UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NEW ENGLAND DONOR SERVICES, INC., 60 First Avenue, Waltham, Massachusetts 02451;

GIFT OF LIFE MICHIGAN, 3861 Research Park Drive, Ann Arbor, MI 48108;

WE ARE SHARING HOPE SC, 2215 Henry Tecklenburg Drive, Charleston, SC 29414; and

DONOR NETWORK OF ARIZONA, 2010 W Rio Salado Parkway, Tempe, AZ 85281,

Plaintiffs,

v.

Case No. 25-cv-04329

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W., Washington D.C. 20201;

ROBERT FRANCIS KENNEDY JR., in his official capacity as Secretary of Health and Human Services, 200 Independence Avenue, S.W., Washington D.C. 20201;

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

MEHMET OZ, M.D., in his official capacity as Administrator of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244,

Defendants.

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs New England Donor Services, Gift of Life Michigan, We Are Sharing Hope SC, and Donor Network of Arizona bring this action against the Department of Health and

Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), the HHS Secretary (Secretary), and the CMS Administrator, and allege as follows:

INTRODUCTION

1. The United States leads the world in organ donation and transplants. More than one million patients around the country have received a transplanted kidney, liver, heart, or other organ. And the number of transplants has been growing steadily for over a decade, driven by increases in organ donations facilitated by local non-profit entities known as Organ Procurement Organizations (OPOs), which are specifically designated by CMS to perform this crucial work. Last year alone, OPOs recovered organs from nearly 17,000 deceased donors and facilitated over 41,000 transplants—more than any year previously, and the 14th year of consecutive growth.

2. These remarkable achievements have taken place under a carefully calibrated statutory framework that provides structure and oversight for local organ donation and the broader work of organ allocation. Congress created this framework 40 years ago because it saw the need to increase the number of available organs and to effectively and equitably allocate them to patients in need of transplant. In doing so, Congress expressly rejected the idea of allowing organ donation to be driven by competitive market forces; instead, Congress designed a high-performing, principled system that prioritizes collaboration, stability, and public trust.

3. A defining feature of this system is its reliance on OPOs at every step in the donation and transplantation process. 42 U.S.C. § 273(b)(3)(A)–(K). By statute, these non-profit entities are responsible for arranging for the acquisition, preservation, and transportation of donated organs to patients at transplant center hospitals. *Id.* § 273(b)(3). Each OPO is required to closely coordinate with local healthcare providers—including by receiving imminent death referrals from donor hospitals, obtaining authorization from donor families, assessing the medical suitability of organs for transplant, medically managing donors after death is declared, allocating organs to recipients at transplant centers in accordance with

national policy, coordinating the surgical recovery of organs, supporting donor families, and arranging transportation of donated organs to transplant center hospitals. *Id.* § 273(b)(3)(F)–(G), (I).

4. Congress entrusted OPOs with the responsibility of serving as central coordinators among donors, donor families, donor hospitals, transplant centers, and the national entity overseeing organ matching and allocation. This choice reflects Congress's recognition that the organ donation and transplantation process requires the kind of rapid and complex choreography that is best performed by small public health entities with deep roots and meaningful relationships with the communities they serve and with local medical ecosystems.

5. OPOs are on the frontline of the organ donation and transplantation system, as they are responsible for procuring the organs upon which the entire system relies. These local, community-based non-profits are the first to communicate with a potential donor family to discuss organ donation. The decision to donate is an emotional one, made during a time of profound loss. Understanding the emotional complexity of that moment, the need for the community's trust in the system, and the OPO as a known community steward of that trust, is critical to the system's success.

6. To help facilitate the development of that trust, Congress created a unique system of regional exclusivity, requiring CMS to designate one and only one OPO for each of the country's defined geographic areas known as "donation service areas" or "DSAs." *Id.* § 273(b)(1)(F); *id.* § 1320b-8(b)(2); 42 C.F.R. § 486.302 (defining "DSA"). This framework deliberately insulates OPOs from competition against one another to enable them to focus their resources on building and maintaining stable relationships with the communities they serve. This, in turn, supports the collaboration between stakeholders required to facilitate a high-performing organ donation and transplantation system. It also ensures that every pocket of the nation, including rural or otherwise difficult-to-serve geographies, is served by an OPO. This statutory framework makes organ transplantation accessible to every American, no matter where they live, and maximizes every possible opportunity for organ donation in a safe

and stable system. Not coincidentally, the highest performing nations in organ donation and transplant share the same model, for the same policy reasons.

7. But CMS now stands poised to upend this high performing system. To the substantial detriment of donors, donor families, and patient candidates on the transplant waiting list, in 2026, CMS will begin enforcing a rule establishing a new set of requirements for OPO recertification and designation that contravenes the foundational elements of Congress's design—and which will throw the nation's organ donation system into chaos. *See Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations*, 85 Fed. Reg. 77,898 (Dec. 2, 2020) (Outcome Rule); 42 C.F.R. §§ 486.302, 486.316, 486.318.

8. At its core, the Outcome Rule throws the non-profit community based OPOs into a cutthroat, iterative Hunger-Games-style competition where only the top are guaranteed "organizational survival." 85 Fed. Reg. at 77,933. In the coming months, CMS will evaluate OPOs based on two highly correlated measures: the rate of organ donations from donors in the OPO's DSA and the rate of transplantations of organs from donors in their DSA. 42 C.F.R. § 486.316(a). CMS acknowledged that "OPOs will not know" in advance of the performance assessment year "the actual threshold rate that" CMS will consider sufficient (and use to decertify OPOs) on either measure. 85 Fed. Reg. at 77,916. This is because CMS determined the actual threshold rate it will deem satisfactory based on data from 2023 (which it just released in 2025) but will use performance data from 2024 to calculate each OPO's donation and transplantation rate.

9. Using this stale 2024 performance data, CMS will then rank OPOs and designate those whose donation and transplantation rates place them in the top 25th percentile of OPOs as "Tier 1;" they, alone, will be guaranteed eligibility to continue working in their DSAs for the next four-year cycle. 42 C.F.R. § 486.316(a)(1). OPOs with either transplantation and/or donation rates below the 25th percentile threshold but above the median rate will be placed in "Tier 2." *Id.* § 486.316(a)(2). Tier 2 OPOs will be eligible for re-certification but

will have to compete against Tier 1 and other Tier 2 OPOs to retain their DSA. *Id.* §§ 486.316(a)(2), (b)–(d). And the remaining OPOs, with either measure below the median rate, will be assigned to Tier 3, and be decertified entirely: meaning, they will be eliminated from the organ donation and transplant system and prohibited from performing their life-saving work. *Id.* § 486.316(a)(3). Notably, an OPO's overall assignment will default to the lowest Tier for either measure. Thus, if an OPO is, for example, assigned to Tier 1 for donation rate and Tier 3 for transplant rate, its overall assignment will be Tier 3 and it will be decertified.

10. For the first culling cycle, CMS estimated that this process could eliminate 22 OPOs—or nearly 40% of the nation's total. 85 Fed. Reg. at 77,911. Future cycles of this rank-and-yank policy will reduce the field further, until the whole system is reduced to less than a handful of national OPOs.

