UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRYLEE McCUTCHEN, by his next friend,
BRANDI McCUTCHEN,
[redacted],

BINTA BARROW, by her next friend,
SADIATOU JALLOW,
[redacted],

M.A.C., by her next friend, M.E.C.,
c/o Tennessee Justice Center, 211 7th Avenue N., Ste. 100,
Nashville, TN 37219,

AMIRA COFER, by her next friend,
MELANIE COFER,
[redacted],

J.T., by his next friend, B.S.,
c/o Tennessee Justice Center, 211 7th Avenue N., Ste. 100,
Nashville, TN 37219,

G.H., by his next friend, D.H.,
c/o Tennessee Justice Center, 211 7th Avenue N., Ste. 100,
Nashville, TN 37219,

K.M., by his next friend, L.M.,
c/o Tennessee Justice Center, 211 7th Avenue N., Ste. 100,
Nashville, TN 37219,

A.G.W., by her next friend, J.A.W.,
c/o Tennessee Justice Center, 211 7th Avenue N., Ste. 100,
Nashville, TN 37219,

A.M.W., by her next friend, J.K.W.,
c/o Tennessee Justice Center, 211 7th Avenue N., Ste. 100,
Nashville, TN 37219,

N.P., by her next friend, T.A.,
c/o Tennessee Justice Center, 211 7th Avenue N., Ste. 100,
Nashville, TN 37219,

JONATHAN RICCARDI, by his next friend,
JOHN RICCARDI,
[redacted],

No. 21-___________

CASEY SIZEMORE, by her next friend,
TRINA SIZEMORE,
[redacted],

M.S., by her next friend, T.S.,
c/o Tennessee Justice Center, 211 7th Avenue N., Ste. 100,
Nashville, TN 37219,

SUZANNE BERMAN, M.D.,
[redacted], and

TENNESSEE JUSTICE CENTER, INC.,
211 7th Avenue N., Ste. 100, Nashville, TN 37219,

Plaintiffs.

v.

XAVIER BECERRA, in his official capacity as
Secretary of Health and Human Services,
200 Independence Avenue, S.W., Washington, DC 20201,

ELIZABETH RICHTER, in her official capacity as Acting
Administrator of the Centers for Medicare & Medicaid
Services,
7500 Security Boulevard, Baltimore, MD 21244,

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES,
200 Independence Avenue, S.W., Washington, DC 20201,
and

CENTERS FOR MEDICARE & MEDICAID SERVICES,
7500 Security Boulevard, Baltimore, MD 21244,

Defendants.

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 their low-income residents. On January 8, 2021––just before leaving office—the Trump administration departed from this deal, authorizing a new project that caps the federal Medicaid funding available to Tennessee and allows the State to use a portion of that funding for non-Medicaid purposes. It did so without affording the public the required opportunity to submit their objections to features of the project that limit Medicaid beneficiaries' access to coverage and care. In its haste to issue this approval, the administration also violated the substantive requirements that govern the approval of Medicaid demonstration projects. Plaintiffs include thirteen individuals with disabilities who rely on Medicaid coverage, who will see their access to health care suffer under the new project, and who have been denied the opportunity to submit comments opposing the project. Plaintiffs accordingly bring this action to vacate its approval.

2. Section 1115 of the Social Security Act does permit the Secretary of Health and Human Services to waive certain specified provisions in the Medicaid Act for "experimental, pilot, or demonstration projects … likely to promote the objectives" of the Medicaid Act. 42 U.S.C. § 1315(a). The Secretary may only grant a waiver for the period of time necessary to carry out the experiment. And before the Secretary (acting through the Centers for Medicare & Medicaid Services ("CMS")) may approve a waiver, the statute requires both the State and then CMS to hold a public notice and comment period on the project. Section 1115 was not followed here.

3. Over a quarter of a century ago, CMS 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 coverage. 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, like the Plaintiffs, experiencing harmful medical consequences as a result.

4. In November 2019, Tennessee submitted a vague and internally inconsistent request to CMS to "amend" TennCare II. Tennessee provided scant details of its plans for the amendment or even of the particular Medicaid requirements that it asked the federal agency to waive, but it 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.

5. In November 2020, while the amendment request was still pending and with TennCare II scheduled to expire at the end of June 2021, Tennessee opened a state-level comment period on a request to extend the TennCare II managed care program for another decade. However, the State never submitted this request to CMS. CMS did not hold, and to this day has not held, a comment period on the continuation of the managed care program.

6. Nevertheless, on January 8, 2021, CMS approved a new project that it labeled as "TennCare III." Despite never having solicited comment from the public, CMS allowed Tennessee to continue its mandatory managed care program and its waiver of three-months' retroactive coverage. But CMS did not stop there. It also authorized a variation on Tennessee's request for a block grant, capping the amount of federal funding available for Medicaid services and allowing Tennessee to keep more than half of the federal share of savings achieved if it comes in under the

cap. TennCare III further authorized Tennessee to limit coverage of medically necessary prescription drugs. In approving these components of the project, CMS authorized the State to ignore provisions of the Medicaid Act that Congress does not permit to be ignored.

7. CMS also approved the project for ten years, contrary to Section 1115 and its own stated policy, and without even knowing the details of the experiment; Tennessee had not (and still has not) revealed an evaluation design for the project.

8. In approving the project, CMS exceeded its authority under Section 1115, failed to engage in reasoned decision-making in considering whether the project met the criteria for approval under the statute, and violated the procedural requirements for the approval of such a project. Accordingly, the approval violated the Administrative Procedure Act and the Social Security Act and cannot stand.

JURISDICTION AND VENUE

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

10. 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.

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

PARTIES

A. Plaintiffs

12. Plaintiff Brylee McCutchen is an adult resident of Hendersonville, Sumner County, Tennessee. He is a TennCare enrollee who brings this action by his mother, Brandi McCutchen, acting as his next friend.

13. Plaintiff Binta Barrow is an adult resident of Knoxville, Knox County, Tennessee. She is a TennCare enrollee who brings this action by her mother, Sadiatou Jallow, acting as her next friend.

14. Plaintiff M.A.C. is a minor resident of Clarksville, Montgomery County, Tennessee.[1] She is a TennCare enrollee who brings this action by her mother, M.E.C., acting as her next friend.

15. Plaintiff Amira Cofer is an adult resident of Emory Gap, Roane County, Tennessee. She is a TennCare enrollee who brings this action by her mother, Melanie Cofer, 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 G.H. is a minor resident of Powell, Anderson County, Tennessee. He is a TennCare enrollee who brings this action by his mother, D.H., acting as his next friend.

18. Plaintiff K.M. is a minor resident who lives in Christiana, Rutherford County, Tennessee. He is a TennCare enrollee who brings this action by his mother, L.M., acting as his next friend.

19. 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.

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[1] Pursuant to Fed. R. Civ. P. 5.2(a)(3), those Plaintiffs who are minors are identified only by their initials. Because the names and addresses of these Plaintiffs' next friends would tend to identify these Plaintiffs, who have revealed sensitive details of their medical conditions in this Complaint, this pleading substitutes the next friends' initials and the address of their counsel. Plaintiffs are concurrently filing a motion for leave to proceed pseudonymously that asks the Court to accept the Complaint in this form.

20. 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.

21. 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.

22. Plaintiff Jonathan Riccardi is an adult Tennessee resident who is receiving care in a neurorestorative facility in Carbondale, Illinois. He is a TennCare enrollee who brings this action by his father, John Riccardi, acting as his next friend.

23. Plaintiff Casey Sizemore is an adult resident of Arlington, Shelby County, Tennessee. She is a TennCare enrollee who brings this action by her mother, Trina Sizemore, acting as her next friend.

24. 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.

25. 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.

26. Plaintiff Tennessee Justice Center, Inc. ("TJC") is a non-profit, tax exempt Tennessee corporation whose office is in Nashville, Davidson County, Tennessee. TJC was founded by Tennessee bar leaders to provide free legal representation and advocacy on behalf of vulnerable Tennessee residents. TJC pursues its mission by representing low-income clients in court; through policy advocacy before administrative agencies and legislative bodies; through providing information and education to the public and individuals about programs, program eligibility, and legal rights; and by providing technical assistance and training to other organizations and individuals that serve vulnerable Tennesseans.

B. Defendants

27. 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.

