond September 30, 2025.

CMS awaits Georgia’s completed application for an extension of Pathways, and has repeatedly told Georgia that the agency is eager to work cooperatively with Georgia. Without such an application, CMS cannot act. Accordingly, this Court should deny Georgia’s motion for summary judgment and enter judgment for Defendants.

BACKGROUND

A. Statutory and Regulatory Background

“Medicaid is a cooperative federal-state program through which the Federal Government provides financial assistance to States so that they may furnish medical care to needy individuals.” *Wilder v. Virginia Hosp. Ass’n*, 496 U.S. 498, 502 (1990). State participation in Medicaid is voluntary, but if a state elects to participate it “must comply with certain requirements imposed by the [Medicaid] Act and regulations promulgated by the Secretary of Health and Human Services.” *Id.* To receive federal financial assistance, a state’s plan for medical assistance and any amendments thereto must be approved by the Secretary of Health and Human Services (“the Secretary”). *Id.*

Congress has separately 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).¹ 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). 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.), *reprinted in* 1962 U.S.C.C.A.N 1943, 1961-62.

A state already running a demonstration project may seek to extend that project. There are three relevant steps outlined in federal regulations: the pre-application state-level notice and comment period; the state’s application to CMS with required information; and the post-application federal-level notice and comment period. In the statute directing the Secretary to promulgate regulations concerning demonstration project applications and renewals, Congress specified that these regulations must include “a process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input.” 42 U.S.C. § 1315(d)(2)(A). Therefore, by regulation, before submitting an extension application to CMS, a state seeking to extend an existing demonstration project must first provide a state-level notice and comment period of at least 30 days. 42 C.F.R. § 431.408(a). The public notice must include a “comprehensive description” of the “extension to be submitted to CMS,” including information specified in the regulations such as

¹ This provision is also sometimes referred to as Section 1115 of the Social Security Act.

“estimate of the expected increase or decrease in annual enrollment, and in annual aggregate expenditures” and “[t]he hypothesis and evaluation parameters of the demonstration.” *Id.* § 431.408(a)(1)(i).

Second, the state must submit that required application to CMS. The regulations spell out what information is required of the state, and the deadline to submit an extension application. An “application to extend an existing demonstration will be considered complete, for purposes of initiating the Federal-level public notice period, when the State provides” an application package consisting of seven enumerated documents. 42 C.F.R. § 431.412(c)(2). This provision requires the state to submit:

- (i) A historical narrative summary of the demonstration project, which includes the objectives set forth at the time the demonstration was approved, evidence of how these objectives have or have not been met, and the future goals of the program.
- (ii) If changes are requested, a narrative of the changes being requested along with the objective of the change and the desired outcomes.
- (iii) A list and programmatic description of the waivers and expenditure authorities that are being requested for the extension period, or a statement that the State is requesting the same waiver and expenditure authorities as those approved in the current demonstration.
- (iv) Summaries of External Quality Review Organization (EQRO) reports, managed care organization (MCO) and State quality assurance monitoring, and any other documentation of the quality of and access to care provided under the demonstration, such as the CMS Form 416 EPSDT/CHIP report.
- (v) Financial data demonstrating the State’s historical and projected expenditures for the requested period of the extension, as well as cumulatively over the lifetime of the demonstration. This includes a financial analysis of changes to the demonstration requested by the State.
- (vi) An evaluation report of the demonstration, inclusive of evaluation activities and findings to date, plans for evaluation activities during the extension period, and if changes

are requested, identification of research hypotheses related to the changes and an evaluation design for addressing the proposed revisions.

(vii) Documentation of the State's compliance with the public notice process set forth in § 431.408 of this subpart, including the post-award public input process described in § 431.420(c) of this subpart, with a report of the issues raised by the public during the comment period and how the State considered the comments when developing the demonstration extension application.

Id.

These required materials provide the agency with the data and information it needs to make a reasoned decision on the extension request. CMS uses this information to ensure “a process that promotes transparency, facilitates public involvement and input, and encourages sound decision-making as demonstration applications are designed at the State level.” Medicaid Program; Review and Approval Process for Section 1115 Demonstrations, 77 Fed. Reg. 11678-01, 11680 (Feb. 27, 2012). The regulations seek to “assure achievement of the[] statutory objectives while minimizing administrative burden.” *Id.*

The third step is initiated when CMS receives a completed application to extend a demonstration project. CMS will “solicit public comment” on the project for 30 days by publishing the state's extension application materials and other information on the CMS website. 42 C.F.R. § 431.416 (b)(i)-(iv). CMS “will not render a final decision [on the extension request] . . . until at least 45 days after notice of receipt of a completed application, to receive and consider public comments.” 42 C.F.R. § 431.416(e)(1). As with § 431.412(c), the federal- and state-level comment periods ensure that information about “approved demonstration projects is publicly available, [to] promote greater transparency in the review and approval of demonstrations.” 77 Fed. Reg. 11678-01. The regulations ensure the agency can “minimize confusion around the demonstration review process, satisfy key stakeholders’ need for information and improve communication at the Federal level.” *Id.* at 11685.