11. This new regime is unlawful in multiple independent ways. Congress directed CMS to measure OPOs' performance *within* their defined service area. *See* 42 U.S.C. § 273(b). Nothing in the statute authorizes CMS to ignore the specific challenges endemic to each service area and to rank OPOs against each other—or to base re-certification on ever-shifting and unknown comparisons to other OPOs serving different areas with different populations, death rates, donor hospitals, transplant centers, and resource constraints. *Id.* Nor does the statute provide any authority for CMS to force OPOs to compete against each other to take over a designated service area. *See id.* To the contrary, Congress deliberately designed the system to eliminate and prevent competition—because it recognized that a competitive and commercial market for organ donation would lead to unsafe conditions, abuse and exploitation, and would be damaging to public health.

12. CMS's disregard of its statutory mandate threatens the very existence of the organ donation system. In the 2026 recertification cycle, CMS is on track to de-certify outright or throw into life-or-death competition about 50% of OPOs, and assign different OPOs to vast swaths of the nation's service areas. Data shows that the remaining OPOs, those

designated as Tier 1, are disproportionality likely to be those serving smaller geographic areas and, thus, lack the resources and experience to serve complex urban areas. This slash-and-burn campaign will disrupt donation and transplant throughout the country, impose unsustainable burdens on the remaining OPOs, and result in fewer available organs, leaving tens of thousands of patients vulnerable and doctors without their trusted OPO partners.

13. CMS itself recognized these likely outcomes. But it discounted these consequences, and the supporting research and comments undermining its reasoning. Commenters explained in detail that CMS's overly simplistic methodology would not reliably or accurately assess OPO performance or drive performance improvement; would systemically disadvantage certain communities and demographics; and would inevitably lead to worse or even unsafe patient care as the current mosaic of community-specific OPOs are ultimately replaced by just a few national conglomerates with no ties to or experience in the communities and DSAs they serve. By dismissing or simply ignoring the comments and evidence, CMS disregarded its statutory oversight responsibilities, and failed to satisfy the most basic criteria of reasoned decision-making.

14. Plaintiffs are four OPOs that operate in nine different states. These organizations are deeply committed to maintaining and improving the state of organ donation in their DSAs and throughout the country. CMS's rule compromises these organizations' work and threatens their continued survival. Plaintiffs therefore bring this challenge to CMS's Outcome Rule under the Administrative Procedure Act (APA), 5 U.S.C. § 702, to force the agency to comply with its statutory mandates and to prevent the resulting imminent and irreparable harm to the donation and transplant system and its stakeholders—patients, donor families, transplant centers, and OPOs—if the Outcome Rule goes into effect.

JURISDICTION AND VENUE

15. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 2201(a). Jurisdiction is also proper under the judicial review provisions of the APA, 5 U.S.C. § 702.

16. Venue 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 Defendant HHS resides in this district.

17. Because the Outcome Rule directly regulates and adversely affects Plaintiffs, and their injuries would be redressed by a decision in their favor, an actual, justiciable controversy exists between the Parties.

PARTIES

I. Plaintiffs

18. Plaintiff New England Donor Services, Inc. (NEDS) is a non-profit corporation incorporated in the Commonwealth of Massachusetts that coordinates organ and tissue donation across the New England states—Connecticut, Maine, Massachusetts, New Hampshire, and Rhode Island—as well as eastern counties of Vermont and Bermuda. *See* Attach. A. ¶¶ 3-7 (Declaration of Alexandra K. Glazier). NEDS serves nearly 15 million people and more than 200 hospitals through its federally designated OPO, New England Organ Bank, Inc., which was the first independent OPO established in the United States. *Id.* ¶¶ 4-5. Its founder, Dr. Joseph Murray, the "father of transplantation," won the Nobel Prize for his work performing the first organ transplant in the United States at the Brigham and Women's Hospital in Boston, Massachusetts. *Id.* NEDS has its principal place of business at 60 First Avenue, Waltham, Massachusetts 02451.

19. Plaintiff Gift of Life Michigan is a non-profit corporation incorporated in Michigan that serves as the designated OPO for the state. *See* Attach. B. ¶¶ 4-5 (Declaration of Ladora A. Dils). Gift of Life Michigan serves a population of nearly 10 million people across Michigan's Upper and Lower Peninsulas. *Id.* ¶¶ 4, 13.

20. Plaintiff We Are Sharing Hope SC (SHSC) is a non-profit corporation incorporated in South Carolina that serves as the designated OPO for the state. Attach. C. ¶¶ 4-5 (Declaration of David DeStefano). SHSC serves a population of over 5 million people. *Id.*

21. Plaintiff Donor Network of Arizona (DNA) is a non-profit corporation incorporated in Arizona that serves as the designated OPO for the state. Attach. D. ¶¶ 3-4 (Declaration of Katherine Mills). DNA serves a population of over 7.5 million people. *Id.*

II. Defendants

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

23. Defendant CMS is a component of HHS with responsibility for day-to-day operation and administration of the Medicare and Medicaid programs and is located at 7500 Security Boulevard, Baltimore, Maryland 21244. CMS regulates OPOs under authority delegated by Congress and the Secretary. *See* 42 U.S.C. §§ 273, 274c; 42 C.F.R. §§ 486.301, 486.303.

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

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

GENERAL ALLEGATIONS

I. Statutory and Regulatory Framework

26. 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. But, ever since organ transplantation began in earnest in the 1960s, the demand for organ donation has far exceeded the available supply.

27. Concerned that this shortage would lead to the creation of an exploitative commercial market for human organs, Congress passed the National Organ Transplant Act of 1984 (NOTA), Pub. L. No. 98–507, 98 Stat. 2339 (codified at 42 U.S.C. §§ 273 *et seq*.). That act criminalized the sale of human organs for profit. *Id.* § 301 (codified at 42 U.S.C. § 274e). And, in place of a commercial market, NOTA amended the Public Health Service Act (PHSA) and established a system of public-private partnerships to increase organ donation and ensure that organs are allocated equitably to patients across the United States. Today, the PHSA and Social Security Act (SSA) provide the framework for the Secretary and CMS's regulatory oversight of organ procurement and transplantation.

28. OPOs play a central role in this system. The process of deceased organ donation starts with a hospital referring patients who have either died or meet certain clinical triggers indicating they are near death to the designated OPO for the area. This is required by federal regulation. 42 C.F.R. §§ 121.7–.8; *id.* § 486.308(a). This system design ensures that all possible opportunities for organ donation are evaluated by OPOs, which is critical because only a very small fraction of deaths (approximately 2%) have any medical opportunity for successful organ donation for transplantation.[1] Accordingly, the first step in the donation process is the hospital's referral to the OPO, which works with the donor hospital's care team to assess donor potential. Also, OPOs work with donor families to obtain a comprehensive medical and social history for potential donors; identify whether potential donors are in the donor registry; work with and obtain authorization for organ donation from grieving families for individuals not included in the donor registry; oversee medical management of donors after they have obtained authorization; and allocate organs according to allocation policies established by the Organ Procurement and Transplantation Network (OPTN).

[1] Ajay K. Israni, et al., *OPTN/SRTR 2022 Annual Data Report: Deceased Organ Donation*, SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, https://srtr.transplant.hrsa.gov/ADR/Chapter?name=DOD&year=2022#tab:DD-cms-donor-funnel (last visited Dec. 12, 2025).

29. Notably, OPOs do *not* decide which patients receive organs from deceased donors. CMS instead mandates that OPOs allocate organs according to an algorithm established by OPTN policies that result in a prioritized list—provided by the OPTN—that is specific to each donor organ that becomes available (the "match run"). OPOs make organ offers to transplant surgeons for specific patient candidates identified in the prioritized order assigned by the match run. Each transplant surgeon receiving an offer has a limited amount of time to decide whether to accept the organ for their listed patient candidate. OPOs have no role in the medical decision to accept or transplant an available organ. If the organ is not accepted by the surgeon for the first offered patient, the OPO continues down the list, sometimes making hundreds of offers for a single available organ.