28. Defendant Elizabeth Richter is the Acting Administrator of the Centers for Medicare and Medicaid Services ("CMS") and is sued in her official capacity. Acting Administrator Richter is responsible for implementing the Medicaid program in the manner required by federal law.

29. 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.

30. 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

31. 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-5. 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.

32. 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).

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

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

35. 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.

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

37. 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").

38. 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).

39. 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

40. 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).

41. 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.

42. The Act requires states to ensure that any person who wishes to apply for medical assistance has an opportunity to do so and that such medical assistance is furnished to all eligible individuals with reasonable promptness. *Id.* § 1396a(a)(8).

43. The Medicaid Act requires States to grant an opportunity for a fair hearing "to any individual whose claim for medical assistance … is denied or is not acted upon with reasonable promptness." *Id.* § 1396a(a)(3); 42 C.F.R. §§ 431.200 to 431.250, 438.400 to 438.424; *see also Goldberg v. Kelly*, 397 U.S. 254 (1970).

44. 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).

45. Since its enactment, the Medicaid Act has required 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. 42 U.S.C. §§ 1396a(a)(34), 1396d(a). 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).

46. 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).

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

48. States have had the option to cover outpatient prescription drugs since 1965. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, §§ 1902(a)(10), 1905(a)(12), 79 Stat. 286, 345, 351 (codified at 42 U.S.C. §§ 1396a(a)(10), 1396d(a)(12)).

49. In 1990, Congress amended the statute to establish detailed requirements for coverage of outpatient prescription drugs, placing the requirements in a new provision, Section 1396r-8. *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 (1990) (codified at 42 U.S.C. §§ 1396a(a)(54), 1396r-8, 1396b(i)(10)). The amendment set forth the Congressional scheme for reducing Medicaid spending on outpatient prescription drugs. *See* Pub. L. No. 101-158, § 4401, 104 Stat. 1388, 1388-143 (1990) (placing the amendment under the heading "Reductions in Spending"); H. Rep. No. 101-881, at 2108-2109 (1990).

50. To have their drugs covered under the Medicaid program, manufacturers must enter into a rebate agreement with the federal government or with individual states. 42 U.S.C. § 1396r-8(a). In return, states must cover all FDA-approved outpatient drugs (offered by manufacturers with a rebate agreement in place) when prescribed for a medically accepted indication. *See id.* § 1396r-8(d), (k)(2).

51. Congress specified mechanisms for states to control utilization of and spending on outpatient prescription drugs. For example, the statute contains a list of particular drugs or classes of drugs that states are not required to cover. *Id.* §§ 1396r-8(d)(1)(B)(ii), (d)(2), (d)(3) (authorizing the Secretary to update the list of drugs that states are not required to cover by regulation). The

statute also allows states to require health care providers to obtain prior authorization for drugs they are prescribing. *Id*. § 1396r-8(d)(1)(A), (d)(5).

52. In addition, the Medicaid Act specifies when and how states may develop drug formularies. *Id*. § 1396r-8(d)(4). 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).

53. Other optional Medicaid services include private duty nursing, or PDN, for beneficiaries who require individual and continuous care, *id*. §§ 1396a(a)(10)(A), 1396d(a)(8); 42 C.F.R. § 440.80, and personal care services for individuals who are not living in an institution, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(24); 42 C.F.R. § 440.167.

54. As noted above, the Medicaid Act requires states to cover certain services. One example is home health services for individuals who are entitled to receive nursing facility services. 42 U.S.C. § 1396 a(a)(10)(D); 42 C.F.R. § 440.70.

55. Another 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).

56. 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). States must "arrang[e] for (directly or through referral to appropriate agencies,

organizations, or individuals) corrective treatment for any conditions identified by a child's health care provider. *Id*. § 1396a(a)(43)(C).

57. Under the Medicaid Act, "the medical assistance made available to any individual" cannot be "less in amount, duration or scope than the medical assistance made available to any other such individual." 42 U.S.C. § 1396a(a)(10)(B)(i); *see also* 42 C.F.R. § 440.240(b). This is known as the comparability requirement.

C. Medicaid Managed Care

58. Medicaid was structured primarily as a fee-for-service program, and 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* 42 U.S.C. § 1396a(a)(23).

59. In the 1980s, the federal Medicaid agency authorized some states to implement Section 1115 experiments to test the effects of converting from fee-for-service to managed care delivery systems. *E.g.*, Medicaid and CHIP Payment and Access Commission, *Report to the Congress: The Evolution of Managed Care in Medicaid* 18-20 (2011), https://bit.ly/32CCnEA.

60. Thereafter, Congress amended the Medicaid Act to allow states to use managed care delivery systems to provide Medicaid services to most beneficiaries. *See* 42 U.S.C. §§ 1396n(b), 1396u-2, 1396b(m), 1396d(t); 42 C.F.R. §§ 438.1 to 438.930.

61. 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.

62. 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).

63. 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)(4), 1396u-2(b)(2), 1396a(a)(23)(B) (creating exceptions for emergency and family planning services).

64. 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 April 21, 2021); U.S. Dep't of Health & Human Servs. Office of Inspector Gen., Medicaid Managed Care Organization Denials, https://bit.ly/3xd8f0z (last visited April 21, 2021) (noting that an MCO's "contractual arrangement shifts financial risk for the costs of services from the State Medicaid agency and the Federal Government to the MCO, which can create an incentive to deny beneficiaries' access to covered services.").

65. Managed care is the dominant Medicaid delivery system. Across the country, nearly 70 percent of Medicaid beneficiaries receive services through MCOs. Kaiser Fam. Found., *State Health Facts: Total Medicaid MCO Enrollment* (2018), https://bit.ly/3va5gnH.

D. The Secretary's Section 1115 Waiver Authority

66. 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.

67. 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).

68. Section 1115 permits the Secretary to waive compliance only with the requirements located in 42 U.S.C. § 1396a. 42 U.S.C. § 1315(a)(1).

69. The Secretary may not waive compliance with, or authorize a state to ignore, the requirements of 42 U.S.C. § 1396b, which establishes how the federal government must fund Medicaid programs in the states.

70. The Secretary may not waive compliance with, or authorize a state to ignore, the requirements of 42 U.S.C. § 1396r-8, which establishes how outpatient prescription drugs are covered through Medicaid.

71. Congress intended for Section 1115 waivers to be time-limited. The Secretary may grant a Section 1115 waiver only "to the extent and for the period necessary" to enable the state to carry out the experimental project. 42 U.S.C. § 1315(a)(1).

72. Once the Secretary has approved a Section 1115 project, the costs of the project are "regarded as expenditures under the State plan," and thus are paid under the same statutory formula that applies for a state's expenditures under its State plan. *Id.* § 1315(a)(2).

73. The Patient Protection and Affordable Care Act ("ACA") amended Section 1115 to require transparency and improved opportunities for public comment for state requests that would affect "eligibility, enrollment, benefits, cost-sharing, or financing." Pub. L. No. 111-148, § 10201(i), 124 Stat. 119, 917 (2010) (adding 42 U.S.C. § 1315(d)).

74. Specifically, the ACA directed HHS to promulgate regulations requiring notice and comment periods at both the state and federal levels that would be "sufficient to ensure a meaningful level of public input." 42 U.S.C. § 1315(d)(2)(A), (C).

75. The implementing regulations require the Secretary to follow certain procedural requirements before he may approve a Section 1115 project. *See* 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 C.F.R. § 431.416.

76. In addition, Section 1115 places explicit limits on any extension of "state-wide, comprehensive demonstration projects." *See* 42 U.S.C. §§ 1315(e), (f).

77. 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).

78. 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).

79. In January 2020, CMS issued a letter to State Medicaid Directors titled "Healthy Adult Opportunity," which announced its intent to approve Section 1115 projects implementing an aggregate or per-capita cap and shared savings financing model. Ctr. for Medicaid & CHIP Servs., CMS, Dear State Medicaid Director Letter 20-001 (Jan. 30, 2020), https://bit.ly/3xeyOCw.

Under the policy, states adopting that financing approach "will be granted extensive flexibility to test alternative approaches to implementing their Medicaid programs, including the ability to make many ongoing program adjustments without the need for demonstration or state plan amendments that require prior approval." *Id.* at 1. CMS will permit states to, among other things: eliminate retroactive eligibility, implement a closed prescription drug formulary, "consistent with the EHB [Essential Health Benefits] requirements," and make "many program changes without prior CMS approval."[2] *Id*. at 39–42.

