UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRYLEE McCUTCHEN, *et al.*,	)	
	)	
Plaintiffs.	)	
	)	
v.	)	
	)	No. 1:21-cv-01112-TSC
XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	
	)	

PLAINTIFFS' UNOPPOSED MOTION FOR LEAVE TO FILE SUPPLEMENTAL COMPLAINT AND STATEMENT OF POINTS AND AUTHORITIES

For the reasons set forth below, Plaintiffs respectfully move the court to grant them leave to file a Supplemental Complaint under Federal Rule of Civil Procedure 15(d). *See* Min. Order, Nov. 6, 2023 (ordering Plaintiffs to file any motion for leave to file a Supplemental Complaint by December 22, 2023). Pursuant to Local Civil Rules 7(i) and 15.1, Plaintiffs' proposed Supplemental Complaint accompanies this motion.

Plaintiffs conferred with Federal Defendants and Intervenor-Defendant and they have authorized Plaintiffs to state their position on this motion as follows: Federal Defendants would not object to the filing of the supplemental complaint on the condition that they would get, per the government's usual response time under the rules, at least 60 days to respond from the date it is deemed filed (and in any event at least until February 23, 2024). Federal Defendants reserve all rights, objections, and challenges with respect to the pleading itself, procedural, substantive, and otherwise. Intervenor-Defendant does not oppose this motion under the same terms as the Federal Defendants. Plaintiffs have agreed to those terms for both Intervenor-Defendant and Federal Defendants.

STATEMENT OF POINTS AND AUTHORITIES

Statement of Facts

This case challenges Federal Defendants' use of Section 1115 of the Social Security Act to enable Tennessee to implement the TennCare project, which affects the vast majority of Medicaid beneficiaries in Tennessee. Section 1115 allows the Secretary of Health and Human Services to waive (*i.e.*, permit states to ignore) specified provisions in the Medicaid Act to implement an "experimental, pilot, or demonstration project" likely to promote the objectives of the Medicaid Act. 42 U.S.C. § 1315(a). The waiver can last only for the period of time necessary to enable the state to carry out the experiment. *Id.* § 1315(a)(1).

In 1993, the Secretary approved TennCare as a Section 1115 demonstration project. The initial goals of the demonstration were to extend health care coverage to virtually all uninsured Tennesseans while controlling costs, primarily through mandatory enrollment of program beneficiaries into capitated, risk-based managed care plans and beneficiary cost-sharing. Gov. Ned McWherter, *TennCare: A New Direction in Health Care* 6–7 (1993). As part of the project, the Secretary allowed Tennessee to waive the Medicaid Act requirement for states to provide three months' retroactive coverage to Medicaid beneficiaries. Letter from Bruce C. Vladeck, Adm'r, Health Care Fin. Admin., Dep't of Health & Hum. Servs., to Mr. H. Russell White, Comm'r, Tenn. Dep't of Health 2 (Nov. 18, 1993).

Over the last 30 years, the Secretary has allowed Tennessee to keep the TennCare project in place – including the waiver of retroactive coverage and the mandatory enrollment of beneficiaries in managed care. In November 2019, Tennessee submitted a request to amend the approved TennCare waiver, at that point referred to as TennCare II. *See* Div. of TennCare, TennCare II Demonstration Amendment 42, Modified Block Grant and Accountability 2 (2019),

https://bit.ly/3dDQNua. On January 8, 2021, CMS approved the request, rebranding the project as "TennCare III." *See* Letter from Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs., to Stephen Smith, Dir., TennCare, Tenn. Dep't of Fin. and Admin. (Jan. 8, 2021), https://bit.ly/3RhTHaX ("TennCare III Approval Letter"); *see also* CMS, TennCare III 2021 Waiver List; CMS, TennCare III 2021 Expenditure Authority; CMS, TennCare III 2021 Special Terms and Conditions (corrected Jan. 20, 2021) (collectively at https://bit.ly/47HZME2). The approval permitted Tennessee to continue its mandatory managed care program and waiver of retroactive coverage. CMS, TennCare III 2021 STCs at 78-80; CMS, TennCare III 2021 Waiver List at 2. The approval also authorized new project features, primarily: (1) an aggregate cap and shared savings financing structure; and (2) a closed prescription drug formulary, which authorized Tennessee to limit coverage of medically necessary medications. *See* TennCare III Approval Letter at 4-6. CMS approved TennCare III for a period of ten years. *Id*. at 1, 5.

Plaintiffs filed their Complaint challenging the approval of TennCare III on April 23, 2021, ECF No. 4, and their First Amended Complaint on May 26, 2021, ECF No. 23. Plaintiffs alleged that, in approving the TennCare III project under Section 1115, Federal Defendants violated the Administrative Procedure Act and the Social Security Act. ECF No. 23. In particular, Plaintiffs alleged the following: (1) In approving TennCare III, CMS exceeded its statutory authority by waiving provisions that cannot be waived. ECF No. 23 ¶¶ 310-313; *see also id*. ¶¶ 128-131. (2) The approval was arbitrary and capricious. *Id*. ¶¶ 314-19. (3) CMS approved TennCare III without following the required Section 1115 public notice and comment procedures. *Id*. ¶¶ 320-28.

On June 22, 2021, Federal Defendants sought a 60-day extension of time to respond to the Amended Complaint so that the new agency leadership could familiarize themselves with

this case and consider whether any further action should be taken with respect to the TennCare III approval. Federal Defs.' Unopposed Mot. for Extension of Time to Resp. to the Compl., ECF No. 28 ¶ 3. The Court granted that request, making Federal Defendants' response due on August 27, 2021. Min. Order, June 28, 2021. On August 5, 2021, the Court granted Tennessee's unopposed motion to intervene. Min. Order, Aug. 5, 2021.

On August 10, 2021, CMS opened a new 30-day public comment period on the approved TennCare III project. *See* Letter from Andrea J. Casart, Dir., Div. of Eligibility and Coverage Demonstrations, CMCS, to Stephen Smith, Dir., Bureau of TennCare (Aug. 10, 2021), https://bit.ly/48a3g2v. On August 11, 2021, Federal Defendants filed an unopposed motion to stay the case until the agency issued a decision "with respect to whether it will make any changes to its approval of the TennCare III demonstration based on comments received and considered." Federal Defs.' Unopposed Mot. to Hold This Case in Abeyance, ECF No. 29 ¶¶ 3. Federal Defendants indicated their belief that the process could narrow the issues in the case, *id*. ¶¶ 3, 6, and their understanding that "[s]hould the parties be dissatisfied with whatever decision emerges from the new comment process, they will have the opportunity to raise their challenges at the appropriate time," *id*. ¶ 6. The Court granted that motion. Min. Order, Aug. 11, 2021.

On June 30, 2022, CMS advised Tennessee of its decision to propose changes to the TennCare III project in response to the public comment period. *See* Letter from Daniel Tsai, Deputy Adm'r. and Dir., CMCS, to Stephen Smith, Dir., TennCare (June 30, 2022), https://bit.ly/3T5mFNL. CMS asked Tennessee to submit an amendment to the project that would replace the aggregate cap/shared savings financing model with a traditional financing model and remove the closed formulary for prescription drugs. *Id*. at 1-2. Tennessee submitted such an amendment, and on August 4, 2023, CMS approved Tennessee's request to amend

TennCare III. *See* Letter from Daniel Tsai, Deputy Adm'r and Dir., CMCS, to Stephen Smith, Dir., TennCare (Aug. 4, 2023), https://bit.ly/47BnD8H ("TennCare III 2023 Amendment Approval Letter"). CMS made clear that the approval represents its "final decision to address the concerns highlighted in the reopened public comment period and closes out the changes" CMS recommended to Tennessee on June 30, 2022. *Id*. at 2.

With the approval, CMS moved TennCare III from an aggregate cap/shared savings financing structure back to the traditional financing structure and withdrew permission for a closed prescription drug formulary. *Id*. at 2-3. While many comments expressed concerns about the duration of the project and the waiver of retroactive eligibility, CMS left those components of the project undisturbed. *See id*. at 4, 5.

On November 3, 2023, the parties filed a joint status report and a motion to lift the stay in the case. Joint Status Rep. and Mot. to Lift Stay, ECF No. 34, 35. The Court granted the motion and ordered Plaintiffs to file any motion for leave to file a Supplemental Complaint by December 22, 2023. Min. Order, Nov. 6, 2023.

In their proposed Supplemental Complaint, Plaintiffs continue to challenge the January 8, 2021 approval, as amended by the August 4, 2023 approval. Specifically, Plaintiffs allege the following: (1) In approving the TennCare III project, as amended, CMS exceeded its statutory authority and acted in an arbitrary and capricious manner. Supp. Compl. ¶¶ 181-89. (2) The approval of the retroactive coverage waiver in TennCare III was arbitrary and capricious. *Id*. ¶¶ 190-95.