30. Once the organ is accepted by a transplant center for a patient candidate, the designated OPO coordinates the organ's surgical recovery and transportation from the donor hospital to the accepting transplant center(s). The logistics for organ recovery are highly complex and may include coordination of over 100 individuals in addition to OPO staff, including, *inter alia*, laboratory and diagnostic testing providers, the donor hospital, ancillary services (e.g., anesthesia), multiple transplant centers, multiple transplant center recovery teams working with multiple organ recipients, ground transportation providers, air transportation providers, and, most importantly, the donor and the donor family.

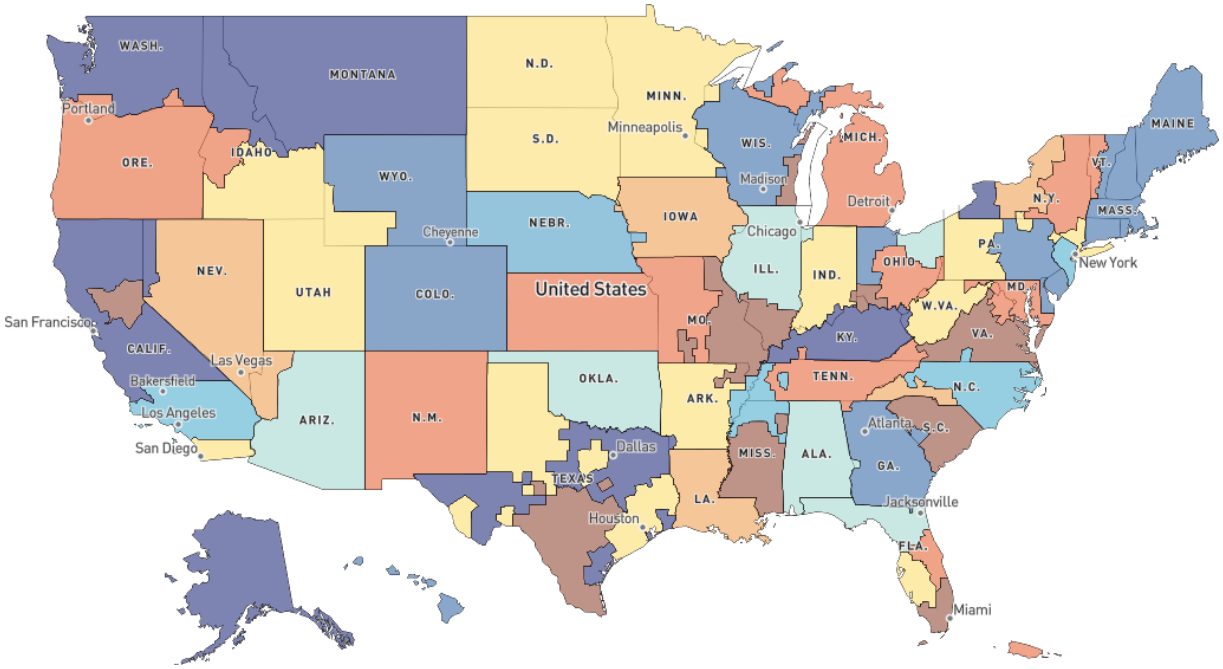
31. If the accepting transplant surgeon later declines the organ—either in the operating room after recovery or when the organ arrives at the transplant center—the OPO must go back to the match run and try to continue allocation. This requires that the OPO again coordinate the logistics of getting the organ to a new accepting transplant center, if the organ remains viable.

A. OPO DSA Exclusivity

32. Each OPO operates within its DSA. 42 C.F.R. § 486.302. By statute, each DSA must be sufficiently large to maximize both the effectiveness of organ procurement and the equitable distribution of organs. 42 U.S.C. § 273(b)(1)(E). DSAs are defined based on

metropolitan statistical areas (rather than political boundaries), which further helps to ensure that at least one major population center is included in each DSA for purposes of maintaining an adequate supply of organs. *See id.* § 273(b)(1)(F).

33. The Secretary must designate one, and only one, OPO for each DSA. *Id.* §§ 273(a)–(b); 1320b-8(b)(2); 42 C.F.R. § 486.308(a). Currently, there are fifty-five certified OPOs that each service their exclusive DSA, as depicted below:



Source: Scientific Registry of Transplant Recipients (SRTR), https://report.srtr.org/opo.

34. OPOs must serve an entire DSA—an OPO is not permitted to select individual hospitals or even partial geographic regions within a DSA. *See* 42 C.F.R. § 486.316(c). CMS has explained that this requirement operates to prevent attempts by OPOs to "obtain certain neighboring service areas purely for business reasons, with no regard for whether the [OPO] can increase organ donation in those areas." *Revisions to the Outcome Measure Requirements for Organ Procurement Organization*, 84 Fed. Reg. 70,628, 70,637 (Dec. 23, 2019). CMS has explained that, absent such a requirement, OPOs may seek to "raid" portions of a nearby DSA

to bolster their own performance measures—with "no actual increase in organ donation." *Conditions for Coverage for Organ Procurement Organizations*, 70 Fed. Reg. 6,086, 6,094 (Feb. 4, 2005).

35. This system of geographic exclusivity reflects Congress's judgment that maintaining these DSAs is crucial to the national public health infrastructure of organ donation and transplantation. It serves numerous purposes.

36. First and foremost, geographic exclusivity facilitates lasting and stable relationships between OPOs, donor hospitals, transplant centers, and the community. Deep engagement in these relationships is vital to successful organ donation. Organ recovery and transplantation requires clear and timely coordination between multiple clinical teams and organization staff working under different protocols and in multiple settings. OPOs that develop a detailed knowledge of individual hospitals' systems, clinicians' preferences, and available resources are better able to navigate this process and ensure the timely placement of donated organs with transplant patients. Further, serving one geographic area for a prolonged time helps OPOs better understand the unique communities they serve, which facilitates the forming of ties to those communities and the development of trust in the organ donation process. This, in turn, increases donation and transplantation rates.

37. Geographic exclusivity also ensures that OPOs adequately serve smaller hospitals and more rural populations—which might otherwise be overlooked by OPOs competing to claim hospitals with the largest patient populations and highest donation rates. CMS itself had previously expressed concern about such competition, noting that it would create instability and fail to increase donation rates. *See* 70 Fed. Reg. at 6,094. Finally, geographic exclusivity lowers overall system costs by eliminating the expense and resources that OPOs would otherwise devote to marketing themselves in a commercially competitive marketplace. Under the current system, OPOs' fees reflect the functions Congress mandated: facilitating organ donation and transplantation, and educating the public about the benefits of organ donation. *See* 42 U.S.C. § 273(b)(3). Without public support, the organ donation and

transplantation system fails: it requires engagement and participation *of* the public in order to *serve* all sectors of the public.

38. To maintain this regional exclusivity, Congress also imposed strict requirements on hospitals. All hospitals participating in Medicare are required to have an agreement with *only* the OPO assigned to serve their geographic location—or else they forfeit eligibility for Medicare reimbursements for *any* service. 42 U.S.C. § 1320b-8(a)(1)(C); 42 C.F.R. § 486.308(c). Because federal Medicare funding is indispensable to most hospitals, few if any can afford to forgo it.