80. CMS issued the policy, which it described as "transformative" and "unprecedented," *see* CMS, Press Release: Trump Administration Announces Transformative Medicaid Healthy Adult Opportunity (Jan. 30, 2020), https://go.cms.gov/2PamWjP, after Congress had repeatedly declined to amend the Medicaid Act to cap federal Medicaid funding. *See, e.g.,* American Health Care Act, H.R. 1628, 115th Cong., § 121 (2017).

E. Medicaid in Tennessee

81. Tennessee, like all other states, has elected to participate in Medicaid. *See* Tenn. Code Ann. § 71-5-101 *et seq*.

82. 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).

83. The federal government's FMAP for Tennessee is approximately 66% of the cost of providing medical assistance through its Medicaid program. *See* 84 Fed. Reg. 66,204, 66,205 (Dec. 3, 2019) (fiscal year 2021), 85 Fed. Reg. 76,586, 76,588 (Nov. 30, 2020) (fiscal year 2022).

[2] The Affordable Care Act requires certain health insurance plans to cover a set of Essential Health Benefits, which include prescription drugs. *See* 42 U.S.C. § 18022(b). Federal EHB regulations establish requirements regarding the scope of coverage. *See* 45 C.F.R. § 156.122.

84. Tennessee is currently receiving an additional 6.2% in federal matching funding due to the COVID public health emergency. *See* Families First Coronavirus Response Act, Pub. L. No. 116-127, § 6008, 134 Stat. 178, 208 (2020). To receive the enhanced FMAP, Tennessee must maintain the coverage of individuals enrolled in Medicaid through the end of the month in which the public health emergency ends. *Id*. § 6008(b)(3).

The TennCare Project

85. In 1993, HHS approved Tennessee's application to implement a Section 1115 Medicaid 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 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").

86. 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 & Human Servs., to Mr. H. Russell White, Comm'r, Tenn. Dep't of Health 2 (Nov. 18, 1993).

87. 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. Several of the MCOs that the State contracted with did not have sufficient experience or capital "to be successful." *Id.*

88. In 1999, the third largest MCO participating in TennCare was placed in receivership for failing to pay health care providers. Division of TennCare, *TennCare Timeline*, https://bit.ly/3xb7k0y (last visited April 21, 2021); Bill Carey, *Taxpayers May Dish Out $20*

Million More for Xantus Creditors, NASHVILLE POST, June 9, 2000, https://bit.ly/3aqT9e0 (reporting that when it was placed in receivership, the MCO owed $87 million to health care providers).

89. In 2000, another MCO was placed under the supervision of the State for the same reason; the State terminated its contract the following year. Div. of TennCare, *TennCare Timeline*. Several other managed care plans left TennCare. *See id.*

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

91. 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. Div. of TennCare, *TennCare Timeline*.

The TennCare II Project

92. 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). TennCare II continued the core features of TennCare.

93. Over the next 18 years, CMS repeatedly renewed TennCare II.

94. The latest renewal extended TennCare II 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 Finance and Admin. (Dec. 16, 2016), https://bit.ly/3gu5ZMA.

95. Over the course of TennCare II, CMS approved various amendments to the project. Responding to concerns about costs, in 2005, Tennessee eliminated coverage for uninsured adults and reduced covered services, limiting the number of prescription drugs a patient can have and eliminating coverage of dental care for adults and methadone for adults with opioid use disorder. 2015 Extension Application at 13, 15, 46–47.

96. In 2009-2010, Tennessee received $850 million in increased federal Medicaid funds when the American Recovery and Reinvestment Act ("ARRA"), Pub. L. No. 111-5, increased the FMAP. Because the funds were part of an economic stimulus package intended to immediately benefit households affected by the Great Recession, Section 5001(f)(3) of ARRA provided that, "[a] State is not eligible for an increase in its FMAP … if any amounts attributable (directly or indirectly) to such increase are deposited or credited into any reserve or rainy day fund of the State."

97. Tennessee nonetheless deposited the entire ARRA Medicaid increase in the state reserve fund, thereby diverting it to purposes unrelated to Medicaid.

98. Over the years, CMS permitted Tennessee to include additional Medicaid populations and services in its managed care system. For example, in 2010, Tennessee initiated the "CHOICES" program, which requires older adults and individuals with disabilities who receive long term services and supports to receive those services through MCOs. *See* CMS, TennCare II Special Terms and Conditions, 4–5, 15–16 (2009), https://bit.ly/2QHP5z2.

99. Tennessee has expanded CHOICES over time. *See, e.g.*, 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 (allowing the State to implement "ECF CHOICES," which requires certain individuals with intellectual or developmental disabilities to receive home and community-based services through MCOs).

100. In July 2019, CMS approved an amendment that, on or after August 1, 2019, children who are found eligible for SSI are moved 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.

101. Over the past three years, Tennessee has terminated Medicaid or Children's Health Insurance Program ("CHIP") coverage for 238,000 children, most of them without a finding that they were ineligible. Tennessee is among the states with the largest increases in uninsured children, with about 83,000 children having no health insurance in 2018. *See* Joan Alker and Lauren Roygardner, Georgetown Univ. Health Policy Inst., *The Number of Uninsured Children is on the Rise* 9, 15 (2019). During the same period, thousands of elderly and disabled Medicaid-Medicare beneficiaries have also erroneously lost coverage without prior notice or an opportunity for a fair hearing.

Proposed Amendment 42 to the TennCare II Project

102. 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." Letter from John G. Roberts, Dir., Div. of TennCare, to Judith Cash, Dir., State Demonstrations Group, Ctrs. for Medicare & Medicaid Servs., 2 (Nov. 20, 2019); Div. of TennCare, TennCare II Demonstration Amendment 42, Modified Block Grant

and Accountability (2019), https://bit.ly/3dDQNua ("2019 Amendment Application"). The State claimed that over the course of TennCare, it had saved the federal government billions of dollars, 2019 Amendment Application at iii, and CMS should reward its "good stewardship" with additional federal investment, *id.* at 4.

103. 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.

104. 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.

105. 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.

106. 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.

107. 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.

108. On December 4, 2019, the Tennessee Justice Center ("TJC") wrote to the then Administrator of CMS, Seema Verma, expressing concern that the comment period was occurring during the winter holiday (including both Thanksgiving and Christmas) and requesting that it be extended beyond December 27, 2019 to ensure a meaningful level of public input.

109. The CMS comment portal went offline on December 21, 2019. On December 23, 2019, the National Health Law Program emailed a letter to Administrator Verma warning that the comment portal was down and had been down since December 21, 2019. The letter requested that, because of the confusion and obstacles to submitting comments while the portal was offline, CMS extend the comment period.

110. The CMS comment portal reopened later on December 23, 2019. CMS closed the comment period as scheduled on Friday, December 27, 2019. The portal was open for less than 28 days.

111. In a February 25, 2020 letter, CMS rejected TJC's December 4, 2019 request for an extension of the comment period.

112. 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.

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

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

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

The TennCare III Project

116. On January 8, 2021, Administrator Verma 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/2QPxuVN ("TennCare III Approval Letter"); *see also* CMS, TennCare III Waiver List; CMS, TennCare III Expenditure Authority; CMS, TennCare III Special Terms and Conditions (corrected Jan. 20, 2021) (collectively at https://bit.ly/3atXTiV). 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).

117. 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/3vcqYaS.

118. CMS approved TennCare III for a period of ten years. *Id.* at 1, 5. CMS stated that it approved the project for ten years to give the State sufficient time to test its "innovative approach," *id.*, and reduce "the future administrative burden associated with having to renew the demonstration more frequently," *id.* at 9.

119. 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.

120. The TennCare III approval preserves the features of TennCare II, with minor changes. *See id.* at 3–4. As a result, although CMS never gave the public an opportunity to comment on the extension of the TennCare II project, under TennCare III, all beneficiaries must continue to enroll in managed care. TennCare III Special Terms and Conditions ("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).

121. The TennCare III approval also continues the waiver of retroactive eligibility, which has been in place since 1994. TennCare III Waiver List at 2; 2015 Extension Application at iv, 25. As a result, although CMS never gave the public an opportunity to comment on the extension of the TennCare II project, under TennCare III, adult beneficiaries continue to lose the protection of retroactive coverage. As of July 1, 2021, the waiver of retroactive coverage will not apply to beneficiaries who are pregnant and/or under age 21. TennCare III Waiver List at 2.