Argument

Under Federal Rule of Civil Procedure 15(d), the Court may, on motion, reasonable notice, and just terms, permit a party to filed a supplemental pleading setting out a transaction,

occurrence, or event that happened after the date of the pleading to be supplemented. The "appropriate bases for supplemental pleadings are new facts bearing on the relationship between the parties." *U.S. v. Hicks*, 283 F.3d 380, 386 (D.C. Cir. 2002). A motion to file a supplemental pleading is to be "freely granted when doing so will promote the economic and speedy disposition of the entire controversy between the parties, will not cause undue delay or trial inconvenience, and will not prejudice the rights of any of the other parties to the action." *Hall v. C.I.A.*, 437 F.3d 94, 101 (D.C. Cir. 2006) (cleaned up); *see also Jones v. Bernanke*, 685 F. Supp. 2d 31, 35 (D.D.C. 2010) ("The court has broad discretion in determining whether to allow supplemental pleadings in the interests of judicial economy and convenience.") The opposing party bears the "burden to demonstrate why leave should not be granted." *Lannan Found. v. Gingold*, 300 F. Supp. 3d 1, 12 (D.D.C. 2017) (citation omitted).

Plaintiffs' proposed Supplemental Complaint meets the requirements of Rule 15(d). Since Plaintiffs filed their First Amended Complaint in April 2021, CMS amended the TennCare III approval, which affected the legal relationship between the parties. *See Hicks*, 283 F.3d at 386. Based on that amendment, Plaintiffs are seeking to set forth new facts and to adjust their legal claims. *See id.* at 386 ("Rule 15(d) is used to set forth new facts that update the original pleading or provide the basis for additional relief; to put forward new claims or defenses based on events that took place after the original complaint or answer was filed.") (cleaned up). In addition, Plaintiffs are seeking to remove nine Plaintiffs (eight Medicaid beneficiaries and Tennessee Justice Center) and add one Plaintiff (TennCare enrollee Tatjana Anderson) due to the change in circumstances.

Granting Plaintiffs' motion will promote judicial economy. The Supplemental Complaint "focuses on the same core issue" as the First Amended Complaint – whether approval of the

TennCare III project violates the APA and the Social Security Act. *Pub. Emps. for Env't Resp. v. Nat'l Park Serv.*, Case No. 19-3629, 2021 WL 1198047 at *6 (D.D.C. March 30, 2021); *see also Competitive Enter. Inst. v. McCarthy*, Case No. 21-1238, 2021 WL 9937858 at *3 (D.D.C. Oct. 7, 2021) (finding supplementation will promote judicial efficiency where the "proposed supplemental allegations relate directly to the subject matter of [the] current operative pleading"). And, when the Court granted a stay in August 2021, this case was in its infancy. Federal Defendants had not even answered or otherwise responded to Plaintiffs' Complaint. Given that, "[c]ompared to the alternative, supplementing the complaint is a far more reasonable course of action. In lieu of supplementation, Plaintiffs would have to file an entirely new case, a largely redundant and costly move." *Pub. Emps. for Env't Resp.*, 2021 WL 1198047 at *6. Requiring Plaintiffs to file a new case would cause significant delay and run counter to the parties' and the Court's interests in the efficient administration of justice. *See id.*

Allowing Plaintiffs to file their Supplemental Complaint will not prejudice or disadvantage Federal Defendants or Intervenor-Defendant. Defendants are aware of the factual developments giving rise to the need for supplementation. Indeed, when they requested a stay, Federal Defendants explicitly contemplated that Plaintiffs would have the opportunity to challenge a new decision on TennCare III in front of this Court. *See* Federal Defs.' Unopposed Mot. to Hold This Case in Abeyance, ECF No. 29 ¶ 6.

CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' request for leave to file the Supplemental Complaint.

Dated: December 22, 2023

Respectfully submitted,

/s/ Catherine McKee

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CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send an electronic notice to all authorized CM/ECF filers in this case.

By: /s/ Catherine McKee
Catherine McKee

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

A.G.W., by her next friend, J.A.W., c/o Tennessee Justice Center, 155 Lafayette Street, Nashville, TN 37210, J.T. by his next friend, B.S., c/o Tennessee Justice Center, 155 Lafayette Street, Nashville, TN 37210, A.M.W., by her next friend, J.K.W., c/o Tennessee Justice Center, 155 Lafayette Street, Nashville, TN 37210, N.P., by her next friend, T.A., c/o Tennessee Justice Center, 155 Lafayette Street, Nashville, TN 37210, M.S., by her next friend, T.S., c/o Tennessee Justice Center, 155 Lafayette Street, Nashville, TN 37210, TATJANA ANDERSON, 1526 Storm Hill Road, Mt. Juliet, TN 37122, and SUZANNE BERMAN, M.D., 629 Holiday Drive, Crossville, TN 38555, Plaintiffs. v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*, Defendants.	)	No. 1:21-cv-01112-TSC

SUPPLEMENTAL COMPLAINT
FOR DECLARATORY AND INJUNCTIVE RELIEF

PRELIMINARY STATEMENT

1. Federal law sets out a deal for states that wish to participate in the Medicaid program. In exchange for meeting federal requirements, including those regarding eligibility for and coverage of services, states are guaranteed federal funding for a substantial percentage of the ongoing costs of providing medical assistance to low-income residents.

2. Section 1115 of the Social Security Act permits the Secretary of Health and Human Services to waive (*i.e.*, allow states to ignore) certain specified provisions in the Medicaid Act, but only for an "experimental, pilot, or demonstration project" likely to promote the objectives of the Medicaid Act, and only for the period of time necessary to enable the state to carry out its experiment. 42 U.S.C. § 1315(a).

3. Thirty years ago, the Secretary authorized Tennessee to launch a Section 1115 experiment called "TennCare" that, among other things, required most Medicaid beneficiaries to enroll in risk-based managed care plans and waived their right to three months of retroactive Medicaid coverage.

4. Even though managed care has long ceased to be experimental, the core features of the project (rebranded as "TennCare II" in 2002) are still in effect. Throughout this time, Medicaid beneficiaries in Tennessee have struggled to get needed services from their managed care plans, with many of them experiencing harmful medical consequences as a result. Over the course of the TennCare project, many Medicaid beneficiaries have forgone health care or incurred significant medical debt due to the waiver of retroactive eligibility.

5. In November 2019, Tennessee submitted a vague and internally inconsistent request to the Department of Health and Human Services' Centers for Medicare & Medicaid Services ("CMS") to "amend" TennCare II. While providing scant details, Tennessee essentially

asked CMS to ignore the Medicaid Act's federal funding requirements and allow Tennessee to convert its Medicaid program to a block grant with a "shared savings" component.

6. On January 8, 2021, CMS approved the request, this time rebranding the project as "TennCare III." CMS allowed Tennessee to continue its mandatory managed care program and waiver of three-months' retroactive coverage. CMS also authorized several new project features, primarily: 1) a variation on Tennessee's request for a block grant; and 2) a closed prescription drug formulary, which authorized Tennessee to limit coverage of medically necessary medications in a way not allowed by the Medicaid Act.

7. CMS approved the TennCare III project for ten years, contrary to its own stated policy.

8. On April 23, 2021, Plaintiffs filed their Complaint alleging, among other things, that CMS approved TennCare III without following the required public notice and comment procedures. Roughly four months later, CMS held a public comment period on TennCare III. After reviewing the comments received, CMS asked Tennessee to propose amendments to the project that would revamp the financing structure and remove the restrictions on prescription drug coverage.

9. Tennessee submitted the requested amendments to CMS, and on August 4, 2023, CMS approved them. The approval returned TennCare to a traditional financing model and withdrew permission for a closed prescription drug formulary. CMS left the managed care component of TennCare III and the waiver of retroactive eligibility untouched. Likewise, CMS did not change the ten-year duration of the project.

10. In approving TennCare III, as amended, CMS failed to offer any explanation as to why the project is an experimental, pilot, or demonstration project, or why Tennessee would need

an additional ten years to carry out a project that has been ongoing for three decades. Similarly, the Secretary offered no rationale as to why the continuation of the longstanding waiver of retroactive coverage is necessary.

11. In approving the project, as amended, CMS exceeded its authority under Section 1115 and failed to engage in reasoned decision-making. Accordingly, the approval violated the Administrative Procedure Act and the Social Security Act and cannot stand.

JURISDICTION AND VENUE

12. This is an action for declaratory and injunctive relief for violations of the Administrative Procedure Act and the Social Security Act.

13. The Court has jurisdiction over Plaintiffs' claims pursuant to 28 U.S.C. §§ 1331 and 1361, and 5 U.S.C. §§ 702 to 705. This action and the remedies it seeks are further authorized by 28 U.S.C. §§ 1651, 2201, and 2202, and Federal Rule of Civil Procedure 65.

14. Venue is proper under 28 U.S.C. §§ 1391(b)(2) and (e).

PARTIES

A. Plaintiffs

15. Plaintiff A.G.W. is a minor resident of Madison, Davidson County, Tennessee. She is a TennCare enrollee who brings this action by her mother, J.A.W., acting as her next friend.