39. The only way for a hospital to work with an OPO that is not the designated OPO for the hospital's DSA is through a waiver granted by the Secretary. 42 U.S.C. § 1320b-8(a)(2). Waivers may be granted only if the Secretary determines that the waiver is both (1) expected to increase organ donations, and (2) will assure equitable treatment of patients within the two OPO's DSAs. *Id.* § 1320b-8(a)(2)(A). Prior to a final waiver determination, interested parties must be given the opportunity to submit written comments to CMS. *Id.* § 1320b-8(a)(2)(D)(ii).

B. OPO Certification & Recertification

40. When it passed NOTA, Congress authorized the Secretary to make grants for the establishment, operation, consolidation, or expansion of qualified OPOs. *Id.* § 273(a)(2). It also charged the Secretary with creating a framework for certification, recertification, and decertification of OPOs. *Id.* § 273(b)(1)(D)(ii). However, it is no exaggeration to suggest that the Secretary has never carried out this job to Congress's satisfaction.

41. In 2000, Congress passed the Organ Procurement Organization Act of 2000, Pub. L. 106–505, 114 Stat. 2346 (2000), taking direct aim at what it saw as the flaws in the then-existing certification process. These flaws included: (1) the Secretary's "exclusive reliance on population-based measures of performance that [did] not account for the potential in the population for organ donation[;]" (2) the failure to allow for "consideration of other

outcome and process standards that would more accurately reflect the relative capability and performance of [OPOs];" and (3) deficiencies in the process provided to OPOs. *Id.*

42. Accordingly, Congress directed the Secretary to "develop improved performance measures" and to "improve the overall certification process by incorporating process as well as outcome performance measures, and developing equitable processes for appeals." *Id.* Per congressional instruction, these revisions of the certification and recertification process were to "reflect organ donor potential and interim outcomes" *and* they were to be "test[ed] . . . to ensure that they accurately measure[d] performance differences among the [OPOs]." *Id.*

43. Under the amended statutory framework, the Secretary must now "rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified [OPOs.]" 42 U.S.C. § 273(b)(1)(D)(ii)(II). And he must use "multiple outcome measures" as part of the certification process. *Id.* § 273(b)(1)(D)(ii)(III).

44. The Secretary must also promulgate regulations providing for an appeals process, on both substantive and procedural grounds, for any OPO wishing to appeal a decertification decision. *Id.* § 273(b)(1)(D)(ii)(IV).

45. Decertification is a death sentence for OPOs. OPOs that are not certified or recertified cannot receive Medicare or Medicaid funds. *See id.* § 1320b-8(b)(1)(A)(ii); 42 C.F.R. § 486.312(e). Nor can they work with any hospital that wishes to receive such funding. 42 U.S.C. § 1320b-8(a)(1)(C). Thus, CMS's certification is indispensable within the donation and transplantation system.

II. CMS's Prior Rulemaking

46. Beginning in 2006, CMS began to promulgate rules defining new outcome and "process" performance measures as directed by Congress. But these measures failed to

comply with the statutory requirements and were widely recognized—including, later, by CMS—as unreliable and inadequate for assessing OPO performance.

47. The "process" measures CMS created in 2006 are still in effect, with only minor modifications. *See generally* 42 C.F.R. §§ 486.320–486.360. Yet they are not true "measures," in the proper sense of the word. Rather, CMS largely imposed a set of minimum requirements, mandating, among other things, that OPOs participate in the Organ Procurement and Transplantation Network, *id.* § 486.320; "have a written agreement with 95 percent" of qualifying hospitals in its service area, *id.* § 486.322; have an advisory board that meets certain requirements and a sufficient number of qualified staff, *id.* § 486.324-486.326; have written protocols for donor evaluation and management, *id.* § 486.344, etc. Although these regulations echo other statutory provisions, they do not actually assess *how well* an OPO performs its function. That is, they do not measure any process but rather test the simple existence of certain requirements. As a result, CMS has functionally read the phrase "process . . . measures" out of the statute. There are no true "process measures" currently in effect.

48. The 2006 rule took a different approach to outcome measures. CMS decided to measure outcomes based on three factors: (1) donation rate; (2) observed donation rate; and (3) yield. *Conditions for Coverage for Organ Procurement Organizations*, 71 Fed. Reg. 30,982, 31,000 (May 31, 2006). To qualify for recertification, OPOs had to show that their donation rate—which the rule measured as the conversion of potential to actual donors—was at or above 1.5 standard deviations below the national mean donation rate for the prior 3 years. *Id.* at 31,005. They also had to demonstrate that their *observed* donation rate met or exceeded their expected donation rate. *Id.* at 31,002. And, lastly, they had to establish that their yield measure (assessing the number of organs transplanted or used for research per donor) stayed at or above a single standard deviation below the national mean (averaged over the 3-year recertification cycle). *Id.* at 31,003.

49. Although this 2006 rule was initially designed to go into effect for the 2006–2010 recertification cycle, CMS soon determined that it lacked sufficient data to adequately

assess OPO performance. As such, CMS delayed enforcement, and the 2010–2014 recertification cycle became the first application of CMS's new outcome measures.

50. During this first application of the 2006 rule, flaws in CMS's approach were glaring, even to CMS. In particular, CMS acknowledged its own concern that the "requirement to automatically decertify OPOs" failing to meet all three of the outcome measures was "unnecessarily stringent." *Medicare and Medicaid Programs*, 78 Fed. Reg. 43,534, 43,671 (July 19, 2013).

51. CMS also recognized that "OPOs DSAs' var[ried] substantially" with respect to demographic factors and that this could "have a significant impact on the organ yield that could reasonably be expected in that DSA." *Id.* CMS gave the example that a DSA with an "older donor population or one that is typically not as healthy" could have a significantly different organ yield than "a DSA with a population of generally more healthy individuals." *Id.* CMS also worried that its measures incentivized "making clinical decisions based on [the OPOs'] assessment of their own performance on the outcome measures." *Id.*

52. Recognizing that its methodology was unnecessarily stringent and that even those OPOs that were "performing satisfactorily" might fail to meet recertification criteria, CMS modified its prior 2006 approach to require that an OPO meet only two out of three outcome measures in order to qualify for recertification. *Id.* at 43,672. This approach failed to meaningfully grapple with the problems that CMS itself acknowledged, as it left in place the core elements of the flawed outcome measures and kicked the can down the road for more significant reform. *See Medicare and Medicaid Programs*, 78 Fed Reg. 74,826, 75,142 (Dec. 10, 2013).

A. CMS's Proposed Outcome Rule

53. In 2019, then-President Trump issued an Executive Order criticizing CMS's existing regulations as "outmoded" and "counterproductive." Exec. Order No. 13879, 84 Fed. Reg. 33,817 (July 10, 2019). This order directed CMS to promptly "revis[e] the Organ

Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance." *Id.*

54. Five months later, CMS proposed a rule that complied with none of these instructions. *See* 84 Fed. Reg. 70,628 (2019 proposed rule).

55. That proposed rule did not seek to make substantive changes to existing "process" measures. Instead, CMS focused only on outcome measures. Acknowledging its previous failures to implement objective performance metrics, CMS stated that its prior "outcome measures [were] not sufficiently objective and transparent . . . nor [did] they properly incentivize the adoption of best practices and optimization[.]" *Id.* at 70,628–29. But, rather than develop a set of objective and validated outcome measures that would use empirical evidence to evaluate the performance of OPOs within their DSAs, as mandated by Congress, CMS decided to throw up its hands—and turn certification into an aggressive gamified reality competition.

