UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

LIFELINK FOUNDATION, INC.,
ONELEGACY,
IOWA DONOR NETWORK,
LIFECENTER NORTHWEST, and
LIFEGIFT ORGAN DONATION
CENTER,

Plaintiffs

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.

Case No. 8:25-cv-02042

COMPLAINT

Plaintiffs LifeLink Foundation, Inc., OneLegacy, Iowa Donor Network, LifeCenter Northwest, and LifeGift Organ Donation Center, by and through their undersigned counsel, bring this action 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 "CMS Administrator"), the Department of Health and Human Services ("HHS"), and the Centers for Medicare and Medicaid Services ("CMS"). In support, plaintiffs allege as follows:

PRELIMINARY STATEMENT

1. This action challenges CMS's final rule, Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 Fed. Reg. 77,898 (Dec. 2, 2020) (codified at 42 C.F.R. pt. 486) ("Final Rule"). *See* 42 C.F.R. §§ 486.302, 486.316, 486.318.

2. The Final Rule radically changes the certification system used to evaluate the performance of the nation's 55 non-profit, organ procurement organizations. Plaintiffs are bringing this action because CMS's Final Rule contravenes Congress's express instructions, violates the statute, and is contrary to the requirements of reasoned decision-making under the Administrative Procedure Act. The Final Rule's new certification scheme does not reasonably, accurately, or fairly measure the performance of organ procurement organizations, as Congress directed. It upsets the reasonable, reliance-backed expectations of the nation's organ procurement organizations, including plaintiffs. And CMS promulgated the Final Rule without reasonably responding to significant objections that its new scheme will cause massive disruptions and destabilize the nation's organ donation and transplantation system, causing material harm not only to organ procurement

organizations and their highly trained staff but also to patients, donors, and donor families.

3. Plaintiffs are seeking to expedite this matter to ensure that the Court has time to render a decision on the merits before CMS begins decertification and recertification proceedings, which are expected to start as soon as July 2026.

4. Plaintiffs are asking the Court to (a) declare that CMS's Final Rule violates the statute and the requirements of reasoned decision-making, (b) vacate the Final Rule, and (c) direct the agency to comply with the law.

INTRODUCTION

5. Congress enacted the National Organ Transplant Act in 1984 — and has since amended the statutory requirements multiple times, including most significantly in 2000 — to promote organ donation by creating a nationwide system of distinct geographic areas to be served by individually designated non-profit entities known as "organ procurement organizations." 42 U.S.C. § 273 *et seq*. Recognizing the different challenges posed by each donation service area's unique geographic and demographic characteristics, Congress crafted the statute's requirements to encourage organ procurement organizations to tailor their services and outreach efforts to the needs of their local communities and to develop the stable, long-standing relationships necessary to "effectively obtain organs from donors in [each of their] service area[s]." *Id*. § 273(b)(1)(F).

6. Congress adopted express performance requirements that all organ procurement organizations are expected to meet. Those requirements include being

fiscally stable; having effective agreements with hospitals and other healthcare entities in the local communities they serve; conducting and participating in "systematic efforts" to "acquire all useable organs from potential donors"; arranging for the acquisition and preservation of donated organs; developing a system to "allocate donated organs equitably among transplant patients"; providing for the "transportation of donated organs to transplant centers"; arranging to "coordinate" the activities of "transplant centers in [their] service areas"; and "assist[ing] hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors." *Id.* § 273(b)(1), (b)(3).

7. To further the statute's goals, Congress instructed CMS to establish a certification process that would evaluate over the "previous 4-year period" whether an organization has met the "performance standards" necessary to remain a "qualified organ procurement organization." *Id.* § 273(b)(1)(D). In conducting that evaluation, Congress directed CMS to "rely on" both "*outcome* and *process* performance *measures* that are based on *empirical evidence* … of organ donor potential *and other* related factors *in each*" designated service area. *Id.* § 273(b)(1)(D)(ii)(II) (emphasis added). It also made clear that CMS must apply "*multiple outcome measures* as part of the certification process." *Id.* § 273(b)(1)(D)(ii)(III) (emphasis added).

8. In legislative findings that accompanied the 2000 statutory amendments, Congress provided further guidance and criticized CMS for causing "uncertainty" that "interfere[d] with the effectiveness of organ procurement organizations in raising the level of organ donation[s]." Organ Procurement Organization Certification Act

of 2000, Pub. L. No. 106-505, § 701(b)(2), 114 Stat. 2346, 2346. It directed CMS to "develop *improved performance measures* that would reflect organ donor potential and interim outcomes"; "*test these measures* to ensure that they *accurately measure performance differences* among the organ procurement organizations"; "improve the overall certification process by incorporating *process* as well as *outcome* performance measures"; and ensure an "equitable" process for challenging CMS's certification decisions on "substantive" and "procedural" grounds. 42 U.S.C. § 273 note (emphases added) (quoting 114 Stat. at 2347).

9. Plaintiffs have made significant efforts to improve performance and strongly support reforms that — consistent with Congress's expressed intent — would improve the nation's organ donation system. Plaintiffs favor reforms that would evaluate the performance of organizations against the statutory standards that Congress imposed; recognize those organizations that are working diligently to increase the number of donated, recovered, and successfully transplanted organs; create incentives for hospitals and transplant centers to work with organ procurement organizations to improve the overall procurement and equitable distribution of organs; and decertify organizations that shirk their statutory obligations. But CMS's Final Rule does not accomplish any of those salutary objectives. Instead, it violates Congress's express statutory instructions and establishes an arbitrary and unreasonable certification process that by design will cause systemic disruption to the nation's organ donation system to the detriment of patients, donors, and donor families.

10. Instead of putting in place both process measures and multiple outcome measures to accurately evaluate performance against statutory requirements, as Congress directed, CMS's Final Rule applies only two closely correlated outcome metrics — (1) the donation rate (the number of actual donors as compared to the number of potential eligible donors) and (2) the transplantation rate (the number of organs transplanted as compared to the number of potential eligible donors). *See* 42 C.F.R. § 486.318.

11. The Final Rule requires CMS to compare the organ donation and transplantation rates of organ procurement organizations using only data from the previous 12 months and, based on that comparison, to rank organizations in one of three tiers (Tier 1, 2, or 3). It then imposes draconian penalties on any organization that does not fall within the 95% confidence interval of the nation's top 25% in either of the two, correlated outcome metrics. Even though those metrics are substantially influenced by factors beyond the control of any organ procurement organization, the Final Rule requires the decertification of organizations assigned to Tier 3, prohibiting those organizations from participating in the nation's organ donation and transplantation system, and it threatens to replace any organizations assigned to Tier 2 by assigning their designated service areas to different organizations.

12. Nothing in the statute authorizes this "hunger games" approach. Congress designed the nation's organ donation network to promote a cooperative system designed to allow non-profit organizations to develop the long-term, community-focused relationships necessary to increase organ donation, support

donor families, and facilitate successful transplantation. Congress also understood the danger that outcome-based performance targets often distort rather than enhance performance, especially when they collapse complex challenges into simplistic measures that are not reliable. Congress directed CMS to use *multiple* outcome measures, as well as *process* measures, to ensure that organizations are meeting the statutory requirements over each four-year certification period. 42 U.S.C. § 273(b)(1)(D)(ii)(II)–(III). It instructed CMS to consider not only "organ donor potential" but also "other related factors in each service area" to evaluate performance. *Id.* § 273(b)(1)(D)(ii)(II). And it wanted CMS to adopt an assortment of objective and empirical standards to evaluate whether organizations are meeting their statutory obligations. *Id.* § 273(b)(1), (b)(3).

13. Congress never authorized CMS to decertify an organization based solely on donation and transplantation rates using 12 months of data, and with no consideration as to whether an organization's actual performance over time complies with the statute's express performance requirements. And it certainly never authorized CMS to devastate the nation's organ donation and transplantation system by decertifying large numbers of the nation's organ procurement organizations, subjecting more than 50% of the nation's donation service areas to a threat of disruptive change, and ultimately causing counterproductive consolidation that will destabilize the system and result in inferior outcomes for patients, donors, and donor families.

14. CMS's two closely correlated outcome metrics do not reasonably, accurately, or reliably evaluate performance. Contrary to Congress's instructions, the metrics do not take into consideration the challenges presented by each unique donation service area based on "organ donor potential and other related factors in each service area." *Id.* § 273(b)(1)(D)(ii). Nor do CMS's outcome metrics evaluate the "processes" that organ procurement organizations implement to satisfy their statutory obligations. Moreover, one of the metrics — the transplantation rate — is not even a measure of performance by the organizations themselves. Organ procurement organizations neither decide which recovered organs (if any) are appropriate for transplant nor perform transplants — they are performed by transplant surgeons at transplant centers — and it is unreasonable to hold the organizations responsible for the conduct of other parties in connection with medically complex transplantation.

15. Considering only donation and transplantation rates within an organization's service area without considering the reasons those rates naturally vary — and without evaluating the processes implemented by each organization to address the challenges posed by the unique characteristics of its designated service area — does not reliably or objectively measure performance. Geographic and demographic factors — such as death rates, economic disparities, cultural differences, varied attitudes to donation, donor hospital and transplant center performance and concentration, and causes of death and secondary diagnoses that allow for or prevent

donation — are all material factors that influence the number of potential organ donors, and in turn donor and transplantation rates, in each service area.

16. An organ procurement organization that serves a homogenous community in a geographically small and densely populated suburban area served by numerous, closely situated hospitals and transplant centers with multiple transplant programs and high organ acceptance rates does not face the same challenges as an organization that serves many different local communities in large and sparsely populated rural areas served by only a few, distantly located hospitals and transplant centers, particularly those with only a few transplant programs and low organ acceptance rates.

17. Moreover, donation and transplantation rates are both contingent on the calculated number of potential eligible donors in a service area — which is the denominator in both metrics — and that calculation is based on flawed state death-certificate data that does not accurately measure "organ donor potential" as required by the statute. *See* 42 U.S.C. § 273(b)(1)(D)(ii)(II). The state death-certificate data used by CMS as a proxy for "organ donor potential" are frequently miscoded by physicians and do not account for other causes of death or secondary conditions that render organ donation impossible. As a result, even on their own terms, the two closely correlated metrics that CMS has chosen to use — donation rate and transplantation rate — are not reliably calculated, and the flaws in the data mean that CMS's comparative evaluation is not objectively accurate.

18. Nor did CMS reasonably respond to the many objections that were raised criticizing its approach. CMS instead embraced the "hunger games" feature of its Final Rule, "assum[ing]" that, on average, organ procurement organizations would be able to improve their performance when forced to "[s]triv[e]" for "organizational survival" and that the outcomes would be "consistent with the results from other situations where large numbers of organizations faced potential closure." 85 Fed. Reg. at 77,933. CMS never adequately responded to concerns that its Final Rule does not reliably measure organizational performance, or that the metrics within a donation service area vary significantly for reasons that do not reflect the performance of the designated organ procurement organization. It failed to address in any meaningful way significant objections that the Final Rule fails to count eligible donors who did not ultimately result in a successful transplant because of performance, policies, and rejection by the transplant centers (and transplant surgeons). Nor did it reasonably or meaningfully address concerns that the data source it uses to assess donor potential (*i.e.*, state death certificate data) is widely recognized to be inaccurate and unreliable, and that its ranking system relies on a confidence interval that is mathematically biased against larger organizations in ways that do not reflect actual performance.

19. If CMS's Final Rule is not vacated before the decertification process begins in July 2026, the nation's donation and transplantation system will suffer massive disruption, large numbers of the nation's organ procurement organizations will be driven out of service, and transplant patients will suffer. Donation and the

availability of transplantable organs are already being impacted by CMS's Final Rule and the imminent risk that large numbers of organizations will be decertified or replaced. With an uncertain future, some organizations are struggling to hire and retain the highly trained staff necessary to drive the organ donation process. Narratives built around CMS's Final Rule and CMS's decision to label certain organizations as "low performers" has undermined the community and public trust necessary for continuing to improve the nation's donation system.

20. CMS has never explained how it intends to deal with the destabilizing consequences of its Final Rule. Nor has CMS offered any credible reason why forcing consolidation and shuttering dozens of existing organ procurement organizations is likely to result in improvements for the benefit of patients, donors, and donor families. Without measuring actual performance against the statutory criteria — and without evaluating the processes that each organ procurement organization puts in place to meet the unique challenges posed by its designated service area — CMS is only guessing.

21. The U.S. transplant system saves more lives than the system of any other country in the world, with overall donation rates significantly increasing over the past decade. Organ procurement organizations increased the number of organ offers made to transplant centers by 58.4% between 2020 and 2024, and in 2024 they outperformed CMS's stated goal of having 41,000 deceased donor transplants by 2025. *See* Alexandra K. Glazier, *Out-of-Sequence, Out of Alignment, and Out of Time: Why the Organ Procurement Organization Measures Are at the Root of This Problem*, 25 Am.

J. Transplantation 1367, 1367–69 (2025) (Ex. I). If Congress had intended CMS to promulgate regulations to dismantle that system — causing substantial harm to patients and a loss of life — it would have spoken in much clearer terms. Congress's instructions to implement *multiple* outcome *and* process measures to evaluate organizational performance cannot plausibly be construed to authorize CMS to ignore meaningful differences between service areas and what may be necessary in each service area to increase donations and improve services to patients and donor families. Nor can it plausibly be construed to allow CMS to avoid the obligations that Congress imposed and instead evaluate organizations based only on two closely correlated outcome metrics that are not accurate measures of performance.

22. Plaintiffs have made substantial investments and undertaken significant efforts to comply with the statutory requirements and to improve organ donation for the benefit of patients. Given the substantial reliance interests at stake, this Court should not allow CMS to contravene Congress's intended system with an upside-down decertification process designed to force non-profit organizations to fight for their survival based on arbitrary metrics that do not accurately measure performance. The Court should instead grant declaratory and injunctive relief to vacate, set aside, and enjoin enforcement of CMS's Final Rule. It should then remand for CMS to comply with the statute and complete the work required by Congress.

PARTIES

A. Plaintiffs

23. ***Plaintiff LifeLink Foundation, Inc.*** LifeLink Foundation, Inc. is a Florida nonprofit corporation organized and existing under the laws of Florida with its principal place of business in Tampa, Florida. It has more than 700 full-time and part-time staff in Florida, Georgia, and Puerto Rico. Three of its divisions are organ procurement organizations: LifeLink of Florida, LifeLink of Georgia, and LifeLink of Puerto Rico. *See* Stephanie Hernandez Decl. ¶¶ 3–7 (Ex. A).