B. Georgia's Demonstration Project

In December 2019, the state of Georgia applied for the Secretary's approval of a Medicaid demonstration project entitled "Pathways to Coverage." Letter from Frank W. Berry and Blake T. Fulenwider to Alex M. Azar II, Seema Verma, and Calder Lynch (Dec. 23, 2019) at 1, *see* <https://perma.cc/7WMQ-EY8Y> (last accessed May 2, 2024). The project sought to conditionally expand coverage to certain low-income Georgia residents between the ages of 19 and 64 who did not otherwise qualify for Medicaid coverage in the state. *Id.* To qualify for benefits under the proposed project, an individual had to, among other things, complete a work or community engagement requirement of 80 hours per month, *id.* at 10, and if earning a specified level of income, timely pay a monthly premium (with certain exceptions), *id.* at 18.

On October 15, 2020, the Secretary, acting through the Administrator of CMS, approved Georgia's project in large part. Letter from Seema Verma to Frank W. Berry (Oct. 15, 2020), AR 0134-0155. CMS's approval letter stated that "[t]his approval is effective October 15, 2020, through September 30, 2025, upon which date, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire." *Id.* The letter also explained that "[t]he state may implement the demonstration effective July 1, 2021." *Id.* (footnote omitted). The CMS Expenditure Authority document accompanying the approval letter reiterated that Pathways was approved for "the period from October 15, 2020 – September 30, 2025." AR 0156. Specifically, it stated that, "[u]nder the authority of section 1115(a)(2) of the Social Security Act (the Act), expenditures made by Georgia for the items identified [in the document], which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from October 15, 2020 – September 30, 2025, unless otherwise specified, be regarded as expenditures under the state's title XIX plan." *Id.*

The approved project also contained "special terms and conditions." The STCs "set forth in detail the nature, character, and extent of federal involvement in the demonstration and the state's

obligations to CMS related to this demonstration.” AR 0027. Several STCs are relevant here. First, the STCs again reiterate that Pathways was “approved for a 5-year period from October 15, 2020 – September 30, 2025,” and that Georgia would implement the demonstration “effective July 1, 2021.” *Id.*

Second, the STCs describe the separate procedures for requesting an amendment or extension of the project. As to amendments, STC 6, entitled “Changes Subject to the Amendment Process,” explains that “[c]hanges related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration.” AR 0029. STC 6 further provides that the “state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid state plan or amendment to the demonstration,” and any such approval is “at the discretion of the Secretary in accordance with section 1115 of the [Social Security] Act.” *Id.* STC 7, entitled “Amendment Process,” describes the process for seeking an amendment. It explains that “[r]equests to amend the demonstration must be submitted to CMS for approval prior to the planned date of implementation of the change and may not be implemented until approved.” AR 0030. This paragraph then itemizes the information that “must” be included in the state’s amendment request so CMS can evaluate the request. *Id.* STC 7 further provides that “CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to failure by the state to submit required elements of a viable amendment request as found in this STC.” *Id.*

As to extensions, STC 8, entitled “Extension of the Demonstration,” explains that “States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of [42 C.F.R.

§ 431.412(c)].” AR 0030. As detailed above, 42 C.F.R. § 431.412(c) itemizes specific information required from the state before CMS may consider an extension application.

Early in 2021, CMS notified Georgia that, given the ongoing COVID-19 pandemic, CMS had “preliminarily determined that allowing work and other community engagement requirements to take effect in Georgia would not promote the objectives of the Medicaid program.” Letter from Elizabeth Richter to Frank W. Berry (Feb. 12, 2021) at 2, *see* <https://perma.cc/2SDX-ANMB> (last accessed May 2, 2024). Georgia responded to CMS’s preliminary determination letter and opposed withdrawing the authorities for its work and community engagement requirement. Letter from Frank W. Berry to Elizabeth Richter and Judith Cash (March 12, 2021), <https://perma.cc/KU9R-FDYD> (last accessed May 2, 2024). On July 27, 2021, Georgia indicated that it anticipated delaying implementation of the demonstration until the end of 2021 to assess its options to resolve the issues CMS identified in its preliminary determination letter. *See* Letter from Caylee Noggle to Judith Cash, <https://perma.cc/3U5C-VBVT> (last accessed May 2, 2024). In December 2021, after reevaluating the risks posed by the pandemic and its aftermath, and the potential benefits of continuing the work and community-engagement requirement and premium requirement in Georgia’s demonstration project, CMS withdrew approval for those components. Letter from Chiquita Brooks-LaSure to Caylee Noggle (Dec. 23, 2021), <https://perma.cc/W6KB-TXMD> (last accessed May 2, 2024).