56. Specifically, CMS proposed to automatically decertify all OPOs that fell outside of the top 25% of OPOs based on two threshold rates: donation rate (i.e., the number of donors compared to the number of *potential* eligible donors) and transplant rate (i.e., the number of organs transplanted compared to the number of *potential* eligible donors). And further, CMS arbitrarily proposed to look only at a single twelve-month data snapshot (out of four years' worth of data in the certification cycle) before stripping OPOs of their certification. *Id.* at 70,636. Under this system, a single bad year could doom an OPO even if it demonstrated exceptional performance during all the other years of the certification cycle and excelled on all the other statutorily-required criteria such as the "process performance measures." 42 U.S.C. § 273(b)(D)(ii). In this way, CMS elevated its chosen data snapshot above all the other statutory requirements.

57. Further, although the national OPO system is expressly premised on geographically exclusive and vastly diverse service areas, nowhere in its 2019 proposed rule did CMS account for differences between DSAs—including, for example, based on geographic and

population size, racial or ethnic composition, size or features of any included metropolitan statistical area, number of transplant hospitals—nor any other DSA-specific metrics that would impact OPO performance.

58. CMS proposed that both of its new outcome measures would be calculated using the same "donor potential" denominator, which meant—as commenters identified—that the two measures would be highly correlated and insufficiently distinct to comprise the statutorily required *multiple* outcome measures. 85 Fed. Reg. at 77,905. Likewise, commenters expressed concern regarding CMS's use of data from the Centers for Disease Control's Multiple Cause of Death (MCOD) data files to determine donor potential, noting that this data was consistently identified by experts as inaccurate, was widely known and acknowledged to contain errors, and would not be timely available. *Id.* at 77,906. For example, OPTN commented that it was concerned that the data were insufficiently precise or timely for use in a regulatory fashion and expressed concern that these inaccuracies would not be shared equally across OPOs or geographic regions.[2] And several medical examiners expressed concern that the underlying death certificate data would not reflect donation-disqualifying comorbidities and that this and other inaccuracies would lead to misleading conclusions if the data was used to measure OPO performance.[3]

59. This proposed rule engendered a massive public response, including over 800 public comments submitted by hospitals, industry associations, healthcare professionals, OPOs, donor families, academic researchers, advocacy groups, transplant recipients, and other members of the public. 85 Fed. Reg. at 77,900.

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[2] OPTN Ltr. to CMS Administrator Re: CMS-3380-P, at 2–3 (Feb. 19, 2020).

[3] *See, e.g.,* Medical Examiner of Riverside County California Ltr. to CMS Administrator Re: CMS-3380-P, at 1–2 (Feb. 14, 2020), https://www.regulations.gov/comment/CMS-2019-0187-0060; Bergen County Medical Examiner Cmt. on CMS-2019-0187-0001 (Feb. 19, 2020), https://www.regulations.gov/comment/CMS-2019-0187-0322; Chief Medical Examiner Vermont Department of Public Health Ltr. to CMS Administrator Re: CMS-3380-P, at 1–2 (Feb. 20, 2020), https://www.regulations.gov/comment/CMS-2019-0187-0404.

60. Commenters noted that CMS provided no statistical rationale for its rigid 25% cutoff, despite the fact that it would result in CMS decertifying nearly 40% of OPOs by the agency's own measure. *See id.* at 77,923–24.[4] They also detailed the flaws in CMS's proposal to calculate OPOs' performance metrics based on twelve months of data taken from 2024, two years prior to the recertification decision date (2026) and noted that, during the 2026 recertification cycle, CMS would be evaluating stale OPO data that may no longer be accurate or relevant to current OPO performance. *Id.* at 77,921.

61. Many of the comments also took exception to the proposed rule's harsh punishments for well-performing organizations and organizations demonstrating substantial performance improvement. Commenters explained that many factors outside the OPOs' control—such as population density in a service area, the demographics and overall health of the population, and the availability and performance of transplant hospitals—profoundly impact donation and transplantation rate in a DSA. *Id.* at 77,909–10. In particular, the transplantation rate is highly dependent on factors outside an OPO's control given that OPOs do not decide whether or not to transplant an organ. As a result, objectively successful OPOs that operate in under-resourced or disadvantaged areas will be penalized and threatened with decertification—even if their organizational performance is above the national average and their ranking is based on factors wholly outside their control.

62. Commenters further explained that thrusting OPOs into competition with each other "would damage the relationships between the OPOs" and discourage them from "cooperat[ing] or shar[ing] best practices with each other" for fear that doing so would compromise their own ability to survive. *Id.* at 77,919. And they objected to CMS upending the relationships between OPOs and their communities without fairly or accurately measuring OPO performance, instead using arbitrary and unsustainable cutoffs.

[4] *See also* New England Donor Services and LifeChoice Donor Services Ltr. to CMS Administrator Re: CMS-3380-P, at 6 (Feb. 19, 2020), https://www.regulations.gov/comment/CMS-2019-0187-0324.

B. 2020 Final Outcome Rule

63. CMS issued its final Outcome Rule in 2020. 85 Fed. Reg. 77,898. The Outcome Rule implemented the basic architecture CMS proposed, where CMS would assign OPOs into tiers based on two outcome measures: (1) donation rate in their DSA and (2) organ transplant rate in their DSA. *Id.* at 77,911–14; 42 C.F.R. § 486.318(d).

64. Each outcome measure is a rate calculated using the same denominator—donor potential—which is based on the number of inpatient deaths among patients within the DSA who meet certain broad criteria. 85 Fed. Reg. at 77,911–14; 42 C.F.R. § 486.318(d)(1)(iv).

65. But CMS made a crucial change to its initial design. Whereas its proposed rule contemplated splitting OPOs into two groups—those that qualified for certification and those that did not—its final Outcome Rule introduced a middle category: Tier 2. 85 Fed. Reg. at 77,911-12; 42 C.F.R. §§ 486.318(e)(4)–(6). Unlike OPOs consigned to Tier 3, OPOs in Tier 2 could be recertified. 42 C.F.R. § 486.316(a). But, unlike the Tier 1 OPOs, they would not be recertified automatically; instead, they would need to compete to retain their DSA. *Id.* With now only months to go before this Hunger-Games-style competition becomes a reality for Tier 2 OPOs, CMS has still yet to define how the competition would work. But CMS made clear that competition was *the* central feature of its policy, using the term "competition" no less than eighty-four times in the Final Outcome Rule.

66. To determine a given OPO's tier assignment, CMS established "threshold rates," which are determined for each outcome measure based on the 25th percentile rate and the median rate among OPOs based on the most recent twelve months of death certificate data. *Id.* §§ 486.318(e)(1)–(2) (methodology for OPOs in the contiguous United States). These threshold rates are then used to rank the OPOs into the three tiers. OPOs with both

donation and transplantation rates[5] at or above the 25th percentile threshold rate are ranked Tier 1. *Id.* § 486.318(e)(4). OPOs that have both donation and transplantation rates at or above the median threshold rate are designated Tier 2. *Id.* § 486.318(e)(5). And OPOs that have either a donation rate or a transplantation rate—or both—below the median threshold rate are considered Tier 3. *Id.* § 486.318(e)(6). CMS cited no empirical evidence to support its adoption of these particular threshold rates.

