UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UPSTATE NEW YORK TRANSPLANT SERVICES, INC. D/B/A CONNECTLIFE

Plaintiff,

v.

ROBERT FRANCIS KENNEDY JR.,
in his official capacity as Secretary of Health and Human Services

MEHMET OZ, M.D.
in his official capacity as Administrator of the Centers for Medicare and Medicaid Services,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

COMPLAINT

Civil Action No.:

Plaintiff, Upstate New York Transplant Services, Inc. d/b/a ConnectLife ("ConnectLife"), by its attorneys, Phillips Lytle LLP, for its Complaint against Defendants, Robert F. Kennedy, Jr., in his official capacity as Secretary of the Department of Health and Human Services (the "Secretary"), Dr. Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services (the "Administrator"), the Department of Health and Human Services ("HHS"), and the Centers for Medicare and Medicaid Services ("CMS"), alleges as follows.

INTRODUCTION

1. Organ donation decisions are among the most difficult choices any family can make. For more than forty years, ConnectLife has served the Western New York community by counseling families in times of crisis, and offering an opportunity to provide a lifesaving gift from an otherwise tragic loss. Organ donation does not lessen a family's grief, but it can be a tribute to the individual they have lost.

2. ConnectLife serves the community in this fashion as the designated Organ Procurement Organization ("OPO") for the eight counties of Western New York. ConnectLife is one of 55 OPOs operating across the country. These non-profit organizations play a key role in the organ donation system Congress established under 42 U.S.C. §§ 273 *et seq.*

3. Congress charged OPOs with arranging for the acquisition and preservation of donated organs, engaging in public education, and establishing relationships with local hospitals, transplant centers, and the Organ Procurement Transplantation Network ("OPTN"). *See* 42 U.S.C. § 273(b)(3)(A)-(K). OPOs thus serve as a central facilitator among donors, families, and healthcare providers, making life-saving decisions—often on an emergency basis.

4. In placing OPOs at the center of the organ donation system, Congress recognized the importance of community trust and local relationships, and the potentially deleterious effects of market forces in the organ procurement context. It mandated that each OPO operate in its own "donation service area" ("DSA"), and that only one OPO be designated for each DSA. 42 U.S.C. §§ 273(b)(1)(E), 1320b-8(b)(2).

5. While OPOs can be decertified if they fail to satisfy outcome and process criteria within their DSAs, the structure established by Congress does not force OPOs to battle against each other for territory. Instead, Congress recognized that donation decisions are best coordinated by local organizations with established relationships focused solely on saving lives. This system ensures that organ procurement efforts are pursued throughout the country, rather than clustering in major metropolitan areas or otherwise advantageous locations. Congress thus established a binary system, under which OPOs operate within a DSA and face decertification only if their performance—as measured within their DSA—is objectively unacceptable.

6. Through this system of local OPOs, the United States achieved an organ donation system that is the envy of the world. We have the highest organ donation rate of any country. The number of organs donated and lives saved has steadily climbed through the years. In 2024, OPOs facilitated more than 45,000 organ transplants, saving more than 39,000 lives.

7. Although some OPOs have performed poorly, Congress has provided a system for resolving those performance issues. The statute permits decertification if OPOs fail to meet objective criteria. *See* 43 U.S.C. § 273(b)(1)(D)(ii)(IV); 42 C.F.R. § 486.312.

8. But Defendants are poised to eliminate this largely successful system. Later this year, CMS will begin enforcing a new rule that will radically transform the organ donation landscape. *See Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations*, 85 Fed. Reg. 77,898 (Dec. 2, 2020) (the "Final Rule"). Through the Final Rule, Defendants attempt to rewrite the statute in a manner directly contrary to Congressional intent.

9. The Final Rule will eliminate the system of regional exclusivity under which OPOs have long operated. The Final Rule creates a new scheme, one not authorized by Congress, under which even high-performing OPOs will face the prospect of losing their DSA. This *de facto* decertification would result not from an objective measurement of an OPO's performance, but through the use of a new set of narrow, flawed, and incomplete comparative assessments. The Final Rule guarantees a substantial number of the nation's OPOs will be eliminated regardless of objective performance metrics, or even measurable improvement under the new, flawed comparative assessments.

10. Rather than furthering the system established by Congress, the Final Rule will divide OPOs into three tiers based on two overlapping and tightly correlated data points: donation rate and transplantation rate. 42 CFR § 486.316. Only those ranked in the top 25th percentile on both measures will qualify for Tier 1, and only those OPOs will be ensured of continued operation during the next certification period. OPOs falling into Tier 2, which include those performing above average but outside the top tier on either data point, will have their DSAs put out to bid from other OPOs. An OPO that does not re-secure its DSA will be effectively eliminated. OPOs with either measurement falling below the median will fall into Tier 3 and be directly decertified.

11. By using comparative data and setting a cut-off at the 25th percentile, the Final Rule guarantees that OPOs will be rapidly eliminated from serving their DSAs. CMS estimates that 34 OPOs, a majority, would fall outside Tier 1 and face elimination in the first re-certification cycle under the Final Rule. *See* 85 Fed. Reg. at 77,911. Additional cycles will necessarily reduce the number of OPOs further, eventually leaving only a handful of large organizations lacking the local relationships Congress envisioned. And

because the statute does not provide for certification of new OPOs, the end result will be consolidation and disruption, eliminating whatever competition Defendants hoped to impose.

12. The Final Rule is unlawful because it is inconsistent with the statute. Congress did not authorize CMS to pit OPOs against each other in a fight for new territory. Instead, it mandated a one-to-one OPO-to-DSA relationship. Congress explicitly directed that "[t]he Secretary may not designate more than one organ procurement organization for each service area." 42 U.S.C. § 1320b-8(b)(2). And it expressly required that each OPO "has a defined service area," not multiple DSAs. 42 U.S.C. § 273(b)(1)(E). The Final Rule demands the opposite: it would strip some certified OPOs of their DSAs while awarding multiple DSAs to other OPOs. Nothing in the statute permits this forced competition. Nor does the statute permit an OPO to be eliminated absent appropriate decertification.

13. The Final Rule further violates the statute by relying exclusively on comparative rather than objective data. The statute directs that CMS must "rely on outcome and process performance measures that are based on empirical evidence . . . *in each service area* of qualified organ procurement organizations." 42 U.S.C. § 273(b)(1)(D)(ii)(II). But under the Final Rule, OPOs are eliminated from service based on data from other DSAs. In other words, the Final Rule places each OPO in a tier based on data from outside the subject OPO's DSA, rather than measuring the OPO's performance in its DSA, as the statute requires.

14. Worse still, the Final Rule fails to use "multiple outcome measures" as the statute directs. 42 U.S.C. § 273(b)(1)(D)(ii). Instead, it uses only two outcome measures that share a common denominator, making them effectively a single measure.

15. The Final Rule is also arbitrary and capricious for numerous reasons. By relying solely on two interrelated data points, donation rate and transplantation rate, the Final Rule fails to provide meaningful assessment of the OPOs' performance.

16. The donation rate measurement adopted in the Final Rule is based on unreliable and inconsistent data and fails to account for significant differences in health and demographics across DSAs.

17. Moreover, the transplantation rate suffers from those same problems, and because OPOs play no role in determining whether an organ is transplanted, is wholly outside an OPO's control.

18. Further, the Final Rule requires CMS to limit its review to data from a single year of the four-year recertification cycle established by Congress. *See* 42 U.S.C. § 273(b)(1)(D). CMS failed to provide a reasonable explanation for its decision to ignore not less than 75% of the available data in making recertification decisions. By adopting a limited snapshot, the Final Rule fails to account for inherent year-to-year variability or more to the point, improvement, a problem that is especially acute for smaller OPOs like ConnectLife.

19. CMS likewise failed to account for the inevitable consequences of the Final Rule. By decertifying OPOs that fall under the median on either donation rate or transplantation rate, and imposing *de facto* decertification on OPOs that fall below the 25th percentile on either measure, the Final Rule will lead to a dramatic and sudden reduction in the number of OPOs. Throwing the existing organ donation system into chaos will impose severe harm on existing OPOs, as well as hospitals, organ donation centers, organ donors, their families, potential organ recipients, and the general public.

20. ConnectLife accordingly brings this action to halt Defendants' unlawful enforcement of the Final Rule and prevent the irreparable harm that would occur through its imposition.