In February 2022, Georgia sued in this Court to challenge CMS’s withdrawal of approval for the work and community engagement, and premium, components of the project. *See Georgia v. Brooks-LaSure, et al*, No. 2:22-cv-06, 2022 WL 3581859 (S.D. Ga., August 19, 2022) (“*Georgia P*”). This Court granted Georgia’s motion for summary judgment in August 2022, concluding that CMS’s rescission of approval for these components “was arbitrary and capricious.” *Id.* 2022 WL 3581859, at *9. And the Court “set aside” the rescission. *Id.* Following this order, CMS worked collaboratively with Georgia

to implement Pathways. Georgia determined that it would implement Pathways beginning in July 2023.

C. Georgia's Request To Extend The Demonstration

In February 2023, before Georgia began enrolling participants in Pathways, Georgia wrote to CMS, requesting “to amend the effective dates of [Pathways] to allow additional time in which to evaluate and assess the effectiveness of the demonstration waiver.” AR 0001. Georgia asked “to extend the end date of the demonstration to September 30, 2028.” *Id.* at 0005. Georgia did not include with its request any of the materials required for an extension by STC 8 and the applicable regulation; or for an amendment by STC 7.

CMS responded by explaining that Georgia’s “request does not qualify as an ‘amendment,’ but rather would be considered a request for an extension of the demonstration, because it does not request to change the program elements referenced in STC 6,” such as eligibility, benefits, delivery systems, or budget neutrality, among others. AR 0006. CMS noted that “[e]xtending the demonstration period is not among the changes listed under STC 6 that can be made through an amendment, and, consistent with CMS practice, a change to a demonstration’s effective dates is properly considered an extension.” *Id.* CMS further explained that, under STC 8, any extension request “must comply with 42 CFR 431.412(c),” and Georgia’s letter to CMS “did not meet” those requirements. AR 0006. “Absent meeting these requirements,” CMS explained, it was “unable to consider a formal request for extension.” *Id.* CMS noted, however, that “[s]hould the state choose to seek an extension of the Pathways demonstration” in accordance with these requirements, “CMS will review the request.”² *Id.*

² CMS also explained that, even if Georgia’s letter could be construed as a request for an amendment of the demonstration project, Georgia had not submitted any of the information required by STC 7 either. AR 0006-07.

In November 2023, Georgia asked CMS to reconsider its response. AR 0013-18. CMS made three principal points in response. First, the agency responded to Georgia's assertion that the state is entitled to run Pathways for a full five years. The agency noted that states routinely implement a demonstration project for a period "that is shorter than the period for which the necessary demonstration authorities are approved" and this is "not unique to the Pathways." AR 0019. States running demonstration projects "experience delayed implementation of their demonstration projects . . . for various reasons." *Id.* Second, the agency reiterated its conclusion that Georgia's February 2023 letter sought an amendment, not an extension, and that given the change Georgia planned for Pathways, i.e. to move back the end date, this was improper. Under the STCs of the project, "the state's request does not qualify as an 'amendment,' but rather, is considered a request for an extension of the demonstration because it does not request to change the program elements referenced in STC 6." AR 0020. The agency explained that, "consistent with long-standing CMS practice, a change to a demonstration's effective dates is considered an extension," and noted this is covered by STC 8. *Id.* And, in any event, Georgia's submissions did not comply with STC 7 to seek an amendment. Finally, the agency reminded Georgia that STC 8 and federal regulations clearly outline the requirements for any state wishing to extend a demonstration project. "Georgia must submit an extension request that complies with 42 C.F.R. 431.412(c) for CMS to be able to consider extending the demonstration approval period." *Id.* CMS is not empowered to grant Georgia an exception from federal law. CMS stated that it "must consider Georgia's request to extend the Pathways demonstration approval period consistent with how we approach all state requests for demonstration extensions, which is uniform notwithstanding any implementation delays the requesting state may have experienced with respect to a particular demonstration." AR 0019. In conclusion, the agency reiterated, if Georgia submitted a properly constituted amendment or extension request, CMS would work with Georgia to evaluate that request. CMS "remains keenly interested in the opportunity for

meaningful monitoring and evaluation to inform an understanding of the coverage received through” Pathways. AR 0021.