67. In preparation for the end of the first four-year certification cycle under the new tiering system, CMS published a series of "interim" public performance reports with tier ratings. Like the final ranking, these interim reports lagged two years behind the underlying data.[6] CMS stated that it was providing these reports to help OPOs monitor and enhance their own performance. Such a justification is difficult to reconcile with the reality—OPOs receive these reports two years late, making them obsolete for the purpose of monitoring and changing OPO performance. Plus, these interim reports have no bearing on the final tier status for the 2026 certification cycle, which will be based solely on twelve months of data from 2024.

68. As expected, the interim reports have shown that OPO rankings are highly volatile. For example, the 2021 interim report found that 27 OPOs would be categorized as Tier 1—but that number fell to 15 in the 2023 iteration. *See* Organ Procurement Organizations, Annual Public Aggregated Performance Report 2023, https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf. In the latest interim report, the number of Tier 1 OPOs is back up to 30, but a number of OPOs that had previously been placed

[5] For tiering purposes, donation and transplantation rates are determined using the upper tail of a 95% confidence interval, calculated using the OPO's raw donation and transplantation rates within its DSA. 85 Fed. Reg. at 77,914.

[6] *See, e.g., 2024 (2nd rev.) & 2025 OPO Interim Annual Public Aggregated Interim Performance Report*, CMS, https://qcor.cms.gov/documents/Public%202024%20&%202025%20OPO%20Report%20-%20July%202025.xlsx (2025 OPO Interim Performance Report).

in Tier 2 have now been rated as Tier 3. *See* 2025 OPO Interim Performance Report ("2025 Assessment" Tab).

69. The volatility is epitomized by CMS's calculations showing how many additional transplants each OPO would need to achieve a higher rating. *Id.* ("2025 Assessment" Tab, "Transplant" columns). For four OPOs, the number is less than a dozen. *Id.* One OPO in Florida and one OPO in California—which together serve a population of 26 million people—each needed just *two more transplants* to achieve Tier 1. *Id.* Not surprisingly, peer-reviewed studies have concluded that the CMS measures are highly "fragile"—meaning that these measures do not deliver reliable, stable results over time.[7]

III. The New Outcome Regulations Are Unlawful

A. CMS Lacks Authority to Force OPOs to Compete Against Each Other for Certification

70. CMS's decision to base certification on a relative ranking between OPOs is wholly inimical to the language, structure, and purposes of the PHSA and the SSA. Neither the PHSA nor the SSA grants CMS the authority to rank OPOs, let alone force them to compete for certification.

71. As a starting point, Congress required CMS to certify OPOs based on multiple "outcome and process performance measures" that are "based on empirical evidence . . . in each service area." 42 U.S.C. § 273(b)(D)(ii). The plain language of the statute requires that CMS certify OPOs on a wholly individual basis looking to an OPO's *own* performance and processes, with its donor potential *and in* its unique service area, for its determination. Nothing in the PHSA authorizes CMS to also rely on evidence in *other* service areas. Nor does anything in the PHSA authorize CMS to look to the performance of other organizations.

72. This insulation of OPOs from competition is a central element of Congress's design. Congress explicitly required CMS to designate one and only one OPO for each DSA.

[7] Jesse D. Schold, Rocio Lopez, Sumit Mohan, *Are the Centers for Medicare & Medicaid Services metrics evaluating organ procurement organization performance too fragile?*, 24 Am. J. Transplant. 1136, 1337 (2024), available at https://doi.org/10.1016/j.ajt.2024.03.025.

Id. § 1320b-8(b)(2). All hospitals wishing to receive federal funds from Medicare must sign an agreement with *only* the OPO designated for its geographic service area. *Id.* § 1320b-8(a)(1)(C). This remarkable leveraging of federal funds underscores how seriously Congress treated DSA exclusivity. In fact, Congress provided only one narrow exception to this framework of geographic exclusivity, in instances where an individual hospital wishes to work with a different OPO. *Id.* § 1320b-8(a)(2) (individual hospital waivers). Doing so further confirmed the general principle that OPOs are not to be placed in competition with each other for any other purpose.

73. In creating unique, exclusive service areas where only one OPO may operate, Congress clearly demonstrated its belief that market competition is incompatible with organ donation and procurement. Even in its own discussion of this Outcome Rule, CMS conceded that the organ procurement space is "unusual because it was established as a system of private monopolies by statute" and in which "OPOs are part of the supply chain for final goods—organs for transplant—that are *not transacted in a market*." 85 Fed. Reg. at 77,933 (emphasis added). As such, "care must be taken in using concepts such as market competition." *Id.*

74. Tellingly, CMS has consistently understood the need to evaluate OPO's "process" performance measures based *solely* on an individual OPO's characteristics, not on a competitive basis. *See* 42 C.F.R. §§ 486.320–486.360. Not a single one of the "process" performance measures CMS established in its regulations relies on national statistics nor on some form of OPO competition. *Id.* Instead, these measures evaluate OPOs based only on their service areas. *See, e.g., id.* § 486.322(a) (agreements with hospitals); *id.* § 486.324(a)(1) (requiring an advisory board); *id.* § 486.328(c) (requiring OPOs to supply OPTN with DSA-specific data); *id.* § 486.348(b) (requiring OPOs to conduct reviews of certain hospitals in their service area); *id.* § 486.360(c)(1)(v) (OPOs must have emergency communication plans with hospitals in their DSA).

75. By departing from this approach with respect to "outcome measures," and forcing OPOs to compete to reach an ever-shifting set of standards, CMS ignored Congress's framework and exceeded its statutory authority.

B. CMS Lacks Authority to Force OPOs to Compete for Service Areas

76. CMS further exceeded its authority by divorcing Tier 2 OPOs from their DSAs and opening those DSAs up for competition.

77. No statute authorizes CMS to open an OPO's DSA for competition. Quite the opposite. Each OPO has a strict, codified relationship with its DSA. Each OPO is required to have a "defined service area" and CMS is similarly directed to assess the OPO's performance on the basis of that service area alone. 42 U.S.C. §§ 273(b)(1)(D)(ii)(II), 273(b)(1)(F). That service area must be designed to "assure maximum effectiveness in the procurement and equitable distribution of organs" and may not split a metropolitan statistical area. *Id.* § 273(b)(1)(E). CMS's authority to interfere with an OPO's DSA is limited. CMS is expressly forbidden from "designat[ing] more than one [OPO] for each service area." *Id.* § 1320b-8(b)(2). And hospitals are only permitted to work with their region's designated OPO. *Id.* § 1320b-8(a).

78. In the limited circumstances where Congress permitted CMS to deviate from this framework, it was explicit. Congress carved out only one narrow exception for when one certified OPO could replace another, allowing CMS to grant individual hospitals waivers to work with a non-designated OPO. *Id.* § 1320b-8(a)(2). Such permission does not extend to an entire DSA. And the exceptional circumstance of a waiver can only happen following a stringent process defined by statute—which requires a hospital's formal request, a public notice-and-comment period specific to that hospital and that waiver request, and a subsequent analysis by CMS in which it must decide whether to grant the waiver based on certain criteria. *Id.* § 1320b-8(a)(2)(A)–(D).

79. Congress created no similar authorization for CMS to open an OPO's entire DSA up to competition. Nor did it authorize CMS to promulgate criteria for any such

competition. Yet with its 2020 Outcome Rule, CMS set forth standards for opening Tier 2 OPOs' service areas for competition and it did so wholly without statutory basis or authority. *See* 42 C.F.R. §§ 486.316(b)–(d).