122. 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.

123. TennCare III also includes several new components, as described in detail below.

Aggregate Cap and Shared Savings

124. TennCare III will operate under what CMS has labeled an "aggregate cap." *See* TennCare III Approval Letter at 4. For the first five years of the project, the amount of the cap is based on Medicaid enrollment and expenditures from 2019, increased for inflation using the President's budget trend rate. TennCare III STCs at 104–05. If enrollment in any given year is 1% above or below the baseline level, CMS will adjust the cap to reflect actual enrollment. *Id.* For the second five years of the project, CMS will adjust the cap to reflect actual expenditures from 2021 to 2025. *Id.* at 105.

125. This aggregate cap means that Tennessee is at financial risk if: (1) enrollment is between 0% and 1% higher than the baseline level; and/or (2) per-member-per-month costs rise faster than inflation.

126. If Tennessee's costs exceed the aggregate cap, the State will not receive federal reimbursement for the excess amount. *Id.*; TennCare III Approval Letter at 12; *see also* TennCare III STCs at 105. If that occurs, Tennessee will receive an FMAP for its expenditures on medical assistance that is lower than the FMAP Congress has required in 42 U.S.C. § 1396b.

127. If the State underspends the aggregate cap in any given year, it can "earn" up to 55% of the federal savings achieved. TennCare III Approval Letter at 5, 6; TennCare III STCs at 58.

128. The State is prohibited from using the savings on Medicaid items or services covered under the state plan. TennCare III STCs at 57. Instead, the approval directs the State to spend the savings on "Designated State Investment Programs" (DSIPs), as specified in the STCs. *See id.* at 57, 209–10. Nothing in the STCs prevents Tennessee from using the additional federal funding to supplant current state funding for DSIPs.

129. CMS claimed that the new financing structure is likely to promote the objectives of the Medicaid Act by allowing the State to "better manage its limited resources in such a way that may result in achieving savings, which in turn can be used to pay for expanded state health programs …." TennCare III Approval Letter at 10. These state health programs, CMS asserted, could "improve health outcomes and increase the efficiency and quality of care that Medicaid beneficiaries and similar populations receive." *Id.*; *see also id.* at 7.

130. In the approval, CMS acknowledged that Section 1115 does not give it the authority to alter the federal Medicaid matching rate set forth in § 1396b. *Id*. at 11. *See also* Letter from Seema Verma, Adm'r, CMS, to Dave Richard, Deputy Sec'y for Medical Assistance, N.C. Dep't of Health & Human Servs. 6 (Oct. 19, 2018), https://bit.ly/32z2H26 (asserting that Section 1115 does not allow alteration of the federal matching rate).

131. CMS also stated that "[w]hile TennCare III is not [a Healthy Adult Opportunity] demonstration as set forth in the Secretary's January 30, 2020 State Medicaid Director Letter, it provides Tennessee with some similar flexibilities in exchange for managing its program under a funding ceiling and assuming some financial risk." TennCare III Approval Letter at 4; *see also id*. at 6 (noting that the Healthy Adult Opportunity initiative "provided for a new opportunity to use a portion of savings for existing state-funded health programs when quality metrics were met" and CMS "extended similar [Healthy Adult Opportunity] policy principles to this approval for DSIP").

See also Letter from Seema Verma, Adm'r, CMS, to President Trump at 3 (Jan. 14, 2021) ("Just this month, the state of Tennessee became the first state CMS approved for a block grant funding structure, using our innovative proposal early last year as a conceptual foundation.").

Limiting Coverage of Prescription Drugs: Closed Formulary

132. The TennCare III approval allows Tennessee to implement a prescription drug formulary for beneficiaries age 21 and over that does not comply with the requirements in 42 U.S.C. § 1396r-8. TennCare III Approval Letter at 5–6. Generally, consistent with the Essential Health Benefits requirements, the State's formulary can exclude drugs as long as it covers the greater of: (1) one drug in each United States Pharmacopeia category and class; or (2) the same number of drugs in each category and class as the Essential Health Benefits benchmark plan. TennCare III STCs at 82.

133. There are exceptions. Tennessee must cover all FDA-approved drugs to treat opioid use disorders. *Id.* The State must comply with the Medicare Part D requirement to cover "substantially all" drugs in six classes. *Id.*

134. The State must establish a process for beneficiaries to request coverage for drugs that are not on the formulary when clinically appropriate. *Id.* at 83.

135. Despite not covering prescription drugs as required under Section 1396r-8, Tennessee will continue to receive rebates from manufacturers as set forth in the Medicaid Act. TennCare III Approval Letter at 5–6; TennCare III STCs at 83.

136. In 2018, CMS denied Massachusetts's request to implement a closed formulary. *See* Letter from Tim Hill, Acting Dir., Ctr. for Medicaid & CHIP Servs., to Daniel Tsai, Assistant Sec'y, Mass Health, at 2 (June 27, 2018). CMS indicated at that time that a state would only be

permitted to adopt a closed formulary if the state agreed to forgo the rebates available under § 1396r-8 and negotiate prices directly with manufacturers. *Id.*

137. In approving TennCare III, CMS did not acknowledge its existing policy on this issue and did not provide a rationale for its change in position.

138. In approving TennCare III, CMS did not offer any reasoning to explain how restricting coverage of prescription drugs is experimental or likely to promote the objectives of the Medicaid Act.

Waiving Reasonable Promptness and Comparability for New Eligibility Groups or Services

139. The TennCare III approval authorizes Tennessee to ignore the Medicaid Act's requirements for reasonable promptness and comparability if it chooses, at some unspecified time over the next 10 years, to cover Medicaid populations and/or services that it did not cover as of December 31, 2020. TennCare III Approval Letter at 5; CMS, Expenditure Authority at 4, 9, 10. This means that if the State decides to cover a new eligibility group, it is free "to limit the [eligibility] group and vary the benefit package from the state plan." TennCare III Approval Letter at 5; *see* CMS, Expenditure Authority at 4, 9, 10.

140. In approving TennCare III, CMS did not attempt to explain how granting a blanket waiver of the reasonable promptness and comparability requirements for unspecified optional populations and/or services already described by the Medicaid Act is permissible under Section 1115.

141. CMS only made a general statement that the "administrative flexibility" could enable the State to more quickly "respond to changes in demographics, economic conditions, or emerging public health issues." TennCare III Approval Letter at 5.

142. CMS's TennCare III Approval Letter did not mention the COVID-19 public health emergency or its effect on Medicaid enrollment, Medicaid spending, or the health of Medicaid beneficiaries.

F. Effects of the TennCare III Approval on the Plaintiffs

143. Tennessee, and its contracting managed care plans, have repeatedly failed to provide the thirteen Plaintiff Medicaid beneficiaries with access to medically necessary services. By continuing the managed care program, introducing the aggregate cap and shared savings financing scheme, and permitting the State to impose additional limits on prescription drug coverage, the TennCare III approval will only intensify the harm that these beneficiaries have suffered.

144. The TennCare III approval rewards Tennessee for reducing its Medicaid spending on covered services. To do that, Tennessee will have to reduce the capitated rates paid to MCOs and TennCare Select. The managed care plans, in turn, will have two principal avenues to cut their costs under TennCare III: reduce the amount paid to providers for covered services or further restrict enrollee utilization of covered services.

145. Either path will harm frail enrollees with the greatest medical need and highest costs, including the Plaintiff Medicaid beneficiaries. Lowering provider reimbursement rates will discourage providers, including specialists, from treating TennCare patients and erode the already grossly inadequate managed care provider networks. Inadequate 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 Plaintiffs.

146. Permitting managed care plans to apply more stringent utilization controls will also cause enrollees to lose access to covered services. Tennessee already grants plans broad discretion

to deny care prescribed by an enrollee's treating provider by finding that it is not medically necessary. As illustrated by the Plaintiff Medicaid beneficiaries' experiences, the plans frequently (and erroneously) determine that a less costly service—or no service at all—is adequate. Because aggressive utilization controls are costly to administer, and therefore only produce net savings if reserved for the most expensive services, the TennCare III approval will disproportionately harm enrollees with disabilities, including the Plaintiff Medicaid beneficiaries, none of whom were given the opportunity to comment on the TennCare III project as required.