D. This Lawsuit

Thereafter Plaintiffs, the State of Georgia and the Georgia Department of Community Health, filed this lawsuit. Complaint, ECF No. 1 (“Compl”). Plaintiffs raise five claims. They allege that CMS’s decision to deny Georgia’s request to extend the end date of Pathways was (1) arbitrary and capricious, *id.* ¶¶ 103-112 (Count IV); (2) contrary to Section 1115 of the Medicaid statute, *id.* ¶¶ 93-102 (Counts II and III); and (3) in violation of the parties’ contractual agreements, *id.* ¶¶ 87-91, 113-115 (Counts I and V). Plaintiffs seek an order setting aside CMS’s decision, as well as declaratory and injunctive relief. *Id.* at 30.

Plaintiffs moved for summary judgment on March 29, 2024. Pls.’ Mot. for Summ. J. and Mem. in Support, ECF No. 19 (“Pls.’ Mot.”). Defendants hereby oppose Plaintiffs’ motion and cross-move for summary judgment.

LEGAL STANDARDS

Generally, summary judgment is appropriate where “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 cases raising claims under the Administrative Procedure Act (“APA”), summary 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 standard of review.” *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng’rs*, 354 F. Supp. 3d. 1253, 1267 (N.D. Ala. 2018). “The factfinding capacity of the district court is thus typically unnecessary.” *Fla. Power & Light Co. v.*

Lorion, 470 U.S. 729, 744 (1985). “[C]ourts are to decide, on the basis of the record the agency provides, whether the action passes muster under the appropriate APA standard of review.”³ *Id.*

The burden is on the plaintiff to demonstrate that the agency acted arbitrarily and capriciously, and any “party seeking to have a court declare an agency action to be arbitrary and capricious carries a heavy burden indeed.” *Legal Envt’l Assistance Found. Inc. v. EPA*, 276 F.3d 1253, 1265 (11th Cir. 2001) (citation omitted). “Agency action is considered arbitrary or capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). *See Sierra Club, Inc. v. Leavitt*, 488 F.3d 904, 911 (11th Cir. 2007).

ARGUMENT

CMS determined that Georgia’s request to extend Pathways beyond the September 30, 2025 end date specified in CMS’s approval letter, the Expenditure Authority document, and the STCs was a request for an extension and thus must comply with the requirements in STC 8 and 42 C.F.R. § 431.412(c). Because Georgia’s submission did not meet any of those requirements (much less all of them), CMS did not grant authority to Georgia to extend the demonstration. This Court should uphold that decision because it is consistent with the applicable statute, regulations, and STCs, and it was neither arbitrary nor capricious.

³ Because the court’s review of Plaintiffs’ claims is limited to the administrative record, there are no disputed material facts. *See, e.g., 3V Sigma USA, Inc. v. Richardson*, No. 2:20-CV-0807-DCN, 2021 WL 809399, at *3 (D.S.C. Mar. 3, 2021); *see also* Joint Motion for Briefing Schedule, ¶ 5, ECF No. 16; Briefing Schedule Order at 1, ECF No. 17. Accordingly, the Defendants do not provide a “statement of the material facts as to which it is contended there exists no genuine dispute.” L. R. 56.1.

Georgia remains free to submit a proper extension request that complies with the applicable requirements, and CMS will consider it. Until then, the Court lacks jurisdiction to consider Georgia's claims regarding the alleged consequences of any subsequent decision by CMS on a proper extension request.

I. THE CMS DECISION CHALLENGED HERE IS LAWFUL.

A. Georgia's Desire to Extend Pathways Beyond the End Date Specified in CMS's Approval Is An Extension, Not An Amendment.

The STCs clearly distinguish between requests to amend a demonstration project and requests to extend a project, setting out different requirements for each. A request to make “[c]hanges related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements” is an amendment and “must be submitted to CMS as [an] amendment[] to the demonstration” in accordance with the requirements of STC 7. AR 0029 (STC 6). A request to “exten[d] the demonstration beyond the period authorized in the[] STCs” is an extension and must be submitted to CMS as an extension in accordance with the requirements of STC 8. AR 0030 (STC 8).

Georgia's desire to change the end date specified in CMS's approval is a request to extend the demonstration, not a request to amend it. Modifying the end date is not one of the changes specified in STC 6, nor is it a “comparable program element” to, for example, eligibility, benefits, delivery systems, or budget neutrality. AR 0029. Instead, a change to the end date would “exten[d] the demonstration beyond the period authorized in the[] STCs,” and thus, under the STCs, what Georgia sought was an extension. AR 0030. This also aligns with the common usage of the word, wherein an extension is defined as an “enlargement,” or an “increase in length; prolongation, lengthening.” *Extension*, OXFORD ENGLISH DICTIONARY, Mar. 2024. *See also* AR 0006 (CMS's Oct. 2023 letter) (“consistent with CMS practice, a change to a demonstration's effective dates is properly considered an extension”).