80. Indeed, this new competitive marketplace rests upon an ill-defined set of standards that do not match the process Congress provided for individual hospital waivers. *Compare id.* § 486.316 *with* 42 U.S.C. §§ 1320b-8(a)(2)(A)–(B). Re-competition of a whole service area would inevitably have far-reaching consequences beyond the impacts of a single hospital waiver. Yet, where the waiver process permits public participation, re-competition does not. That Congress would bind CMS's discretion to allow a single hospital to work with an OPO other than its designated OPO, then grant CMS unencumbered authority to award an entire service area—some of which span several states, thousands of square miles, millions of people, and house numerous hospitals—defies logic.

81. Further, CMS lacks any statutory authority to designate an OPO for multiple service areas. As a condition of certification, Congress required each OPO to have "*a* defined service area"—singular—within which its performance is measured. 42 U.S.C. §§ 273(b)(1)(D)(ii)(II), (b)(1)(E) (emphasis added). Yet CMS has given itself the authority to select an existing OPO for multiple service areas, without merging them. *See, e.g.*, 85 Fed. Reg. at 77,913 ("[O]ur regulations do not require that DSAs merge when a new OPO takes over"). And, to enable this regime, it has also claimed authority to certify or decertify OPOs *for a DSA*—rather than holistically as an organization. *Id.* Nothing in the statute authorizes CMS to fracture the one-to-one relationship between an OPO and a DSA in this way.

82. A final indication that CMS has strayed far beyond its statutory brief is the absence of any appeal process provided to OPOs that lose their DSA competition. *See* 85 Fed. Reg. at 77,918 ("OPO will not be able to appeal" the loss of competitions and resulting non-renewal of its agreement with CMS). Such a loss is functionally and legally equivalent to a decertification decision, because an OPO that does not have an assigned DSA is precluded from performing any work in the area. *Id.* Congress was gravely concerned about the

economic impact of such decisions. Indeed, when it amended the PHSA in 2000, Congress expressed serious concern that CMS had no adequate process for OPOs to appeal decertification—and mandated that CMS create one. *See* Pub. L. 106–505, 114 Stat. 2346. That it provided no equivalent mechanism for OPOs that lose their DSAs as a result of competitions suggests that it did not contemplate any such competition occurring.

83. Taken together, all of these statutory elements show that, unless they are decertified, OPOs are presumptively entitled to operate within their designated service areas. Because Congress did not authorize CMS to open such areas for competition, CMS's Outcome Rule greatly exceeds the agency's authority.

C. CMS's Has Attached Impermissible Conditions to Federal Funds

84. Any construction of the PHSA and the SSA that would authorize the approach CMS adopted in its 2020 Outcome Rule would create severe constitutional problems.

85. CMS's Outcome Rule attaches a string of new conditions to federal funding provided to OPOs. As described above, OPOs must now compete against each other to be certified. 42 C.F.R. § 486.316(a). And Tier 2 OPOs, which are not automatically decertified, must compete to retain their service area. *Id.* § 486.316(b)–(d). The Rule thus makes competition on outcome measures a condition of continuing to receive federal funding.

86. The Constitution requires funding recipients to have clear notice of funding conditions. *See Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17-18 (1981); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 583-84 (2012) (*NFIB*). Where "Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously" and it must do so in advance. *NFIB*, 567 U.S. at 583 (quoting *Pennhurst*, 451 U.S. at 17). Congress's "power to legislate under the spending power . . . does not include surprising [participants] with post-acceptance or retroactive conditions" that work "a major change in a program." *Id.* at 584–85 (quotes and citations omitted); *see also Cummings v. Premier Rehab Keller, P.L.L.C.*, 596 U.S. 212, 219 (2022).

87. Because of this constitutional requirement, when Congress authorizes agencies, including HHS, to conduct competition for federal projects, it does so explicitly. *See, e.g.*, 42 U.S.C. §§ 1395w-3 ("[c]ompetitive acquisition of certain items and services"); *id.* § 1395w-3b ("[c]ompetitive acquisition of outpatient drugs and biologicals"); *id.* § 1395kk-1(b)(1)(A) ("Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors . . . taking into account performance quality"). Yet Congress did not clearly authorize any such competition between OPOs. To the contrary, as CMS itself previously recognized, Congress provided repeated protections *against* OPOs facing such competition. *See, e.g.*, *id.* § 1320b-8(a)(1)(C) (requiring hospitals to work with only one CMS-designated OPO); *id.* § 273(b)(3)(A) (mandating that OPOs have effective agreements with the substantial majority of hospitals in their DSA). As a result, Congress provided OPOs with no notice that the performance of other organizations in other areas of the country could result in them losing federal funding.

88. And not just federal funding. Under the PSHA and the SSA, hospitals that wish to receive Medicare funding are not permitted to work with any OPO but the one CMS has designated—even for procedures that would be entirely funded by private insurance. *Id.* § 1320b-8(a)(1)(C). Because hospitals cannot afford to lose *their* federal funding, OPOs that are decertified and those that lose the competition for their DSA will lose all their work and be driven out of business. Congress's choice to leverage federal funding in this way renders the requirement of clear and unambiguous notice that much more vital. *See F.C.C. v. Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012) (explaining that a law must not be unduly vague to ensure "that regulated parties [] know what is required of them" and "so that those enforcing the law do not act in an arbitrary or discriminatory way"). Yet the statutes do not give the OPOs any indication that their survival could depend on competition with other OPOs.

D. CMS's Outcome Rule is Arbitrary and Capricious In Multiple Respects

89. Under the APA, any action taken by an agency must be accompanied by "a satisfactory explanation . . . [that] include[es] a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983) (citation omitted). Where an agency action is not "reasonable and reasonably explained[,]" the action is deemed arbitrary and capricious. *FCC v. Prometheus Radio Project,* 592 U.S. 414, 423 (2021). An agency action is also arbitrary and capricious if the agency "failed to consider . . . important aspect[s] of the problem" before it. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal..,* 591 U.S. 1, 25 (2020) (quoting *State Farm,* 463 U.S. at 43). Because CMS's Outcome Rule fails all of those standards in multiple respects, the APA requires that it be held "unlawful and set aside." 5 U.S.C. § 706(2)(A).

1. The Final Rule Relies on Only Two Highly Correlated Outcome Measures That Do Not Accurately Measure Performance

90. Congress required CMS to base OPO certification on "multiple" outcome "performance measures that are based on empirical evidence . . . of organ donor potential and other related factors in each service area." 42 U.S.C. § 273(b)(1)(D)(ii). The Outcome Rule, however, measures OPO performance on the basis of only two outcome measures—the donation rate and the transplant rate—both of which are calculated based on the single underlying denominator—donor potential—and are thus highly correlated. 85 Fed. Reg. at 77,948.

91. Not surprisingly then, commenters identified that these outcome measures are "too similar" and "not independent" making it impossible to qualify as the "multiple" measures that the statute requires. 85 Fed. Reg. at 77,905. These comments are corroborated by studies showing that the two measures are highly correlated, with only a few OPOs likely to succeed on one but fail on the other. *See* Jon J. Snyder, et al., *The Centers for Medicare and Medicaid Services' proposed metrics for recertification of organ procurement organizations: Evaluation by the Scientific Registry of Transplant Recipients*, 20 Am. J. Transplant. 2466, 2469–74 (2020), available at https://pubmed.ncbi.nlm.nih.gov/32157810/ ("Evaluation by the Scientific

Registry of Transplant Recipients"). This indicates that CMS has not complied with Congress's statutory directive to adopt multiple outcome measures to assess OPO performance.