THE PARTIES

21. Plaintiff ConnectLife is a New York not-for-profit corporation headquartered in Williamsville, New York. Connect Life is the designated OPO for Western New York and has operated in that role since 1981. It also operates community blood banking, and eye and tissue donation services. It was the first organization in the country to combine organ, eye, tissue, and blood donation services under one roof. ConnectLife remains dedicated to helping organ, eye, and tissue donor families honor the wishes of their loved ones during an emotional time and supporting Western New Yorkers' inherent desire to do good.

22. Defendant Robert Francis Kennedy, Jr., sued only in his official capacity, is the Secretary of HHS. His official address is 200 Independence Avenue SW, Washington, DC 20201.

23. Defendant Mehmet Oz, M.D., sued only in his official capacity, is the Administrator of CMS. His official address is 7500 Security Boulevard, Baltimore, Maryland 21244.

24. Defendant HHS is an executive department in the United States government headquartered at 200 Independence Avenue SW, Washington, DC 20201.

25. Defendant CMS is a component of HHS with responsibility for day-to-day operation and administration of the Medicare program and is located at 7500 Security

Boulevard, Baltimore, Maryland 21244. CMS regulates OPOs under authority delegated by Congress and the Secretary.

JURISDICTION AND VENUE

26. This Court possesses subject-matter jurisdiction under 28 U.S.C. § 1331.

27. ConnectLife's causes of action arise under federal law, the Administrative Procedure Act, and the Declaratory Judgment Act. *See* 5 U.S.C. §§ 701-706, 28 U.S.C. § 2201.

28. Venue is proper in this District under 28 U.S.C. § 1391(e) because this is a civil action in which defendants are officers or agencies of the United States, no real property is involved in this action, and ConnectLife resides in this district.

29. ConnectLife has standing to pursue its claims because it is directly regulated by the Final Rule. ConnectLife is forced to spend significant time, effort, and funds as a result of the Final Rule in order to continue operating. ConnectLife is threatened with decertification if placed into Tier 3 under the Final Rule, or *de facto* decertification if it is placed into Tier 2 under the Final Rule. These injuries would be redressed by a favorable judicial decision.

30. There is an actual, justiciable controversy between ConnectLife and Defendants concerning whether the Final Rule is enforceable.

GENERAL ALLEGATIONS

I. CONGRESS CREATES A SYSTEM FEATURING LOCAL OPOS, BUT DEFENDANTS IMPOSE A RULE THAT VIOLATES THE STATUTE

A. The National Organ Transplant Act places OPOs at the center of the organ donation process

31. Scientific and technological advancements, paired with medical breakthroughs in the development of drugs that combat organ rejection, have increased the frequency of successful organ transplantation and broadened the scope of transplantable organs in the United States. Today, many organ transplantation procedures are routine medical treatments. *See* Health Resources & Services Administration (HRSA), *History* (December 2025), https://www.hrsa.gov/optn/patients/organ-transplants/history.

32. Despite these advances, the need for organ transplants continues to exceed the supply of transplantable organs.

33. Congress has thus attempted to bridge the organ demand gap by promoting the donation of organs, developing and maintaining efficiencies in organ transplantation, and limiting external commercial influences that may lead to the exploitation of organs for profit. It first established a statutory framework in furtherance of the goals by enacting the National Organ Transplant Act of 1984 ("NOTA"), Pub. L. No. 98-507, 98 Stat. 2339 (codified at 42 U.S.C. §§ 273 *et seq*.), which amended the Public Health Service Act ("PHSA").

34. Together with the Social Security Act, the PHSA establishes the Secretary and CMS's regulatory authority with respect to organ procurement and transplantation.

35. In relevant part, NOTA granted the Secretary authority to make grants for the planning, establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations. 42 U.S.C. § 273(a)(1)–(2).

36. OPOs serve a pivotal function at each step of the organ donation and transplantation process. Under NOTA, OPOs must: (1) maintain effective agreements to identify donors with a substantial majority of hospitals in its DSA and other health care entities in its DSA with facilities for organ donations; (2) conduct and participate in systematic efforts to acquire all useable organs from potential donors; (3) arrange for the acquisition and preservation of donated organs; (4) provide or arrange for the transportation of donated organs to transplant centers; (5) have arrangements to coordinate their activities with transplant centers in its DSA; (6) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage and distribution of tissue as may be appropriate to assure that all useable tissue is obtained from potential donors; and (7) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors. *See* 42 U.S.C. § 273(b)(3).

37. In practice, OPOs are facilitators. They are the touchpoint for donors, donor families, donor hospitals and transplant centers over the course of the donation and transplantation process. Because the opportunity for organ donation arises in only a small fraction of deaths, OPOs must work closely with hospitals to identify potential donor referrals. OPOs then work closely with families to determine whether individuals are medically eligible for donation, whether they are on the donor registry, and if not, whether families choose to authorize donation. All of this occurs in an emotionally sensitive environment, under tight time constraints.

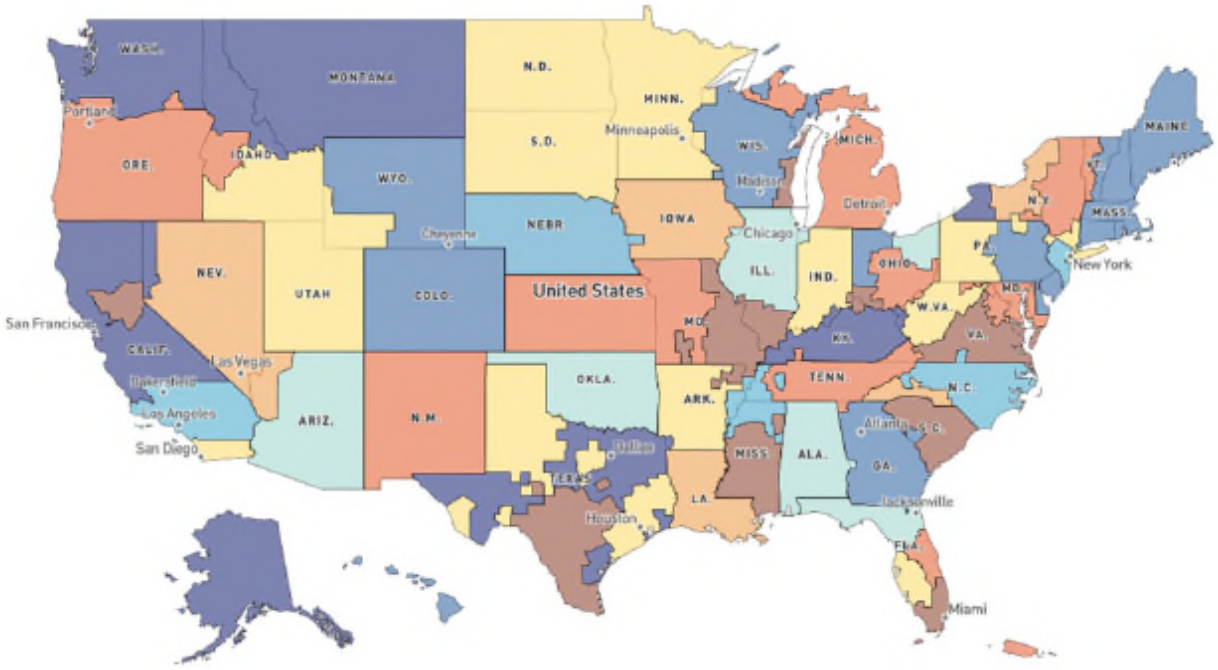
38. While OPOs are central to the organ donation system, they do not decide what happens to organs after they are donated. OPOs are required to allocate organs through a centralized process administered by OPTN. *See* 42 U.S.C. § 274; 42 C.F.R. § 512.402. OPOs offer organs to transplant surgeons for individual patients identified through OPTN's potential transplant recipient list. The transplant surgeon then decides whether to accept the organ for their patient. If the organ is declined, the OPO then offers the organ to the next patient identified, sometimes offering a single organ to dozens of individual patients in succession.

39. Once an organ is accepted, the OPO coordinates surgical recovery and transportation. This process involves difficult work on an extremely tight schedule given the limited period of time organs can function outside of the body. OPOs work with donor hospitals, clinical recovery teams, diagnostic laboratories, transplant centers, and specialized transportation providers to move an organ from donor to recipient.

40. OPOs, as local, community-based not-for-profit entities, must establish extensive relationships in the communities they serve. To be successful, an OPO must be recognized in its DSA as the trusted source for facilitating organ procurement and transplantation. As a result, OPOs rely on deep relationships with health care providers, community health organizations, and other community resources to maximize their ability to facilitate organ procurement and transplantation in their communities.