B. CMS Properly Denied Georgia’s Request Because It Did Not Comply with the Requirements for an Extension Request.

The requirements to extend a demonstration project are outlined in both the STCs and federal regulations. STC 8 explains that “States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of [42 C.F.R. § 431.412(c)].” AR 0030 (STC 8). That regulation requires a state to submit an extension request “at least 12 months prior to the expiration date of the demonstration when requesting an extension under section 1115(e) . . . or 6 months prior to the expiration date of the demonstration when requesting an extension under section 1115(a) or (f).” 42 C.F.R. § 431.412(c). The regulation further specifies that an “application to extend an existing demonstration will be considered complete, for purposes of initiating the Federal-level public notice period, when the State provides” an application package consisting of seven enumerated documents, as discussed above. *Id.* § 431.412(c)(2). In brief, these documents include a summary of the demonstration project, a narrative of the changes requested (if any), an accounting of expenditure authorities requested, documentation of the access and quality of care provided under the demonstration, financial data, an evaluation report of the demonstration, and demonstration of the state’s compliance with the public notice process outlined in 42 C.F.R. § 431.408. *See* 42 C.F.R. § 431.412(c).

Georgia did not submit any of this information to CMS, and Georgia does not claim otherwise. Because Georgia’s request did not meet the application requirements, CMS was accordingly unable to grant Georgia the extension it seeks. *See* AR 0006 (“Absent meeting these requirements [in STC 8 and 42 C.F.R. § 431.412(c)], CMS is unable to consider a formal request for extension.”). Because Georgia

did not submit the materials required by the STCs and applicable regulations for an extension request, CMS properly responded to Georgia's request.⁴

Georgia nonetheless claims that CMS's decision was arbitrary and capricious. Pls.' Mot. at 18-22. But agency action "must comply with the agency's governing statutes and regulations." *Bean v. Purdue*, 316 F. Supp. 3d 220, 227 (D.D.C. 2018). "[A]dministrative decisions made in accordance with applicable statutes and regulations are not arbitrary and capricious." *Id.*; *Cerniglia v. Glickman*, 118 F. Supp. 2d 27, 34–36 (D.D.C. 2000) (holding that USDA did not act arbitrarily and capriciously in sending a notice to the plaintiff because the agency complied with the relevant regulatory notice requirements); *Kawran Bazar, Inc. v. United States*, 721 F. App'x 7, 9 (2d Cir. 2017) ("A sanction does not violate [the arbitrary and capricious] standard when the agency properly adheres to its own settled policy and guidelines."); *Grinstead v. United States*, 122 F.3d 1071 (9th Cir 1997) (finding that the Farmers Home Administration ("FmHA") did not act arbitrarily and capriciously in foreclosing a farmer's property and denying further time extensions because the FmHA action was mandated by the statutory guidelines). Indeed, the opposite is true. An agency that ignores its own regulations can be deemed to have acted arbitrarily and capriciously. *See, e.g., Aerial Banners, Inc. v. FAA*, 547 F.3d 1257, 1260 (11th Cir. 2008) ("An agency may also act arbitrarily and capriciously by failing to follow its own regulations and procedures."). Contrary to Georgia's assertion, CMS cannot ignore its own regulations merely because Georgia believes they present "two highly undesirable options" or are "burdensome." Pls.' Mot. at 20.⁵

⁴ Even if the Court determines that Georgia's request to extend the end date of the demonstration was an amendment instead of an extension, CMS's decision should be upheld. Georgia's submission did not comply with the requirements for an amendment request in STC 7 either. AR 0006-07; 0019-21 (both CMS's Oct. and Dec. 2023 letters).

⁵ Georgia has another active 1115 demonstration, called Georgia Planning for Healthy Babies, that has been in place since 2011. This demonstration was last extended in 2019, after Georgia submitted an extension application that complied with applicable regulations. *See* <https://perma.cc/7XKT-CBB7> (last accessed May 6, 2024).

Georgia suggests that CMS should have excused compliance with the STCs and regulations. The state argues Pathways has not been operational long enough for the state to gather the necessary data and information, and then to provide that information to CMS. *See* Pls.’ Mot. at 19. But Georgia does not point to any applicable exemption in the regulations or STCs. In any event, depending on the statutory basis for the extension request, Georgia would not be required to submit an extension application until September 2024 or March 2025. *See* 42 C.F.R. § 431.412(c) (providing that an extension request must be submitted at least 12 months (under section 1115(e)) or 6 months (under section 1115(a) or (f)) prior to the expiration date of the demonstration). By that time, Pathways will have been operational for 14 months or 20 months, respectively. CMS explained that it “believes that the current implementation period, taking into consideration the timeframe required for submitting an extension request, should provide sufficient data to help understand the preliminary effects of the demonstration, considering the robust monitoring and evaluation efforts from our continuing collaboration.” AR 0021.