Brylee McCutchen

147. Plaintiff Brylee McCutchen is 20 years old and lives in Hendersonville, Tennessee with his parents Brandi and Jody McCutchen.

148. Brylee was diagnosed with severe cerebral palsy shortly after he was born. He has also been diagnosed with scoliosis. He has a gastronomy tube ("G-tube") and a tracheostomy. He is unable to walk, communicate verbally, clear his airway, or perform any activities of daily living.

149. Brylee must be monitored continually by skilled nurses to ensure that his G-tube is not displaced by a spasm, to monitor the operation of his baclofen pump, which was surgically implanted in his stomach and helps reduce spasms, and to monitor his venting and feeding to prevent aspiration. Failure to immediately detect and respond to such events could be fatal. In addition, his baclofen pump has to be filled every three months and replaced every five years. If the pump fails and the family does not hear the internal alarm to rush him to the hospital, it could be fatal.

150. Because Brylee can only communicate pain by grimacing, continuous skilled nursing care is required to monitor his facial expressions and spasms at all times to determine when he needs pain medication. If he does not receive pain medication when needed, his oxygen

saturation decreases while his heart rate and body temperature increase. He must be hospitalized when this happens.

151. Brylee must be repositioned at least every two hours to keep his skin from breaking down and to preserve motility in his lungs. He has a history of skin breakdowns from being hospitalized, and private duty nursing ("PDN") care has helped to maintain his skin integrity and prevent infection.

152. Due to his severe disabilities, Brylee has received SSI benefits and been enrolled in TennCare since 2006. TennCare has assigned him to TennCare Select.

153. Since 2006, TennCare Select has covered full-time, or 168 hours per week, of PDN care for Brylee. His physician wrote a renewal order for Brylee to continue receiving 168 weekly hours of skilled care for 52 weeks starting February 27, 2020. Since TennCare Select has acknowledged the medical necessity of 24/7 nursing care for so long, and Brylee's condition only worsens with age, approval of the continued care should have been routine.

154. On June 19, 2020, TennCare Select sent a letter to Brylee's mother informing her that, as of June 29, 2020, it was reducing his PDN care to 20 hours per day (140 hours per week) because the care he was receiving was no longer medically necessary.

155. Brandi filed an appeal on her son's behalf on June 29, 2020. On July 17, 2020, TennCare Select sent Brandi a letter continuing to deny the 168 hours per week ordered by her son's physician but increasing its authorization from 140 to 150 hours per week.

156. In response to Brandi's appeal, TennCare arranged for a Nashville obstetrician-gynecologist to review TennCare Select's denial of continuous PDN care. The consultant ratified the denial, observing that Brylee's parents could meet his needs during the 18 hours each week when skilled nurses would no longer be available. Neither of Brylee's parents have any nursing

training. The reduction in Brylee's PDN care has been delayed due to the COVID-19 pandemic, but is expected to take effect once the public health emergency ends.

157. Brylee'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. Brylee's health care is highly expensive. CMS's approval of TennCare III harms him because it will cause the State to further reduce the quality and sufficiency of his care. CMS's approval of TennCare III also harms Brylee because it deprives him of freedom of choice of providers and continues to subject him to managed care contractors' efforts to deny coverage for medically necessary care.

158. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived Brylee and his mother, Brandi, of the opportunity to have their objections to the project considered.

Binta Barrow

159. Plaintiff Binta Barrow, who is 25 years old, lives with her mother, Sadiatou Jallow, in Knoxville, Tennessee.

160. Binta has been diagnosed with Dandy-Walker syndrome, a rare congenital brain malformation. She is blind and non-ambulatory, and she has frequent seizures. Binta's extremely fragile condition will never improve and is gradually declining with age.

161. Binta has been receiving SSI since 2000. She is enrolled in TennCare and is assigned to TennCare Select.

162. TennCare Select is currently supposed to provide 126 hours per week of PDN care and 72 hours per week of home health aide care for Binta.

163. However, TennCare Select has routinely failed for more than a decade to adequately staff the shifts it is paid to cover.

164. Sadiatou has a serious heart disease and is unable to lift Binta. In January 2018, when one of many missed shifts left Sadiatou to try to care for her daughter by herself, the exertion exacerbated her heart condition, requiring her emergency hospitalization for several days.

165. On April 26, 2019, a TennCare representative and two TennCare Select representatives went to Sadiatou's home. An assessment just the previous year had confirmed the medical necessity of the nursing care that Binta's doctors prescribed and the reality that her condition would never improve. Still, the official visitors were there to re-evaluate Binta's condition to determine whether the level of nursing care was still medically necessary. They confirmed that Binta still required the prescribed level of care, but TennCare Select still failed to reliably provide it.

166. By July 16, 2020, no certified nurse assistant was providing night coverage for Binta. Sadiatou was forced to stay up for the entire night every day of the week to care for her. In a letter dated July 2, 2020, TennCare Select informed Sadiatou that it would not be able to staff those shifts for another month. This letter became a template, with the health plan writing at the beginning of each month to inform Sadiatou that the shifts would remain unstaffed for the next month. The Tennessee Justice Center continued to report these lapses to TennCare's General Counsel.

167. On August 2, 2020, Binta was hospitalized due to aspiration pneumonia. The hospital staff doubted she would survive. Fortunately, she recovered and was sent home with oxygen treatment that required even more careful monitoring than she was already receiving. However, she continued to go without certified nurse assistant care during the night.

168. That same month, under the physical and emotional strain of trying to care for her daughter without the necessary PDN or home health care, Sadiatou's heart disease worsened.

169. On September 10, 2020, TennCare Select wrote to Sadiatou that it would not be able to provide the full 72 hours of home health aide care for Binta until October 21, 2020. On October 21, 2020, TennCare Select wrote to Sadiatou that it would not provide the full 72 hours of home health aide care for Binta until December 2, 2020.

170. On January 25, 2021, after complaints by the Tennessee Justice Center to TennCare's General Counsel, a TennCare Select manager assured Sadiatou that, going forward, nursing shifts would be fully staffed. However, multiple shifts remained unstaffed as of April 20, 2021. When nurses are not present, Binta cannot be moved from her bed; being immobile for hours on end causes her pain and even seizures.

171. Binta's disabling, chronic conditions will not go away or improve. Yet, she has experienced repeated efforts on TennCare's behalf to reduce her services. Her care is highly expensive and has been targeted for cuts by TennCare Select. CMS's approval of TennCare III harms Binta because it will cause the State to further reduce the quality and sufficiency of her care. CMS's approval of TennCare III also harms Binta 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.

172. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived Binta and her mother of the opportunity to have their objections to the project considered.

M.A.C.

173. Plaintiff M.A.C., who is 17 years old, lives in Clarksville, Tennessee, with her parents, M.C. and R.C. Her parents have cared for M.A.C. since she was 7 years old, when the Tennessee Department of Children's Services ("DCS") placed M.A.C. and her siblings with them as foster parents. Her parents formally adopted M.A.C. when she was around 10 years old.

174. M.A.C. is diagnosed with cerebral palsy, diabetes, and multiple chronic medical conditions as well as severe developmental delays. She is nonverbal, non-ambulatory, and requires constant nursing care and assistance with all activities of daily living. Her medical care is directed at preventing deterioration in her health.

175. M.A.C. is enrolled in TennCare and is assigned to the Amerigroup MCO.

176. Approximately two years ago, when M.A.C. was 15 years old, her MCO cut coverage of her PDN services from 80 hours to 50 hours per week. The reduction in services occurred even though there had been no improvement in her medical conditions.

177. From August 2020 until early January 2021, the MCO did not provide any of the 50 hours per week of approved PDN services. M.A.C. is locked into her MCO's provider network; however, her mother and care coordinators were unable to find skilled nurses to care for M.A.C. M.A.C.'s mother, who is not trained or licensed as a nurse, had to try to provide all of M.A.C.'s care for five months with help from other untrained family members.

178. Only after M.A.C.'s parents obtained the Tennessee Justice Center's assistance in pursuing an appeal to an administrative hearing did Amerigroup restore her PDN services, and it has provided her 50 hours per week since January 4, 2021.

179. On March 22, 2021, the MCO again could not find staff for M.A.C.'s PDN services. Her mother, M.C., is again providing all of M.A.C.'s care.