16. Plaintiff J.T. is a minor resident of Heiskill, Knox County, Tennessee. He is a TennCare enrollee who brings this action by his grandmother, B.S., acting as his next friend.

17. Plaintiff A.M.W. is a minor resident of Greeneville, Greene County, Tennessee. She is a TennCare enrollee who brings this action by her father, J.K.W., acting as her next friend.

18. Plaintiff N.P. is a minor resident of Johnson City, Washington County, Tennessee. She is a TennCare enrollee who brings this action by her mother, T.A., acting as her next friend.

19. Plaintiff M.S. is a minor resident of Caryville, Campbell County, Tennessee. She is a TennCare enrollee who brings this action by her father, T.S., acting as her next friend.

20. Plaintiff Tatjana Anderson is an adult resident of Mt. Juliet, Wilson County, Tennessee who is enrolled in TennCare.

21. Plaintiff Suzanne Berman, M.D., is an adult resident of Crossville, Cumberland County, Tennessee. She is a board-certified pediatrician who treats children and young adults in her medical practice.

B. Defendants

22. Defendant Xavier Becerra is the Secretary of the United States Department of Health and Human Services ("HHS") and is sued in his official capacity. Secretary Becerra ("the Secretary") has overall responsibility for implementation of the Medicaid program, including responsibility for federal review and approval of state requests for waivers pursuant to Section 1115 of the Social Security Act.

23. Defendant Chiquita Brooks-LaSure is the Administrator of CMS. Administrator Brooks-LaSure is responsible for implementing the Medicaid program in the manner required by federal law.

24. Defendant HHS is a department of the executive branch of the U.S. government and an agency of the federal government within the meaning of 5 U.S.C. § 551(1). It is headquartered in Washington, D.C.

25. Defendant CMS is a subdivision of HHS and an agency within the meaning of 5 U.S.C. § 551(1). It is headquartered in Baltimore, Maryland.

BACKGROUND AND FACTUAL ALLEGATIONS

A. The Medicaid Program

26. Title XIX of the Social Security Act establishes the cooperative federal-state medical assistance program known as Medicaid. *See* 42 U.S.C. §§ 1396 to 1396w-7. Medicaid's stated purpose is to enable each state, as far as practicable, "to furnish … medical assistance" to individuals "whose income and resources are insufficient to meet the costs of necessary medical services" and to provide "rehabilitation and other services to help such families and individuals attain or retain capability for independence or self-care." *Id*. § 1396-1.

27. The statute defines "medical assistance" to include a range of health care services that participating states must cover or are permitted to cover. *Id.* § 1396d(a).

28. Although states do not have to participate in Medicaid, all do.

29. Each participating state must maintain a comprehensive state Medicaid plan for medical assistance that the Secretary has approved. *Id*. § 1396a.

30. The state Medicaid plan must describe the state's Medicaid program and affirm the state's commitment to comply with the requirements imposed by the Medicaid Act and its associated regulations.

31. State and federal governments share responsibility for funding Medicaid.

32. The Medicaid Act requires the Secretary to pay each participating state the federal share of "the total amount expended … as medical assistance under the State plan." *Id*. §§ 1396b(a)(1), 1396d(b). The federal share of funding is called the federal medical assistance percentage ("FMAP").

33. Congress has established the formula for determining the states' FMAP in the Medicaid Act. The FMAP is based on the state's relative per capita income and is higher in states with lower per capita income relative to the national average. *See id.* § 1396d(b).

34. Medicaid funds cannot be used to pay "any amount expended for … any other item or service not covered under a State [Medicaid] plan" under Title XIX. *Id.* § 1396b(i)(17).

B. Medicaid Eligibility and Coverage Requirements

35. Using household income and other specific criteria, the Medicaid Act delineates who is eligible to receive Medicaid coverage. The Act identifies required coverage groups, *see id.* § 1396a(a)(10)(A)(i), as well as options for states to extend Medicaid to additional population groups, *see id.* §§ 1396a(a)(10)(A)(ii), (C).

36. In addition to addressing *who* is eligible for medical assistance, the Medicaid Act delineates *how* states must make and implement eligibility determinations to ensure that all eligible people who apply are served and get coverage.

37. The Medicaid Act requires states to "provide such safeguards as may be necessary to assure that eligibility … and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." *Id.* § 1396a(a)(19).

38. The Medicaid Act requires states to provide medical assistance for care provided in or after the third month before the month of application, as long as the enrollee would have been eligible for Medicaid at the time the services were received. *Id*. §§ 1396a(a)(34), 1396d(a).

39. The purpose of the retroactive coverage provision is to protect individuals "who are eligible for [M]edicaid but do not apply for assistance until after they have received care, either because they did not know about the [M]edicaid eligibility requirements or because the sudden nature of their illness prevented their applying." S. Rep. No. 92-1230, 92nd Cong., 2nd Sess., at 209 (1972).

40. The Medicaid Act sets forth the services that participating states must cover and gives States the option to cover additional services. *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a).

41. One optional service is outpatient prescription drugs. *Id*. §§ 1396a(a)(10), 1396a(a)(54), 1396d(a)(12), 1396r-8.

42. The Medicaid Act specifies when and how states may develop a prescription drug formulary. *Id*. § 1396r-8(d)(4). In adopting a formulary, states may exclude any drug that does not have "a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome … over other drugs included in the formulary," so long as they provide the public with a written explanation of the basis for the exclusion. *Id*. § 1396r-8(d)(4)(C). However, states must provide for coverage of a drug excluded from the formulary with prior authorization. *Id*. § 1396r-8(d)(4)(D). Thus, the Medicaid Act does not permit states to implement a closed prescription drug formulary.

43. One required service is Early and Periodic Screening, Diagnostic and Treatment ("EPSDT") for children and youth under age 21. 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), 1396d(r).

44. The EPSDT provisions require states to provide the services listed in 42 U.S.C. § 1396d(a) when they are "necessary … to correct or ameliorate defects and physical and mental illnesses and conditions," regardless of whether or not such services are covered for adults. *Id*. § 1396d(r)(5). Included in such services are outpatient prescription drugs, private duty nursing, home health services, and personal care services. *Id*. States must also "arrang[e] for (directly or through referral to appropriate agencies, organizations, or individuals)" necessary corrective treatment. *Id*. § 1396a(a)(43)(C).

C. Medicaid Managed Care

45. Medicaid was originally structured primarily as a fee-for-service program; states reimbursed individual health care providers for each service delivered. In a fee-for-service delivery system, Medicaid beneficiaries are generally entitled to receive services from any qualified provider who is participating in the Medicaid program. *See id.* § 1396a(a)(23).

46. In the first decade of the Medicaid program, the Secretary authorized states to begin experimenting with managed care delivery systems using Section 1115 waivers. Medicaid and CHIP Payment and Access Comm'n, *Report to the Congress: The Evolution of Managed Care in Medicaid* 19 (2011), https://bit.ly/32CCnEA ("MACPAC Report").

47. On the heels of that experimentation, in 1981 Congress amended the Medicaid Act to allow states to seek a Medicaid Act waiver to require beneficiaries to receive services through managed care. *Id.*; *see* Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, §§ 2175, 2178, 95 Stat. 357, 809, 813 (enacting 42 U.S.C. § 1396n(b) and amending § 1396b(m)).

48. In the early 1990s, HHS approved a number of Section 1115 projects, including in Tennessee, that combined the use of managed care delivery systems with states' promises to expand Medicaid eligibility to low-income, uninsured populations not otherwise eligible for Medicaid. *See* MACPAC Report at 19.

49. In 1997, Congress again amended the Medicaid Act to give states another avenue—a state plan amendment—to require most beneficiaries to enroll in managed care. *Id.* at 20; *see* Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4701-02, 4704, 111 Stat. 251, 489, 495 (codified at 42 U.S.C. §§ 1396u-2, 1396d(t)). *See also* 42 C.F.R. §§ 438.1 to 438.930.

50. Thus, the Medicaid Act now contains two mechanisms for states to deliver services via managed care plans. First, states can adopt a state plan amendment requiring certain beneficiaries to enroll in managed care. *See* 42 U.S.C. § 1396u-2. States that elect the state plan

option cannot require children with special needs to enroll in managed care. *Id*. § 1396u-2(a)(2)(A).

51. Second, states can seek a time-limited waiver from CMS to implement managed care. *Id*. § 1396n(b)(1), (4). To grant such a waiver, the Secretary must find it to be cost-effective and efficient and not inconsistent with the purposes of the Medicaid Act. *Id*. § 1396n(b). In addition, the Secretary must find that the managed care arrangement does not impair access to or quality of services. *Id*. § 1396n(b)(1), (4); *see also* 42 C.F.R. § 431.55(b)(2)(ii), (c)(2)(ii), (f)(2).