24. LifeLink of Florida is the 22nd largest organ procurement organization by population size and the 42nd largest by land area with 11,325 square miles. It serves a population of over 6 million residents across 15 Florida counties in west and southwest Florida. LifeLink of Florida's donation service area has more than 65 hospitals but only 3 transplant centers, and the organization faces significant geographic challenges. Those challenges include a six-month hurricane season and severe weather events that can often threaten transportation and hospital infrastructure; a limited number of direct flight options; and long internal travel distances between donor hospitals and transplant centers with only limited ground transport corridors. LifeLink of Florida's donation service area has a diverse and aging population, with different communities that have different cultural beliefs, primary languages, and related factors that have a significant influence on donation registration and authorization rates. *See* Darren Lahrman Decl. ¶¶ 9–12, 29–33, 36–44 (Ex. B).

25. LifeLink of Georgia is the ninth largest organ procurement organization by donation service area population size and the 17th largest by land area with 57,837 square miles. It serves a population of over 10.5 million residents across 158 of Georgia's 160 counties and two counties in central South Carolina. The organization's comparatively large donation service area encompasses diverse urban, suburban, and rural areas. In rural areas, the significant distances between rural hospitals and transplant centers, coupled with the limited availability of dependable transportation providers, causes significant transportation challenges. Moreover, many hospitals in Georgia are currently facing escalating financial, resource, and staffing challenges that have complicated organ donation. These realities underscore the importance of locally tailored strategies and continuous public engagement within LifeLink of Georgia's service area. *See* Susan Rabel Decl. ¶¶ 6–7, 25–33 (Ex. C).

26. LifeLink of Puerto Rico is the 40th largest organ procurement organization by donation service area population size and the smallest by land area with 3,557 non-contiguous square miles. It serves nearly 3.2 million residents across 81 counties spanning the whole of Puerto Rico and the U.S. Virgin Islands. LifeLink of Puerto Rico's donation service area has 60 acute care hospitals and 2 transplant centers. LifeLink of Puerto Rico faces significant challenges because of its service area's highly distinctive geographic, demographic, and cultural profile, including that Puerto Rico is an island more than 1,000 miles from the mainland and other transplant centers. The two transplant centers in Puerto Rico have only four transplant programs and, as a result, many organs, particularly lungs and pediatric

organs, must be transported to the mainland. In addition, the population in Puerto Rico faces significant levels of poverty and health disparities, and the island's healthcare infrastructure faces significant workforce and financial challenges. *See* Guillermina Sanchez Decl. ¶¶ 5–18, 24–32 (Ex. D).

27. ***Plaintiff OneLegacy***. OneLegacy is a non-profit public benefit corporation with its principal place of business in Azusa, California. *See* Prasad Garimella Decl. ¶ 5 (Ex. E). OneLegacy is the largest organ procurement organization in the nation by donation service area population size, and the 25th largest by land area, encompassing 44,822 square miles in the seven-county greater Los Angeles area. *See id.* ¶ 11. OneLegacy serves 215 hospitals, nine transplant centers, and a highly diverse population of 20 million residents in the Southern California region. *See id.* ¶¶ 9–10. OneLegacy is a leader in innovation, *see id.* ¶ 19, and has worked hard to build long-standing relationships within the local communities its serves, *see id.* ¶¶ 20–30. Between 2014 to 2024, OneLegacy grew the number of organs transplanted by more than 50%. *See id.* ¶ 32. In 2024, OneLegacy coordinated the transplantation of a record 1,941 organs, more than any organ procurement organization in the history of the United States. *See id.* ¶ 31.

28. OneLegacy faces significant geographic and demographic challenges. *See id.* ¶ 33. For many of the organs it recovers, it has access to few transplant centers as compared to other donation service areas in other parts of the nation. *See id.* ¶¶ 34–38. Moreover, the transplant centers within OneLegacy's geographic reach are often

more restrictive in terms of when they will accept organs for transplant. For example, between May 2023 and May 2025, transplant centers across the country transplanted 128 livers from organ donors who were 79 years of age or older. Only *three* of those livers were accepted by transplant centers west of the Rocky Mountains. *See id.* ¶ 38. OneLegacy also faces significant demographic challenges stemming from the many diverse and different local communities in its donation service area. *See id.* ¶¶ 39–41. These different communities have varying different levels of education attainment and different religious and cultural attitudes to donation. *See id.* ¶¶ 33–41.

29. ***Plaintiff Iowa Donor Network***. Iowa Donor Network is an Iowa nonprofit corporation with its principal place of business in North Liberty, Iowa. Iowa Donor Network was founded in 1994 and is the 42nd largest organ procurement organization by donation service area population size and the eighteenth largest by land area with 54,713 square miles. It is the designated organ procurement organization for the state of Iowa, serving just over 2.9 million residents across 97 counties. It also serves one Nebraska county in the Sioux City metropolitan statistical area, as well as two hospitals in counties in Nebraska and Illinois. Iowa Donor Network's donation service area has more than 120 hospitals and 3 transplant centers. *See* Suzanne Conrad Decl. ¶¶ 12–15 (Ex. F).

30. Iowa Donor Network has a largely rural service area with significant geographic challenges to increasing donation rates. Iowa has only two small hub airports offering limited commercial flights and service. Many donor hospitals in the service area are a three- to five-hour drive from those airports or from the three

transplant programs in the state, only one of which (at the University of Iowa Hospital in Iowa City) is multi-organ. Over time, broader organ sharing and low acceptance rates have led to decreased transplant activity in Iowa City, and Iowa Donor Network has had to adjust operationally to placing fewer than 20% of organs with transplant programs in its service area. At the same time, the service area has skewed to an aging population with higher rates of comorbidities that affect those individuals' eligibility to donate organs. *See id.* ¶¶ 46–49.

31. ***Plaintiff LifeCenter Northwest***. LifeCenter Northwest is a Washington nonprofit corporation with its principal place of business in Bellevue, Washington. LifeCenter Northwest was founded in 1996 and is the 12th largest organ procurement organization by donation service area population size and the largest by land area with 808,306 non-contiguous square miles. It serves a highly diverse population of over 9.1 million residents across 131 counties encompassing the entirety of Washington, Alaska, Montana, and the northern half of Idaho. LifeCenter Northwest's donation service area has more than 200 hospitals and 10 transplant centers. *See* Santokh Gill Decl. ¶¶ 5–9, 19–20, 40 (Ex. G).

32. LifeCenter Northwest's service area is 808,000 square miles, which covers nearly 25% of the United States, and it has the lowest population density of any service area in the country. The low density of transplant programs within LifeCenter Northwest's donation service area, the low volume of transplants within the service area, and the vast distances from many donor hospitals to transplant centers pose significant challenges for increasing organ donation and transplantation.

Despite these challenges, LifeCenter Northwest has demonstrated continuous growth in both organ donation and transplantation, with increases in donors and transplants from 2020 to 2024 that have outpaced national growth rates. *See id.* ¶¶ 12, 19–24.

33. ***Plaintiff LifeGift Organ Donation Center ("LifeGift").*** LifeGift is a Texas nonprofit corporation organized and existing under the laws of Texas with its principal place of business in Houston, Texas. Founded in 1987, LifeGift is a highly productive organ procurement organization achieving growth in donation and transplants despite the challenges inherent in its donor population. *See* Kevin A. Myer Decl. ¶ 6 (Ex. H). LifeGift is the seventh largest organ procurement organization by donation service area population size and the ninth largest by land area with 105,325 square miles. It serves a highly diverse population of 11.3 million residents across 109 Texas counties in the greater Houston and Fort Worth areas, as well as the Texas Panhandle. LifeGift's donation service area has more than 275 hospitals and 10 transplant centers. *See id.* ¶¶ 7–10.

34. The geographic and demographic challenges to increasing organ donation in LifeGift's designated service area are specialized, requiring LifeGift to hone culturally competent outreach to maximize its donor potential. *See id.* ¶¶ 35–64. LifeGift has worked tirelessly with local communities in its donation service area to break down barriers to donation. LifeGift has also invested significant time and resources to ensure year-over-year growth, increasing its staff significantly with an emphasis on patient safety and quality. LifeGift has shown active leadership in many clinical areas, deploying new organ recovery techniques and participating in

important clinical research projects and the development of innovative technologies. *See id.* ¶¶ 18–26.

35. ***Defendant Health and Human Services ("HHS").*** HHS is an executive department in the United States government headquartered at 200 Independence Avenue SW, Washington, DC 20201.

36. ***Defendant Centers for Medicare & Medicaid Services ("CMS").*** 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 promulgates outcome measure requirements and conditions for Medicare certification of organ procurement organizations under authority delegated by Congress and the Secretary of HHS.

37. ***Defendant Robert Francis Kennedy, Jr. ("Secretary").*** Mr. Kennedy, who is sued only in his official capacity, is the Secretary of Health and Human Services. The Secretary has responsibility for the administration of the Medicare program. His official address is 200 Independence Avenue SW, Washington, DC 20201.

38. ***Defendant Mehmet Oz, M.D. ("CMS Administrator").*** Dr. Oz, who is sued only in his official capacity, is the Administrator of CMS. The CMS Administrator is responsible for administering the Medicare program and promulgating outcome measure requirements and conditions for Medicare certification of organ procurement organizations. His official address is 7500 Security Boulevard, Baltimore, Maryland 21244.

JURISDICTION AND VENUE

39. This Court has original subject matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the laws of the United States.

40. Plaintiffs have a right to bring this action under the Administrative Procedure Act and the Declaratory Judgment Act. *See* 5 U.S.C. §§ 701–706, 28 U.S.C. § 2201.

41. Plaintiffs have standing because CMS's Final Rule directly regulates them, they are adversely affected by the Final Rule, and their injuries would be redressed by a decision in their favor. Plaintiffs have a direct and concrete interest in the Final Rule because it governs the conditions that organ procurement organizations (including plaintiffs) must satisfy to remain certified to operate in the nation's organ procurement network. It also establishes the requirements that organ procurement organizations (including plaintiffs) must meet to receive payments under the Medicare program for the services they provide.

42. Plaintiffs are suffering concrete injuries as a result of CMS's Final Rule, including the significant reputational and operational harms in being labeled Tier 1, Tier 2, or Tier 3, even though those rankings do not accurately reflect their actual performance. They are also being forced to make significant investments in time and resources to address the immediate disruptions caused by CMS's Final Rule and the risks that they face imminent decertification or replacement under the Final Rule. If the Final Rule were vacated, they would focus their resources on other activities that are better suited to helping patients and donor families.

43. The Final Rule is imposing immediate costs and consequences on plaintiffs. It is also already destabilizing the nation's organ donation system and creating incentives that are undermining Congress's goals. Among other examples, CMS is already applying the interim (non-final) results of its new tier-ranking system, including using them as a proxy for determining when to grant waivers permitting hospitals to work with organ procurement organizations outside their donation service area.

44. Plaintiffs actively participated in the rulemaking proceedings, and many submitted comments in response to CMS's proposed rule, either directly or through industry associations.

45. There is an actual, justiciable controversy between the parties concerning whether CMS's Final Rule is consistent with the requirements of reasoned decision-making under the Administrative Procedure Act and the requirements of federal law, including the provisions of the National Organ Transplant Act, 42 U.S.C. § 273 *et seq.*, and the Organ Procurement Organization Certification Act of 2000, Pub. L. No. 106-505, 114 Stat. 2346, which amended section 371(b)(1) of the Public Health Service Act, 42 U.S.C. § 273(b)(1).

46. Venue for this action is proper 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 plaintiff LifeLink Foundation, Inc. resides in this district.

GENERAL ALLEGATIONS

A. The Statutory Background

47. Organ transplantation is one of the great accomplishments of modern medicine. Advances in medical science and technology have made it an increasingly successful and common medical procedure. It offers a second chance at a healthy and productive life for people of all ages who suffer from life-threatening diseases or injuries to their vital organs.

48. The need for transplanted organs transplants far exceeds the organs available for donation. Although the number of transplants has grown steadily over time, so has the number of patients in need of a transplant. In the United States, more than 100,000 people are waiting for a transplant, but only about 48,000 transplants took place in 2024, with just over 45,000 organs recovered from deceased donors.

49. This shortage has always existed in the United States, as it has in every other country, but the gap in the United States is the smallest in history.

50. Despite the growth in organ failure reflecting notable population-wide increases in diabetes, obesity, and coronary disease, the nation's organ transplant system has steadily improved. Many organ procurement organizations have made significant strides in educating their communities, improving their operational processes, and increasing available organ donors, as illustrated in the recently published OPTN/SRTR 2023 Annual Data Report:

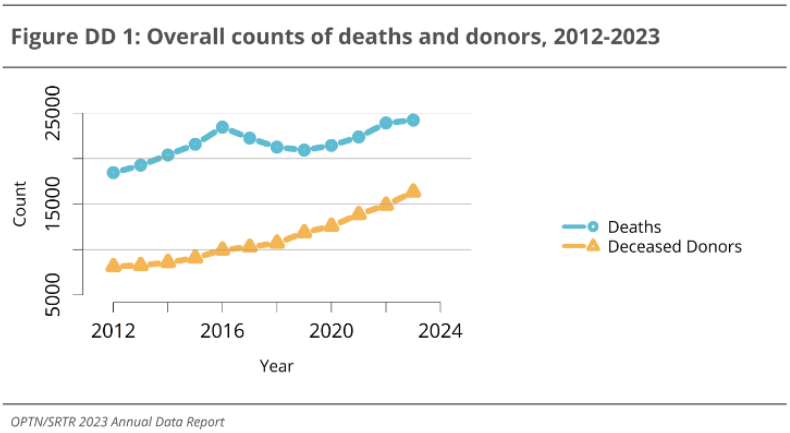


Figure DD 1: Overall counts of deaths and donors, 2012-2023. The number and source of donors.

51. Despite significant increases in organ donation, a gap persists between the need for donated organs and the number of organs that are available for transplant. That gap reflects the many challenges associated with obtaining authorization from eligible donors, recovering organs, transporting those organs, and then successfully transplanting them to waiting patients. Many potential donors choose not to donate, many people die in a way that does not allow for their organs to be donated, and many donated organs are not healthy enough to transplant. Moreover, the willingness of individuals to become organ donors varies significantly from local community to local community depending on cultural attitudes, religious backgrounds, and many other individualized factors. *See* Jonathan M. Miller et al., *Adjusting for Race in Metrics of Organ Procurement Organization Performance*, 24 Am. J. Transplantation 1440, 1441–42 (2024) (Ex. J).