180. M.A.C.'s disabling, chronic health conditions will not go away. M.A.C. has experienced repeated efforts on TennCare's behalf to reduce her services even though her disabling conditions have not improved. M.A.C.'s care is highly expensive. CMS's approval of TennCare III harms M.A.C. because it will cause the State to further reduce the quality and sufficiency of her care. CMS's approval of TennCare III also harms M.A.C. 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.

181. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived M.A.C. and her parents of the opportunity to have their objections to the project considered.

Amira Cofer

182. Plaintiff Amira Cofer is 21 years old. She lives in Emory Gap, Tennessee, with her mother, Melanie Cofer.

183. When she was 18 years old, Amira sustained a traumatic brain injury in a car accident. She is quadriplegic and has dystonia, a progressive condition involving uncontrolled muscle contractions. Amira is nonverbal, requires tube feeding, is incontinent of bowel and bladder, and requires constant hands-on assistance to meet her needs.

184. Amira has received TennCare since 2018. She was initially enrolled in Amerigroup and then changed to TennCare Select when she was transferred to a nursing home.

185. In the fall of 2019, Melanie planned to take Amira out of the nursing home. To meet Amira's medical needs, her physician ordered full-time, or 168 hours per week, in-home PDN services.

186. In October 2019, TennCare Select refused to cover the full 168 hours of PDN, claiming that only half that amount was medically necessary. Melanie filed an appeal in December 2019.

187. While her appeal was pending, Amira received three notices from TennCare, one stating that she had been reassigned to the Amerigroup MCO; another stating she had been reassigned to the BlueCare MCO; and yet another stating she had been reassigned to the UnitedHealthcare MCO. Melanie called the TennCare call center to object. Despite the difficulties she was having in getting TennCare Select to meet Amira's needs, she was afraid that Amira would face even greater obstacles to care if she were moved to an MCO.

188. Shortly thereafter, Amira's MCO terminated coverage of her incontinence supplies. In response to persistent objections by Melanie and the supplies vendor, TennCare restored that coverage.

189. TennCare subsequently denied her request for an administrative hearing and unilaterally closed the appeal challenging the denial of PDN services.

190. After Melanie obtained the assistance of the Tennessee Justice Center, TennCare reopened the appeal of the refusal to fully cover Amira's PDN. TennCare offered to cover 104 hours of PDN services per week, and Melanie reluctantly agreed to this offer to get more care in the home as quickly as possible. TennCare refused to switch Amira back to TennCare Select.

191. In August 2020, the evening before Amira's appointment to receive routine Botox injections, which treat her spasticity and contractures, the neurologist's office called Melanie to

cancel the appointment. They stated that they were having difficulty confirming payment for their services by the TennCare MCO. On March 10, 2021, Melanie was notified by the neurologist's office that they were no longer accepting TennCare patients. Amira relies on the neurologist for her wheelchair needs and muscle relaxers to treat her seizures.

192. Amira's disabling, chronic health conditions will require ongoing and consistent treatment, yet her managed care plans have repeatedly reduced her services. Amira's health care is highly expensive. CMS's approval of TennCare III harms her because it will cause the State to further reduce the quality and sufficiency of her care. CMS's approval of TennCare III also harms Amira 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.

193. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived Amira and her mother, Melanie, of the opportunity to have their objections to the project considered.

J.T.

194. Plaintiff J.T. is eleven 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.

195. 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.

196. J.T. is enrolled in TennCare.

197. 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.

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

199. 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.

200. 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.

201. 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.

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

203. 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.

204. 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 him because it will cause the State to further reduce the quality and sufficiency of his care. CMS's approval of TennCare III also harms J.T. because it continues to subject him to managed care contractors' efforts to deny coverage for medically necessary care.

205. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived J.T. and his grandmother of the opportunity to have their objections to the project considered.

G.H.

206. Plaintiff G.H. is 9 years old. He lives in Powell, Tennessee with his mother, D.H., and his father and three siblings.

207. G.H. suffers from spinal muscular atrophy - type 2 (a neuromuscular disorder that leads to progressive muscle weakness), focal seizures, and other debilitating medical conditions. He is wheelchair bound and requires extensive PDN and personal attendant ("PA") services. Because of his severe disabilities, G.H. receives SSI.

208. G.H. has been enrolled in TennCare since shortly after he was born, and throughout that period, has been assigned to TennCare Select.

209. G.H.'s physician has prescribed 70 hours of PDN services per week for him. Among other things, a skilled nurse is needed to assist with percussion (cough assist), nebulizer, medications, and seizure intervention.

210. Since January 2016, TennCare Select has failed to fully staff G.H.'s prescribed PDN. As a result, TennCare Select has subjected G.H. to recurrent interruptions of his prescribed care, which have resulted in recurrent hospitalizations.

211. G.H.'s disabling, chronic health conditions will not go away. Yet, TennCare Select has repeatedly reduced his services even though his conditions have not improved. G.H.'s health care is highly expensive. CMS's approval of TennCare III harms G.H. because it will cause the State to further reduce the quality and sufficiency of his care. CMS's approval of TennCare III also harms G.H. because it deprives him of freedom of choice of providers, locking him into TennCare contractors' provider networks that are inadequate to safely and reliably meet his medical needs.

212. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived G.H. and his mother, D.H., of the opportunity to have their objections to the project considered.

K.M.

213. Plaintiff K.M. is a 7-year-old child who lives with his parents, W.M. and L.M., in Christiana, Tennessee.

214. K.M. has been diagnosed with Cornelia de Lange syndrome, a rare genetic developmental disorder, as well as a seizure disorder. K.M. has a tracheostomy, requires mechanical ventilation, and is fed through a gastrostomy tube. He is incontinent of bowel and bladder and needs help to transfer and change positions. K.M. also has a chronic pseudomonas lung infection, which requires the frequent use of inhaled antibiotics, breathing treatments, and chest percussions.

215. K.M. has required continuous bedside care by skilled nurses since he was born. In addition to ongoing assistance with all activities of daily living, nurses must constantly monitor his oxygen levels and heart rate. As the need arises, which can be several times a day at

unpredictable intervals, K.M.'s nurses must intervene immediately to suction his tracheostomy and to administer oxygen and breathing treatments.

216. When his parents adopted K.M. on July 31, 2018, he was receiving 24/7 skilled nursing care. W.M. and L.M. are foster parents to one child and have adopted another child, both of whom have special needs and require a similar level of care as K.M.

217. K.M. has been enrolled in TennCare since birth and is assigned to TennCare Select.

218. On March 19, 2020, K.M.'s physician submitted an order to TennCare Select for K.M. to continue receiving full-time PDN care, for a total of 168 hours per week, for the next 52 weeks. Since K.M.'s condition and well-documented nursing needs will never improve, reauthorization of his nursing care should have been routine.

219. L.M. works for Maxim, the home health agency that contracts with TennCare Select to provide K.M.'s nursing services. On September 24, 2020, she learned from her employer that TennCare Select planned to reduce K.M.'s paid nursing hours from 168 to 120 hours per week.

220. TennCare Select sent notice of the change to the wrong address. When K.M.'s parents finally received the notice on October 13, 2020, L.M. filed an appeal that same day. She was told that the appeal was too late to enable her to maintain K.M.'s prescribed level of care pending the appeal and that the reduction in hours would therefore go into effect.

221. Desperate, L.M. pled with TennCare Select to maintain K.M.'s coverage until it could be reviewed on appeal. She pointed out that the other two children in the household also have complex medical needs and that she and her husband could not safely care for K.M. without the continuous help of nurses. On November 5, 2020, after further haggling with L.M., TennCare Select agreed to allow K.M. to have 140 hours per week of skilled care pending the appeal.

222. On November 23, 2020, a representative of Vanderbilt Children's Hospital telephoned TennCare Select to plead for restoration of K.M.'s nursing hours. In December 2020, three pediatric specialists from Vanderbilt Children's Hospital wrote separate, detailed letters to TennCare explaining why continuous nursing care is an absolute medical necessity for K.M.

223. L.M. was referred to the Tennessee Justice Center, and on December 4, 2020, TJC sent a letter to TennCare's General Counsel. On December 9, TennCare directed TennCare Select to restore K.M. to 168 hours of weekly nursing coverage until the disposition of the appeal, which is currently pending.