41. Recognizing the need for an OPO to develop these community relationships without interference, Congress established a system of regional exclusivity, mandating that CMS designate one OPO for each of the nation's DSAs. 42 U.S.C. §§ 273(b)(1)(F), 1320b–8(b)(2); 42 C.F.R. § 486.302.

42. The following map shows the existing 55 OPOs and their exclusive DSAs:



See Scientific Registry of Transplant Recipients, https://report.srtr.org/opo.

43. Each OPO operates exclusively within its DSA, per the statute. *See* 42 U.S.C. § 1320b–8(b)(2). Congress created only a single exception to DSA exclusivity. An individual hospital may seek a waiver from the Secretary to contract with a different OPO, but only if granting a waiver would increase organ donation and ensure equitable treatment of patients referred for transplants within both the existing DSA and the DSA of the new OPO. 42 U.S.C. § 1320b–8(a)(2)(A). In making waiver decisions, the Secretary is obligated to consider cost effectiveness, improvements in quality, and the length and continuity of a hospital's relationship with an OPO. 42 U.S.C. § 1320b–8(a)(2)(B).

44. Congress thus created a one-to-one ratio. One OPO must serve one DSA under the statute. And with this structure of regional exclusivity, Congress positioned

OPOs to focus their resources on developing community infrastructures to maximize organ procurement and transplantation, not on competing with other OPOs for resources and relationships within a DSA.

45. Certification and recertification are necessary for an OPO to operate. Unless they are certified, OPOs cannot receive Medicare or Medicaid funds. 42 U.S.C. § 1320b-8(b)(1)(A)(ii); 42 C.F.R. § 486.312(e). Further, every hospital participating in Medicare must have an agreement with the OPO in its DSA. 42 U.S.C. § 1320b-8(a)(1)(C); 42 C.F.R. § 486.308(c). Accordingly, an OPO that loses its certification cannot work with any hospital that participates in Medicare.

B. The Organ Procurement Organization Certification Act of 2000 seeks to improve the statutory framework

46. Sixteen years after it enacted NOTA, Congress again amended the PHSA with the Organ Procurement Organization Certification Act., Pub. L. 106–505, tit. VII, Stat. 2314, 2346–48 (Nov. 13, 2000) ("Certification Act").

47. Congress expressly found that "the current process for the certification and recertification of organ procurement organizations . . . has created a level of uncertainty that is interfering with the effectiveness of raising the level of organ donation." *Id.* § 701(b)(2), 144 Stat. at 2346.

48. Specifically, Congress found that the OPO certification and recertification process was limited by: (1) "[a]n exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization"; and (2) "[a] lack of due process to appeal to the Secretary of

[HHS] for recertification on either substantive or procedural grounds." *Id.* § 701(b)(4)(A)–(B), 144 Stat. at 2346.

49. Setting the stage for its instruction to the Secretary to conduct a thoughtful, fulsome review of then-existing OPO performance evaluation measures, Congress cited the Secretary's authority under 42 U.S.C. § 1320b—8(b)(1)(A)(i) to extend the period for OPO recertification from 2 to 4 years on the basis of its past practices "in order to avoid the inappropriate disruption of the nation's organ system." Pub. L. 106–505, tit. VII, Stat. 2314, 2346–48 (Nov. 13, 2000), § 701(b)(5), 144 Stat. at 2346–47.

50. Congress directed the Secretary to use the extended period for OPO recertification to "develop improved performance measures," to "improve the overall certification process by incorporating process as well as outcome performance measures," and "to develop equitable processes for appeals." *Id.* § 701(b)(6)(A)–(B), 144 Stat. at 2347.

51. Congress expressly required that the Secretary's revisions to the OPO certification and recertification process "reflect organ donor potential and interim outcomes" and to ensure that new performance measures were tested "to ensure that they accurately measure performance differences among the organ procurement organizations." *Id* . § 701(b)(6)(A).

52. With the Certification Act's amendments to the certification process, the Secretary must now "rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations." 42 U.S.C. § 273(b)(1)(D)(ii)(II). In doing so, the Secretary must use "multiple outcome measures" as part of its evaluation. *Id.* § 273(b)(1)(D)(ii)(II).

53. The Certification Act also extended the OPO recertification cycle from 2 years to 4 years and established an OPO's right to appeal a decertification on substantive and procedural grounds. *Id.* § 273(b)(1)(D)(ii)(I), (IV).

54. The amendments provided a clear, workable framework for CMS to re-evaluate its existing measurement of OPO performance. The framework made clear that the resulting evaluation process must: (1) utilize both outcome and process measures; (2) use multiple outcome measures; and (3) consider organ donor potential and other related factors in each DSA.

55. With this direction, Congress recognized that OPOs have unique challenges specific to the DSAs they serve. An OPO evaluation process compliant with Congress's directions would accordingly consider the impacts of factors largely outside an OPO's control, including, but not limited to: (1) geographic factors impacting donor and recipient distance from transplant hospitals; (2) demographic and socioeconomic factors impacting the available supply of organs and the transplant of such organs; and (3) the fact that other stakeholders in the organ transplantation process have ultimate discretion on whether or not an organ is transplanted.

56. Congress tasked the Secretary with completing its re-evaluation and promulgating regulations in accordance with this revised framework by January 1, 2002. 42 U.S.C. § 273(b)(1)(D)(ii).

C. Defendants struggle to implement the statute in prior rulemaking

57. In response to Congress's instructions in the Certification Act, CMS embarked on a 13-year trial-and-error period involving various attempts to develop appropriate measures to evaluate OPO Performance. Of particular note is CMS's 2006

Rule, titled Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs). 71 Fed. Reg. 30,982 (May 31, 2006) (the "2006 Rule").

58. The 2006 Rule established process performance measures for the evaluation of OPOs that remain largely unmodified. *See* 42 C.F.R. §§ 486.320–486.360. These process performance measures closely follow Congress's express requirements for OPOs set forth in 42 U.S.C. § 273(b)(3)(A)–(K).

59. Among other requirements, the process performance measures mandate that OPOs (1) participate in the OPTN; *id.* § 486.320; (2) maintain written agreements with 95% of qualified hospitals within the OPO's DSA; *id.* § 486.322 (3) have an advisory board with the membership composition specifically required under § 486.324; and (4) arrange for the testing of organs for infectious disease and develop protocols for packaging, labeling and shipping organs to prevent compromise to the quality of the organ. § 486.346(a), (c).

60. With respect to outcome measures, the 2006 Rule provided that OPOs would be recertified for a four-year period if they satisfied the following three outcome measures:

(a) Donation Rate: The donation rate assessed the number of "eligible donors as a percentage of a number of eligible deaths within an OPO's service area." An eligible death was any hospital death that was ventilated, with a declaration of brain death and without contraindications for organ donation and transplant. 71 Fed. Reg. at 30,985. OPOs with donation

rates no more than 1.5 standard deviations below the mean were deemed in compliance with this donation rate measure. *Id.* at 31,005, 31,050.

(b) Observed/Expected Donation Rate: This measure calculated the observed donation rate (actual performance) as a percentage of the expected donation rate. To satisfy this measure, an OPO's observed donation rate could not fall below the expected donation rate for more than 18 of the 36 months measured for recertification. *Id.* "Expected donation rate" meant the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and DSAs, as adjusted for certain hospital features. *Id.* at 31,047.

(c) Yield: This measure assessed the number of organs transplanted or used for research per donor. To satisfy this measure, an OPO's yield calculation could not fall more than one standard deviation below the national mean over an average of 3 years during the 4-year recertification cycle. *Id.*

61. OPOs that failed to meet any one of these three outcome measures would be automatically decertified.

62. Because CMS lacked sufficient data to conduct an accurate assessment of OPO performance based on these newly prescribed outcome measures, CMS did not evaluate OPOs using the 2006 outcome measures until the 2014 recertification cycle.

63. In 2013, as it began to evaluate OPOs based on the 2006 Rule's outcome measures, CMS acknowledged several fundamental issues with the outcome measures and the detrimental impact they would have on OPOs. Specifically, CMS

admitted that the "requirement to automatically decertify OPOs" failing to meet each of the 2006 Final Rule's outcome measures was "unnecessarily stringent." *Medicare and Medicaid Programs*, 78 Fed. Reg. 43,534, 43,671 (July 19, 2013).