52. The most common managed care arrangement is capitated, risk-based managed care. Under these arrangements, states pay managed care entities a fixed per-member-per-month amount to provide a specified set of Medicaid services when they are medically necessary for an enrollee. The managed care entities, in turn, pay health care providers to deliver those services to beneficiaries.

53. Managed care entities that provide comprehensive benefits are referred to as "managed care organizations" ("MCOs"). *See* 42 C.F.R. § 438.2 (defining MCO). Entities that provide more limited services are referred to as "prepaid inpatient health plans" ("PIHPs") or "prepaid ambulatory health plans" ("PAHPs"), depending on the scope of services covered. *See id.* (defining PIHP and PAHP).

54. Generally, beneficiaries enrolled in a capitated managed care plan do not have free choice of health care providers and can only receive Medicaid services from the "network" providers who have contracted with their plan. *See* 42 U.S.C. §§ 1396n(b)(1), (4), 1396u-2(b)(2), 1396a(a)(23)(B) (creating exceptions for emergency and family planning services).

55. A capitated, risk-based managed care approach gives managed care entities a financial incentive to deny access to Medicaid services. *See* Medicaid and CHIP Payment and

Access Comm'n, *Managed Care's Effect on Outcomes*, https://bit.ly/3sESE6z (last visited Dec. 15, 2023); U.S. Dep't of Health & Hum. Servs. Off. of Inspector Gen., Medicaid Managed Care Organization Denials, https://bit.ly/3xd8f0z (last visited Dec. 15, 2023) (noting that an MCO's "contractual arrangement shifts the financial risk from the State Medicaid agency and the Federal Government to MCOs, which can create an incentive for MCOs to deny beneficiaries' access to covered services").

56. Managed care is the dominant Medicaid delivery system. Across the country, 72 percent of Medicaid beneficiaries receive services through MCOs. Kaiser Fam. Found., *State Health Facts: Total Medicaid MCO Enrollment* (2020), https://bit.ly/3GRXYg6.

57. Many states have implemented comprehensive, capitated managed care delivery systems that do not include waivers of retroactive coverage.

D. The Secretary's Section 1115 Waiver Authority

58. Section 1115 of the Social Security Act, codified at 42 U.S.C. § 1315, grants the Secretary authority to waive a state's compliance with certain requirements of the Medicaid Act under certain conditions. The Secretary exercises this authority through CMS.

59. The Secretary may grant a Section 1115 Medicaid waiver only in the case of an "experimental, pilot, or demonstration project which … is likely to assist in promoting the objectives" of the Medicaid Act. *Id.* § 1315(a).

60. The Secretary may only waive compliance with the requirements located in 42 U.S.C. § 1396a. *Id.* § 1315(a)(1).

61. The Secretary may waive compliance with the congressionally imposed requirements of the Medicaid Act only "to the extent and for the period he finds necessary to enable" the state to carry out its experimental project. *Id.* § 1315(a)(1).

62. Once the Secretary has approved a Section 1115 project, the costs of the project are "regarded as expenditures under the State plan." *Id.* § 1315(a)(2).

63. The Secretary must follow procedural requirements before he may approve a Section 1115 project. *Id.* § 1315(d); 42 C.F.R. §§ 431.400 to 431.416. In particular, after receiving a complete application from a state (following a 30-day state-level public notice and comment period), the Secretary must provide a 30-day public notice and comment period. 42 U.S.C. § 1315(d); 42 C.F.R. § 431.416.

64. Section 1115 places explicit limits on any extension of "state-wide, comprehensive demonstration projects." *See* 42 U.S.C. §§ 1315(e), (f). The statute permits an initial extension of a state-wide comprehensive project of up to 3 years, or in the case of a project involving individuals eligible for both Medicare and Medicaid (known as "dual eligibles"), up to 5 years. *Id.* § 1315(e)(1)-(2). The statute permits one subsequent extension of a state-wide comprehensive project "for a period not to exceed 3 years," or in the case of a project involving dual eligibles, not to exceed 5 years. *Id.* § 1315(f)(6).

65. In 2017, CMS issued an Informational Bulletin announcing its intent to "[w]here possible, and subject to the public notice and transparency requirements … approve the extension of *routine, successful, non-complex*" Section 1115(a) waivers for a period of up to 10 years. Ctr. for Medicaid & CHIP Servs., CMS, CMCS Informational Bulletin 3 (Nov. 6, 2017), https://bit.ly/3eB0hGb ("2017 Informational Bulletin") (emphasis added).

66. CMS did not explain how this new policy could possibly comply with Section 1115, which only permits the Secretary to grant a waiver to the extent and for the period necessary to enable a state to carry out an experimental, pilot, or demonstration project. *See* 42 U.S.C. § 1315(a)(1).

E. Medicaid in Tennessee

67. Tennessee has elected to participate in Medicaid. *See* Tenn. Code Ann. § 71-5-101 *et seq.*

68. The Division of TennCare within the Tennessee Department of Finance and Administration administers the program at the state level. *See* Tenn. Medicaid State Plan, § 1 (1999).

69. The federal government's FMAP for Tennessee is approximately 65% of the cost of providing medical assistance through its Medicaid program. 88 Fed. Reg. 81090, 81092 (Nov. 21, 2023).

The TennCare Project

70. Thirty years ago, HHS approved Tennessee's application to implement a Section 1115 experimental project known as "TennCare." The initial goals of the demonstration were to extend health care coverage to virtually all uninsured Tennesseans while controlling costs, primarily through mandatory enrollment of program beneficiaries in capitated, risk-based managed care plans and beneficiary cost-sharing. Gov. Ned McWherter, *TennCare: A New Direction in Health Care* 6–7 (1993) ("TennCare 1115 Application"); *see also* Tenn. Div. of Health Care Fin. and Admin., TennCare II Extension Request 1 (2015), https://bit.ly/3naettm ("2015 Extension Application"). Less than one year after the project began, TennCare closed enrollment to uninsured individuals due to lack of state funding. 2015 Extension Application at 2.

71. As part of the project, the federal government granted Tennessee a waiver of the requirement to provide retroactive coverage to Medicaid beneficiaries. Letter from Bruce C. Vladeck, Adm'r, Health Care Fin. Admin., Dep't of Health & Hum. Servs., to Mr. H. Russell White, Comm'r, Tenn. Dep't of Health 2 (Nov. 18, 1993). According to Tennessee, retroactive coverage was no longer needed, as the State planned extensive outreach efforts to notify potentially

eligible individuals of the TennCare project and expected "enrolling many of the currently uninsured individuals." TennCare 1115 Application at 18.

72. The TennCare waiver authorized the mandatory enrollment in capitated managed care of all children, including those with special health care needs. Extensions of the TennCare waiver have continued to date the mandatory enrollment of children with special health care needs in capitated managed care.

73. Beginning in 1999, several plans were placed under the supervision of the State and/or left TennCare altogether because they were unable to fulfill their contractual obligations. Div. of TennCare, *TennCare Timeline*, https://bit.ly/3xb7k0y (last visited Dec. 15, 2023).

74. Because MCOs were not reimbursing providers, providers dropped out of their networks, leaving TennCare enrollees without access to health care services.

75. In 2001, the State contracted with BlueCross BlueShield of Tennessee to administer TennCare Select, a PIHP intended "to provide a back-up arrangement that would allow the state to transfer members from a problem MCO quickly if that MCO should have to leave the program unexpectedly." 2015 Extension Application at 12. Over time, Tennessee began using TennCare Select to provide services to children with special health care needs, including foster children, children receiving Supplemental Security Income ("SSI"), and children under age 21 in a nursing facility or intermediate care facility for individuals with intellectual disabilities. *See* Div. of TennCare, *TennCare Timeline*, https://bit.ly/3xb7k0y (last visited Dec. 15, 2023).

76. In 2001, TennCare's managed care contracts were found to give MCOs "pecuniary incentives … for denying, suspending, or terminating care," including, specifically, care for children with special health care needs. *John B. v. Menke*, 176 F. Supp. 2d 786. 805 (M.D. Tenn. 2001) (citing *Daniels v. Wadley*, 926 F. Supp. 1305, 1308 (M.D. Tenn. 1996)).

The TennCare II Project

77. In 2002, HHS approved the "TennCare II" project. Letter from Thomas A. Scully, Adm'r, Ctrs. for Medicare & Medicaid Servs., to Mr. John F. Tighe, Deputy Comm'r of Fin. and Admin., Tenn. Dep't of Fin. and Admin. (May 30, 2002).

78. TennCare II continued the core features of TennCare.

79. CMS repeatedly renewed TennCare II, with the latest renewal extending the project through June 30, 2021. *See* Letter from Vikki Wachino, Dir., Ctr. for Medicaid & CHIP Servs., to Dr. Wendy Long, Dir., Bureau of TennCare, Tenn. Dep't of Fin. and Admin. (Dec. 16, 2016), https://bit.ly/3gu5ZMA (extending the project through June 30, 2021).