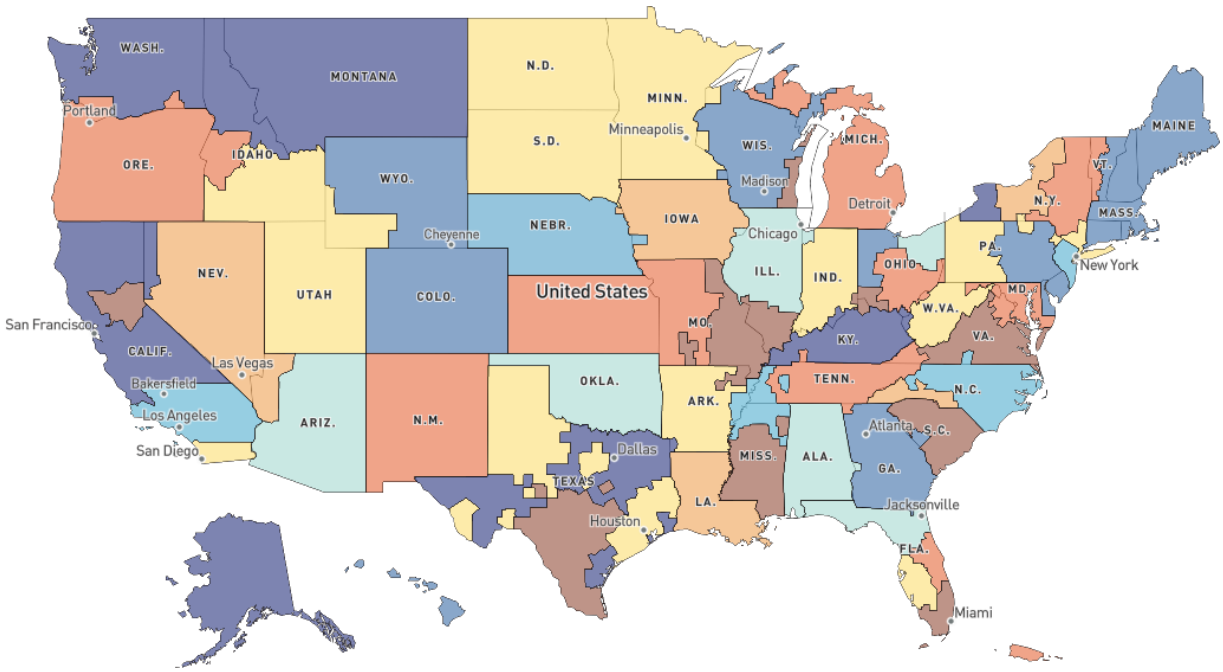
52. In 2024, there were approximately 17,000 deceased organ donors (and just over 7,000 living donors). *See* United Network for Organ Sharing (UNOS), *Data and trends* (2025), https://unos.org/data/.

53. ***Congress's System of Designated Donation Service Areas.*** In 1984, Congress enacted the National Organ Transplant Act. *See* Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified as amended at 42 U.S.C. § 273 *et seq*.). The statute established the nation's "Organ Procurement and Transplantation Network" — a public-private partnership that links professionals involved in the nation's donation and transplantation system — with the goal of improving the processes through which organs are donated and shared across the United States.

54. The statute created a nationwide system of designated "donation service areas." Each area is overseen and served by a single "organ procurement organization" — a non-profit entity designated to oversee the complex and life-saving process of organ donation. *See* 42 U.S.C. § 273(a), (b)(1)(F); *see also* 42 C.F.R. § 486.308(a) ("CMS designates only one OPO per service area.").

55. Donation service areas are unique and typically composed of a number of counties within one or more states. They differ significantly in size and demographics, and they often transcend geographic and political boundaries. They are structured to "assure maximum effectiveness in the procurement and equitable distribution of organs." 42 U.S.C. § 273(b)(1)(E).

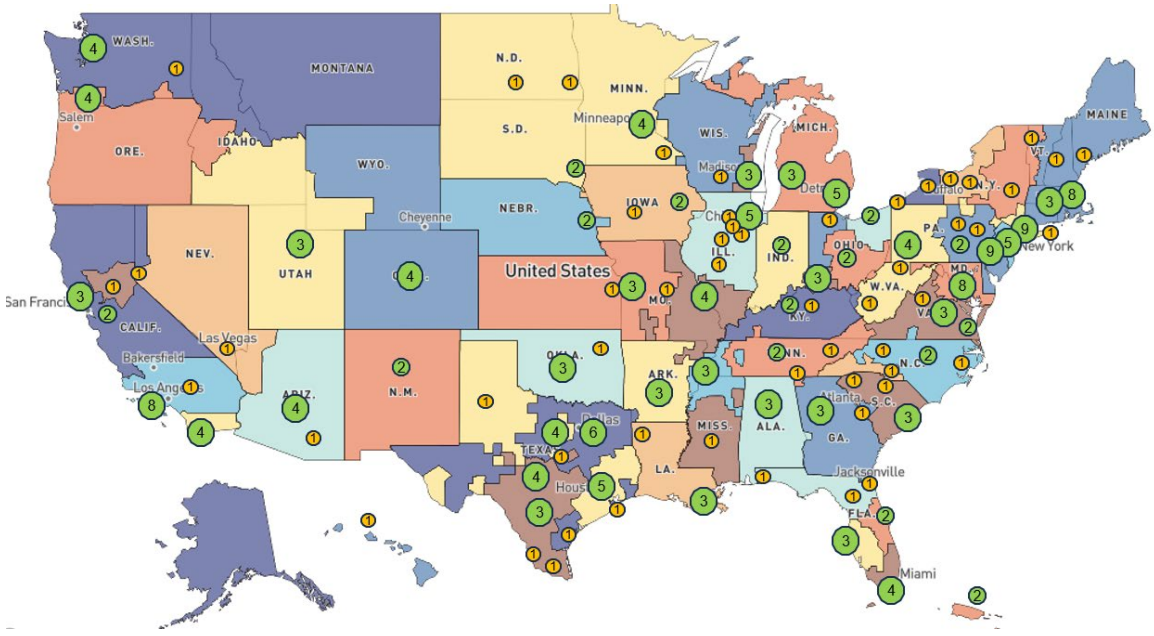
56. There are currently 55 organ procurement organizations that serve the different donation service areas depicted below:



57. In each service area, the designated organ procurement organization coordinates the identification of potential donors, consent and requests for donation, and recovery and transport of donated organs. Working with hospitals, physicians, and transplant programs, the organ procurement organization is responsible for community outreach and educating the public about the importance of organ donation. Many of these organizations lead the way in promoting clinical research and pursuing the innovations needed to increase organ donation and recovery rates.

58. While organ procurement organizations share a core set of responsibilities, they face varied challenges. The donation service areas differ markedly in geographic size and characteristics, demographic composition, and death rates, as well as the number and location of donor hospitals, transplant centers, and patients. That diversity is reflected in meaningful operational differences.

59. One significant difference between individual service areas is their geographic access to transplant centers and the distance between organ donors and their local transplant center. Organ procurement organizations make organs available for transplant, but whether an organ is accepted and transplanted is within the discretion and control of transplant surgeons. The ability to place an organ for transplant (especially organs of lower quality) is greatly diminished when there are fewer transplant centers within transport range of an organ procurement organization. The following image, which uses data from the Scientific Registry of Transplant Recipients ("SRTR"), illustrates the comparative geographic isolation of transplant centers in certain parts of the country, with the numbers in each circle denoting the number of transplant centers in that location.



60. Apart from their geographic access to transplant centers, the nation's donation service areas differ widely in terms of other geographic and demographic

characteristics. There are many material factors — such as death rates, educational attainment, cultural differences, attitudes towards donation, donor hospital and transplant center performance and concentration, and causes of death and secondary diagnoses (which allow for or prevent donation) — that influence the number of potential organ donors, and in turn donor and transplantation rates, regardless of an organ procurement organization's actual performance.

61. For example, OneLegacy, which is the nation's largest organ procurement organization by population, serves 20 million people in the densely populated greater Los Angeles area. Its service area includes 215 donor hospitals and 9 transplant programs. Many segments of its donor population have donation rates well below the national average. The death rate within the service area — reflecting the number of deaths eligible for donation — is 7.52 per 1,000, which ranks 52nd out of the nation's 55 donation service areas.

62. In contrast, ConnectLife, which ranks among the smallest organ procurement organizations by population, serves 1.5 million people in a much less densely populated portion of Western New York (with Buffalo as its sole major metropolitan area). Its donor population has rates above the national average, and the service area includes 100 hospitals and only 1 transplant program. The death rate is 11.54 per 1,000, which ranks 6th out of the nation's 55 donation service areas.

63. It is not possible to conduct an objective, accurate, and non-arbitrary comparison of the performance of these two organizations by statically considering only donation and transplant rates. Those limited outcome metrics do not account

for the vast differences between the two organizations' respective donation service areas, which present unique challenges and require different approaches to helping donor families, serving local communities, and meeting statutory objectives.

64. Congress understood that organ procurement organizations in different donation service areas would face different challenges and, as a result, it designed the system to encourage organizations to structure their operations to best serve their local communities, to respond to local conditions and preferences; to engage in appropriate outreach and education; and to develop close relationships with local donor families, transplant centers, and other partners. Congress also recognized that developing those longstanding and stable relationships was necessary to promote broader community engagement and build trust in organ donation.

65. Consistent with Congress's goals, the statute requires that each organ procurement organization must have "a director and such other staff … necessary to effectively obtain organs from donors in its service area." 42 U.S.C. § 273(b)(1)(F). Each organization also must have an advisory board "composed of" various community stakeholders, including (i) "members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area," (ii) members who "represent the public residing in such area," and (iii) a member from "each transplant center in its service area" who "is a surgeon who has practicing privileges in such center and who performs organ transplant surgery." *Id.* § 273(b)(1)(G).

66. ***Congress's Evidence-Based Certification Process.*** Congress directed CMS to establish "performance standards" for certifying (and re-certifying) individual organ procurement organizations by evaluating their performance in their designated service area against objective criteria. *See* 42 U.S.C. § 273(b)(1)(D).

67. Congress made clear its performance expectations by imposing specific statutory obligations on organ procurement organizations. Those obligations include (1) having effective agreements to identify potential organ donors with a substantial majority of hospitals and other healthcare entities in its service area, (2) conducting and participating in systematic efforts to acquire all useable organs from potential donors, (3) arranging for the acquisition and preservation of donated organs and providing quality standards for the acquisition of organs, (4) arranging for appropriate histocompatability testing of donated organs, (5) implementing a system to allocate donated organs equitably among transplant patients according to established medical criteria, (6) arranging for the transportation of donated organs to transplant programs, (7) making arrangements to coordinate its activities with transplant centers in its service area, (8) participating in the nation's Organ Procurement and Transplantation Network, (9) having arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues to assure that useable tissues are obtained from potential donors, (10) evaluating annually the organization's effectiveness in acquiring potentially available organs, and (11) assisting hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors. 42 U.S.C. § 273(b)(3)(A)–(K);

see also id. § 1320b-8(a)(1)(C) (requiring all Medicare and Medicaid-participating hospitals that conduct organ recovery or transplantation to have an exclusive agreement with the organ procurement organization in their donation service area); 42 C.F.R. § 486.308(c).

68. In developing metrics for evaluating the performance of organ procurement organizations against the statutory requirements, Congress directed CMS to promulgate regulations that (1) require certification of qualified organ procurement organizations "not more frequently than once every 4 years," (2) "rely on outcome and process performance measures that are based on empirical evidence … of organ donor potential and other related factors in each service area," (3) "use multiple outcome measures as part of the certification process," and (4) allow for an administrative appeal "on substantive and procedural grounds." 42 U.S.C. § 273(b)(1)(D)(ii).

69. Congress thus made clear that in establishing a certification process, CMS must apply both "outcome" *and* "process" measures, use "multiple outcome measures," and consider both organ donor potential *and* "other related factors" that are relevant "*in each* service area." *Id.* (emphasis added). In requiring CMS to look not only at organ donor potential but also at "other related factors in each service area," Congress expressed its intent that CMS would evaluate performance in light of the specialized challenges that organizations face within their different service areas (including factors such as the number of eligible donors, death rates, hospital and transplant center concentration, and demographics).

70. By imposing these requirements on CMS, Congress sought to avoid the well-recognized problems that result when organizational performance is measured using only limited outcome metrics. *See* Agency for Healthcare Rsch. & Quality, *Types of Health Care Quality Measures* (July 2015), https://www.ahrq.gov/talking quality/measures/types.html. As government experts have recognized, "the majority of health care quality measures used for public reporting are process measures." *Id.* Process measures are used to evaluate the efficiency and effectiveness of processes applied by an organization, and they often focus on the steps and best practices that organizations implement to meet statutory goals. "Outcome measures" on their own are problematic because outcomes are often "the result of numerous factors, many beyond providers' control." *Id.* As a result, outcome measures often need to be adjusted to "correct for differing characteristics within a population," and experts acknowledge that "better risk-adjustment methods are needed to minimize the reporting of misleading or even inaccurate information about health care quality." *Id.*

71. Directing CMS to establish an objective, non-arbitrary, and accurate system — one that employs both process and multiple outcome measures, and one that takes account of relevant factors "in each service area" — was important because decertification is an extreme penalty. If an organization is decertified, it is prohibited from continuing to provide organ procurement services, and neither Medicare nor Medicaid will pay for other services provided by that organization. 42 C.F.R. § 486.312(e); *see also* 42 U.S.C. § 1320b-8(b)(1)(A)(ii). Decertification also has significant consequences for the donor families and patients who rely on donated

organs and the community-focused services that each non-profit, organ procurement organization provides.

72. ***Congress's Continued Focus on Appropriate Performance Measures.*** CMS has long struggled to establish reasonable process and outcome measures that evaluate performance against Congress's statutory requirements and account for the different challenges faced in different service areas across the nation. *See* 42 C.F.R. §§ 485.306 (1988), 486.310 (1995).

73. In its 1995 rulemaking, for example, CMS assessed only organ donors and transplants per million population in each service area on a two-year recertification cycle. Organ procurement organizations were deemed satisfactory if their recovery and transplant rates were within 1.75 standard deviations of the national mean.