Georgia has not explained why 14 to 20 months of operation is not enough time for it to supply the necessary data and information to CMS. CMS has approved demonstration projects for as short as three years.⁶ A state operating such a project must likewise seek an extension six to twelve months before the demonstration authorities expire. 42 C.F.R. § 431.412(c) (specifying application deadlines for extensions sought under § 1115(a), (e), (f)). Thus, depending how quickly a state implements its project, it may have only 12 to 24 months of data to provide to CMS. States regularly submit extension requests under these circumstances, relying on the data and information they have collected, and CMS

⁶ Iowa Health and Wellness Plan, <https://perma.cc/ZCA8-D3S9> (last accessed May 6, 2024); Healthy Indiana Plan, <https://perma.cc/FH6M-W6TE> (last accessed May 6, 2024); Arkansas Health Care Independence Program, <https://perma.cc/PPQ2-LTTC> (last accessed May 6, 2024).

considers that data and information, among other factors, including the period in which the data was collected, in resolving the extension request.

Georgia notes that, at the time it submitted its initial request in February 2023, Pathways was not yet operational. *See* Pls.’ Mot. at 19. And Georgia questions how CMS’s decision could be reasonable when the information required by the regulations “would not *exist*—or even start being compiled—until” several months later when Georgia implemented Pathways. *Id.*; *see id.* at 15. But the applicable regulations do not require a state to submit an extension request until, at the earliest, 12 months before the expiration of the demonstration—here, September 30, 2024. *See* 42 C.F.R. § 431.412(c). A state cannot apply for an extension 18 months before any deadline and then complain that it has not had sufficient time to collect necessary data.

Georgia also argues that CMS’s decision is arbitrary and capricious because CMS “blamed Georgia” for the delay in implementation. Pls.’ Mot. at 18; *see id.* at 15. But CMS’s response to Georgia’s request was not based on the reason for the delay in implementation. As explained above, CMS denied the request because Georgia sought to extend the demonstration project without complying with the requirements in the STCs and regulations for seeking an extension. AR 0006-07, 0019-21. Moreover, Georgia misunderstands CMS’s discussion of the delay in implementation. CMS was merely explaining that delays in implementation are not uncommon: a “demonstration implementation period that is shorter than the period for which the necessary demonstration authorities are approved is not unique to the Pathways demonstration, and many states experience delayed implementation of their demonstration projects. . . for various reasons.” AR 0019. CMS routinely considers proper extension requests in those circumstances. But CMS is not authorized to extend a demonstration project without an extension application that complies with relevant federal regulations and the project’s STCs. Georgia’s request to circumvent these procedures *is* unique. And, as CMS explained, it “must consider Georgia’s request to extend the Pathways demonstration approval

period consistent with how we approach all state requests for demonstration extensions, which is uniform notwithstanding any implementation delays the requesting state may have experienced with respect to a particular demonstration.” AR 0019.

C. CMS’s Approval of Pathways Did Not Guarantee a Five-Year Period of Operation, Regardless of End Date.

Many of Georgia’s claims are based on the mistaken premise that CMS approved Pathways for a five-year period, regardless of the end date, and thus Georgia must be authorized to operate the project for a full five years before it must request an extension. As an initial matter, this argument is inconsistent with Georgia’s actions here. Georgia submitted a request “to amend the effective dates of Georgia Pathways” precisely because it understood that CMS’s approval will expire on September 30, 2025, not on some unspecified date five years after Georgia implemented the project. AR 0001.

More importantly, any assertion that CMS’s approval of Pathways guaranteed a five-year period of operation is belied by the approval documents themselves. Georgia relies on a sentence in the STCs that says, “The Georgia Pathways to Coverage demonstration . . . is approved for a 5-year period from October 15, 2020 – September 30, 2025.” AR 0027, AR 0158. But it is the date range that controls, as demonstrated by other approval documents. CMS’s approval letter states that “[t]his approval is effective October 15, 2020, through September 30, 2025, *upon which date*, unless extended or otherwise amended, all authorities granted to operate this demonstration will expire.” AR 0134 (emphasis added). In addition, the CMS Expenditure Authority document accompanying the approval letter, which is what authorizes Georgia to obtain federal reimbursement for expenditures under the demonstration that would not otherwise be reimbursed by Medicaid, *see* 42 U.S.C. § 1315(a)(2)(A), makes clear that Pathways is approved for “the period from October 15, 2020 – September 30, 2025.” AR 0156. That document specifies that “expenditures made by Georgia for the items identified [in the document] . . . shall, for the period from October 15, 2020 – September 30, 2025, unless otherwise

specified, be regarded as expenditures under the state’s title XIX plan.” *Id.* Neither document mentions nor guarantees a five-year period.