224. K.M.'s disabling, chronic health conditions will not go away. Yet, his managed care plan has repeatedly reduced his services even though his conditions have not improved. K.M.'s health care is highly expensive. CMS's approval of TennCare III harms him because it will cause the State to further reduce the quality and sufficiency of his care. CMS's approval of TennCare III also harms K.M. because it continues to subject him to managed care contractors' efforts to deny coverage for medically necessary care and deprives him of freedom of choice of providers, locking him into TennCare contractors' provider networks that are inadequate to safely and reliably meet his medical needs.

225. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived K.M. and his mother, L.M., of the opportunity to have their objections to the project considered.

A.G.W.

226. Plaintiff A.G.W. is ten 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.

227. 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.

228. 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.

229. 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.

230. 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.

231. 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.

232. 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 AG.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.

233. 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.

234. 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.

235. 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. continues to receive the level of care prescribed by her physician while her mother's appeal of the reduction is pending. A.G.W.'s neurologist has provided more detailed documentation of the severity of A.G.W.'s seizure disorder and need for medication, as well as the frequency of feedings and G-tube flushes. TennCare Select is pressing forward to reduce her care.

236. 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 her because it will cause the State to further reduce the quality and sufficiency of her care. CMS's

approval of TennCare III also harms A.G.W. because it continues to subject her to managed care contractors' efforts to deny coverage for medically necessary care.

237. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived A.G.W. and her mother, J.A.W., of the opportunity to have their objections to the project considered.

A.M.W.

238. A.M.W. is a 14-year-old child who lives with her father, J.K.W., who is her primary caregiver, in Greeneville, Greene County, Tennessee.

239. 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.

240. 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.

241. 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.

242. 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.

243. 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.

244. 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 her because it will cause the State to further reduce the quality and sufficiency of her care. CMS's approval of TennCare III also harms A.M.W. because it continues to subject her to managed care contractors' efforts to deny coverage for medically necessary care.

245. By approving the TennCare III project for a ten-year period without following the requirements for public notice and comment, CMS deprived A.M.W. and her father, J.K.W., of the opportunity to have their objections to the project considered.

N.P.

246. Plaintiff N.P. is ten 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.

247. NP. is diagnosed with cerebral palsy, developmental delays, and a seizure disorder.

248. 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.

249. 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.

250. 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.

251. 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.

252. 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.

253. 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.

254. 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.

255. 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.

256. 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.

257. 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 her because it will cause the State to further reduce the quality and sufficiency of her care. CMS's approval of TennCare III also 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.

258. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived N.P. and her mother, T.A., of the opportunity to have their objections to the project considered.

Jonathan Riccardi

259. Plaintiff Jonathan Riccardi is a 40-year-old Tennessee resident who has been receiving care in a neurorestorative facility in Carbondale, Illinois since 2004. His parents, John and Susan Riccardi, live in Shelby County, Tennessee.

260. Jonathan has pervasive developmental disability, neurological impairment, acquired brain injury, and mental illness.

261. Due to his severe disabilities, Jonathan received SSI until 2020, when his father retired.

262. Jonathan has been enrolled in TennCare since 2001. He has been enrolled in the BlueCare MCO, and is currently enrolled in TennCare Select.

263. Jonathan needs 24-hour-per-day, seven-day-per week supervision and supports with his activities of daily living. For more than fifteen years, his treating physicians have determined that the neurorestorative facility in Illinois is the only facility capable of safely caring for Jonathan.

264. Jonathan has faced recurrent threats to terminate coverage of the specialized residential care he has received in Illinois. By 2006, Jonathan had received at least four denials from BlueCare for his residential care. In 2010, BlueCare threatened to deny continued residential treatment and put pressure on the family to transfer Jonathan to a Tennessee facility. In the past, BlueCare was approving Jonathan's treatment monthly, but at that point started approving his services for 10 days only. In 2019, BlueCare again attempted to deny continued services. With each denial, the Riccardi family obtained legal counsel, who was able to preserve Jonathan's necessary services.

265. In November 2019, shortly before the coronavirus pandemic began, TennCare switched Jonathan from BlueCare to TennCare Select. TennCare Select has also pursued efforts to transfer Jonathan to a lower cost facility in Tennessee. That effort has been paused because of the pandemic, but due to their interactions with TennCare Select, the Riccardi family lives in constant fear that any interaction with TennCare Select will lead to another denial, and that efforts to deny his care will resume in earnest when the pandemic ends.

266. Jonathan's disabling, chronic health conditions will not go away. Yet, his managed care plans have repeatedly tried to reduce his services even though his conditions have not improved. Jonathan's health care is highly expensive. CMS's approval of TennCare III harms him because it will cause the State to further reduce the quality and sufficiency of his care. CMS's approval of TennCare III also harms Jonathan because it deprives him of freedom of choice of providers and subjects him to managed care contractors' efforts to deny coverage for medically necessary care.

267. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and

comment, CMS deprived Jonathan, and his father, John, of the opportunity to have their objections to the project considered.

Casey Sizemore

268. Plaintiff Casey Sizemore is 36 years old. She lives in Arlington, Tennessee, with her mother, Trina Sizemore, who is a registered nurse.

269. Casey was born with a difficult delivery that resulted in a brain injury. She is diagnosed with cerebral palsy, intellectual disabilities, and seizures. She breathes through a tracheostomy and is fed through a gastrostomy. She also requires constant visual supervision, frequent suctioning, and medication.

270. Casey has been enrolled in TennCare since 2005. TennCare enrolled her in the UnitedHealthcare MCO.

271. In 2005, when Casey was 20 years old, TennCare agreed to cover full-time, or 168 hours per week, of private duty nursing care. There has been no improvement in her condition or lessening of her medical needs since then.

272. In 2014, when Casey was 29 years old, UnitedHealthcare notified Trina that it was cutting Casey's PDN care to 98 hours per week and encouraged Trina to place her daughter in a nursing home. At that time, the MCO was not financially responsible for nursing home care for its enrollees. Trina appealed and, in May 2014, with the support of Casey's treating medical professionals, obtained a ruling that her daughter should continue to receive 168 hours of PDN weekly.

273. Just five months later, on October 28, 2014, UnitedHealthcare again informed Trina that it was cutting Casey's PDN hours. This time, the MCO cut the PDN more significantly, to 70 hours per week, thus intensifying pressure on Trina to place her young daughter in a nursing home.

Again, Trina appealed and was able to get a continuation of benefits for Casey during the appeal. After the Tennessee Justice Center communicated with the Tennessee Attorney General's office on her behalf, UnitedHealthcare was directed to continue 24/7 PDN.

274. In October 2018, UnitedHealthcare again informed the Sizemores that Casey's PDN coverage would be cut to 70 hours per week. As with previous occasions when the MCO was attempting to cut services, Casey's underlying conditions and medical needs had not changed.

275. Casey '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. Casey's health care is highly expensive. CMS's approval of TennCare III harms her because it will cause the State to further reduce the quality and sufficiency of her care. CMS's approval of TennCare III also harms Casey 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.

276. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived Casey and her mother, Trina, of the opportunity to have their objections to the project considered.

M.S.

277. Plaintiff M.S. is two 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.

278. 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.

279. M.S. is enrolled in TennCare. 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.

280. 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.

281. 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.

282. 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.

283. 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 her because it will cause the State to further reduce the quality and sufficiency of her care. CMS's approval of TennCare III also 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.

284. By approving the TennCare III project, including mandatory enrollment in managed care, for a ten-year period without following the requirements for public notice and comment, CMS deprived M.S. and her mother, A.S., of the opportunity to have their objections to the project considered.

Suzanne Berman, M.D.

285. 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.

286. 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.

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

288. The aggregate cap and shared savings component of TennCare III also harms Dr. Berman. As noted above, the new financing structure will cause TennCare to cut Medicaid costs at the expense of providers. Such cuts directly threaten Dr. Berman's personal income. They will also increase her administrative costs by further diminishing the number of specialists willing to accept her referrals of patients enrolled in TennCare.