80. Over the years, CMS permitted Tennessee to include additional Medicaid populations and services in the managed care delivery system. *See, e.g.* CMS, TennCare II Special Terms and Conditions, 4–5, 15–16 (2009), https://bit.ly/2QHP5z2 (requiring older adults and individuals with disabilities who receive long term services and supports to receive those services through MCOs); Letter from Andrew M. Slavitt, Acting Adm'r, Ctr. for Medicaid & CHIP Servs. to Mr. Darin Gordon, Dir., Bureau of TennCare (Feb. 2, 2016), https://bit.ly/3xe7Xq1 (requiring certain individuals with intellectual or developmental disabilities to receive home and community-based services through MCOs).

81. In July 2019, CMS approved an amendment moving children who are found eligible for SSI out of TennCare Select and into MCOs. Letter from Calder Lynch, Acting Deputy Adm'r and Dir., Ctr. for Medicaid & CHIP Servs., to Gabe Roberts, Dir., TennCare 4 (July 2, 2019), https://bit.ly/3aseYd8.

82. These and similar amendments, which permit Tennessee to require additional populations to receive Medicaid services through the managed care delivery system, did not change the fundamental nature of the project or transform the project into an experiment.

Proposed Amendment 42 to the TennCare II Project

83. In November 2019, Tennessee submitted to CMS Amendment 42 to TennCare II, which it described as "reimagining the Medicaid financing model, and with it the relationship between the state and federal government." Div. of TennCare, TennCare II Demonstration Amendment 42, Modified Block Grant and Accountability 2 (2019), https://bit.ly/3dDQNua ("2019 Amendment Application"). To that end, Amendment 42 requested permission to convert the TennCare financing structure to a block grant. *Id.* at 1, 6–12. Under the proposal, if the State were to spend less than the allotted amount in any given year, it would keep 50% of the federal share of the amount saved. *Id.* at 1, 10. The proposal indicated that if the State were to spend more than the block grant amount in any given year, the demonstration would be discontinued. *Id.* at 11.

84. To ensure that it could manage its Medicaid program within the new block grant financing arrangement, Tennessee requested "flexibility from excessive or unnecessary federal intervention in its Medicaid program." *Id.* at iv; *see also id.* at 13.

85. Tennessee asked for "flexibility" to, among other things: (1) spend the block grant on items or services not otherwise eligible for federal Medicaid funding, so long as it "determines that such expenditures will benefit the health of members" or lead to improved health outcomes, *id.* at 14; (2) limit access to outpatient prescription drugs by implementing a "closed formulary" that does not comply with the requirements of the Medicaid Act, *id.* at 14–16; (3) target services to particular beneficiaries, *id.* at 16–17; and (4) add optional services or increase the amount, duration, and scope of covered benefits without CMS approval, *id.* at 21. *See also id.* at 25.

86. According to Tennessee, the goal of the amendment was "to demonstrate that an alternative model of federal participation in state Medicaid programs will lead to Medicaid programs that are more financially sustainable for states and the federal government, without compromising access to care, quality of care, or health outcomes." *Id.* at 26.

87. On November 26, 2019, CMS announced that the Amendment 42 request was complete and that a 30-day public comment period would open on the CMS website. Letter from Andrea Casart, CMS, to John G. Roberts, Dir., TennCare (Nov. 26, 2019), https://bit.ly/3dCbyGI. CMS opened the public comment portal the following day. *See* Medicaid.gov, TennCare II – Amendment 42: Block Grant, https://bit.ly/3dENnrf. The comment portal was not open for the full 30-day period.

88. On November 9, 2020, while the Amendment 42 application was still pending, Tennessee released a draft application proposing to renew the TennCare II managed care program for a period of ten years. *See* Div. of TennCare, Notice of Application to Extend the TennCare II Demonstration (Nov. 9, 2020), https://bit.ly/3xhUYUC; Tenn. Dep't of Fin. & Admin., Div. of TennCare, TennCare II Demonstration Extension Application, Draft (2020), https://bit.ly/3awoJaf.

89. According to Tennessee, "[t]he principle being 'demonstrated' by TennCare is that a state can organize its Medicaid program under a single, statewide managed care service delivery system without spending more than the Medicaid program would have spent in the absence of the demonstration program and without compromising quality of care." Div. of TennCare, Notice of Application to Extend the TennCare II Demonstration (Nov. 9, 2020), https://bit.ly/3xhUYUC.

90. The State held a public comment period on this proposal from November 9, 2020 through December 11, 2020.

91. However, Tennessee never submitted the application to renew TennCare II to CMS.

92. CMS did not hold a public comment period on the proposal to extend the TennCare II project.

The TennCare III Project Approval

93. On January 8, 2021, the CMS Administrator issued a final decision approving a "new" Section 1115 project, which CMS named "TennCare III." *See* Letter from Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs., to Stephen Smith, Dir., TennCare, Tenn. Dep't of Fin. and Admin. (Jan. 8, 2021), https://bit.ly/3RhTHaX ("TennCare III Approval Letter"); *see also* CMS, TennCare III 2021 Waiver List; CMS, TennCare III 2021 Expenditure Authority; CMS, TennCare III 2021 Special Terms and Conditions (corrected Jan. 20, 2021) (collectively at https://bit.ly/47HZME2). In effect, the approval extended the existing TennCare II project and adopted a modified version of the block grant concept that Tennessee had described in its Amendment 42 Application. *See* TennCare III Approval Letter at 1 (explaining that TennCare III "subsumes" the TennCare II project).

94. The TennCare III approval was cobbled together in such haste that it was riddled with errors and internal conflicts. On January 20, 2021, the very day the then-current administration was leaving office, CMS issued extensive "technical corrections" to the project to "ensure that the special terms and conditions (STC) reflect how the state is/will be operating the TennCare III demonstration." Letter from Andrea J. Casart, Dir., Div. of Eligibility and Coverage, State Demonstrations Group, Ctr. for Medicaid & CHIP Servs., to Stephen Smith, Dir., TennCare, Tenn. Dep't of Fin. and Admin. (Jan. 20, 2021), https://bit.ly/47HZME2.

95. CMS approved TennCare III for a period of ten years. TennCare III Approval Letter at 1, 5. CMS stated that it approved the project for ten years to give the State sufficient time to test its "innovative financing approach," *id.* at 1, and reduce "the future administrative burden associated with having to renew the demonstration more frequently," *id.*

96. CMS did not acknowledge its existing policy regarding its criteria for the approval of a Section 1115 project for ten years, *see* 2017 Information Bulletin at 3 (limiting ten-year approvals to "routine, successful, non-complex" waivers), or offer any rationale as to why it was departing from that policy.

97. The TennCare III approval preserved the existing features of TennCare II, with only minor changes. TennCare III Approval Letter at 3-4. As a result, under TennCare III, all beneficiaries must continue to enroll in managed care. TennCare III 2021 Special Terms and Conditions ("2021 STCs") at 78-80; *see also id.* at 54-55 (listing services carved out of managed care and provided on a fee-for-services basis). The TennCare III approval also continued the waiver of retroactive eligibility, which has been in place since 1994. TennCare III 2021 Waiver List at 2; 2015 Extension Application at iv, 25. Under TennCare III, adult beneficiaries continue to lose the protection of retroactive coverage. The approval reinstated retroactive coverage to beneficiaries who are pregnant and/or under age 21, effective July 1, 2021. TennCare III 2021 Waiver List at 2.

98. In approving TennCare III, CMS did not say how the continuation of the elimination of retroactive coverage is experimental, likely to yield any additional information, or likely to promote the objectives of the Medicaid Act.

99. The TennCare III approval also included several new components.

100. First, the approval permitted Tennessee to operate the project under what CMS labeled an "aggregate cap," *see* TennCare III 2021 Approval Letter at 4, and what Tennessee continued to describe as a "block grant," *See* Div. of TennCare, *Tennessee Medicaid Block Grant Waiver Amendment Approved by Federal Government* (Jan. 8, 2021), https://bit.ly/480MDGf.

101. If Tennessee's costs were to exceed the aggregate cap, the State would not receive federal reimbursement for the excess amount. TennCare III Approval Letter at 12; *see also* TennCare III 2021 STCs at 105. If the State were to underspend the aggregate cap in any given year, it could "earn" up to 55% of the federal savings achieved. TennCare III Approval Letter at 5, 6; TennCare III 2021 STCs at 58.

102. The State could not use the savings on Medicaid items or services covered under the state plan, TennCare III 2021 STCs at 57, and would instead spend the savings on "Designated State Investment Programs" (DSIPs) funded as of December 31, 2020, as specified in the STCs, *id.* at 57, 209-10.

103. Second, the TennCare III approval allowed Tennessee to implement a closed prescription drug formulary for beneficiaries age 21 and over. TennCare III Approval Letter at 5-6; *see also* TennCare III 2021 STCs at 82-83.