74. CMS's metric was widely criticized. It did not accurately or fairly measure performance. It also undercut Congress's goals to increase organ donation in the United States by promoting a fair and equitable system. CMS's metric reviewed organ procurement organizations over too short a period, and the dramatic variation in numbers of deaths across service areas meant that the population of any particular service area did not correlate with, let alone reliably predict, organ donor potential.

75. In 2000, Congress took steps to reform CMS's flawed approach and enacted the Organ Procurement Organization Act, Pub. L. No. 106-505, 114 Stat. 2346 (2000). In legislative findings, Congress criticized CMS for its "exclusive reliance on population-based measures of performance" that did not "account for the

potential in the population for organ donation." *Id*. at 2346. CMS's approach, Congress noted, did "not permit consideration of other *outcome* and *process* standards that would more *accurately* reflect the relative capability and performance of each organ procurement organization." *Id.* (emphasis added). It also "created a level of uncertainty that [was] interfering with the effectiveness of organ procurement organizations in raising the level of organ donation." *Id*.

76. Congress cited reports and studies prepared by the General Accounting Office, the Institute of Medicine, and the Harvard School of Public Health that identified limitations in CMS's certification process. *Id*. The reports and studies found that CMS's overly simplistic approach did not account for donation service area differences among organ procurement organizations, including death rates, race and ethnicity, economic disparity, and hospital and transplant center concentration. *See* GAO, No. GAO/HEHS-98-26, Organ Procurement Organizations: Alternatives Being Developed to More Accurately Assess Performance (Nov. 1997).

77. Having made these key findings in amendments to the National Organ and Transplant Act, Congress expressed its intent that CMS would "develop *improved performance* measures that would reflect organ donor potential and interim outcomes" and "*test*" those measures to "ensure that they *accurately* measure performance differences among the organ procurement organizations." 114 Stat. at 2347 (emphasis added).

78. Congress directed CMS to increase the recertification cycle from two to at least four years, and expressed its expectation that CMS would "use [that] extended

period" to "improve the overall certification process by incorporating *process* as well as *outcome* performance measures." *Id*. (emphasis added).

B. CMS Regulations from 2006 to 2019

79. Despite Congress's directions, CMS made no reforms for more than five years. *See* 71 Fed. Reg. 30,982 (May 31, 2006). Starting in 2006 and continuing for the next 13 years, CMS issued a series of regulations that applied only limited "outcome measures" that even CMS eventually recognized were not appropriate metrics for accurately evaluating the performance of organ procurement organizations.

80. ***CMS's 2006 Final Rule***. CMS's final rule in 2006 established that organ procurement organizations would be re-certified for a four-year period if they satisfied three outcome-focused requirements.

a. The first outcome metric — the donation rate — assessed the number of "eligible donors" as a percentage of the number of eligible deaths (i.e., any hospital death that was ventilated, with a declaration of brain death, and without medical contraindications for organ donation and transplant) within an organization's service area. 71 Fed. Reg. at 30,985. Organ procurement organizations were deemed in compliance if their performance was within 1.5 standard deviations of the mean. *Id*. at 31,005, 31,050.

b. The second outcome metric — the observed/expected donation rate — calculated the observed donation rate (actual performance) as a percentage of the expected donation rate. An organization's observed donation rate could not fall

below the expected donation rate for more than 18 of the 36 months used for recertification. *Id.*

c. The third outcome metric — a "yield" calculation — assessed the number of organs transplanted or used for research per donor. This metric could not fall more than one standard deviation below the national mean, averaged over 3 years during the 4-year recertification cycle. *Id.*

81. The three outcome metrics set forth in the 2006 final rule were initially expected to be part of the recertification process set to occur in 2010. But CMS soon concluded that it lacked sufficient data to undertake an accurate assessment. As a result, CMS delayed enforcement of its 2006 rule, and the 2014 recertification cycle became the first cycle in which CMS planned to apply the outcome metrics announced in its 2006 final rule.

82. ***CMS's 2013 Final Rule.*** As the 2014 certification cycle moved forward, the flaws in CMS's approach became increasingly apparent. In 2012, the Secretary's Advisory Committee on Organ Transplantation urged CMS to reform the regulatory requirements. The Committee stated that CMS was imposing "unnecessary burdens and inconsistent requirements" and was not "responsive[] to advances in" the "performance metrics" of organ procurement organizations. 84 Fed. Reg. 70,628, 70,629–30 (Dec. 23, 2019). The Committee urged CMS to "conduct a comprehensive review of regulatory and other requirements" and to promulgate new requirements that would "unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on" transplant

centers and organ procurement organizations. *Id.* at 70,629–30 (quotation marks omitted). The Committee emphasized that revisions "should include … a statistically sound method for yield measures" for organ procurement organizations. *Id.* at 70,630 (quotation marks omitted).

83. CMS was forced to acknowledge that its three outcome metrics raised "concerns." 78 Fed. Reg. 43,534, 43,671 (July 19, 2013). It recognized that substantial variation in the demographics of each organization's donation service area could "have a significant impact on the organ yield that could reasonably be expected in that [donation service area]." *Id.* CMS pointed to the difference in donor yield between a service area with an "older potential donor population or one that is typically not as healthy" and one with a "population of generally more healthy individuals." *Id.* CMS also noted that some organizations could be adversely affected by an "apparent variance" in how they were determining the eligible deaths in their service area. *Id.* at 43,671–72. Anecdotal evidence suggested that CMS's approach was creating improper incentives, prompting organizations to make "clinical decisions based on their assessment of their own performance on the outcome measures." *Id.*

84. CMS thus recognized that even organizations that were "performing satisfactorily" might not satisfy all three outcome metrics, and that the requirement to meet each of the three metrics was "unnecessarily stringent" and could result in "inappropriate enforcement action." *Id.*

85. These concerns were echoed in public comments. Comments objected that CMS's outcome metrics did not accurately measure performance because they were not "empirically based," failed to consider "other related factors" in each donation service area (such as rates of donor registry enrollment, variation in health demographics), and would lead to arbitrary decertification decisions that would profoundly disrupt the nation's donation and transplantation system. *See, e.g.*, N.Y. Organ Donor Network Ltr. to CMS Administrator Re: HHS/CMS Rule 0938-AR54 (Oct. 28, 2013) (Ex. K).

86. Despite significant concerns, in its December 2013 final rule, CMS implemented no meaningful changes and tried only to ameliorate the consequences of its flawed approach. CMS modified its recertification process to require that organ procurement organizations satisfy only two of the three outcome metrics. *See* 78 Fed. Reg. 74,826, 75,142 (Dec. 10, 2013).

87. ***CMS's 2017 Final Rule***. In its 2017 final rule, CMS aligned its regulatory requirements with the types and frequency of data requested by the Organ Procurement and Transplantation Network, but it still failed to implement the reforms Congress had mandated. The small changes included adopting an expanded definition of "eligible death" to increase the maximum age for donation to 75 years of age; allowing potential donors with multi-system organ failure based on clinical criteria for evaluating suitability (as opposed to automatically excluding those donors); and permitting recovery and transplantation of organs from an HIV positive donor into an HIV positive recipient. CMS also aligned its methodology for

measuring aggregate donor yield to make a risk adjustment based on 29 donor medical characteristics and social complexities of the donor pool in a specific donation service area and decreased the yield measure criteria from 3 to 2. *See* 81 Fed. Reg. 79,562, 79,830–35 (Nov. 14, 2016).

88. Although imperfect, CMS's 2017 final rule represented its most expansive effort to date to account for the numerous, unique issues facing organ procurement organizations in increasing organ donation.

C. CMS's 2019 Proposed Rulemaking

89. On July 10, 2019, President Trump signed an Executive Order on Advancing American Kidney Health, citing the prevalence of kidney disease in the United States and characterizing as "unacceptable" the "state of care for patients with chronic kidney disease and end-stage renal disease." Exec. Order No. 13879, 84 Fed. Reg. 33,817, 33,817 (July 15, 2019). Noting that "there are not enough kidneys donated to meet the current demand for transplants," the order stated: "It is the policy of the United States to . . . increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations." *Id.*

90. The 2019 Executive Order directed CMS to propose regulations within 90 days "to enhance the procurement and utilization of organs available through deceased donation by revising the Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective

metrics for evaluating" the performance of organ procurement organizations. *Id*. at 33,818.

91. CMS did not comply. Instead, 166 days later, on December 23, 2019, CMS published a proposed rule entitled, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations." 84 Fed. Reg. 70,628.

92. CMS's proposed rule acknowledged that the agency had fallen short in its efforts to implement fair, objective, and appropriate measures of performance:

> Based on public feedback and our own internal analysis of organ donation and transplantation rates, we agree that the current OPO outcome measures are not sufficiently objective and transparent to ensure public trust in assessing OPO performance, nor do they properly incentivize the adoption of best practices and optimization of donation and organ placement rates.

Id. at 70,628–29.

93. But CMS did not address the concerns it had recognized. Instead of applying multiple, objective process and outcome measures, CMS proposed to adopt only two, highly correlated outcome metrics that would not accurately measure the performance of organ procurement organizations in their respective service areas.

94. CMS received approximately 834 public comments submitted by organ procurement organizations, transplant hospitals, industry associations and coalitions, academic researchers, advocacy organizations, healthcare professionals and providers, donor families, and members of the public. 85 Fed. Reg. at 77,900.

95. Many comments objected to CMS's continued failure to comply with Congress's directives and noted that the agency's proposed rule would pose a serious risk of systemic disruption by punishing well-performing organizations, disrupting patient care, and threatening dozens of the nation's organ procurement organizations with decertification and dissolution.

96. ***First***, instead of evaluating organ procurement organizations' performance using both performance and "multiple" outcome measures, CMS proposed to decertify any organization falling outside the top 25% of organizations (within a 95% confidence interval) based solely on an evaluation of two outcome measures calculated based on the previous year's data — each organization's donation rate (the number of actual donors as compared to the alleged number of potential eligible donors using a flawed definition of "donor potential") and its transplantation rate (the number of organs transplanted as compared to the number of potential eligible donors, again using a flawed definition of "donor potential").

97. Commenters objected that this arbitrary cutoff would not accurately or fairly measure actual performance. *See id.* at 77,913; *see also* LifeLink of Florida Ltr. to CMS Administrator Re: CMS-3380-P, at 7 (Feb. 20, 2020) (Ex. B-1); LifeCenter Northwest Ltr. to CMS Administrator Re: CMS-3380-P, at 4 (Feb. 20, 2020) (Ex. G-3); OneLegacy Ltr. to CMS Administrator Re: CMS-3380-P, at 14–15 (Feb. 17, 2020) (Ex. E-1).

98. Moreover, the proposed threshold would be unsustainable. The repeated culling of organizations not falling within the top 25% would require

(implausibly) a constant supply of higher-ranked non-profit organizations to step in for well-performing organizations that were not in the top 25% and, over time, result in significant consolidation, with eventually only one organization serving the entire nation. Commentators noted that CMS had articulated no valid statistically based rationale for selecting a 25% cut off, had offered no reason to assume that large numbers of organizations were performing so poorly that they should be decertified, and had undertaken no meaningful assessment of the consequences of taking such a procrustean approach.

99. Commenters further objected that the determination as to which organizations' donation and transplantation rates were statistically within the top 25% would be made on the basis of only 12 months of data with no opportunity for an organization to submit or execute an improvement plan. For the certification cycle ending in 2026, CMS would make certification determinations based only on performance measures calculated using data from the 2024 calendar year. As commenters noted, a one-year snapshot does not account for year-over-year improvements in donation and organ transplantation rates, which often vary for reasons that are beyond the ability of any organization to control. *See* 85 Fed. Reg. at 77,915; *see also* Association of Organ Procurement Organizations Ltr. to CMS Administrator Re: CMS-3380-P, at 15 (Feb. 20, 2020) (Ex. F-2).

100. ***Second***, in proposing to evaluate performance based only on donation and transplant rates, CMS proposed a one-size-fits-all approach that would not account for "organ donor potential and other related factors in each service area," as

Congress required, because it would not take account of significant differences in geography and donor populations across the 55 different service areas. A stronger performing organization in a comparatively challenging service area might face naturally lower donation and transplant rates than a weaker performing organization in a comparatively less challenging area. It is well understood that social, economic, and cultural differences can have dramatic impacts on the number of willing donors and the community outreach needed to increase donation and transplantation rates within a service area. *See* Miller, 24 Am. J. Transplantation at 1441–42 (Ex. J).

101. Similarly, comments criticized CMS's simplistic (and incorrect) assumption that, despite differences in geography and concentrations of patient populations, donation service areas share an equal distribution of donor and organ types. *See* 85 Fed. Reg. at 77,909–10; *see also* LifeLink of Florida Ltr. to CMS Administrator Re: CMS-3380-P, at 8 (Feb. 20, 2020) (Ex. B-1); LifeCenter Northwest Ltr. to CMS Administrator Re: CMS-3380-P, at 4 (Feb. 20, 2020) (Ex. G-3).

102. Comments further noted that CMS improperly failed to account for other factors that organ procurement organizations do not control, including the location and performance of donor hospitals and transplant centers within their service area. *See* Association of Organ Procurement Organizations Ltr. to CMS Administrator Re: CMS-3380-P, at 7 (Feb. 20, 2020) (Ex. F-2); OneLegacy Ltr. to CMS Administrator Re: CMS-3380-P, at 16–17 (Feb. 17, 2020) (Ex. E-1).

103. ***Third***, comments explained that CMS's limited outcome measures were not likely to yield accurate or reasonable results. Comments noted that CMS's

calculation of the "donation rate" and "transplant rate" both relied on the same flawed denominator (i.e., "donor potential") — the alleged estimate of organ donor potential — rendering the two measures so closely correlated that they defeat Congress's mandate for CMS to rely on "multiple outcome measures." 42 U.S.C. § 273(b)(1); *see also* 85 Fed. Reg. at 77,905; OneLegacy Ltr. to CMS Administrator Re: CMS-3380-P, at 17–18 (Feb. 17, 2020) (Ex. E-1); LifeCenter Northwest Ltr. to CMS Administrator Re: CMS-3380-P, at 4–5 (Feb. 20, 2020) (Ex. G-3).