64. Among other issues, CMS noted the substantial variance in demographics in the populations served by different OPOs. It was concerned that the 2006 Rule's outcome measures may not accurately allow for adjustment of various factors, including the variance in population demographics in different DSAs. *See id.*

65. In response, CMS's proposed "quick-fix" for these issues was to require OPOs to meet two of the three outcome measures established in the 2006 Rule, instead of all three outcome measures. *Id.*

66. CMS finalized this proposal in its 2013 Rule. *See Medicare and Medicaid Programs*, 75 Fed. Reg. 74,826, 75,142 (Dec. 10, 2013). In doing so, CMS explained that it observed that many of the OPOs that were failing to meet all three outcome measures were meeting two of the three measures and complied with the process performance measures set forth in §§ 486.320 through 486.348. It believed these OPOs were "performing satisfactorily" and should not be decertified based solely on their failure to meet one outcome measure. 75 Fed. Reg. at 75,142.

67. CMS's remarks evidenced its understanding that it would be improper to apply rigid outcome measures significantly influenced by factors outside an OPO's control. Outcome measures easily impacted by factors outside of the control of an OPO cannot accurately evaluate the performance of an OPO.

68. CMS, however, did not address the underlying problem that it had in fact created, and still would rely on, outcome measures that do not comport with Congress's

direction that such measures be "based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations." *See* 42 U.S.C. § 273(b)(1).

D. The 2019 proposed rule strays from Congressional and Presidential intent

69. In 2019, President Trump signed an Executive Order on Advancing American Kidney Health. Exec. Order No. 13,879, 84 Fed. Reg. 33,817 (July 10, 2019). The Order specifically charged the Secretary, within 90 days of the date of the Order, to propose a regulation "to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance." *Id.*

70. On December 23, 2019, CMS issued the "Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization" proposed rule. 84 Fed. Reg. 70,628 (Dec. 23, 2019) (the "2019 Proposed Rule").

71. CMS once again acknowledged its shortcomings in establishing outcome measures that appropriately measure OPO performance and agreed with stakeholders that "the current OPO outcome measures are not sufficiently objective and transparent in assessing OPO performance." *Id.* at 70,628–29.

72. The 2019 Proposed Rule, however, failed to establish objective metrics to evaluate OPO performance. Instead, it introduced a scheme that relies on comparative data to evaluate the performance of an OPO, such that OPOs would not be evaluated based on performance within their respective DSAs.

73. The 2019 Proposed Rule focused solely on outcome measures and proposed no changes to the process performance measures.

74. In the 2019 Proposed Rule, CMS proposed to rely exclusively on two closely related outcome measures: donation rate and transplantation rate.

75. CMS proposed that the "donation rate" be measured as the number of actual deceased donors as a percentage of the "donor potential," meaning the total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation. *Id.* at 70, 631.

76. CMS proposed that the "transplantation rate" would be measured as the number of organs procured within the DSA and transplanted as a percentage of the "donor potential." *Id.*

77. Using these two closely related outcome measures, CMS proposed to automatically decertify all OPOs falling outside of the top 25 percent of donation and transplantation rates for OPOs. *Id.* at 70,634. CMS would use donation and organ transplantation rates from one year of the four-year recertification cycle to assess OPO performance. *Id.* at 70,637.

78. The 2019 Proposed Rule received approximately 834 public comments from various stakeholders, including hospitals, health care professionals, OPOs, industry associations and health care consumers. 85 Fed. Reg. 77,898, 77,900.

79. Comments on the 2019 Proposed Rule cited a multitude of reasons why CMS's newly proposed outcome measures were inadequate to evaluate OPO performance in accordance with Congress's express directives.

80. Criticisms cited the highly correlated nature of the proposed donation rate and transplantation rate, both of which used the same denominator of "donor potential." As a result, commenters explained that the two measures were not sufficiently distinct to meet Congress's requirement that the Secretary use multiple outcome measures when evaluating OPOs. 85 Fed. Reg. at 77,905.

81. Other comments criticized CMS's proposal to use data from the Centers for Disease and Control's Multiple Cause of Death ("MCOD") data files to determine "donor potential," citing issues with the accuracy and timely availability of such data. *Id.* at 77,906.

82. Commenters also noted that CMS offered no statistical support or rationale for its proposed 25 percent cut-off. *Id.* at 77,923–24. With the 25 percent cut-off, CMS estimated that 22 OPOs could be decertified in the first cycle. *Id.* at 77,911. Such a drastic and aggressive approach would set the stage for the inappropriate disruption of the nation's organ donation system.

83. A significant number of comments were concerned with an issue that should be familiar to CMS, based on its prior admissions in reviewing the outcome measures in its 2006 Rule: demographic and geographic factors impacting the organ donation and transplantation process vary from DSA to DSA. *See id.* at 77, 909–10. Thus, a "one-size fits-all" evaluation approach, without adequate risk adjustment to account for factors largely outside of an OPO's control, does not accurately assess OPO performance. The approach does not "rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and

other related factors in each service area of qualified OPOs," as required by 42 U.S.C. § 273(b)(1)(D)(II).

E. The Final Rule creates a new comparative scheme that is inconsistent with the statute

84. Despite these glaring flaws, CMS promulgated its Final Rule on December 2, 2020. 85 Fed. Reg. 77,898. The Final Rule was implemented on August 1, 2022, to coincide with the start of the 2022-2026 OPO recertification cycle. *Id.* CMS will apply the outcome measures established under the Final Rule to the 2026 OPO recertification cycle.

85. The Final Rule contains the same aggressive, comparative, narrow approach in evaluating OPOs introduced in the 2019 Proposed Rule, despite the language of the statute. In addition, the Final Rule introduced a new tiering system. Under the Final rule, CMS will sort OPOs into tiers based on their comparative performance in just the immediately preceding 12-month period on its two new, narrow outcome measures: donation rate and organ transplantation rate. *Id.* at 77,911–14; 42 C.F.R. § 486.318(d).

86. Nothing in the relevant statutory language provides for a comparative model under which high-performing OPOs may be stripped of their DSAs absent decertification. Through the Final Rule, CMS has created from whole cloth a system inconsistent with the statutory directives.

87. CMS calculates an OPO's donation rate and organ transplantation rate using the same denominator, donor potential. "Donor potential" is based on the inpatient deaths within an OPO's DSA from patients aged 75 or younger with a primary cause of death that is "consistent with organ donation." CMS will use state death certificate data from "MCOD" data files from the most recent 12 months to determine the donor potential

within a DSA. 85 Fed. Reg. at 77,911–14; 42 C.F.R. § 486.318(d)(1)(iv). However, the MCOD data has error rates of 30–60%. *See* 85 Fed. Reg. at 77,906-07.

88. CMS declined to utilize more sophisticated statistical models to determine actual performance as compared to true donor potential, including the Scientific Registry of Transplant Recipients ("SRTR") Donor Yield Model, which includes 34 to 50 risk-adjustments. *See* 85 Fed. Reg. at 77,905. Although CMS acknowledged that better models "may have value for understanding potential areas for improvement and may be used by the OPTN and OPOs for internal performance assessment," it rejected the SRTR model "[b]ecause of the complexity of the model and the need for frequent updating." *Id.*

89. The term "donor," as used in each outcome measure, means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted and includes individuals who have their pancreas procured for islet cell transplantation. § 486.302.

90. The donation rate is calculated as the number of donors in the DSA as a percentage of the donor potential. § 486.318(d)(1)(i).

91. The transplantation rate is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential. The organ transplantation rate is adjusted for the average age of donor potential. § 486.318(d)(1)(ii).

92. Rather than providing for two tiers (recertification or decertification), the Final Rule added an intermediate Tier 2. An OPO assigned to Tier 2 would not be automatically decertified but must compete with other OPOs to retain its DSA.

93. Under the Final Rule, to determine an OPO's tier assignment, CMS established threshold rates applicable to each outcome measured based on the 25th

percentile rate and the median rate among OPOs based on the 2024 donation rate and organ transplantation rate data. *Id.* §§ 486.318(e)(1)–(2).

94. An OPO with donation and organ transplantation rates not significantly below the top 25% of OPOs for both respective outcome measures for the one year period is assigned to Tier 1, § 486.318(e)(4), provided that it also meets the process measures set forth under 42 C.F.R. §§ 486.320 through 486.360.

95. Defendants calculate statistical significance by calculating the upper limit of an OPO's metrics using a 95% confidence interval.