Post-Approval Changes to TennCare III

104. On April 23, 2021, Plaintiffs filed their Complaint challenging the approval of TennCare III. Compl., ECF No. 4. The Complaint included a claim that the approval violated the Administrative Procedure Act and the Social Security Act because Defendants failed to follow the required notice and comment process. *Id.* at ¶¶ 313-21; *see also* Am. Compl., ECF No. 23, ¶¶ 320-28.

105. On August 10, 2021, CMS opened a new 30-day public comment period on the approved TennCare III project. *See* Letter from Andrea J. Casart, Dir., Div. of Eligibility and Coverage Demonstrations, CMCS, to Stephen Smith, Dir., Bureau of TennCare (Aug. 10, 2021), https://bit.ly/48a3g2v.

106. During the comment period, CMS received 2,777 comments. *See* Letter from Daniel Tsai, Deputy Adm'r and Dir., CMCS, to Stephen Smith, Dir., TennCare 4 (Aug. 4, 2023), https://bit.ly/47BnD8H.

107. On June 30, 2022, CMS advised Tennessee of its decision to propose changes to the TennCare III project in response to the public comment period. Letter from Daniel Tsai, Deputy Adm'r. and Dir., CMCS, to Stephen Smith, Dir., TennCare (June 30, 2022), https://bit.ly/3T5mFNL. CMS expressed "significant concerns" about whether aspects of the project "promote the objectives of Medicaid" and should be approved. *Id*. at 1. To address those concerns, CMS asked Tennessee to submit an amendment to the project that would replace the aggregate cap/shared savings financing model with a traditional financing model and remove the closed formulary for prescription drugs. *Id*. at 1-2.

108. CMS did not express concerns about the ten-year duration of the project, the continuation of the waiver of retroactive coverage, or the requirement that beneficiaries enroll in MCOs.

109. Tennessee submitted an amendment, as requested. *See* Letter from Stephen Smith, Dir., Div. of TennCare, to Daniel Tsai, Deputy Adm'r and Dir., CMCS (Aug. 30, 2022); Div. of TennCare, TennCare III Demonstration, Amendment 4 Program Modifications (Aug. 30, 2022), https://bit.ly/47NvNun.

110. CMS accepted public comment on the proposed amendment from September 6, 2022 through October 6, 2022, receiving 48 comments. *See* Letter from Daniel Tsai, Deputy Adm'r and Dir., CMCS, to Stephen Smith, Dir., TennCare (Aug. 4, 2023), https://bit.ly/47BnD8H ("TennCare III 2023 Amendment Approval Letter").

111. On August 4, 2023, CMS approved Tennessee's request to amend TennCare III. *See* TennCare III 2023 Amendment Approval Letter; CMS, TennCare III 2023 Waiver List; CMS, TennCare III 2023 Expenditure Authority; CMS, TennCare III 2023 Special Terms and Conditions (collectively at https://bit.ly/47BnD8H). The approval "represents CMS's final decision to address the concerns highlighted in the reopened public comment period and closes out the changes" CMS recommended to Tennessee on June 30, 2022. TennCare III 2023 Amendment Approval Letter at 2; *see also id*. at 4 (noting that in approving the amendment, CMS reviewed comments received during the reopened comment period in 2021 and comments received during the comment period for the amendment in 2022).

112. With the approval, CMS moved TennCare III from an aggregate cap/shared savings financing structure back to the traditional structure used in other Section 1115 projects. TennCare III 2023 Amendment Approval Letter at 2. Thus, Tennessee no longer has permission to implement what the initial TennCare III approval termed its "innovative financing approach." *See* TennCare III Approval Letter at 1.

113. In addition, CMS withdrew permission for a closed prescription drug formulary. TennCare III 2023 Amendment Approval Letter at 3.

114. In the approval letter, CMS noted that a majority of comments expressed concerns with the length of the approval period. *Id*. at 4. In response to those comments, CMS said that it was not altering the approval period. *Id*. The agency provided no explanation for its decision.

115. CMS also noted that many commenters raised concerns with the waiver of retroactive eligibility. *Id*. at 5. In response to those comments, CMS said that "[d]ata related to the effects of the waiver of retroactive eligibility have not previously been collected by Tennessee." *Id*. This, despite the fact that the waiver has been in place for nearly three decades. CMS stated

that going forward, Tennessee will be required to monitor and evaluate the effects of the waiver. *Id*.

F. Effects of the TennCare III Approval on the Plaintiffs

Mandatory Enrollment in Managed Care of Plaintiff Children with Special Health Care Needs

116. Tennessee, and its contracting managed care plans, have repeatedly failed to provide Plaintiffs A.G.W., J.T., A.M.W., N.P., and M.S. with access to medically necessary services.

117. Inadequate MCO provider networks have been and continue to be a particular problem for children and adults who have complex medical co-morbidities that require treatment from medical specialists and/or long-term services and supports, including the minor Plaintiff beneficiaries.

118. In addition, Tennessee gives MCOs broad discretion to deny care prescribed by an enrollee's treating provider by finding that it is not medically necessary. As illustrated by the minor Plaintiff Medicaid beneficiaries' experiences, the MCOs frequently (and erroneously) determine that a less costly service—or no service at all—is adequate.

119. By continuing the managed care program through December 31, 2030, the TennCare III approval allows such abuses to persist.

A.G.W.

120. Plaintiff A.G.W. is twelve years old. She lives in Madison, Tennessee, with her mother, J.A.W., and with her sister, who is also a child with special health care needs.

121. A.G.W. has been diagnosed with hydrocephalus and Lennox-Gastaut syndrome, a severe form of seizure disorder. Her condition was evident even before she was born. A.G.W. is incontinent of bowel and bladder, non-verbal, non-ambulatory, and legally blind. She requires

constant monitoring and the administration of emergency medication in the event of a seizure. She can consume soft pureed foods by mouth, but all water and medications must be administered through a G-tube. When she is sick, she is fed pureed foods by G-tube as well.

122. Due to her severe disabilities, A.G.W. has received SSI benefits since she was about one month old. Since that time, she has been enrolled in TennCare and assigned to TennCare Select. A.G.W. is a child with special needs under the Medicaid Act.

123. In 2011, A.G.W. started receiving 27 hours per week of private duty nursing care. Her needs steadily increased, and by May 2013 she was receiving 168 hours per week of PDN.

124. In October of 2014, although her conditions and medical needs had not changed, TennCare Select reduced her hours to 132 hours per week of PDN and 24 hours per week of home health aide care, for a total of 156 hours per week. Home health aides can assist with activities like repositioning and bathing A.G.W. and changing her diapers, but they cannot perform nursing functions, including crucial tasks like G-tube feedings and maintenance, and providing emergency seizure medication.

125. On August 4, 2017, J.A.W. received a letter stating that TennCare Select was going to slash A.G.W.'s PDN hours to 28 hours per week. J.A.W. appealed the decision, and a nurse conducted a home health assessment of A.G.W. on behalf of TennCare Select. After the assessment, TennCare stated that they would add 50 hours of home health aide services to the 28 hours of PDN care.

126. With the assistance of pro bono representation arranged by the Tennessee Justice Center, J.A.W. appealed the service reduction. A hearing was held on January 31, 2018, with testimony from multiple health care professionals that any reduction of A.G.W.'s care would be

harmful. The judge ordered TennCare to continue providing A.G.W. the 156 hours per week of care that she had been receiving.

127. Despite this ruling, TennCare Select attempted on three different occasions in 2018 to reduce A.G.W.'s service hours. With the assistance of counsel, J.A.W. was able to maintain the level of care that A.G.W. had been receiving.

128. On January 6, 2020, TennCare Select refused to approve her doctor's order extending the 132 hours of weekly PDN care for 23 weeks. TennCare Select informed J.A.W. that they would approve PDN care temporarily for eight weeks during which time they would conduct another assessment to determine how many hours of care they would approve for A.G.W.

129. On February 18, 2020, TennCare Select informed J.A.W. that they were reducing A.G.W.'s PDN hours to 119 hours per week, starting February 28, 2020. A.G.W.'s mother appealed the decision and was ultimately successful.

130. Plaintiff A.G.W.'s disabling, chronic health conditions will not go away. Yet, her managed care plan has repeatedly reduced her approved services even though her conditions have not improved. A.G.W.'s health care is highly expensive. CMS's approval of TennCare III harms A.G.W. because it continues to subject her to managed care contractors' efforts to deny coverage for medically necessary care.

J.T.

131. Plaintiff J.T. is fourteen years old. He lives in Heiskill, Tennessee, with his grandmother, B.S., and four siblings. His grandmother formally adopted him when he was 10 years old.

132. J.T. is diagnosed with Duchenne muscular dystrophy ("DMD"). DMD is a genetic disorder that causes progressive muscle degeneration and weakness. There is no cure for DMD, but J.T. receives treatment to slow the progression of motor, pulmonary, and cardiac function loss.

133. J.T. is enrolled in TennCare.

134. His doctor has prescribed weekly infusions of Exondys 51. Without this medication, J.T.'s quality of life would substantially decline due to increased muscle weakness. He would experience a loss in his already limited ability to perform activities of daily living, as well as deterioration of pulmonary and cardiac function. J.T. has been receiving this treatment since October 5, 2017.