104. Comments explained that the data CMS proposed to use — data obtained from the Centers for Disease Control's Multiple Cause of Death ("MCOD") research file — is widely rejected because it lags by two years and has been shown by studies to be misleading and consistently inaccurate (30–60% of the time). *See* 85 Fed. Reg. at 77,906–07; *see also* LifeLink of Florida Ltr. to CMS Administrator Re: CMS-3380-P, at 2–3 (Feb. 20, 2020) (Ex. B-1); LifeGift Ltr. to CMS Administrator Re: CMS-3380-P, at 2 (Feb. 20, 2020) (Ex. H-1).

105. Comments emphasized that, contrary to the statute, CMS's use of the Centers for Disease Control's MCOD research files would not be an accurate measure of "organ donor potential." 42 U.S.C. § 273(b)(1)(D)(ii)(II). When calculating the number of potential donors, CMS's approach would include individuals who had agreed to donate their organs but who were not coded at the time of death as having conditions or illnesses making them unsuitable for organ donation (such as cancer or sepsis) or who were not on a ventilation system (as without proper ventilation, organ donation is not possible). *See* 85 Fed. Reg. at 77,907; *see also* LifeLink of Florida Ltr.

to CMS Administrator Re: CMS-3380-P, at 6–7 (Feb. 20, 2020) (Ex. B-1); Association of Organ Procurement Organizations Ltr. to CMS Administrator Re: CMS-3380-P, at 5–6 (Feb. 20, 2020) (Ex. F-2).

D. CMS's 2020 Final Rule

106. On December 2, 2020, CMS promulgated its Final Rule, which generally took effect on February 1, 2021, and was implemented on August 1, 2022, to coincide with the start of the 2022–2026 recertification cycle. *See* 85 Fed. Reg. 77,898.

107. CMS failed to comply with Congress's directions and refused to address many of the flaws in its proposed rule that commenters warned would disrupt and destabilize the system in profound ways.

108. Unless it is corrected, the 2020 Final Rule will operate to decertify well-performing organ procurement organizations, award donation service areas to comparatively less well-equipped organ procurement organizations, decrease the overall organ supply, and destabilize the nation's organ donation system.

109. ***A Flawed Tiered Ranking System.*** In its Final Rule, CMS created a new "tiering system" that is inconsistent with Congress's statutory requirements. Instead of applying "objective" criteria, CMS's system applies only two closely correlated outcome metrics that do not fairly or accurately measure performance.

110. The Final Rule requires CMS to compare each organization's donation rate and transplantation rate to the donation and transplantation rates of all other

organ procurement organizations over a 12-month assessment period to produce a Tier 1, Tier 2, or Tier 3 ranking. *See* 42 C.F.R. § 486.316.

a. An organ procurement organization will be assigned a Tier 1 ranking by CMS if it has both a donation rate and a transplant rate that are in the top 25% of all organizations in the country over the 12-month assessment period. *See* 42 C.F.R. § 486.316(a)(1); 42 C.F.R. § 486.318(e)(4).

b. An organ procurement organization will be assigned a Tier 2 ranking by CMS if it has a donation rate and a transplant rate that are both above the mean threshold rate but one of the rates is below the top 25 percentile for all organizations in the country. *See* 42 C.F.R. § 486.316(a)(2); 42 C.F.R. § 486.318(e)(5).

c. An organ procurement organization will be assigned a Tier 3 ranking by CMS if it is below the mean threshold rate for either its donation rate or its transplant rate. *See* 42 C.F.R. § 486.316(a)(3); 42 C.F.R. § 486.318(e)(6).

111. Because of how the calculations are performed, which tier an organization is ranked in can often turn on as little as the difference between 1 or 2 transplanted organs. *See* Rocio Lopez et al., *Evaluation of the Stability of Organ Procurement Organization Performance Metrics*, 25 Am. J. Transplantation 1, 6 (forthcoming 2025) (Ex. L) ("Minor performance differences around these fixed thresholds can result in an OPO being placed in a higher or lower tier, even when their performance is similar to other OPOs."). For example, according to CMS's annual interim reports, a deficit of only one or two organs caused plaintiff LifeLink

of Florida to miss a Tier 1 ranking in 2024 and 2025, respectively. *See* Lahrman Decl. ¶ 26 (Ex. B).

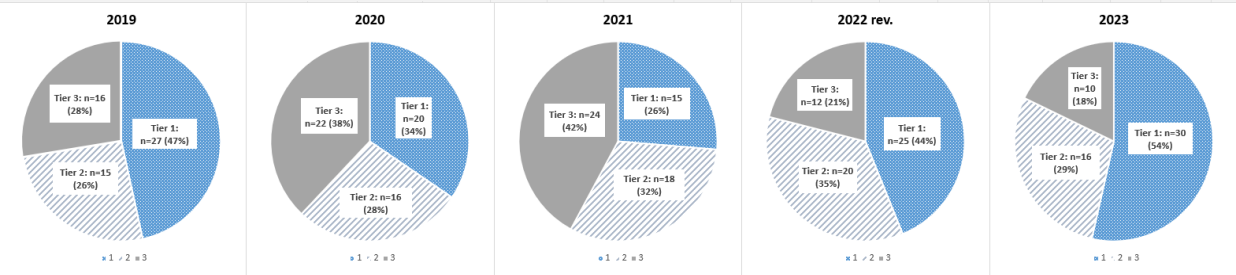
112. The consequences of CMS's tiered rankings are significant. Tier 1 organizations will be recertified by CMS. Tier 2 organizations can be recertified but only if CMS does not decide to assign their service areas to different organ procurement organizations. 42 C.F.R. § 486.316(a)(2). Tier 3 organizations will be decertified and barred from participating in the nation's organ procurement system. *See* 42 C.F.R. § 486.316(a)(3).

113. The Final Rule includes no process for organizations to respond to concerns or to adjust performance after CMS has assigned a tier ranking based on the last 12 months of data. There are also no procedures that allow for a change in ranking even if the 12 months of data is inconsistent with overall performance over the previous four-year period. That omission is particularly significant given the wide fluctuations in tier rankings that both large and small organ procurement organizations have experienced year-over-year as reported in CMS's annual interim performance reports.

114. Moreover, although the Final Rule contemplates that CMS would publish interim data to allow organ procurement organizations to track their performance in advance of CMS's final certification decisions in 2026, mistakes in CMS's implementation delayed the release of data and created greater levels of uncertainty that have once again "interfere[d] with the effectiveness of organ procurement organization in raising the level of organ donation[s]." Organ

Procurement Organization Certification Act of 2000, Pub. L. No. 106-505, 114 Stat. 2346, 2346; *compare* 85 Fed. Reg. at 77,911–12 (noting that organ procurement organizations would be assessed annually on the outcome measures and would receive interim reports with information that could be used to improve performance); *see also* CMS Memorandum on Organ Procurement Organization (OPO) Conditions for Coverage – Reporting Data Related to Pancreata Procured for Research 2 (Aug. 29, 2024) (requiring all organ procurement organizations to revise and resubmit their 2021–2024 pancreata data to OPTN to permit an analytic contractor to re-run the 2024 annual individual performance reports).

115. The following chart excerpted from CMS's 2025 annual report shows the massive disruption and upheaval that is expected to result from CMS's new tiered-ranking system. While tier rankings fluctuate significantly from year to year, CMS's Final Rule threatens to decertify as many as 10 organ procurement organizations (19% of the nation's organ procurement organizations), and to create destabilizing uncertainty in the service areas of an additional 16 organ procurement organizations (31%) that will be opened to bidding and potential replacement process — meaning that almost half of the nation's organ procurement organizations will be deemed underperforming and at risk of being forced to cease operations.



116. There is no indication that when Congress directed CMS to adopt objective performance measures almost two decades ago, it intended CMS to decimate the system and drive large numbers of non-profit organizations out of service. If Congress had intended CMS to implement such a disruptive approach, it would have spoken in much clearer and more direct terms.

117. One also would have expected CMS to explain the reasons for its own failures — after all, the agency has been responsible for overseeing the system of regulation that has governed the operations of organ procurement organizations for more than 40 years. CMS's unsupported conclusion that almost half of the nation's organ procurement organizations are failing — and that large numbers are irredeemable and should be decertified — is a damning indictment of CMS's own performance and policy failures.

118. CMS's approach is also not consistent with Congress's stated objectives. Congress established a stable system to increase organ donation by assigning organ procurement organizations to designated service areas; by facilitating cooperation among those organizations; and encouraging them to develop the close relationships with local donor hospitals, transplant centers, and other partners that are necessary to increase organ donation and successful transplantations within their designated service areas. Organ procurement organizations have relied on that system and invested significant resources with the assurance that Congress directed CMS to apply multiple objective process and outcome measures to evaluate performance. In contrast, CMS's three-tier scheme — automatically and arbitrarily eliminating

organizations — undermines the system that Congress created and, instead of rewarding improved performance, can only result in counterproductive consolidation and disruption.

119. CMS justified its Final Rule on the view that "[s]triving for organizational survival" would create incentives for organ procurement organizations to improve until all donation service areas have donation and organ transplantation rates that "cluster near the top" and that it would "retain a sufficiently large number of [organ procurement organizations] to maintain an adequately diversified market in [the United States]." 85 Fed. Reg. at 77,913, 77,933. But there is no evidence to support those irresponsible conclusions, which are contrary to logic and common sense. CMS's system inevitably leads to conflict and consolidation and, because it requires CMS to decertify organizations assigned to the bottom tier, inevitably results in an ever-smaller pool of organizations eligible for certification until only one remains standing.

120. CMS's Final Rule also unreasonably assumes that higher ranked organizations that serve comparatively smaller and more homogeneous donation service areas will be equipped to take over the larger and more diverse areas currently served by lower ranked organizations, but there is no basis for that unsupported assumption. CMS has never explained essential details, such as how long replacement organizations would be given to improve donation and transplantation rates. In short, CMS's Final Rule is destined, by design, to disrupt and destabilize the nation's organ procurement system.

121. ***Failure to Apply Multiple Outcome and Process Measures***. Because it relies on only two closely correlated *outcome* metrics — donation rate and transplantation rate—CMS's Final Rule violates Congress's express instructions because it does not apply any *process* measures, fails to assess improvements in performance over time, and does not even attempt to consider "other related factors in each service area." 42 U.S.C. § 273(b)(1)(D)(ii).

122. CMS's Final Rule also violates Congress's clear instruction for CMS to "develop *improved* performance measures" and to "*test*" those measures to "ensure that they *accurately* measure *performance differences* among the organ procurement organizations." 114 Stat. at 2347 (emphasis added); *see* Lopez, *Evaluation*, 25 Am. J. Transplantation (Ex. L); Jesse D. Schold et al., *Are the Centers for Medicare & Medicaid Services Metrics Evaluating Organ Procurement Organization Performance Too Fragile?* 24 Am. J. Transplantation 1336 (2024) (Ex. M); G. Lyden et al., *Are the New CMS Performance Tiers Biased Against Larger OPOs?, Scientific Registry of Transplant Recipients*, 24 Am. J. Transplantation S531 (2024) (Ex. N).

123. Nor has CMS remedied the problem that its two outcome measures rely on the same flawed denominator, rendering them too correlated to satisfy the statutory requirement that CMS employ "*multiple*" outcome measures as part of the certification process. 42 U.S.C. § 273(b)(1)(D)(ii) (emphasis added). Studies have shown that only 1 of 33 organ procurement organizations failing the donation rate metric would pass the organ transplantation rate metric and that only 6 of 26 organ

procurement organizations passing the donation rate metric would fail the organ transplantation rate metric. *See* 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) (Ex. O). The study in the American Journal of Transplantation concluded that CMS's two outcome metrics have a correlation in the range of .88. *Id*.

124. CMS rejected these concerns, even as it acknowledged that (1) the denominators for the two metrics measure the same donor potential, and (2) the numerators are "somewhat correlated" because more donors will likely mean more organs transplanted. 85 Fed. Reg. at 77,905.

125. Its approach is in sharp contrast to, and an unexplained and unreasonable departure from, its previous responses to similar evidence-based comments. In February 2005, in response to comments that the five outcome measures it was then proposing were estimated to have had a correlation in the range of .81 to .97 and that failure of an organ procurement organization to meet one outcome measure would make it highly unlikely to meet the threshold for the other four measures, CMS agreed that a "broader set of measures would better satisfy the statutory requirement for multiple outcome measures." 71 Fed. Reg.at 30,999–31,000.

126. ***No Objective Measure of Performance over Time.*** CMS's 12-month assessment period does not evaluate improvements in performance over time. Statistics show that over the past 10 years, there have been significant improvements

in performance, with overall organ donors doubling in number. Instead of examining these and other longer-term trends, CMS relies solely on a single year of data.

127. That decision is irrational because it does not account for substantial evidence demonstrating that donation and transplantation rates (as calculated by CMS) vary significantly from year to year regardless of objective performance. *See* Lopez, *Evaluation*, 25 Am. J. Transplantation at 4 (Ex. L) ("After excluding research pancreata, . . . 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."). Empirical evidence shows that organ procurement organizations of all sizes have seen fluctuations in various service area characteristics and healthcare delivery patterns over the course of the survey cycle that are beyond their control. *See* CMS Organ Procurement Organizations Annual Public Aggregated Performance Report (2023).

128. To provide just one example, the challenges that LifeLink of Puerto Rico faces are significant. Its donation service area has unique healthcare challenges that vary because of its unique blend of family-centric values, religious traditions, and socioeconomic disparities; its more limited access to acute care and palliative care or transplant centers that are common in mainland states; and numerous hurricanes and other natural disasters that impact Puerto Rico. *See* Sanchez Decl. ¶ 16–17, 22 (Ex. D).

129. It is impossible to evaluate performance accurately over a 12-month period without examining performance over time, without evaluating performance

against the particular challenges faced in that unique service area, and without considering the variations in donation and transplant rates that occur for reasons beyond any organ procurement organization's ability to control.

130. CMS also did not address concerns that the single-year assessment is without context and does not take account of year-over-year improvement preceding the assessment year. As a point of contrast, in recent years, CMS introduced an initiative that proposed a six-year evaluation period for transplant centers. *See* 42 C.F.R. § 512.547 (2024). CMS's widely divergent approach for the assessment period for organ procurement organizations is arbitrary and has not been statistically validated.

131. ***No Consideration of Objective Differences in Service Areas.*** CMS's Final Rule evaluates organizations based only on donor and transplantation rates with no consideration of how those metrics are influenced by factors outside the control of the organizations —such as geographic and socio-economic factors — that impact the number of organs recovered and transplanted for any given designated service area.