96. An OPO with donation rate and transplantation rates that is not significantly below the median, but that does not qualify for Tier 1, is assigned to Tier 2. § 486.318(e)(5). The DSA of an OPO placed in Tier 2 becomes available for bid by other OPOs. Provided a Tier 2 OPO meets the Secretary's process measures, a Tier 2 OPO may also participate in the competitive bidding process for its DSA, or another open DSA.

97. An OPO with either a donation rate or transplantation rate statistically significantly below the median is placed in Tier 3. § 486.318(e)(6). If assigned to Tier 3 in a recertification year, or if it fails any of the Secretary's process measures, the OPO is decertified. *Id.* § 486.316(a)(3).

98. For purposes of determining the 25% and median cutoffs, CMS compares data from the assessment period to the "the 12–month period immediately prior to the period being evaluated." 42 C.F.R. § 486.318(e)(1). Accordingly, for the present recertification cycle, CMS compares the donation rate and transplantation rate from 2024 to the 25th percentile and median from 2023.

99. Incredibly, OPOs may not appeal placement in Tier 2. Nor does the Final Rule permit an appeal if an OPO loses its DSA to another OPO through the new bid process. The only administrative appeal provided for in the Final Rule follows a decertification from a Tier 3 placement.

100. However, a Tier 2 OPO that is not awarded a DSA through CMS's newly prescribed bid process is *de-facto* decertified. Such an OPO would be left without a DSA, a result inconsistent with the statute.

101. Since the Final Rule does not provide for the decertification of a Tier 2 OPO that is not awarded a service area, such Tier 2 OPOs are not entitled to the administrative appeal process set forth in § 486.314.

102. Applying its three-tier structure, CMS own estimate is that almost 40% of OPOs would fall into Tier 3 and nearly 20% would fall into Tier 2. 85 Fed. Reg. at 77, 911.

103. The structure initiates an inevitable disruption to the nation's organ donation industry, as over half of the nation's DSAs will likely become available for bid. And CMS acknowledged that there is "no current statutory authority to add new OPOs." 85 Fed. Reg. at 77,898.

104. OPOs eligible to bid on open DSAs will necessarily divert resources away from improving performance in their own DSAs and utilize them to participate in the competitive bidding process.

II. THE FINAL RULE EXCEEDS STATUTORY AUTHORITY

105. The statutory scheme set forth by Congress establishes a one-to-one relationship between OPOs and DSAs, does not permit competition among OPOs for new

territory, requires that OPOs be evaluated objectively using data from within their DSAs, and requires that Defendants use multiple outcome measures to assess performance. The Final Rule violates all four of these requirements.

A. The Final Rule impermissibly breaks the required one-to-one relationship between OPOS and DSAs

106. Congress was explicit in requiring that each OPO serve one, and only one DSA. The statute does not permit a certified OPO to be left without a DSA. Nor can an OPO be awarded multiple DSAs. The Final Rule directly contravenes these mandates.

107. There can be no dispute that multiple OPOs cannot operate within a single DSA. Congress directed that "[t]he Secretary may not designate more than one organ procurement organization for each service area." 42 U.S.C. § 1320b-8(b)(2).

108. Congress also expressly directed that each certified OPO "has a defined service area." 42 U.S.C. § 273(b)(1)(E). By using the singular, "a," Congress clearly directed that each certified OPO be assigned a single DSA.

109. CMS has recognized that the one-to-one relationship is crucial to meeting the statutory scheme. It prevents OPOs from seeking to "obtain certain neighboring service areas purely for business reasons, with no regard for whether the [OPO] can increase organ donation in those areas." 84 Fed. Reg. 70,628, 70,637 (Dec. 23, 2019).

110. Nonetheless, the Final Rule would expressly result in a violation of Congress's one-to-one framework. CMS stated that "[s]ince DSAs are not required to merge, one OPO could run several DSAs." 85 Fed. Reg. at 77,913.

111. Further, CMS expressly recognized that a certified OPO could be left without a DSA under the Final Rule: "If a Tier 2 OPO does not win the competition for its DSA and does not win the competition for any other open DSA it competes for, CMS will

not renew its agreement with the OPO." 85 Fed. Reg. at 77,918. CMS further explained that such an "OPO will not be able to appeal this non-renewal," but insisted that this process "is not a de-certification." *Id.*

112. The Final Rule thus provides for some certified OPOs to have multiple DSAs, while other certified OPOs are left without a DSA, without appeal rights.

113. Nothing in the relevant statutes provides for *de facto* decertification of high-performing OPOs through placement in Tier 2. This scheme accordingly directly contravenes the statute on multiple levels.

B. The Final Rule creates a forced competition scheme without statutory authorization

114. As explained above, Congress required that each OPO operate exclusively within its DSA.

115. Congress created a single, limited exception to this requirement under which a hospital may seek a waiver to contract with an OPO other than the one designated for its DSA. As explained above, such waivers are strictly limited. They may be approved only if the waiver would increase organ donation and ensure equitable treatment of patients in both the existing DSA and the DSA of the new OPO. 42 U.S.C. § 1320b–8(a)(2)(A). Further, a waiver may be approved only if the Secretary considers a number of factors, including the depth of the hospital's relationship with its existing OPO. 42 U.S.C. § 1320b–8(a)(2)(B).

116. Nothing in the statute permits Defendants to create an additional exception beyond the hospital waiver process under which OPOs would be forced to compete against each other for "organizational survival." 85 Fed. Reg. at 77,933.

117. By creating a single exception permitting competition, Congress precluded Defendants from crafting other forms of intra-DSA competition under the canon *expressio unius est exclusio alterius*.

118. Further, the hospital waiver provision confirms that Congress is explicit when it seeks to create a system of competition. *See, e.g.*, 42 U.S.C. § 1395kk-1(b)(1)(A) (directing that the "Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors").

119. Congress created the statutory framework for the organ donation system to avoid the harmful impact of market forces. It created criminal penalties for any person who engages in the "transfer [of] any human organ for valuable consideration for use in human transplantation" 42 U.S.C. § 274e.

120. And CMS itself has recognized that Congress "established as a system of private monopolies by statute" and that "OPOs are part of the supply chain for final goods—organs for transplant—that are not transacted in a market." 85 Fed. Reg. at 77,933.

121. Although the statute permits decertification for OPOs that fail to meet objective criteria within its DSA, *see* 43 U.S.C. § 273(b)(1)(D)(ii)(IV); 42 C.F.R. § 486.312, there is no statutory authorization for *de facto* decertification of high-performing OPOs who are placed in Tier 2. Yet the Final Rule permits CMS to effectively eliminate such OPOs by stripping them of their DSAs.

122. Defendants' attempt to break the system of regional exclusivity and impose forced competition on the organ donation system is not authorized by statute.

C. The Final Rule fails to comply with the statutory requirement that certification decisions be based on data from within an OPO's DSA

123. Congress required that OPOs be assessed by reference to their objective performance within their DSAs. It directed that certification decisions turn on both "outcome and process performance measures" (not just outcome measures) that are "based on empirical evidence . . . in *each service area*." 43 U.S.C. § 273(b) (emphasis added).

124. Consistent with the statute, the President ordered CMS "to establish more transparent, reliable, and enforceable *objective* metrics for evaluating an OPO's performance." *Id*. 84 Fed. Reg. at 33,817 (emphasis added).

125. Defendants ignored that direction. Rather than measuring an OPO's performance using objective metrics based on evidence from within that OPO's DSA, the Final Rule adopted a system of comparative metrics measured in other DSAs.

126. Indeed, OPOs cannot determine which tier they will fall into simply by looking to their objective performance measures. Instead, the cutoff for Tiers 1 and 2 can only be determined by obtaining data from other DSAs throughout the country.

127. Specifically, determining the 25th percentile cutoff for Tier 1 and the median cutoff for Tier 2 requires that data from all other DSAs be used to rank individual OPOs. Only by looking to data outside of an OPO's DSA can Defendants determine whether an OPO will be recertified.

128. To comply with the statute, CMS was obligated to make certification decisions based on objective measurements of an OPO's performance within its own DSA.

129. Defendants' comparative scheme accordingly contravenes the statute.

D. The Final Rule fails to utilize multiple outcome measures as required by statute

130. Congress required that Defendants base certification decisions on "empirical evidence, obtained through reasonable efforts, of organ donor potential *and other related factors* in each service area." 42 U.S.C. § 273(b)(1)(D)(ii)(II) (emphasis added).