Even the STCs, which refer to “a 5-year period from October 15, 2020 – September 30, 2025,” do not guarantee a five-year period. AR 0027. The date range specified is itself less than five years. More tellingly, the STCs explain that the Georgia intends to implement the demonstration “effective July 1, 2021.” AR 0027. Thus, even at the project’s conception, the parties anticipated that, barring any extensions, Pathways would have a maximum duration of four years and three months (July 2021 – September 2025).

In addition to contradicting the approval documents, Georgia’s assertion that CMS’s approval authorized it to run Pathways for a “full five years,” regardless of end date, would be administratively unworkable. Implementing a demonstration project typically requires substantial work, and coordination between the state and federal governments, and unexpected complications can arise. *See* AR 0019 (states running such projects experience delays “related to operational constraints, readiness delays, and/or other factors, [such that] states may be unable to implement a certain demonstration authority immediately when the authority is initially approved.”). Under Georgia’s version of program administration, CMS would be required to “pause” a demonstration approval period if, for example, the state’s contractors needed to be substituted out, or there was a lapse in state appropriations, or other unforeseen complications arose in the process of implementing or running a demonstration project. For good reason, then, Georgia’s preferred approach is not CMS’s standard practice. Instead, CMS generally permits a state to begin a demonstration project any time after the project is authorized (here, implementation was slated for July 2021) and, if no extension is requested or granted, the project must conclude on the end date (September 2025).

Debunking Georgia’s mistaken premise that CMS’s approval of Pathways guaranteed a five-year period of operation, regardless of end date, disposes of many of Georgia’s arguments. Georgia

asserts that CMS’s decision is contrary to law because CMS does not have authority to shorten an already-approved demonstration project, Pls.’ Mot. at 23. But CMS has not shortened the approval period. CMS’s approval continues to run from October 15, 2020 to September 30, 2025, as it always has. It is Georgia’s request for CMS to extend the approval period in the absence of a proper extension request that would require CMS to act contrary to law. *See* 42 C.F.R. §§ 431.412(c) (requiring extension application materials from the state); 431.416 (outlining agency obligations triggered by a completed extension application package); STC 8 (explaining extension application procedures, referencing § 431.412(c)); AR 0029-0030 (STCs).

Georgia likewise argues that CMS’s decision violates the parties’ agreement, as set forth in the STCs, because it “seeks to shorten Pathways from five years to two by denying Georgia’s request to comply with the program’s [alleged] original terms.” Pls.’ Mot. at 25. But it is Georgia that seeks to rewrite the STCs, which establish an end date of September 30, 2025 and require the state to submit an extension application in accordance with 42 C.F.R. § 431.412(c) to extend the demonstration beyond that date. AR 0158. Georgia’s request would also require CMS (and the Court) to ignore the express terms of CMS’s approval letter and CMS’s grant of expenditure authority. *See* AR 0134 (CMS approval letter) (“This approval is effective October 15, 2020, through September 30, 2025, *upon which date . . . all authorities . . . will expire.*”) (emphasis added); AR 0156 (Expenditure Authority) (“expenditures made by Georgia for the items identified [in the document] . . . shall, for the period from October 15, 2020 – September 30, 2025, unless otherwise specified, be regarded as expenditures under the state’s title XIX plan”).

Lastly, Georgia claims that CMS’s decision was arbitrary and capricious because it “contradicted [CMS’s] earlier policy . . . that Pathways warranted a five-year demonstration period” and ignored Georgia’s “reliance interests” in “the STCs’ promise of a five-year demonstration period.” Pls.’ Mot. at 21. As explained above, however, CMS’s approval of Pathways did not guarantee a five-

year period of operation, regardless of end date. CMS thus determined that Georgia must submit a proper extension request to extend the demonstration beyond September 30, 2025. CMS's decision to comply with the STCs and applicable regulations was not arbitrary and capricious.⁷

D. CMS Has Not Made a Decision on Any Proper Request to Extend Pathways Beyond the September 30, 2025 End Date Because Georgia Has Not Submitted Any Such Request.

Georgia's remaining claims hinge on characterizing CMS's decision as a substantive determination that an extension of Pathways is not appropriate. For example, Georgia argues that CMS "failed to consider the risk" that not extending Pathways "could ultimately result in less Medicaid coverage for Georgians," allegedly in violation of the Medicaid statute and the APA. Pls.' Mot. at 20, 24. Georgia similarly asserts that CMS did not consider whether the state's "investments of time, money, and manpower in implementing Pathways" would be "wasted if the project ended just two years after commencing." *Id.* at 22; *see also id.* at 23 (contending CMS's decision seeks to ensure Pathways "can never be fully implemented").

Contrary to Georgia's suggestion, CMS has not made any substantive decision about whether it is appropriate to extend Pathways. Georgia has not yet submitted a proper extension request, and thus, CMS does not have the information necessary (and required by the STCs and regulations) to assess any request for an extension. If and when Georgia submits a proper extension request, CMS will consider the factors Georgia identifies, among others, in resolving that request. And Georgia can seek judicial review of any decision made by CMS on a proper extension request. *See generally* 42 C.F.R.