289. Dr. Berman is also harmed by the waiver permitting Tennessee to adopt a "commercial-style" closed formulary. Dr. Berman and her colleagues have extensive experience conforming their prescribing practices to TennCare's current formulary and to the varied formularies of commercial insurers. Because commercial insurance formularies are designed for patient populations that are generally healthier than the adult population enrolled in TennCare, it will be more difficult to meet her disabled adult patients' needs within the constraints of TennCare's planned commercial-style formulary. Dr. Berman and her administrative staff will have to spend more time adjusting their adult patients' drug regimens and working through exceptions and appeal processes to enable the patients to receive medically necessary medications not covered by the new formulary. One member of her staff already devotes half of their time to dealing with TennCare formulary paperwork and the failure of TennCare's current formulary to take into account the special medication needs of disabled patients. The TennCare III approval will require Dr. Berman and her staff to divert more of their time from treating patients to finding TennCare formulary workarounds for their patients. Dr. Berman also expects the waiver to

increase her administrative costs in another way. By increasing what Tennessee physicians describe as the "TennCare hassle factor"—the bureaucratic obstacles and administrative burdens erected by the State and its managed care contractors—the closed formulary will further discourage specialists from accepting Dr. Berman's referrals of TennCare patients.

290. By approving the TennCare III project for a ten-year period without following the requirements for public notice and comment, CMS deprived Dr. Berman of the opportunity to have her objections to the project considered, including specifically its formulary provisions and the waiver of retroactive eligibility for adults.

Tennessee Justice Center, Inc.

291. Plaintiff Tennessee Justice Center has focused since its founding on the representation of clients in matters involving public benefits programs that serve low-income residents of all 95 of Tennessee's counties. For 25 years, these priorities have led TJC to pursue its mission by devoting most of its resources to advocacy and representation related to TennCare. The program is of crucial importance to vulnerable adults, families, and children in Tennessee, ranked 40th in health care, with the second highest rate of rural hospital closings in the nation.

292. TennCare is by far the largest public benefits program serving low-income Tennessee residents. With over 1.5 million beneficiaries, TennCare provides health coverage to 22% of Tennesseans. TennCare covers half of all Tennessee children, from prenatal care to adulthood. The program funds 60% of nursing home care and home and community-based services ("HCBS") for the frail elderly, as well as the overwhelming majority of institutional care and HCBS for Tennesseans with intellectual or developmental disabilities. In a state that has been especially hard hit by the opioid epidemic, TennCare serves as the principal source of coverage for addiction treatment.

293. The scope and importance of TennCare's role in serving vulnerable families and children has led TJC, in the pursuit of its mission to advocate for vulnerable Tennesseans, to devote a majority of its resources to advocacy that seeks to ensure the State's compliance with federal Medicaid requirements in the administration of the TennCare program.

294. The importance of TennCare advocacy to the fulfillment of TJC's mission is also reflected in the case acceptance policies that govern its selection of individual cases from among countless queries and prayers for assistance. Those priorities mean that most TJC clients have been individuals or families seeking TennCare coverage to meet urgent medical needs. In 2020, TJC handled 725 cases involving TennCare eligibility or coverage disputes.

295. In a significant number of TJC's TennCare eligibility cases, the effective date when an applicant's coverage begins, and whether TennCare will therefore cover major medical bills, is a principal issue. These disputes arise because the TennCare project has, since its inception, included a waiver of retroactive eligibility. In contrast to other states, Medicaid coverage in Tennessee does not take effect until on or after the date an individual applies for Medicaid.

296. The waiver of retroactive coverage results in individuals incurring catastrophic medical debts. Such debts often make it difficult or impossible for individuals to obtain care, since Tennessee medical practices typically refuse to treat patients, even if they currently have health coverage, until they pay all or a substantial part of their previously incurred balance. To mitigate these effects of the waiver of retroactive eligibility on its clients, TJC is required to expend significant resources on legal disputes about the effective date of coverage. The waiver of retroactive eligibility requires TJC to expend resources assisting and educating clients about applying for hospitals' charity care programs, which, unlike TennCare's comprehensive coverage, leave most patients still saddled with major medical debts. The waiver undermines TJC's capacity

to effectively protect clients from crushing medical debt and its consequences, which can lead to evictions, moves, and family instability that themselves have adverse health effects.

297. The waiver of retroactive eligibility has significantly limited TJC's success in encouraging health care providers to assist patients in applying for TennCare, as providers have little incentive to seek TennCare coverage for vulnerable patients who have already incurred medical bills that would not be paid by the program in any event. This, in turn, necessarily has an adverse effect on the scope of medical care that providers are willing to, and do, provide.

298. As part of its mission of promoting the availability of health coverage for its clients, TJC frequently submits comments to state and federal policymakers on pending health care initiatives and coordinates the submission of comments by interested members of the public. When Tennessee proposed Amendment 42 to TennCare II, TJC mounted an advocacy campaign to inform the public about the proposal and encourage the submission of public comments to CMS in opposition. TJC also submitted a comment on its own behalf in opposition to the amendment.

299. In November 2020, Tennessee posted for public comment a draft application to extend TennCare II, which was scheduled to expire June 30, 2021. TJC analyzed the proposal and identified the following provisions of the draft application as issues of particular concern: (a) renewal of the waiver of retroactive eligibility; (b) the mandatory enrollment of children with special health care needs in MCOs that are fully at financial risk; and (c) extension of the project for ten years.

300. TJC planned to mount a vigorous campaign in opposition to these features of Tennessee's proposal to extend its TennCare II project, in the same manner as it had done in opposition to previous requests to amend or extend TennCare, to encourage the submission of

comments to CMS and to submit its own comments during the federal public notice and comment period.

301. By approving the TennCare III project for a ten-year period without following the requirements for public notice and comment, CMS deprived TJC of the opportunity to have its objections to the project considered. As a result of the approval, TJC will need to devote more of its resources to provide services to its clients who are affected by TennCare III's continuation of the waiver of retroactive coverage. TJC will have to prepare for and participate in protracted hearings and appeals addressing coverage. In addition, approval of the closed formulary will require TJC to spend additional resources ensuring that clients can access the prescription drugs that they need.

302. The ten-year approval will increase the time and expenses of TJC's representation of vulnerable Tennesseans with respect to their health care claims, as well as the costs and expenses of educating both TennCare enrollees and providers.

COUNT ONE: VIOLATION OF ADMINISTRATIVE PROCEDURE ACT (ACTION IN EXCESS OF STATUTORY AUTHORITY)

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

304. 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).

305. CMS exceeded its statutory authority in approving TennCare III as a demonstration project under Section 1115 of the Social Security Act by waiving and/or allowing the State to ignore provisions outside of 42 U.S.C. § 1396a.

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

COUNT TWO: VIOLATION OF ADMINISTRATIVE PROCEDURE ACT (ARBITRARY AND CAPRICIOUS AGENCY ACTION)

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

308. 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).

309. The TennCare III project is not an experimental, pilot, or demonstration project, nor is it likely to promote the objectives of the Medicaid Act.

310. In approving the TennCare III project, CMS relied on factors which Congress has not intended him to consider, entirely failed to consider several important aspects of the problem, offered an explanation for his decision that runs counter to the evidence, and failed to acknowledge or explain changes in agency position.

311. The approval of the TennCare III project was arbitrary and capricious and an abuse of discretion.

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

COUNT THREE: ABSENCE OF NOTICE AND OPPORTUNITY TO COMMENT

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

314. 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).

315. CMS may not approve or extend a Medicaid demonstration project under Section 1115 without first according the public notice of, and an opportunity to comment upon, a proposed project. CMS must provide "public notice and comment after the application is received by the Secretary, that is sufficient to ensure a meaningful level of public input." 42 U.S.C. § 1315(d)(2)(C). *See* 42 C.F.R. § 431.416 (requiring a 30-day comment period).

316. CMS did not observe these notice-and-comment requirements before approving the TennCare III project.

317. CMS did not provide a full 30-day comment period on Tennessee's request to amend the TennCare II project.

318. Members of the public, including the Plaintiffs, did not have any opportunity to comment on the extension of the existing features of the TennCare II project, including the waiver of retroactive eligibility and continuation of mandatory enrollment in managed care.

319. Moreover, because the project as approved, in important respects, was not a "logical outgrowth" of Tennessee's original proposal, CMS was obligated to reopen the comment period before proceeding to final approval.

320. CMS's approval of the TennCare III project, without observing the statutory and regulatory requirements for public notice and comment, was in excess of its Section 1115 waiver authority, and was arbitrary and capricious.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask that this Court:

1. Declare that Defendants' approval of TennCare III violates the Administrative Procedure Act and the Social Security Act in the respects set forth above;
2. Vacate Defendants' approval of TennCare III;
3. Enjoin Defendants from implementing the practice 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: April 22, 2021

Respectfully submitted,

/s/ Joel McElvain

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