131. Congress further directed Defendants "*to test those measures* to ensure that they accurately measure performance differences among procurement organizations." 42 U.S.C. § 273 note (emphasis added) (quoting 114 Stat. at 2347).

132. Additionally, Congress instructed Defendants to "use *multiple outcome measures* as part of the certification process." 42 U.S.C. § 273(b)(1)(D)(ii)(III) (emphasis added).

133. Defendants have failed to comply with these statutory mandates. Instead, Defendants adopted two tightly correlated metrics, donation rate and transplantation rate, that provide only a single relevant data point.

134. Both figures use the same denominator, donor potential. 42 C.F.R. § 486.318(d)(1). Accordingly, Defendants have not complied with the mandate to consider empirical evidence of "donor potential *and other related factors* in each service area." 42 U.S.C. § 273(b)(1)(D)(ii)(II) (emphasis added).

135. Further, Defendants have not tested the selected outcome measures to ensure they accurately measure performance as required by Congress. 42 U.S.C. § 273 note (quoting 114 Stat. at 2347).

136. Finally, Defendants have not adhered to Congress's direction to use "use multiple outcome measures," 42 U.S.C. § 273(b)(1)(D)(ii)(III), because the two metrics it adopted effectively act as a single measurement.

137. Donation rate is determined by calculating "the number of donors in the DSA as a percentage of the donor potential." 42 C.F.R. § 486.318(d)(1)(i). Transplantation rate "is calculated as the number of organs transplanted from donors in the DSA as a percentage of the donor potential." 42 C.F.R. § 486.318(d)(1)(ii).

138. Accordingly, one can determine an OPO's transplantation rate simply by multiplying the donor rate by the number of organs transplanted per donor.

139. Yet OPOs do not play any role in determining the number of organs transplanted from each donor. Such determinations are made by medical professionals without input from OPOs. Accordingly, transplantation rate is not an independent "outcome measure" in any meaningful sense.

140. Defendants could not comply with the statutory mandate to use multiple outcome measures simply by taking one outcome measurement and multiplying it by numerous arbitrary factors. For example, Defendants would violate the statute if they calculated a "left handed donation rate" by multiplying the donation rate by the percentage of left-handed people in a DSA and then used that metric in addition to the donation rate.

141. The requirement that Defendants apply multiple outcome measures requires Defendants to employ more than one relevant metric in making certification decisions, which the Final Rule fails to do.

142. Because the Final Rule contravenes the statute, this Court should set it aside.

III. THE FINAL RULE IS ARBITRARY AND CAPRICIOUS

143. In addition to exceeding statutory authorization, the Final Rule is arbitrary and capricious for multiple reasons.

A. Defendants failed to reckon with the inevitable results of the forced competition system

144. The Final Rule will inevitably reduce the number of OPOs in the country to, at most, a handful of organizations. These new mega-OPOs will lack meaningful local connections and instead operate in multiple DSAs contrary to the congressionally mandated one-to-one relationship between OPOs and DSAs.

145. Under the Final Rule, approximately half of OPOs will be directly decertified every cycle because any OPO falling below the median as to either donation rate or transplantation rate is placed into Tier 3 and immediately decertified. 42 C.F.R. § 486.318(e)(6).

146. An additional number of OPOs will be *de facto* decertified by falling into Tier 2 and having their DSA assigned to a different OPO. All OPOs that fall outside the 25th percentile on either outcome measure will be placed in Tier 2. 42 C.F.R. § 486.318(e)(5).

147. The Final Rule thus results in a significant reduction to the number of OPOs every recertification cycle, regardless of objective performance.

148. CMS concluded there is "no current statutory authority to add new OPOs." 85 Fed. Reg. at 77,898. Accordingly, the Final Rule will steadily erode the number of OPOs.

149. Defendants failed to address this obvious consequence. Instead, it asserted that "all OPOs have the opportunity to cluster at the top because we generate confidence intervals for their donation and organ transplantation rates" and hypothesized that "[i]f all the remaining OPOs (below the top 25 percent threshold rate) had rates close to

the threshold rate, their confidence interval could have all of them equal or exceed the threshold rate, resulting in clustering near the top." 85 Fed. Reg. at 77,913.

150. This explanation fails as a matter of common sense. Simply asserting that every OPO could theoretically fall within the top quartile as a matter of statistical significance does not grant Defendants license to ignore the inevitable reduction of OPOs.

151. While every runner in a race might tie as a theoretical manner, one would certainly describe a race organizer who declines to purchase silver or bronze medals as acting capriciously.

152. Defendants' failure to grapple with a predictable consequence of the Final Rule is arbitrary and capricious.

B. Defendants unreasonably elected to ignore most of the relevant data

153. Congress required that Defendants make recertification decisions "not more frequently than once every 4 years." 42 U.S.C. § 273(b)(1)(D)(I).

154. Despite the statute's four-year recertification cycle, the Final Rule bases certification decisions on a single year of data, ignoring 75% of the relevant information. 42 C.F.R. § 486.318(e)(1).

155. By selecting just one year of data, Defendants increased the amount of statistical variance. Accordingly, OPOs face the prospect of being decertified, or losing their DSAs, as the result of a single down year.

156. Peer-reviewed research (and actual facts) confirm dramatic year-to-year variation, with OPOs falling into different tiers depending on particular years observed. *See* Rocio Lopez *et al.*, *Evaluation of the Stability of Organ Procurement Organization Performance Metrics*, 25 Am. J. Transplantation 1, 6 (2025), available at

https://pubmed.ncbi.nlm.nih.gov/40409471/ (explaining "tier year-to-year reclassification rates were observed, with 36% (21/58) changing tiers from 2018 to 2019, 43% (25/58) from 2019 to 2020, and 28% 203 (16/57) from 2020 to 2021.").

157. CMS "recognize[d] that OPOs serving smaller DSAs are mathematically subject to greater variability in their inpatient deaths and number of donors and organ transplants." 85 Fed. Reg. at 77,915. Accordingly, Defendants' arbitrary limitation will have a greater impact on smaller OPOs like ConnectLife.

158. CMS suggested that its use of just one year of data was permissible because it focused on recent data. But the data CMS uses is not available until eighteen to twenty-four months after the year in which it was generated. 85 Fed. Reg. at 77,915. Accordingly, Defendants are using stale data and increasing year-to-year variability, all the while ignoring data regarding year-to-year improvement.

159. By ignoring most of the information available in a recertification cycle, Defendants have unreasonably blinded themselves from observing trends or improvements in OPO performance.

160. Defendants' use of a single year of data from the mandatory four-year recertification cycle is arbitrary and capricious.

C. Defendants unreasonably base certification decisions on a single relevant data point

161. As described above, Congress required Defendants to use multiple outcome measures, to test the validity of those measures, and to consider factors beyond donor potential from within an OPO's DSA. Instead, Defendants elected to use two tightly correlated metrics that do not provide the information Congress required. This decision was arbitrary and capricious.

162. Peer-reviewed research (and actual facts) demonstrate that the two metrics selected by Defendants are not sufficiently distinct. *See* Jon J. Snyder, et al., *The Centers for Medicare and Medicaid Services' proposed metrics for recertification of organ procurement organizations: Evaluation by the Scientific Registry of Transplant Recipients*, 20 Am. J. Transplant. 2466, 2469-74 (2020), available at ttps://pubmed.ncbi.nlm.nih.gov/32157810/; David Goldberg *et al.*, *Changing Metrics of Organ Procurement Organization Performance in Order to Increase Organ Donation Rates in the United States*, 17 Am. J. Transplantation 3183, 3187=88 (2017), available at https://pubmed.ncbi.nlm.nih.gov/28726327/.

163. Transplantation rate is determined by the number of transplanted organs per donor. But OPOs do not decide whether individual organs are transplanted. Instead, those decisions are made by medical professionals based on a number of criteria unrelated to an OPO's performance. *See Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model*, 89 Fed. Reg. 96,280, 96,298 (Dec. 4, 2024) (explaining that "[s]tudies have documented the substantial extent of deceased donor kidney non-utilization in the U.S."); S. Mohan, *et al.*, *Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy*, Kidney Int. Rep. (Feb. 25, 2023), available at https://pubmed.ncbi.nlm.nih.gov/37180509/ (noting that "over 1 in 4 [kidneys] recovered for transplant are not being transplanted").