132. CMS did not consider geographic factors that directly impact donation and transplantation rates, including most importantly the location and distance between hospitals and transplant centers, and the performance of those health-care providers.

133. CMS also did not consider relevant factors that could directly impact donation and transplantation rates in any given service area, such as natural disasters, increases/decreases in populations, shifting socio-economic status in the population,

donor hospital service interruptions, increasing/decreasing death rates, and incidence of comorbidities, etc. *See* 85 Fed. Reg. at 77,909–10 (adjusting based only on the average age of the donor potential).

134. Other significant factors include the relative incidence of chronic diseases that tend to make the population in a donation service area less likely to be organ donors; differences in access to intensive care unit ventilators across the donation service area, which are consequential in evaluating when a patient is a viable organ donor; and racial, ethnic, religious, or other cultural characteristics that can impact the availability of organs and the authorization rates within a donation service area.

135. Studies and reports have long shown that treating service areas as demographically homogeneous does not accurately assess the performance of organ procurement organizations. *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. Transplantation 2466, 2479 (2020) (Ex. P); *see also* Miller, 24 Am. J. Transplantation at 1442 (Ex. J) (noting that "[m]istrust of the health care system, lack of racial and ethnic concordance between potential donors or donor families and OPO outreach staff, and certain religious beliefs have been shown to reduce willingness to donate blood and organs").

136. In response to these studies, CMS contended that applying a blanket adjustment for race and ethnicity could mask poor performance and perpetuate racial

and ethnic stereotypes. But that response misses the point and only underscores that CMS is not faithfully fulfilling its statutory obligations. Plaintiffs support efforts to improve organ donation within diverse communities, and they are opposed to racial and ethnic stereotypes. But those concerns are one of the many reasons why Congress directed CMS to apply *both* process measures and multiple outcome measures.

137. CMS cannot adopt overly simplistic metrics that do not accurately measure performance and then respond to suggestions to ameliorate the severe repercussions of its statutory departures by contending that making adjustments could have unintended consequences. CMS's concerns should have been a reason for CMS to reevaluate its misguided approach, not to dig in its heels.

138. Rather than identifying poor performance, CMS's Final Rule *penalizes* the organ procurement organizations that have invested in developing practices to address barriers to donation and improving performance with local communities that have historically been reluctant to commit to organ donation. CMS's system thus cuts directly against Congress's goal of improving overall donation rates.

139. CMS's tier system is also flawed because it fails to account for differences in donor population health and the prevalence of organ donor types within a service area, including the ratio of brain-dead donors to donors after cardiac death, where brain dead donors have documented higher rates of transplant; donor age, which is highly correlated with the probability of transplant center acceptance of donor organs; and the incidence of chronic diseases that impact suitability of organs for transplant. *See* Rhiannon D. Reed et al., *Geographic Differences in Population Health*

and Expected Organ Supply in the Gulf Coast Region of the United States Compared to Non-Gulf States, 104 Transplantation 421, 423–27 (2020) (Ex. Q) (finding that population health contributes to the observed disparities in organ supply within individual donation service areas).

140. CMS recognized that donation service areas may have differing population characteristics but claimed that it lacked data establishing that those well-recognized differences, including the incidence of certain chronic diseases in donation service areas, affected donor potential in ways that might disadvantage organ procurement organizations. 85 Fed. Reg. at 77,909–10. To reach that conclusion, CMS merely analyzed the number of patients on the waiting list in an organization's donation service area (treating the waiting list as a surrogate for magnitude of end-stage organ failure) and found no correlation between performance and the size of the waiting list. *Id*. That simplistic analysis is not a reasonable assessment of population-level characteristics and expected donation rates.

141. ***No Adjustment to Account for Complex Donors or Discarded Organs***. CMS declined to include medically complex donors — organ donors who volunteer to donate but ultimately do not provide any donated organs ("zero-organ donors") — in the definition used to calculate donor rates, even though the evidence shows that these donors represent up to 17% of total donors, with a range of 2.73 to 11.86% of donors among the top performing organ procurement organizations. *See id*. at 77,904. Whether a donor becomes a zero-organ donor ultimately turns on the performance and medical judgment of the transplant

center, not the organ procurement organization that has very little control over which donors ultimately prove to be unsuccessful.

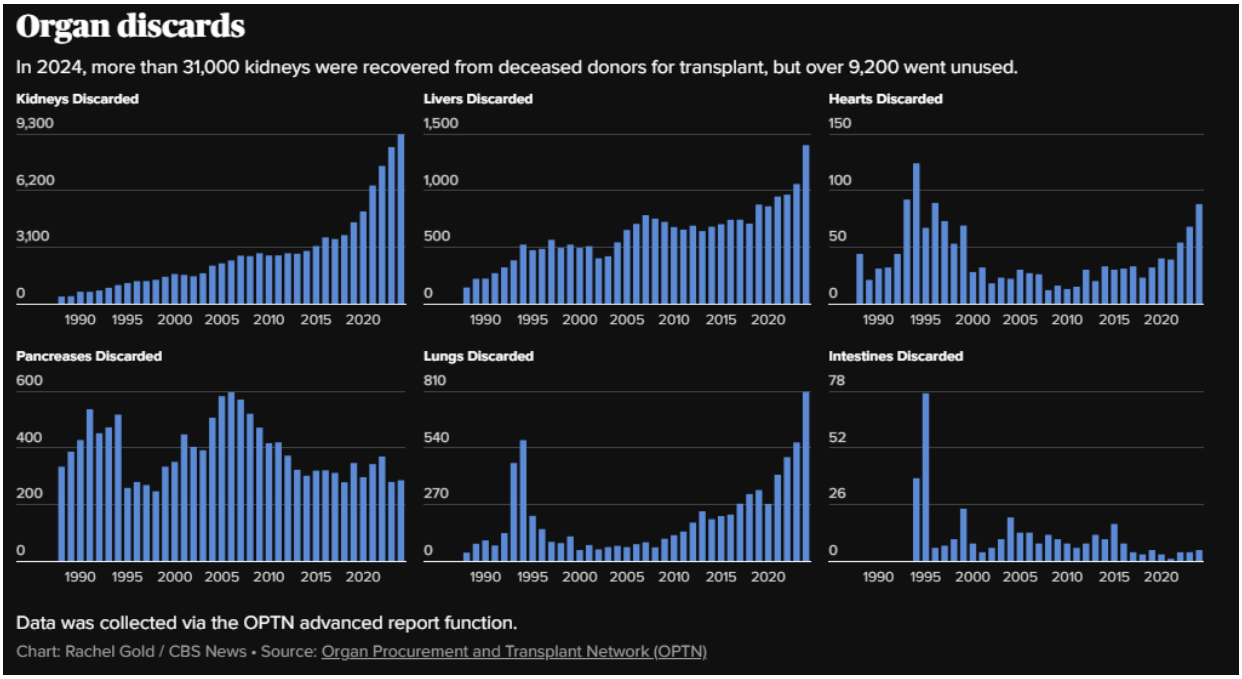
142. In response to these concerns, CMS suggested that if an organization "engages in best practices for placement, packaging, and transportation of organs …, there should not be significant differences in the frequency of zero organ donors among" organizations "because the occurrence of unexpected anatomical issues which contraindicate donation that arise after consent is secured are random and not statistically significant" in one service area "compared to another." *Id.*

143. CMS's response is irrational and unsupported. Even assuming all organizations engage in best practices, their performance is affected by factors outside their ability to control. For example, the anatomical issues that contraindicate donation are not random — they are linked to higher rates of medically complex donors, and myriad other known factors that can vary significantly between different donation service areas. Other factors include transplant centers' rejection of organs after recovery and the incidence of certain donor comorbidities that result in higher organ discard rates.

144. As noted above, CMS ranks organ procurement organizations based on their calculated transplantation rate, but that rate depends on decisions and judgments made by transplant surgeons working in transplant programs, not the performance of the organizations themselves, which have little control over the number of successful transplants.

145. Transplant centers are evaluated by CMS based on the long-term survival of a patient following transplant, which creates incentives for transplant surgeons to accept only the highest-quality organs for transplant and to decline lower-quality organs, which may have a higher failure rate once transplanted. As a result of these incentives, transplant surgeons have become increasingly selective, declining recovered organs and "waiting" for healthier organs that increase the likelihood of post-transplant success.

146. In 2024, the industry saw a record number of kidneys, lungs, and livers recovered by organ procurement organizations and then discarded by transplant surgeons, as well as the highest number of hearts recovered and discarded in nearly 30 years.



Tom Hanson et al., *Discarded: Why donated organs are left unused*, CBS News (Apr. 14, 2025), https://www.cbsnews.com/organdonors/

147. CMS did not reasonably explain why verifying organ procurement organizations' data on zero-organ donors would be unworkable. 85 Fed. Reg. at 77,903–04. There is no reason CMS could not identify which donors do not ultimately provide useable organs.

148. ***Improper and Unreliable Data Source to Calculate Organ Donor Potential***. In the Final Rule, CMS elected to use admittedly flawed state death certificate information reported in Centers for Disease Control's MCOD research files, which relies on county-level national mortality data derived from death certificates maintained by the states and territories, as a proxy for organ donor potential. *See id.* at 77,906–07.

149. That data is statistically unreliable and not an objective measure of donor potential. Published studies demonstrate that 30–60% of state death certificates included in the MCOD files report an inaccurate cause of death. *See* OneLegacy Ltr. to CMS Administrator Re: CMS-3380-P, at 9–11 (Feb. 17, 2020) (Ex. E-1) (collecting studies on statistical unreliability of state death certificates); *see also* Iowa Donor Network Ltr. to CMS Administrator Re: CMS-3380-P, at 1–3 (Feb. 21, 2020) (Ex. F-1).

150. The MCOD data is also misleading because it omits concurrent medical conditions that affect donor suitability. It does not report secondary diagnoses that would readily exclude an individual from the pool of potential donors, and it does not track whether the potential donor has been ventilated, which is a fundamental requirement for a patient to be suitable as a potential organ donor. Lopez, *Evaluation*,

25 Am. J. Transplantation at 6 (Ex. L) ("Death certificate data omit concurrent medical conditions affecting donor suitability.").

151. CMS acknowledged the concerns with using the MCOD files and did not dispute the high rates of error in the state death certificate information on which the MCOD is based.

152. CMS nevertheless finalized the death certificate information found in the MCOD as the sole data source for calculating the donor potential denominator in both outcome metrics. According to CMS, the MCOD data represents the "most complete information that is readily and publicly available, that can be used for estimating the donor potential at this time." 85 Fed. Reg. at 77,906–07.

153. CMS thus accepted that organ procurement organizations would be decertified or potentially replaced based on a data source widely acknowledged to be rife with errors in cause of death and other information.

154. CMS's use of flawed MCOD data as an attempted proxy for "organ donor potential" is at odds with the statute, which requires CMS to use outcome and process measures that are "based 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).

155. In attempting to defend its use of flawed data, CMS contended that it was "not aware of differences in the error rates that would disadvantage one" donation service area over another. 85 Fed. Reg. at 77906. But that too is irrational and wholly non-responsive to commenters' concerns. The problem is not the general

rates of error, but the fact that the errors are so significant that the data is unreliable. Extensive evidence shows that errors in death certificate data over a 12-month period are not uniformly experienced across donation service areas.

156. Moreover, CMS did not meaningfully respond to comments that the two-year lag in the availability of data from the MCOD would lead to the absurd result that organ procurement organizations could be decertified or replaced even if they had achieved meaningful improvements in donation and transplantation rates in the two years that elapsed between the assessment period and the end of the survey cycle. *Id.* at 77,915–16.

157. Nor did CMS reasonably respond to comments recommending that the agency consider data currently being reported by all hospitals pursuant to existing regulatory requirements or that it look at other sources of data that factor in medical conditions that affect donor suitability.

158. In rejecting these comments, CMS asserted that there is no single source of "empirical evidence that could be obtained by reasonable effort of organ donor potential in each designated service area sufficient to meet [the agency's] needs and expectations." *Id.* at 77,906. But that only proves the broader point. At minimum, CMS should have considered the significant discrepancies between the hospital data and the MCOD data as further evidence that applying only two outcome metrics — and failing to apply any process measures as Congress instructed — that both depend on calculations of donor potential based on inaccurate and unreliable death-certificate data (and that fail to evaluate other related factors in the service

areas) is not a permissible method of evaluating overall performance by organ procurement organizations.

159. As the National Academy of Sciences has found, "no single metric — whether based on death certificates or ventilated deaths data" from hospitals — is "adequate to fully understand and assess the performance of the interconnected parts of the organ transplantation system." Realizing the Promise of Equity in the Organ Transplantation System 6-6 (Kenneth W. Kizer et al. eds., 2022) (Ex. R). Instead of looking only at outcomes, "performance measures *in multiple domains* are needed to assess the performance of donor hospitals, [organ procurement organizations], and transplant centers in achieving overall system performance goals. *Id.* (emphasis added)*; see also id.* at 6-7, box 6-2 (recommending a "consensus-based process to arrive at the donation rate measure" and "[p]atient-level data that uses a measure denominator that is accurate and granular enough to contain essential information about referrals of ventilated deaths, medical suitability of donors, and other key information").

160. ***Biased Confidence Interval***. CMS finalized its proposal to calculate the 95th percentile confidence interval for each donation service area's donation and organ transplantation rates using a one-sided test, even though that approach has been demonstrated to be mathematically biased against larger organ procurement organizations.

161. CMS limited its response to comments on this issue to a single, two-sentence paragraph in which it reiterated that the purpose of the confidence interval

was to shield small organ procurement organizations from bias. CMS then stated that it did "not concur with the commenters' assertion that our methodology is biased against large [organ procurement organizations]; they have a [confidence interval] generated, but because they have more data, their [confidence intervals] are proportionally smaller." *Id.* at 77,914. In failing to address the analysis and conclusions of the United Network for Organ Sharing and the Scientific Registry of Transplant Recipients in early 2020 that the significance of the bias against large organ procurement organizations was substantial, CMS failed to offer a reasoned explanation for finalizing a methodology that ran directly counter to the statistically reliable evidence before it.