135. TennCare covered Exondys 51 without issue until August 14, 2020.

136. J.T. was initially enrolled in TennCare Select, but on July 8, 2020, TennCare reassigned him to the UnitedHealthcare MCO. Soon afterwards, UnitedHealthcare sent a notice to his grandmother denying coverage for J.T.'s Exondys 51 medication.

137. J.T.'s weekly doses of Exondys 51 can cost as much as $750,000. J.T.'s grandmother cannot afford to pay for this medication out-of-pocket.

138. In its denial, UnitedHealthcare claimed that this medication was not medically necessary and cited its policy that an individual must meet a "6-minute walk test." UnitedHealthcare assessed J.T. as non-ambulatory and therefore decreed that he could not receive the medication.

139. J.T.'s doctor appealed this decision and provided a letter reiterating J.T.'s urgent need for Exondys 51.

140. Only after J.T.'s legal counsel became involved and prosecuted the appeal did TennCare agree to reverse the MCO's denial and reinstate coverage for Exondys 51.

141. Plaintiff J.T.'s disabling chronic health conditions will not go away. Yet, he has experienced repeated efforts on TennCare's behalf to reduce his approved services even though his conditions have not improved. J.T.'s health care is highly expensive. CMS's approval of TennCare III harms J.T. because it continues to subject him to managed care contractors' efforts to deny coverage for medically necessary care.

A.M.W.

142. A.M.W. is a 16-year-old child who lives with her father, J.K.W., who is her primary caregiver, in Greeneville, Greene County, Tennessee.

143. A.M.W. is diagnosed with spastic quadriplegic cerebral palsy, congenital pulmonary valve stenosis, heart failure, developmental delays, and seizure disorder. A.M.W. is non-verbal, non-ambulatory, and incontinent of bladder and bowel. Because she is at risk of having life-threatening seizures, A.M.W. must receive constant supervision by someone able to monitor her condition and immediately administer emergency medication. Her condition will not improve, and her medical and nursing needs will not diminish.

144. Due to her diagnoses, A.M.W. has received SSI since 2008. A.M.W. has been enrolled in TennCare since she was born and throughout that period, she has been assigned to TennCare Select. A.M.W. is a child with special needs under the Medicaid Act.

145. For more than two years, A.M.W. received 60 hours per week of private duty nursing care. Then, in 2018, despite the lack of improvement in her medical conditions, TennCare Select refused to reauthorize PDN and offered instead to provide 50 hours per week of certified nursing assistant ("CNA") services. Her father appealed because a certified nurse assistant cannot administer the medicine that A.M.W. requires. Her father succeeded in maintaining PDN services for A.M.W., but her hours of coverage were cut to 50 per week.

146. On February 13, 2020, TennCare Select sent J.K.W. a notice denying A.M.W. 50 hours per week of PDN and instead offering 50 hours per week of home health aide services. Home health aides have no medical training; like CNAs, they are not allowed to administer medications. A.M.W.'s conditions had not changed. J.K.W. again filed an appeal on February 21, 2020 explaining that A.M.W.'s medication needs must be met by a skilled nurse. He was unrepresented at the administrative hearing and lost the appeal. Ignoring the warnings of A.M.W.'s doctors, TennCare Select stopped providing the PDN care prescribed by A.M.W.'s doctor and substituted home health aide services.

147. Over ensuing weeks, TennCare Select's substitution of untrained home health aides for the skilled nursing coverage repeatedly jeopardized A.M.W.'s health and safety. She suffered numerous seizures. Faced with the ongoing danger to his daughter's life, J.K.W. continued to advocate for A.M.W., repetitively calling TennCare and TennCare Select and pleading with anyone who would talk to him. On September 1, 2020, TennCare Select finally agreed to reinstate the 50 hours per week of PDN care that A.M.W.'s doctor had ordered.

148. Plaintiff A.M.W.'s disabling, chronic health conditions will not go away. Yet, her managed care plan has repeatedly reduced her approved services even though her conditions have not improved. A.M.W.'s health care is highly expensive. CMS's approval of TennCare III harms A.M.W. because it continues to subject her to managed care contractors' efforts to deny coverage for medically necessary care.

N.P.

149. Plaintiff N.P. is twelve years old. She lives in Johnson City, Tennessee, with her parents, D.P. and T.A., and her brother. Her parents have cared for N.P. since she was four months

old, when DCS placed her with them as her foster parents. They adopted N.P. when she was four years old.

150. N.P. is diagnosed with cerebral palsy, developmental delays, and a seizure disorder.

151. N.P. is enrolled in TennCare. When D.P. and T.A. were her foster parents and DCS retained legal custody, N.P. was enrolled in TennCare Select. N.P. is a child with special needs under the Medicaid Act.

152. On TennCare Select, N.P. was approved for 30 hours per week of CNA care to enable her to attend day care and receive care at home. However, TennCare Select failed to reliably staff N.P.'s coverage and there were frequent missed shifts, resulting in disruption of N.P.'s day care.

153. Soon after her adoption, TennCare reassigned N.P. to the Amerigroup MCO, which had difficulties staffing her care. Since 2016, Amerigroup repeatedly responded to these difficulties by reducing or denying her care. Her mother would then get a new doctor's order submitted, which Amerigroup would approve as medically necessary, but then fail to reliably staff the prescribed number of hours.

154. At first, T.A. was N.P.'s principal caregiver in the home. Though she has her own health conditions, she was able to meet N.P.'s care needs when N.P. was at home as a small child.

155. As N.P. grew, her mother had difficulty performing some care tasks and injured herself lifting N.P. N.P.'s doctor ordered 30 hours of home health aide care per week.

156. Amerigroup approved the order, but still consistently had trouble staffing the in-home care. In July 2020, N.P.'s doctor sent an updated order for 30 hours of home health aide care per week. Amerigroup approved this order on August 6, 2020 and promised that it would staff the hours by the first week of September 2020.

157. After the first week of September 2020, Amerigroup was again unable to fully staff the approved hours. With the assistance of pro bono legal counsel, T.A. filed an appeal with TennCare seeking corrective action to remedy the MCO's delay in providing the prescribed care. She then received a notice from Amerigroup stating that it would deliver the care by the first week of October 2020. TennCare then sent T.A. a notice that her delay-of-services appeal was closed because Amerigroup was working to find a provider.

158. After the first week of October 2020, Amerigroup failed to staff any of the approved hours. T.A. then received a notice from Amerigroup stating that it would deliver the care by the first week of November 2020. With the assistance of counsel, she filed a second delay-of-services appeal. Amerigroup failed to provide the prescribed care and instead sent her similar notices in November 2020 and in December 2020, each promising the delivery of services in the first week of the following month.

159. On January 14, 2021, under pressure from a Tennessee Justice Center attorney representing N.P., Amerigroup partially staffed her plan of care. N.P. still does not receive the full hours of care as ordered by her doctor and approved by Amerigroup as medically necessary.

160. Plaintiff N.P.'s disabling, chronic health conditions will not go away. Yet, her managed care plan has repeatedly reduced her services even though her conditions have not improved. N.P.'s health care is highly expensive. CMS's approval of TennCare III harms N.P. because it deprives her of freedom of choice of providers, locking her into TennCare contractors' provider networks that are inadequate to safely and reliably meet her medical needs.

M.S.

161. Plaintiff M.S. is five years old. She lives in Caryville, Tennessee, with her parents, T.S. and A.S., and her four siblings. Her parents have cared for M.S. from the moment she got out

of the hospital after her birth, and DCS placed her with them as her foster parents when she was three months old. They adopted M.S. when she was one-year-old so that they could get her on a kidney transplant list after the DCS failed to do so.

162. M.S. is diagnosed with Potter's Syndrome, stage IV renal failure, and is on dialysis. She is non-ambulatory, G-J tube dependent, and needs a kidney transplant. She has frequent episodes of apnea, and she requires continuous oxygen while sleeping.

163. M.S. is enrolled in TennCare. M.S. is a child with special needs under the Medicaid Act. During the first year of her life, when T.S. and A.S. were her foster parents and DCS retained legal custody, M.S. was enrolled in TennCare Select. She received 120 hours of PDN care per week.

164. After her adoption, TennCare reassigned M.S. to the Amerigroup MCO. M.S.'s parents requested that TennCare change her assignment back to TennCare Select, but TennCare refused.

165. Almost immediately Amerigroup sent M.S.'s parents a letter reducing PDN services by more than half, to 56 hours per week. With the help of counsel from the Tennessee Justice Center, M.S.'s parents successfully appealed the denial, and TennCare conceded that 120 hours of PDN per week are medically necessary.