164. CMS has recognized that factors beyond an organization's control can impact outcomes in the organ donation context, and thus employs a variety of "risk adjustments" when regulating transplant hospitals. *See Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model,* 90 Fed. Reg. 57,598, 57,599 (Dec. 11,

2025). CMS specifically acknowledged "that the lack of risk adjustment would be unfair" to the transplant hospitals when measuring outcomes. 89 Fed. Reg. at 96,352.

165. But Defendants unreasonably failed to consider the inherent unfairness in basing certification decisions on only two related metrics, one of which OPOs cannot control.

D. The Final Rule utilizes deeply flawed data

166. There is no real dispute that various demographic, economic, and social factors impact the true number of potential donors in a DSA. *See, e.g.*, Jonathan M. Miller *et al.*, *Adjusting for Race in Metrics of Organ Procurement Organization Performance*, 24 Am. J. Transplantation 1440, 1441-42 (2024), available at https://pubmed.ncbi.nlm.nih.gov/38331046/.

167. The federal government has acknowledged that outcome measures in general are typically "the result of numerous factors, many beyond providers' control" and thus "risk-adjustment methods are needed to minimize the reporting of misleading or even inaccurate information about health care quality." Agency for Healthcare Rsch. & Quality, Types of Health Care Quality Measures (July 2015), available at https://www.ahrq.gov/talkingquality/measures/types.html.

168. Indeed, CMS itself has already recognized that demographic differences can impact an OPO's outcome metrics, a conclusion confirmed by independent research. *See* 78 Fed. Reg. at 43,671-72; Sara Crawford & Jesse Schold, *Association Between Geographic Measures of Socioeconomic Status and Deprivation and Major Surgical Outcomes*, 57 Medical Care 949, 959 (2019), available at https://pubmed.ncbi.nlm.nih.gov/31568164/.

169. Yet CMS refused to apply various risk adjustments suggested by commenters during the rulemaking process (other than a *de minimis* minimal adjustment for donor age in transplantation rate). 85 Fed. Reg. at 77,909-910.

170. CMS acknowledged that more sophisticated models have value, such as the SRTR Donor Yield Model, but refused to it "[b]ecause of the complexity of the model and the need for frequent updating." 85 Fed. Reg. at 77,905.

171. Defendants acted arbitrarily in failing to account for difference among DSAs in making certification decisions.

172. Further, Defendants failed to reasonably account for flaws in the data sources it selected.

173. Under the Final Rule, donor potential is calculated using MCOD data files. But studies have demonstrated that this data is wildly inaccurate, with error rates of 30–60%. *See* 85 Fed. Reg. at 77,906-07.

174. As commenters explained in the rulemaking process, Defendants' use of MCOD data creates an inaccurate picture of donor potential. It includes deaths of patients who are not eligible for organ donation, such as those with medical conditions that rule them out, or individuals who were not ventilated at the time of death. *See Id.* at 77,907.

175. But CMS simply assumed that data problems would be uniform across DSAs. *Id.* at 77,906-07. The evidence demonstrates that the contrary is true. *See* Charbel el Bcheraoui, *et al.*, *Trends and Patters of Differences in Infectious Disease Mortality Among US Counties, 1980-2014*, 319 J. Am. Med. Ass'n. 1248, 1249 (Mar. 27, 2018) available at https://pubmed.ncbi.nlm.nih.gov/29584843/.

176. Defendants also rely on state death certificate data. But states are not uniform in reporting death certificate data, an issue CMS acknowledged. *Id.* at 77,907. CMS simply ignored this problem, again assuming that differences would not meaningfully differ across DSAs. *Id.*

177. By ignoring problems in the data it selected, and failing to account for differences across DSAs, Defendants acted unreasonably.

IV. THE FINAL RULE THREATENS TO ELIMINATE CONNECTLIFE AS AN OPO AND SEW CHAOS IN WESTERN NEW YORK'S ORGAN DONATION SYSTEM

178. ConnectLife has steadily improved its performance over the past several years. From 2021 to 2025 it increased the number of donors per year from 43 to 75, a 74.4% increase. Over the same time frame, the number of organs transplanted more than doubled, from 108 to 218, an increase of 101.9%.

179. Moreover, prior to the widespread disruption caused by the COVID-19 pandemic and the government shutdowns in New York State, ConnectLife's performance was among the top OPOs in the nation.

180. Although Defendants have not yet finalized their decisions under the Final Rule, CMS has issued preliminary data to OPOs for planning purposes.

181. For 2025, the final year of this recertification cycle, ConnectLife's donation rate is 18.75. Further, because CMS uses the 95% confidence interval to determine statistical significance, ConnectLife's effective donation rate for 2025 (*i.e.*, the upper limit of its confidence interval) is 22.30. Both figures are above the cutoff for Tier 1, projected to be 18.14.

182. ConnectLife's transplantation rate for 2025 is 55.62, with an upper limit at a 95% confidence interval of 61.85. Again, both figures are above the projected cutoff for Tier 1 of 55.55.

183. Accordingly, based on preliminary data, ConnectLife is likely to land in Tier 1 for 2025.

184. As described above, however, Defendants unreasonably elected to ignore 2025 data, and instead base recertification solely on 2024 data.

185. In 2024, ConnectLife's donation rate was 13.86, with an upper limit at a 95% confidence interval of 16.92. That data would put ConnectLife just below the projected Tier 1 cutoff of 17.18. ConnectLife would land in Tier 1 for donation rate if it had just two additional donors in 2024.

186. With respect to transplantation rate (which turns on the number of transplants per donor, a measure over which OPOs have no control), ConnectLife is likely to land in Tier 2. Its transplantation rate in 2024 was 43.43, with an upper limit at a 95% confidence interval of 48.69. That places ConnectLife just below the projected Tier 1 cutoff of 53.09. Had ConnectLife procured just 18 additional transplanted organs in 2024, it would have landed in Tier 1 for transplantation rate.

187. ConnectLife faces numerous challenges specific to its DSA.

188. First, ConnectLife serves the smallest DSA by population in the continental United states. Because it has fewer individuals within its DSA, the number of donors, and organs it is able to procure, is proportionally smaller than other DSAs.

189. As a result, ConnectLife will naturally experience greater year-to-year variation in donation rate and transplantation rate.

190. The Final Rule's use of just a single year of data accordingly imposes a greater likelihood that ConnectLife will fall outside of Tier 1 as compared to other, larger OPOs.

191. Second, and relatedly, the Western New York DSA includes only one transplant hospital. That hospital conducts only kidney and pancreas transplants, lacking a thoracic program (for lung and heart transplants) or a liver program.

192. CMS has recognized that DSAs with more transplant hospitals are "associated with greater use of organs that might otherwise be discarded." 85 Fed. Reg. at 77,929. But CMS fails to account for this issue in its comparative ranking system.

193. Third, the Western New York DSA is home to an older population with significant health and demographic issues that lessen its true donor potential. Western New Yorkers suffer chronic health conditions at above average rates, including hypertension, obesity, heart disease, and kidney disease. These epidemiologic patterns demonstrate that the Western New York region has elevated chronic disease burden, directly contributing to increased donor medical complexity.

194. Fourth, because ConnectLife is not located in or near a large metropolitan area, a moderate climate, or a large transportation hub, it faces innumerable practical challenges that other OPOs do not face. For example, Western New York faces unique transportation issues that make it difficult to move organs on short tight frames. In addition to significant weather issues through much of the calendar year, the only large commercial airport in ConnectLife's DSA has limited schedules and generally lacks late-night departing flights. Accordingly, ConnectLife cannot rely on commercial flights to transport organs for a significant portion of each day.

195. ConnectLife has been able to overcome these challenges and land in Tier 1 based on 2025 preliminary data through its deep roots, local knowledge, and strong professional and community relationships developed over more than four decades.

196. ConnectLife employs three on-site referral coordinators, eleven clinical donation coordinators, four family care coordinators, and three members of a hospital development team. These employees have established relationships working in 26 hospitals in Western New York. They are well known on the floors of these local hospitals, and to the numerous individuals involved in the organ donation process, from doctors and nurses, to social workers and medical examiners.

197. ConnectLife also has close working relationships with surgeons and third-party vendors, including companies that maintains organ function during transport. Both are essential to meeting the unique challenges of the Western New York DSA.

198. Further, ConnectLife has special expertise in navigating issues specific to New York State, including organ donations involving guardianship proceedings, incarcerated individuals, and wards of the state. ConnectLife also has established relationships with infectious disease testing facilities that require specific New York State certification.

199. ConnectLife can call on its local contacts at any time, day or night, and be met with recognition and cooperation. Likewise, hospital staff know that they can contact ConnectLife employees at any time and be assured of a rapid response.