162. Analysts with the Scientific Registry of Transplant Recipients have continued to study this issue using the 2019–2021 rankings of organ procurement organizations to produce credible and replicable research on this issue. They simulated one hundred thousand CMS evaluations for all organ procurement organizations using varying donation rates and thresholds to assess any statistical bias in the confidence interval. These additional simulations confirmed that the confidence interval in the 2020 Final Rule is "biased against larger OPOs, with smaller OPOs having a higher probability of being automatically recertified or being able to compete for renewal of their contracts." Lyden, 24 Am. J. Transplantation (Ex. N). Smaller organ procurement organizations have greater variability in donation and organ transplantation rates owing to their smaller populations and relatively larger confidence intervals.

163. The same analysts proposed that CMS could attain a uniform error rate in assessing organ procurement organization performance by substituting the observed-to-expected rate ratios utilized by the Scientific Registry of Transplant Recipients in evaluating transplant programs. As demonstrated in thousands of additional simulated evaluations for all organ procurement organizations using the donation rate as an example, the observed-to-expected method removed the bias against larger organ procurement organizations without compromising CMS's ability to detect underperforming organ procurement organizations. *Id.*

164. That research has since been replicated, with the findings later published in the American Journal of Transplantation. *See* Rocio Lopez et al., *Association of Organ Procurement Organization Volume with Centers for Medicare and Medicaid Services Performance Evaluations*, 25 Am. J. Transplantation 1013 (2024) (Ex. S); *see also* Rocio Lopez et al., *Authors' Reply to Letter Regarding "Association of Organ Procurement Organization Volume with CMS Performance Evaluations,"* 25 Am. J. Transplantation 1135 (2025) (Ex. T). The published article relies on three years of actual donation data and compares organ procurement organization rankings under the CMS 95th percentile confidence interval in comparison to the observed-to-expected methodology first proposed by the Scientific Registry of Transplant Recipients. According to that analysis, in 2021, 54% of organ procurement organizations were incorrectly ranked in lower tiers using CMS's statistically unreliable 95th percentile confidence interval methodology compared to the observed-to-expected methodology. In 2019 and 2020, the error rates were 24% and 43%, respectively.

165. ***Unprecedented***. No other CMS-regulated healthcare service provider is subject to a certification process that drives organizations out of service based solely on a highly variable 12-months of data and without accurately measuring performance.

166. Unlike the Final Rule, other CMS measures have been designed by independent experts to accurately evaluate performance through a combination of process measures and multiple outcome measures that are appropriately risk adjusted. *See* CMS, Computer-Based Training Series: Risk Adjustment Methodology 1-3 (Dec. 2021), *available at* https://www.csscoperations.com/internet/csscw3.nsf/RiskAdjustmentMethodologyvTranscript.pdf; CMS, *Measure Specification: Risk Adjustment and Risk Stratification Overview* (June 2025), https://mmshub.cms.gov/measure-lifecycle/measure-specification/risk-adjustment-overview (describing CMS's approach and use of risk adjustment and risk stratification with respect to outcome measures in various CMS programs); *see also* 42 U.S.C. § 1395w-4(s)(2)(A) (requiring CMS to enter into contracts or other arrangements with third-party measurement developer contractors to develop, improve, update, or expand outcome measures used in CMS quality programs).

167. CMS has no justification for failing to follow this approach in contradiction of Congress's express commands.

BASIS FOR INJUNCTIVE RELIEF

168. The plaintiff organ procurement organizations face a substantial threat of irreparable injury if the 2020 Final Rule is not vacated. The first recertification

cycle under the Final Rule will conclude on July 31, 2026, and the first round of potential decertification and replacement of organ procurement organizations will follow from the final performance reporting that CMS releases in advance of that date.

169. CMS's most recent interim tier rankings (based on 2023 data) have assigned plaintiffs Iowa Donor Network and LifeLink of Georgia to Tier 1, plaintiffs LifeLink of Florida, LifeGift, LifeCenter Northwest, and OneLegacy to Tier 2, and plaintiff LifeLink of Puerto Rico to Tier 3.

170. The final tier rankings (based on 2024 data) are expected to issue in mid-2026.

171. Based on the most recent interim data reported by CMS, plaintiffs OneLegacy, LifeGift, and LifeCenter Northwest expect that in 2026 CMS will assign them (based on 2024 data) an overall Tier 3 ranking for the current certification cycle. Each of these organizations faces an imminent threat of being decertified, expelled from the nation's organ procurement system, and forced to cease their operations. *See* Garimella Decl. ¶ 46 (Ex. E); Myer Decl. ¶¶ 28, 69 (Ex. H); Gill Decl. ¶ 15 (Ex. G).

172. LifeLink of Florida is concerned that in 2026 CMS will assign it an overall Tier 2 ranking for the current certification cycle and, as a result, the organization is already in the position of being significantly burdened with preparing for the likelihood that its donation service area will be opened to a bidding process and, if it is not successful in that process, will find itself replaced and forced to cease operations. *See* Lahrman Decl. ¶¶ 25–27 (Ex. B); *see also* Hernandez Decl. ¶ 10 (Ex. A).

173. Given the previous variability in rankings, it is unclear what ranking LifeLink of Georgia will be assigned in 2026 (based on 2024 data). If LifeLink of Georgia is assigned a Tier 2 or Tier 3 ranking by CMS, it could be decertified or replaced by another organization. Based on CMS's interim performance rankings, LifeLink of Puerto Rico is also concerned that CMS will assign it either a Tier 2 or Tier 3 ranking in 2026 (based on 2024 data) and prevented from operating in its service area. *See* Sanchez Decl. ¶¶ 12, 39 (Ex. D); *see also* Hernandez Decl. ¶ 10 (Ex. A).

174. Iowa Donor Network expects to be assigned an overall Tier 1 ranking for the current certification cycle. It is nonetheless concerned about the threat that CMS's Final Rule poses to the nation's organ donation system as a whole, the harms that will be caused to patients and donor families, and the risk that, given CMS's "hunger games" approach, it will face decertification in future certification cycles regardless of how well it continues to perform. *See* Conrad Decl. ¶¶ 19–20, 32, 44–45.

175. Plaintiffs have worked tirelessly in pursuit of their mission to save more lives and share hope among those awaiting transplants. In reliance on the statute Congress enacted, they have made substantial investments to build public trust through relationships with the donor hospitals, medical providers, transplant centers, service contractors, and other community members in their designated donation service areas. They have further invested in community education and culturally competent outreach to potential donors, advanced the science of donation and

transplantation through technological innovation, and collaborated with professional partners to implement best practices in donation and recovery in their unique donation services areas.

176. In the case of plaintiffs ranked in Tier 2 or Tier 3, they will suffer immediate and irreparable injury if CMS decertifies them or awards their donation service areas to other organizations. Those harms are likely to spread to patients because the new organizations are unlikely to have any experience with the characteristics of the specific donor populations in the open donation service areas. The cumulative disruption would be immense and at odds with Congress's statutory objectives. Moreover, decertification is permanent — there is no provision in the 2020 Final Rule for a decertified organ procurement organization to bid on its own or another donation service area at any point in the future.

177. Although there is an administrative appeals process for challenging a Tier 3 ranking, it cannot address the arbitrariness of CMS's Final Rule or CMS's failure to follow statutory mandates. The administrative officers who adjudicate these appeals are bound to apply the Secretary's regulation and have no authority to review the Final Rule for its many substantive and procedural legal failures. Their role will be limited to determining whether CMS correctly applied the 2020 Final Rule, such as determining whether the agency correctly calculated an organ procurement organization's donor or transplant rate. These administrative appeals are therefore futile, and they cannot bring plaintiffs the relief they seek.

178. Even if initial decertification determinations are not upheld, plaintiffs will be forced to divert critical resources to appeals of those determinations and suffer the incalculable reputational damage associated with a Tier 3 ranking by CMS.

179. Likewise, even if plaintiffs are assigned a Tier 2 ranking by CMS, there is currently no provision for an administrative appeal of such a determination, meaning plaintiffs' service areas could be awarded by CMS to other organ procurement organizations that lack the necessary experience, longstanding local relationships, and overall wherewithal to continue plaintiffs' work without widespread disruption in donation services. Without understanding and taking account of the challenges in specific donation service areas, CMS has no reasonable basis for concluding that any successor organization will be better positioned to increase donation and transplant rates, let alone improve overall performance.

180. Plaintiffs assigned Tier 1 rankings by CMS also face destabilizing uncertainty. CMS appears to believe that higher ranked organizations will replace decertified and other lower ranked organizations, but it has never explained how that process could work or offered any reasoned basis for believing that higher ranked organizations are capable of stepping in to take over the service areas of decertified organizations (and meet the unique challenges posed by their donation service areas in different parts of the country).

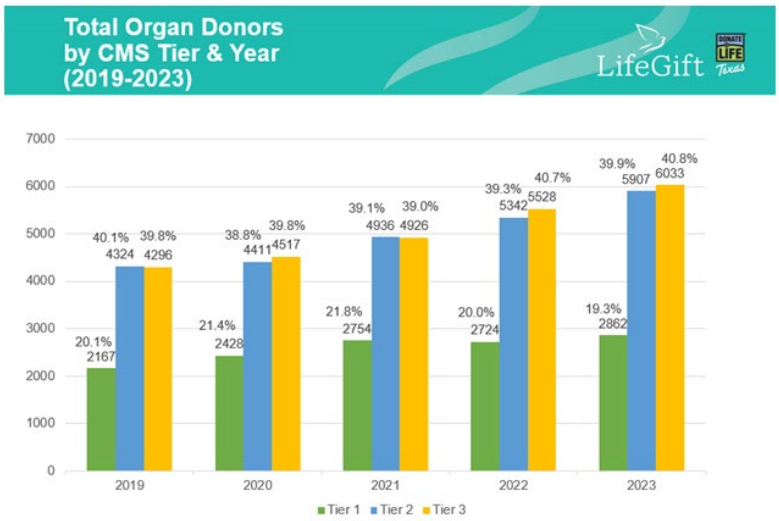
181. As the decertification deadline approaches, plaintiffs face significant and mounting challenges retaining employees and hiring new staff. Those harms make it

very difficult to operate, resulting in disruption to local community relationships, lost donor opportunities, and less life-saving organs for patients.

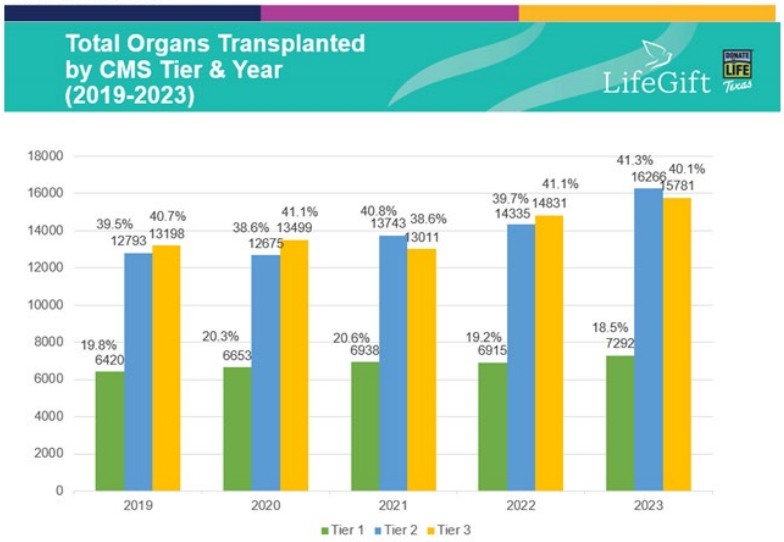
182. If the 2020 Final Rule is not vacated, it will have broader negative consequences for the organ transplant ecosystem that depends on a network of organ procurement organizations working effectively with their professional and community partners to pursue every opportunity for donation and educate the public about their critical mission.

183. Because the system will be thrown into chaos by rapid and unjustified decertification of experienced, specialized organ procurement organizations and by the reshuffling or realignment of donation service areas in ways that do not improve performance, it is no exaggeration to say that a great number of lives will be lost.

184. The disruption caused by the Final Rule is likely to harm patients and donor families across the country. As the following charts show, organizations that have received interim Tier 2 and Tier 3 rankings have consistently accounted for close to 80% of organ donors and transplants over time. The notion that all of these organizations should be either decertified or potentially replaced is irrational on its face. Nothing in CMS's Final Rule includes any explanation that could justify taking that type of axe to the nation's organ donation and transplantation system.



Source: https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/ and CMS: https://qcor.cms.gov/main.jsp



185. Vacatur of the 2020 Final Rule in advance of the 2026 final performance reporting and the conclusion of the recertification cycle is imperative to preserve stability in the organ donation system and provide time for new rulemaking that more closely aligns performance evaluations and recertification determinations for organ procurement organizations with Congress's objectives in enacting the National Organ Transplant Act and the wider efforts to improve access to organ transplants, improve

accountability in the U.S. organ transplantation system, and increase the availability and use of donated organs.

CAUSES OF ACTION

COUNT I

Violation of the Administrative Procedure Act—Contrary to Law and in Excess of Statutory Jurisdiction and Authority

5 U.S.C. § 706(2)(C)

186. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

187. Under the Administrative Procedure Act, a court must set aside agency action that is not in accordance with law or in excess of statutory authority. *See* 5 U.S.C. § 706. An agency action is invalid and must be vacated if it exceeds the power conferred upon the agency by the statute. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 104–05 (2015).

188. CMS's 2020 Final Rule is contrary to the National Organ Transplant Act and in excess of CMS's statutory authority.

189. The Final Rule's tiering system is not "based 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).

190. The Final Rule violates the statutory requirement that CMS "rely on" both "outcome *and* process performance measures." *Id.* (emphasis added). It contravenes Congress's express instructions to "develop improved *performance*

measures" that "reflect organ donor potential" and "*to test* those measures to ensure that they *accurately* measure performance differences among procurement organizations." *Id.* § 273 note (emphasis added) (quoting 114 Stat. at 2347).

191. CMS's Final Rule applies only two outcome metrics — it does not include any process measures — and the metrics that CMS applies have not been tested and do not accurately measure performance.

192. The Final Rule violates Congress's instructions that CMS "use *multiple* outcome measures as part of the certification process." *Id.* § 273(b)(1)(D)(ii)(III) (emphasis added). CMS's two, closely correlated outcome metrics are not sufficiently differentiated to constitute the "multiple outcome measures" that the National Organ Transplant Act mandates. *Id.*; *see also Multiple*, Merriam-Webster's Dictionary (2025), https://www.merriam-webster.com/dictionary/multiple ("something in units of more than one or two").

193. The Final Rule similarly violates Congress's directive that CMS base its outcome and process measures on empirical evidence of both 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).