166. While that appeal was pending in August 2020, TennCare's pharmacy benefit manager, OptumRx, sent a denial notice refusing to cover Norditropin, a growth hormone prescribed to M.S. to prepare her body to undergo a kidney transplant. Coverage of the medication was reinstated, but only after M.S.'s shaken parents made numerous calls to correct the error. M.S. also receives Katerzia to control her hypertension. Any interruption of the drug can cause a potentially dangerous rise in blood pressure and require her hospitalization. On September 11,

2020, the day M.S.'s prescription for Katerzia was running out, OptumRx informed her parents that it was denying TennCare coverage for the drug. After multiple, increasingly frantic calls to Amerigroup and OptumRx, the medication was authorized.

167. Plaintiff M.S.'s disabling chronic health conditions will not go away. Yet, her managed care plan has repeatedly reduced her approved services even though her conditions have not improved. Plaintiff M.S.'s health care is highly expensive. CMS's approval of TennCare III harms M.S. because it continues to subject her to managed care contractors' efforts to deny coverage for medically necessary care and deprives her of freedom of choice of providers, locking her into TennCare contractors' provider networks that are inadequate to safely and reliably meet her medical needs.

Waiver of Retroactive Eligibility's Impact on TennCare Enrollees and Providers

168. By continuing the waiver of retroactive coverage through December 31, 2030, the TennCare III approval deprives Medicaid beneficiaries of coverage for medically necessary services, forcing them to incur significant medical debt or forgo care altogether. The waiver also causes financial harm to providers, including Plaintiff Dr. Suzanne Berman.

Tatjana Anderson

169. Tatjana Anderson resides in Mt. Juliet, Tennessee with her husband and her mother. In June 2023, Ms. Anderson was diagnosed with a form of breast cancer called invasive lobular carcinoma. In July 2023, Ms. Anderson was identified by a health insurance counselor as eligible for TennCare's Breast and Cervical Cancer ("BCC") coverage and referred to the Health Department in Gallatin, Tennessee so that she could enroll in TennCare under BCC. When Ms. Anderson called the Health Department on July 27, 2023, she was advised she could not enroll in TennCare because she had other active insurance coverage.

170. That advice was wrong. While Ms. Anderson had purchased temporary coverage through the federal insurance Marketplace to prevent a gap in coverage while she awaited approval for the BCC TennCare coverage, Marketplace insurance does not preclude eligibility for TennCare in the BCC category.

171. On July 28, 2023, the health insurance counselor emailed TennCare's Cancer Programs Administrator, who confirmed that for BCC, Marketplace coverage does not preclude coverage. The TennCare Administrator promised to contact the Health Department and direct them to approve Ms. Anderson for BCC coverage.

172. On August 7, 2023, while awaiting enrollment in BCC, Ms. Anderson underwent a lumpectomy, and during the surgery, it was discovered that the cancer had spread. On August 18, 2023, TennCare approved Ms. Anderson for BCC. Because of the waiver of retroactive eligibility, Ms. Anderson has $575 of outstanding medical debt incurred for the surgery during the three-month period before she was able to successfully apply for TennCare coverage.

173. Ms. Anderson remains under monitoring for breast cancer and is scheduled for a repeat screen in March of 2024. BCC coverage is temporary, lasting only while an enrollee is receiving active treatment for breast or cervical cancer. Therefore, Ms. Anderson will become ineligible when her current treatments end.

174. Invasive lobular carcinoma is known to recur, and patients diagnosed with breast cancer are three-to-four times more likely to develop a new breast cancer. Ms. Anderson's oncologist has counseled her that, due to identification of a genetic mutation linked to breast cancer, Ms. Anderson will have a life-long elevated risk of recurrence.

175. Due to the waiver of retroactive coverage, she will likely again incur medical expenses related to the treatment of breast cancer before she is able to reapply for Medicaid coverage.

Suzanne Berman, M.D.

176. Suzanne Berman is a pediatrician practicing in Crossville, Tennessee. Although she primarily treats children, a number of her patients are young adults enrolled in TennCare. The practice currently has 344 patients ages 18 and up with TennCare.

177. All of the counties she serves are classified as medically underserved. Three counties in the region have lost their only hospitals and with them the ability to recruit and retain health care professionals, like physicians, nurses, and therapists, who rely on the local presence of a hospital.

178. The waiver of retroactive coverage harms Dr. Berman, as it prevents her from being paid for services that TennCare would otherwise cover.

179. She treats adults who are uninsured but eligible for TennCare, and the waiver of retroactive coverage results in the denial of TennCare reimbursement for the services she provides during the three-month period prior to their application for the program.

180. Few physicians in Dr. Berman's area accept adult patients with TennCare, and the waiver of retroactive eligibility contributes to the reluctance of many Tennessee physicians, especially medical specialists, to accept TennCare patients. As a result, Dr. Berman and her staff have to spend more time finding specialists who will accept referrals for patients who need specialty medical care. Due to the continuation of the retroactive coverage waiver, Dr. Berman and her staff must continue diverting their time from treating patients to locating specialists for their adult patients enrolled in TennCare.

COUNT ONE: VIOLATION OF ADMINISTRATIVE PROCEDURE ACT (PROEJCT AS A WHOLE)

181. Plaintiffs repeat and incorporate herein by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

182. The Administrative Procedure Act provides that a reviewing court may "hold unlawful and set aside" agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; "contrary to constitutional right, power, privilege, or immunity"; "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"; or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A)-(D).

183. Section 1115 only gives the Secretary the authority to grant one initial and one subsequent renewal of state-wide comprehensive demonstration projects. 42 U.S.C. § 1315(e)(1), (f). The renewals cannot exceed three years, or five years for projects involving dual eligibles. *Id*. § 1315(e)(2), (f)(6).

184. CMS first approved TennCare as a state-wide comprehensive demonstration project in 1993. The project has been in place since 1994. In approving TennCare III, as amended, CMS granted Tennessee permission to continue the project through December 31, 2030.

185. The TennCare III project, as amended, is not an experimental, pilot, or demonstration project.

186. In approving TennCare III, as amended, the Secretary exceeded his Section 1115 authority.

187. In addition, in approving TennCare III, as amended, the Secretary relied on factors which Congress has not intended him to consider, entirely failed to consider several important aspects of the problem, offered an inadequate explanation for his decision, offered an explanation

for his decision that runs counter to the evidence, and/or failed to acknowledge or explain changes in agency position.

188. Approval of the TennCare III project, as amended, was arbitrary and capricious and an abuse of discretion.

189. Approval of the TennCare III project accordingly should be set aside.

COUNT TWO: VIOLATION OF ADMINISTRATIVE PROCEDURE ACT (RETROACTIVE COVERAGE WAIVER)

190. Plaintiffs repeat and incorporate herein by reference each and every allegation contained in the preceding paragraphs as if fully set forth herein.

191. The Administrative Procedure Act provides that a reviewing court may "hold unlawful and set aside" agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"; "contrary to constitutional right, power, privilege, or immunity"; "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"; or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A)-(D).

192. In approving the retroactive coverage waiver, the Secretary made no finding that the waiver is "necessary to enable" Tennessee to carry out the TennCare III project. *See* 42 U.S.C. § 1315(a)(1).

193. In approving the retroactive coverage waiver, the Secretary relied on factors which Congress has not intended him to consider, entirely failed to consider several important aspects of the problem, offered an inadequate explanation for his decision, offered an explanation for his decision that runs counter to the evidence, and/or failed to acknowledge or explain changes in agency position.

194. The approval of the retroactive coverage waiver was arbitrary and capricious and an abuse of discretion.

195. Approval of the retroactive coverage waiver accordingly should be set aside.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask that this Court:

1. Declare that Defendants' approval of TennCare III, as amended, violates the Administrative Procedure Act and the Social Security Act in the respects set forth above;
2. Vacate Defendants' approval of TennCare III, as amended;
3. Enjoin Defendants from implementing the practices purportedly authorized by the approval of TennCare III;
4. Award Plaintiffs their reasonable attorneys' fees and costs pursuant to 28 U.S.C. § 2412; and
5. Grant such other and further relief as may be just and proper.

Dated: December 22, 2023

Respectfully submitted,

/s/ Jane Perkins
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Counsel for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRYLEE McCUTCHEN, *et al.*,	)	
	)	
Plaintiffs.	)	
	)	
v.	)	
	)	No. 1:21-cv-01112-TSC
XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	
	)	

[PROPOSED] ORDER GRANTING PLAINTIFFS' UNOPPOSED MOTION FOR LEAVE TO FILE SUPPLEMENTAL COMPLAINT

This matter is before the Court on Plaintiffs' unopposed Motion for Leave to File a Supplemental Complaint. Having determined that Plaintiffs' Supplemental Complaint meets the requirements of Federal Rule of Civil Procedure 15(d), Plaintiffs' motion is GRANTED. Pursuant to Local Civil Rule 7(i), the Supplemental Complaint is deemed to have been filed and served on the date entered below. Federal Defendants and Intervenor-Defendant will have 60 days from the date of this order to respond to Plaintiffs' Supplemental Complaint.

SO ORDERED this _____ day of _____, 2023.

_____

HON. TANYA S. CHUTKAN