200. Stripping ConnectLife of its DSA, and awarding it to an OPO from elsewhere would disrupt the successful organ donation system in place and undermine ConnectLife's existing relationships.

201. ConnectLife has spent years training its employees and developing the individual relationships so critical to successful organ procurement. That familiarity would be lost if ConnectLife's DSA were awarded to an out-of-town OPO.

202. Local hospitals know and trust ConnectLife's team. They have worked closely with ConnectLife staff in high-pressure situations, and are familiar with ConnectLife's processes and procedures. A new OPO would disrupt these relationships by bringing in new employees, new processes, and different procedures.

203. This disruption would likely decrease the number of organ donations in Western New York, thereby harming the general public.

204. The Final Rule has already imposed harm on ConnectLife. To prepare for a potential bid on its existing DSA, ConnectLife has been forced to divert resources from its life-saving mission. ConnectLife's Chief Executive Officer, Senior Director of Organ Services, Hospital Development Team, and Information Technology Team, have all devoted substantial time and effort to preparing for the impact of the new rule. Diverting time and resources away from ConnectLife's core mission is contrary to the public interest.

CAUSES OF ACTION

COUNT I
Administrative Procedure Act
5 U.S.C. § 706(2)(C) - Agency Action Contrary to Law

205. ConnectLife restates the facts set forth in the foregoing paragraphs.

206. A court must "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

207. The Final rule is contrary to statute for several independent reasons.

208. First, the Final Rule contravenes the statutory requirement that each OPO have one, and only one, DSA. Congress directed that "[t]he Secretary may not designate more than one organ procurement organization for each service area." 42 U.S.C. § 1320b-8(b)(2). It further required that each OPO "has a defined service area." 42 U.S.C. § 273(b)(1)(E). Congress provided a single exception to this one-to-one relationship, permitting hospitals to obtain waivers to work with a different OPO under limited circumstances. 42 U.S.C. § 1320b-8(a)(2).

209. Defendants were not free to create additional exceptions to the statutorily required one-to-one relationship between OPOS and DSAs. The Final Rule nonetheless allows certified OPOs to be stripped of their DSAs, and have their DSAs awarded to other OPOs. 42 CFR § 486.316. As a result, some certified OPOs would have no DSA while other would have multiple DSAs. Such an outcome is inconsistent with the statute.

210. Second, Congress did not include any provision in the relevant statutes permitting Defendants to force OPOs into competition with one another. Where Congress seeks to employ competitive procedures in a statutory scheme, it does so explicitly. *See, e.g.*, 42 U.S.C. § 1395kk-1(b)(1)(A) (directing that the "Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors"). Congress did not authorize Defendants to force OPOs to compete against each other for their existing DSAs. Instead, Congress deliberately insulated OPOs from market forces. *See* 42 U.S.C. § 274e.

211. The Final Rule nonetheless pits even high-performing OPOs against each other in a zero-sum competition for "organizational survival." 85 Fed. Reg. at 77,933. Because the statute lacks any provision for stripping an OPO of its DSA absent decertification, this forced competition is not authorized by law.

212. Third, Congress required Defendants to measure the performance of an OPO objectively, using data from its DSA. 42 U.S.C. § 273(b). But the Final Rule assesses OPOs subjectively, using comparative data from other DSAs. 42 CFR § 486.316. Under the Final Rule, an OPO cannot determine whether it will be recertified or whether it will maintain its DSA using empirical evidence from its own DSA. Instead, the Final Rule dictates that those determinations will turn on ever-shifting comparisons to other OPOs, using data from other DSAs. It requires that OPOs falling below the median rate for donation rate or transplantation rate be certified, and that OPOs falling below the 25th percentile on either measure may have their DSAs awarded to competitors. 42 CFR § 486.318(e).

213. Congress did not authorize Defendants to decertify an OPO, or to strip an OPO of its DSA, using comparative data from other DSAs. Nowhere in the statute is there any provision permitting a competitive scheme, which will necessarily eliminate most OPOs over a short period of time.

214. Fourth, Congress directed Defendants to use "multiple outcome measures" in making certification decisions. 42 U.S.C. § 273(b)(1)(D)(ii). But the Final Rule uses only two figures, donation rate and transplantation rate. Both figures use donor potential as the denominator. The only difference between donation rate and

transplantation rate is the number of organs transplanted from a single donor. But OPOs have absolutely no influence on those transplantation decisions.

215. By using two tightly correlated metrics that are differentiated solely by factors outside of an OPO's control, Defendants have failed to comply with Congress's direction that they utilize multiple outcome measures.

216. This Court should set aside the Final Rule as unauthorized by statute.

COUNT II
Administrative Procedure Act
5 U.S.C. § 706(2)(A) - Arbitrary and Capricious Agency Action

217. ConnectLife restates the facts set forth in the foregoing paragraphs.

218. A court must "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

219. The Final Rule is arbitrary, capricious, and abuse of discretion or otherwise not in accordance with law in several respects.

220. First, Defendants failed to reckon with the inevitable consequence of the forced-competition scheme. Each recertification cycle, all OPOs following below the median on either of Defendants' new outcome measures will be directly decertified. Further, OPOs falling outside the top 25th percentile on either measure will face *de facto* decertification by being stripped of their DSAs. Accordingly, the country will be left with a handful of OPOs with numerous DSAs that lack the local connections Congress envisioned. And, ironically, these few remaining mega-OPOs will not face the competitive pressures the Final Rule attempts to impose,

221. Second, the Final Rule unreasonably ignores most of the data available from an OPO. Rather than reviewing an OPOs performance over the course of the four-year recertification cycle the Final Rule looks only to a single year of data. This blinkered approach dramatically increases the variance in the data, an especially acute problem for smaller OPOs like ConnectLife. And it prevents Defendants from identifying meaningful trends in the data showing improved performance.

222. Third, Defendants' decision to use only two tightly correlated data points lacks a rational basis. The only two outcome measures considered under the Final Rule, donation rate and transplantation rate, use the same denominator, donor potential. One can calculate an OPO's transplantation rate simply by multiplying donation rate by the number of organs used per donor, a factor wholly outside of an OPO's control. There is no rational basis for limiting recertification decisions to what is effectively a single meaningful data point.

223. Relatedly, Defendants' use of donor rate and transplantation rate is itself arbitrary and capricious. While OPOs are charged with facilitating donation of organs, the decision of whether to use a donated organ is one in which OPOs play no part. Instead, those decisions are made by medical professionals. Transplantation rate thus measures a variable unrelated to OPO performance. Further, because the numerator for donation rate includes only those donors for which at least one organ is used, donation rate suffers the same defect. Decertifying an OPO based solely on decisions over which they lack any control is unreasonable.

224. Fourth, the data Defendants selected for measuring donation rate and transplantation rate is hopelessly flawed. The underlying statistics are unreliable.

Defendants fail to accurately measure donor potential. And the scale of problems with the relevant data vary from DSA to DSA, leaving CMS without an accurate comparison of OPO performance.

225. This Court should set aside the Final Rule as arbitrary and capricious.

PRAYER FOR RELIEF

WHEREFORE, ConnectLife respectfully requests this Court enter judgment:

A. declaring, pursuant to 28 U.S.C. § 2201, that the Final Rule violates the Administrative Procedure Act, 5 U.S.C. § 706;

B. setting aside and vacating the Final Rule under 5 U.S.C. § 706;

C. granting preliminary and permanent injunctive relief, enjoining Defendants from enforcing the Final Rule against ConnectLife;

D. awarding costs, expenses, and attorneys' fees under 28 U.S.C. § 2412; and

E. granting such other relief as the Court deems just and proper.

Dated: Buffalo, New York
February 27, 2026

PHILLIPS LYTLE LLP

By: _/s/ John G. Schmidt Jr._____

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Doc #13175906

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Western District of New York

UPSTATE NEW YORK TRANSPLANT SERVICES, INC. D/B/A CONNECTLIFE

Plaintiff(s)

v.

ROBERT FRANCIS KENNEDY JR., in his official capacity as Secretary of Health and Human Services; MEHMET OZ, M.D. US DEPARTMENT OF HEALTH AND HUMAN SERVICS, et al.

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: John G. Schmidt Jr.
Joshua Glasgow
Louis Q. Reynolds
PHILLIPS LYTLE LLP
One Canalside, 125 Main Street
Buffalo, New York 14203-2887

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

Print