194. CMS's two outcome metrics consider only organ donor potential and do not take account of "other related factors in each service area." Moreover, CMS's outcome metrics both rely on flawed and misleading state death certificate data reported in the Centers for Disease Control's MCOD research files in the 2020 Final

Rule that cannot be a reasonable, reliable, or accurate proxy for "organ donor potential."

195. The Final Rule impermissibly relies on only the most recent 12 months of data and does not evaluate performance over a four-year period as Congress directed and expected. The Final Rule is contrary to the statutory requirement that CMS establish a certification process to evaluate whether "within the previous 4-year period" an organization has met "the performance standards to be a qualified organ procurement organization." *Id.* § 273(b)(1)(D).

196. The statute does not authorize CMS to evaluate performance without applying any process measures and based only on two closely correlated outcome metrics that do not accurately or reliably measure the actual performance of organ procurement organizations.

197. The statute does not authorize CMS to evaluate performance in an undifferentiated manner that relies on flawed data and does not take account of the differences in organ donor potential and other related factors in their differently situated performance areas and instead assumes that all service areas uniformly reflect the same performance challenges.

198. The statute does not authorize CMS to impose a tiered-ranking system that, without justification, assumes that large numbers of organ procurement organizations are irredeemably underperforming and, having received a Tier 3 ranking from CMS, must be decertified and barred from participation in the nation's organ donation system

199. The statute does not authorize CMS to impose a ranking system under which organizations that are not decertified will nevertheless have their donation services areas awarded to another organ procurement organization.

200. The statute is structured to set up a system of donation service areas that encourage non-profit organizations to cooperate with each other to improve overall performance; there is no indication that Congress expected to put organizations in an adversarial position and force them to compete for their continued existence. Yet the 2020 Final Rule contemplates exactly that for any organ procurement organization assigned a Tier 2 ranking for either or both outcome metrics.

201. The Court should set aside the 2020 Final Rule as not in accordance with law and in excess of CMS's statutory authority. *See* 5 U.S.C. § 706.

COUNT II

Violation of the Administrative Procedure Act— Arbitrary and Capricious and an Abuse of Discretion

5 U.S.C. § 706(2)(A)

202. Plaintiffs reallege and incorporate by reference each of the preceding paragraphs as if set forth fully herein.

203. Under the Administrative Procedure Act, a court must set aside agency action that is arbitrary and capricious, an abuse of discretion, or inconsistent with the requirements of reasoned decision-making. *See* 5 U.S.C. § 706(2)(A).

204. An agency's action is arbitrary and capricious if the agency acted outside the reasonable scope of its lawful authority or "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

205. An agency must act in a way that is "rational," "reasonably explained," and "based on consideration of the relevant factors." *Id.* at 42–43, 52 (quotation marks omitted).

206. CMS's Final Rule is invalid because it is unreasonable and relies on irrational and illogical reasoning.

207. CMS's decision to decertify organ procurement organizations based on only two outcome metrics with an arbitrary 25% cutoff, derived from only 12 months of data, and that do not account for variations in designated service areas is unreasonable. By relying on metrics that are influenced by factors that are beyond any organ procurement organization's ability to control, CMS's certification process is arbitrary and capricious.

208. CMS rejected sound, statistically based evidence demonstrating that CMS's closely correlated outcome metrics do not take account of material variations in donation service area-specific characteristics, despite peer-reviewed studies demonstrating the flaws in CMS's undifferentiated approach. *Compare Ark. Reg'l Organ Recovery Agency, Inc. v. Shalala*, 104 F. Supp. 2d 1084, 1090 (E.D. Ark. 2000)

(striking down agency performance standards that relied on flawed data, did not give organ procurement organizations an opportunity to explain their performance, and that failed to take into account geographic and demographic factors that influence performance).

209. CMS unreasonably assumed that the well-recognized errors in state death certificates would be uniformly experienced in each donation service area.

210. CMS adopted a 12-month assessment period for certification that is at odds with empirical evidence that donation and transplant rates have varied significantly from year to year regardless of objective performance.

211. CMS's 12-month assessment period for certification — relying on outcome metrics calculated using data from the 2024 calendar year only for the 2026 recertification cycle — is arbitrary and in sharp contrast to CMS's newly proposed Increasing Organ Transplant Access Model for transplant centers. *See* CMS, *Increasing Organ Transplant Access (IOTA) Model*, https://www.cms.gov/priorities/innovation/innovation-models/iota (last visited July 30, 2025). There, CMS proposed a six-year timeline to derive final performance scores for transplant programs using five different risk-adjusted outcome measures.

212. CMS's decision to apply the 95th percentile confidence interval in its Final Rule disregards evidence demonstrating a statistically validated bias against large organ procurement organizations. A certification process that arbitrarily places larger organ procurement organizations managing the more complex donor populations at greater risk of decertification or replacement is not sustainable.

213. A certification process that pushes smaller organ procurement organizations with fewer resources to assume much larger, more complex donation services in different areas with different geographic and demographic challenges is not reasonable or sustainable.

214. CMS's new certification process all but assures that large numbers of organ procurement organizations will be mis-classified in the nascent tier ranking system.

215. Under CMS's Final Rule, qualified, well-functioning organizations that have been successful over time in improving their performance and increasing organ donation in their unique donation service areas will be decertified and replaced by less competent organizations. Public confidence in the organ donation system will be eroded, and widespread disruption and destabilization of the transplant system will follow.

216. CMS has not exercised its statutory authority consistent with the requirements of reasoned decision-making under the Administrative Procedure Act and the Constitution's separation of powers.

217. The Court should set aside the Final Rule because it is arbitrary and capricious and an abuse of discretion. *See* 5 U.S.C. § 706.

COUNT III

Violation of the Administrative Procedure Act— Arbitrary and Capricious and Inadequately Reasoned

5 U.S.C. § 706(2)(A)

195. An agency decision is arbitrary and capricious under the Administrative Procedure Act if the agency failed to consider an important factor or aspect of the problem or failed to respond to significant comments. *See Mortg. Bankers Ass'n*, 575 U.S. at 96 ("An agency must consider and respond to significant comments received during the period for public comment."); *Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1312 (D.C. Cir. 2014) ("An agency's failure to respond to relevant and significant public comments generally 'demonstrates that the agency's decision was not based on a consideration of the relevant factors.'" (quoting *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984)). "'[S]ignificant' comments" are "those which raise relevant points and which, if adopted, would require a change in the agency's" action. *Am. Mining Cong. v. EPA*, 965 F.2d 759, 771 (9th Cir. 1992) (quoting *Home Box Off., Inc. v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977)).

196. In promulgating the 2020 Final Rule, CMS has not adequately responded to significant objections by organ procurement organizations and other interested parties. Nor has it provided a reasoned justification for numerous aspects of the 2020 Final Rule or supported its positions with a statistically validated

methodology. Organ procurement organizations and other public comments were grounded in scientific research and empirical observation.

197. CMS based its Final Rule on a series of implausible, unsubstantiated assertions, including that there is a diversity in the population served by the highest performing organ procurement organizations; that taking into account differences in demographic factors would mask poor performance and perpetuate stereotypes; and that organ procurement organizations can simply "adjust their practices to overcome these hurdles" to donation. These concerns should have caused CMS to revisit its decision to rely on only two, closely correlated outcome metrics that do not accurately or reliably measure performance and to apply the process and multiple process measures that Congress required that evaluate organizations' performance against the specific performance obligations that Congress imposed.

198. CMS also failed to offer any reasoned explanation for finalizing both outcome measures despite statistically reliable evidence that applying more objective, empirically based outcome and performance measures that appropriately take into account characteristics and challenges specific to individual designated donation service areas would cause a significant number of organ procurement organizations to move up or down in the tier rankings.

199. CMS finalized the death certificate information found in the MCOD as the data source for calculating the donor potential denominator in both outcome metrics based on the implausible assertion that MCOD represented the most complete information that is readily and publicly available for this purpose. CMS arbitrarily

assumed that the acknowledged error rates in the state death certificates would be uniformly experienced in each donation service area. And it dismissed organ procurement organizations' recommendations that it calculate the donor potential using data in electronic health records currently being reported by all hospitals pursuant to existing regulatory requirements.

200. CMS declined to include zero organ donors in the definition of donor. In reaching this conclusion, it gave insufficient consideration to comments that recovered organs are frequently rejected for reasons entirely outside the control of organ procurement organizations and opined that there should not be significant differences in the frequency of zero organ donors among organ procurement organizations even as it admitted elsewhere in its response that zero organ donors in fact represented anywhere from 0 to 17.02% of donors, with a range of 2.73 to 11.86% of donors among the top performing organ procurement organizations.

201. CMS also provided no response to additional public comments that including zero organ donors in the definition of donor would align the CMS definition of donor with the definition in use by the Organ Procurement and Transplantation Network and the World Health Organization.

202. CMS rejected recommendations that it avoid overestimating donor potential by adding exclusionary criteria for medical conditions incompatible with organ donation and ventilator status. CMS failed to consider evidence supporting the utility of the additional criteria, including recommendations developed in the 2015

Deceased Donor Potential Study in which the Organ Procurement and Transplantation Network identified a process for assessing donor potential that included the exact exclusionary criteria and ventilation status rejected by CMS.

203. The Court should set aside the 2020 Final Rule because it is arbitrary and capricious, does not respond to serious objections, and is an abuse of discretion. *See* 5 U.S.C. § 706.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully request that this Court enter judgment in their favor as follows:

A. Enter a declaratory judgment that CMS's 2020 Final Rule is contrary to law; in excess of statutory jurisdiction, authority, or limitations; and arbitrary or capricious; and that CMS is not authorized to implement a tiered-ranking system that is not based on multiple objective measures of actual performance by organ procurement organizations.

B. Vacate any agency action found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, and remand any matters herein to the Secretary for further proceedings in accord with any legal instructions the Court may deem proper and just.

C. Enter an injunction requiring CMS to comply with the statutory requirements in the National Organ Transplant Act.

D. Enter an injunction that prohibits CMS from enforcing the 2020 Final Rule until such time as it can be brought into compliance with the National Organ

Transplant Act and the requirements of reasoned decision-making under the Administrative Procedure Act.

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

Dated: August 1, 2025

Respectfully submitted,

/s/ Val Leppert

VAL LEPPERT
Florida Bar No. 97996
KING & SPALDING LLP
Southeast Financial Center
200 S Biscayne Boulevard
Suite 4700
Miami, FL 33131
(305) 462-6000
vleppert@kslaw.com

ADAM ROBISON
Texas Bar No. 24035497
Pro hac vice pending
CHRISTIE CARDON
Texas Bar No. 24036326
Pro hac vice pending
KING & SPALDING LLP
1100 Louisiana Street. Suite 4100
Houston, TX 77002
(713) 751-3200
arobison@kslaw.com
ccardon@kslaw.com

Counsel for Plaintiffs LifeLink Foundation, Inc., OneLegacy, Iowa Donor Network, LifeCenter Northwest, and LifeGift Organ Donation Center

MARK D. POLSTON
D.C. Bar No. 431233
Pro hac vice pending
ASHLEY C. PARRISH
D.C. Bar No. 464683
Pro hac vice pending
KING & SPALDING LLP
1700 Pennsylvania Avenue NW
Washington, DC 20006
(202) 737-0500
mpolston@kslaw.com
aparrish@kslaw.com

Lead Counsel for Plaintiffs LifeLink Foundation, Inc., OneLegacy, Iowa Donor Network, LifeCenter Northwest, and LifeGift Organ Donation Center

BRIGID A. MERENDA
Florida Bar No. 0320500
RICHARD M. HANCHETT
Florida Bar No. 0709212
TRENAM, KEMKER, SCHARF, BARKIN, FRYE, O'NEILL & MULLIS, P.A.
101 E. Kennedy Boulevard, Suite 2700
Post Office Box 1102
Tampa, FL 33602
(813) 227-7427
bmerenda@trenam.com
ranctil@trenam.com
rhanchett@trenam.com
achrisman@trenam.com

Co-Counsel for Plaintiff LifeLink Foundation, Inc

Appendix

Index of Exhibits to the Complaint

Exhibit H – LifeGift Declaration of Kevin A. Myer

Attachment 1 LifeGift Ltr. to CMS Administrator Re: CMS-3380-P (Feb. 20, 2020)

Attachment 2 Organ Donation Advocacy Group Ltr. to CMS Administrator Re: CMS-1717-P (Sept. 17, 2019)

Exhibit I – Alexandra K. Glaxier, *Out-of-Sequence, Out of Alignment, and Out of Time: Why the Organ Procurement Organization Measures Are at the Root of This Problem*, 25 Am. J. Transplantation 1367 (2025)

Exhibit J – Jonathan M. Miller et al., *Adjusting for Race in Metrics of Organ Procurement Organization Performance*, 24 Am. J. Transplantation 1440 (2024)

Exhibit K – N.Y. Organ Donor Network Ltr. to OMB Administrator Re: HHS/CMS Rule 0938-AR54 (Oct. 28, 2013)

Exhibit L – Rocio Lopez et al., *Evaluation of the Stability of Organ Procurement Organization Performance Metrics*, 25 Am. J. Transplantation 1, 6 (forthcoming 2025)

Exhibit M – Jesse D. Schold et al., *Are the Centers for Medicare & Medicaid Services Metrics Evaluating Organ Procurement Organization Performance Too Fragile?*, 24 Am. J. Transplantation 1336 (2024)

Exhibit N – G. Lyden et al., *Are the New CMS Performance Tiers Biased Against Larger OPOs?*, 24 Am. J. Transplantation S531 (2024)

Exhibit O – 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 (2017)

Exhibit P – 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. Transplantation 2466 (2020)

Exhibit Q – Rhiannon D. Reed et al., *Geographic Differences in Population Health and Expected Organ Supply in the Gulf Coast Region of the United States Compared to Non-Gulf States*, 104 Transplantation 421 (2020)

Exhibit R – Realizing the Promise of Equity in the Organ Transplantation System (Kenneth W. Kizer et al. eds., 2022)

Exhibit S – Rocio Lopez et al., *Association of Organ Procurement Organization Volume with Centers for Medicare and Medicaid Services Performance Evaluations*, 25 Am. J. Transplantation 1013 (2024)

Exhibit T – Rocio Lopez et al., *Authors' Reply to Letter Regarding "Association of Organ Procurement Organization Volume with CMS Performance Evaluations,"* 25 Am. J. Transplantation 1135 (2025)