⁷ Georgia asserts, without further explanation, that CMS's decision "defie[s] this Court's" order in *Georgia I*. Pls.' Mot. at 1. But CMS has, at all times, complied with the Court's order in that case. In *Georgia I*, this Court "set aside" CMS's rescission of approval for two components of Pathways. *Georgia I*, 2022 WL 3581859, at *9. Consistent with that order, CMS permitted Georgia to fully implement Pathways. The Court's order did not require CMS to extend the demonstration period beyond its existing end date of September 30, 2025. Nor did the Court's order require (or authorize) CMS to ignore the STC's and regulations governing what is required for a state to submit a proper extension request.

§ 430.3; 45 C.F.R. Part 16. Until then, however, Georgia’s claims that are premised on the suggestion that CMS made a substantive denial here are not justiciable. *See, e.g., Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (to be final, agency action must not be “of a merely tentative or interlocutory nature”); *FTC v. Standard Oil of Cal.*, 449 U.S. 232, 239 (1980) (agency action is final if it is “definitive,” and has a “direct and immediate” effect on the party challenging the action) (citation omitted).

Georgia appears to acknowledge that the decision challenged here does not constitute CMS’s substantive determination of whether an extension of Pathways may be appropriate. *See* Pls.’ Mot. at 2, 13. Georgia notes that, in light of CMS’s decision, it “must either request a formal extension of Pathways” or “take steps to wind down the program” when the approval end date approaches. *Id.* at 2. There is nothing novel about this situation. It is contemplated by STC 8, which explains that “States that intend to request an extension of the demonstration must submit an application to CMS . . . in accordance with the requirements of [42 C.F.R. § 431.412(c)]” and “States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs, must submit a transition and phase-out plan consistent with the requirements of STC 9.” AR 0030. In responding to Georgia’s request for reconsideration, CMS made clear that Georgia “has plenty of time before the expiration of the currently approved demonstration authorities to meet the regulatory requirements to request an extension, if it intends to do so.” AR 0021. The agency further explained that, “[s]hould the state choose to seek an extension of the Pathways demonstration, CMS will work with the state to meet these requirements and review the request in accordance with federal rules.” AR 0021. CMS remains committed to doing so.⁸

⁸ Georgia may seek federal administrative match as “program planning and development” for any expenditures incurred to develop any section 1115 application, including any forthcoming extension application. *See* 42 U.S.C. § 1396b(a)(7), 42 C.F.R. § 433.15(b)(7).

II. SOME OF THE RELIEF GEORGIA SEEKS IS NOT AUTHORIZED.

The CMS decision challenged here was lawful for the reasons explained above, and thus, the Court should enter judgment for Defendants. If the Court were nonetheless to conclude that CMS's decision was contrary to law or arbitrary and capricious, the only appropriate remedy would be to "hold unlawful and set aside" CMS's decision. 5 U.S.C. § 706(2). *See* Pls.' Mot. at 25 (requesting this relief). That remedy would not result in an extension of Pathways beyond the September 30, 2025 end date. For CMS to consider such an extension, Georgia would still need to comply with the applicable STCs and regulations by submitting a proper extension request.

Georgia seeks two other specific forms of relief. *See* Pls.' Mot. at 25. It asks the Court to enter a declaratory judgment "declaring that Pathways' effective end date is September 30, 2028." *Id.* And it requests a permanent injunction "enjoining Defendants from enforcing the Denial." *Id.* Neither form of relief is authorized.

Georgia brings its claims under the APA. Pls.' Mot. at 16; Compl. ¶¶13, 14, 87-115. Relief under the APA is circumscribed. As noted above, the APA permits reviewing courts to "hold unlawful and set aside agency action." 5 U.S.C. § 706(2). But "under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law" or application, "the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards." *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995); *see also, e.g., Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); *Gallo v. Amoco Corp.*, 102 F.3d 918, 923 (7th Cir. 1996). The Court "ha[s] no jurisdiction to order specific relief," like that requested by Georgia. *Palisades Gen. Hosp., Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005); *see Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) (holding that district court "erred by directing the Secretary how to calculate the hospitals' [Medicare] reimbursements, rather than just remanding after identifying the error"); *SEC v. Chenery Corp.*, 332 U.S. 194, 201 (1947) ("After the remand was made,

therefore, the Commission was bound to deal with the problem afresh, performing the function delegated to it by Congress.”). Thus, the Court lacks authority under the APA to declare a new end date for Pathways (or to order CMS to do so) or to direct CMS how it should resolve any proper extension request Georgia might submit.

CONCLUSION

For the foregoing reasons, summary judgment should be granted to Defendants.

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