92. In reality, donation (and therefore transplantation) rates vary across service areas for reasons that are entirely outside of the OPOs' control. For instance, an OPO that serves a small, densely populated service area that comprises wealthy, homogenous communities with access to an abundance of nearby hospitals and transplant centers faces fewer challenges than does an OPO that serves a widely dispersed, rural service area comprising diverse and economically disadvantaged communities across a large geographic area in which hospitals and transplant centers are scarce and the opportunity for organ donation is limited. Indeed, CMS has itself previously recognized that demographic differences can impact OPOs' performance. *See* 78 Fed. Reg. at 43,671–72; Sara Crawford, Jesse Schold, *Association Between Geographic Measures of Socioeconomic Status and Deprivation and Major Surgical Outcomes*, 57 Medical Care 949, 959 (2019), available at https://pubmed.ncbi.nlm.nih.gov/31568164/.

93. Further, OPOs' rate of transplantation is heavily dependent not only on the number of available transplant hospitals—which varies widely across different parts of the country—but also on the wholly-independent choices made by transplant surgeons at those hospitals, who are entirely outside the control of the OPO. Regardless of the work that an OPO does to facilitate donation, secure an organ, and offer it to a patient candidate listed at a transplant center, transplant surgeons may (and do) decline to perform a transplant for any number of reasons (e.g., medical suitability for a particular recipient, recipient clinical status, transplant hospital resources). *See generally Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model*, 89 Fed. Reg. 96,280, 96,298-301 (Dec. 4, 2024) (identifying numerous studies "document[ing] the substantial extent of deceased donor kidney non-utilization in the U.S."); *see, e.g.*, S. Mohan, et al., *Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy*, Kidney Int. Rep. (Feb. 25, 2023), available at https://pubmed.ncbi.nlm.nih.gov/37180509/ (noting that "over 1 in 4 [kidneys] recovered for transplant are not being transplanted"). OPOs have no statutory role

nor practical ability to impact those decisions. Yet CMS's outcome measures penalize and hold OPOs accountable with the transplant rate for those independent decisions all the same. And, as the agency's interim reports show, just a handful of such decisions—sometimes as few as two—can consign an OPO to a lower Tier and result in decertification.

94. Notably, CMS itself has recognized that factors outside an entity's direct control—specifically in transplant—can impact and distort performance measures. For that reason, when measuring the performance of transplant *hospitals*, CMS includes at least some "risk adjustment" on various criteria, and just recently proposed "[a]dding a risk-adjustment methodology that includes several transplant recipient and donor characteristics (for example, transplant recipient and donor age, diabetes status, sex, [and] kidney function" when measuring certain "survival rate metric[s]." *Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model*, 90 Fed. Reg. 57,598, 57,599 (Dec. 11, 2025). As CMS previously explained, it has "concern[s] that the lack of risk adjustment would be unfair" to the transplant hospitals when measuring organ transplant outcomes. 89 Fed. Reg. at 96,352.

95. But despite OPO performance measures raising the exact same concerns regarding donor characteristics impacting transplant outcomes, CMS refused to incorporate any of the risk adjustments urged by commentators other than a minimal adjustment for donor age (and even then, donor age is only adjusted in the transplant rate measure). 85 Fed. Reg. at 77,909-910. And, further, CMS refused to incorporate measures that account for DSA-specific factors impacting donor potential as well as donation and transplantation rates.

96. CMS's failure to consider DSA-specific factors or any donor-specific risk adjustment that are well-known and even recognized by CMS to impact donation and transplant outcomes—and which therefore drive so-called OPO performance on the outcome measures—is biased, arbitrary, capricious, and fails to accurately or objectively measure OPO performance as mandated by statute.

2. CMS Failed to Properly Consider Flaws In the Underlying Data

97. The flaws in the outcome measures are compounded by CMS's reliance on flawed data for its calculations.

98. Both donation rate and transplantation rate use the same donor potential denominator. 42 C.F.R. § 486.318(d)(1)(i)–(ii), (iv). In calculating donor potential, CMS will rely on the Centers for Disease Control's Multiple Cause of Death (MCOD) data. 85 Fed. Reg. at 77,906. But CMS itself has acknowledged that it is "aware of the error rates" in this data. *Id.* And these error rates are reported to be substantial—ranging from 30 to 60 percent. *Id.*

99. Commenters to the 2019 proposed rule were quick to point out additional flaws with this data. For example, noting that the MCOD would include deaths of patients *ineligible for donation* (e.g., the patient was not ventilated at the time of death, medical rule outs) and identifying concerns with the data's accuracy. *Id.* at 77,906–07. In response to comments regarding these obvious flaws, CMS merely asserted that it assumed—without support or a reasonable explanation—the rate of these occurrences was consistent across DSAs. *Id.* Contrary to this baseless assumption, it is well known that disease patterns vary significantly across the nation. *See, e.g.,* Charbel el Bcheraoui, et al., *Trends and Patters of Differences in Infectious Disease Mortality Among US Counties, 1980–2014*, 319 J. Am. Med. Ass'n. 1248, 1249 (Mar. 27, 2018) available at https://pubmed.ncbi.nlm.nih.gov/29584843/.

100. Moreover, states are responsible for reporting death certificate data, and they do not do so uniformly. States' varied approaches render the MCOD an inaccurate measure of donor potential in an OPO's DSA. CMS itself acknowledged these varied approaches. 85 Fed. Reg. at 77,907. Nevertheless, CMS plowed ahead, summarily dismissing these concerns because it did not "believe that a different process would disadvantage one OPO compared to another." *Id.* As such, unadjusted comparisons between OPOs using this data are a fundamentally inaccurate means of assessing OPO performance. Nevertheless, this is the data

that CMS will use to calculate not one but *both* outcome measures used to evaluate OPOs for recertification.

101. CMS's disregard of these fundamental problems reflects a lack of reasoned decision-making and is arbitrary, capricious, and contrary to the law.

3. The Outcome Rule Ignores Other Important Aspects of OPO Performance

102. CMS's Outcome Rule also has the practical effect of dramatically downgrading the importance of process measures in the certification process, thus distorting the statutorily-required analysis. Because CMS has decided to evaluate process and outcome measures independently—and only utilize the performance measures for Tier placement—OPOs that fall marginally short on the latter stand to be decertified no matter how well they perform on the "process" measures. And CMS's current method for evaluating "process" measures on a simple pass/fail system does not provide the agency adequate information to contextualize OPOs' performance on outcome measures.

103. These problems are exacerbated by CMS's decision to rely on a single twelve-month period of data—which is two years old at the time of recertification—to make its certification decision. By ignoring the OPO's performance over three quarters of the four-year certification cycle, CMS's rubric further departs from the statutory text and introduces unpredictability. *See* 42 U.S.C. § 273(b)(1)(D)(I) (requiring recertifications of OPOs "not more frequently than once every 4 years").

104. CMS's relative inattention to process measures and use of aged data to measure outcomes is not an accurate measure of an OPO's current or overall performance. Indeed, as commenters observed, CMS's approach could lead to absurd results. The MCOD data CMS uses is not available until eighteen to twenty-four months after the year it purportedly captures. 85 Fed. Reg. at 77,915. Use of this stale data could result in decertification of a currently high performing OPO that had a single year of lower performance based on factors beyond its control (e.g., closure of a local transplant center, population health changes). This

is true even if the single year was an anomaly and even if in the two subsequent years the OPO's donation and transplantation rates would yield a Tier 1 ranking.

105. Rather than address the source of the problem, CMS attempted to paper over it by promising to publish interim data—supposedly enabling OPOs to track their donation and transplantation rates according to CMS's measures and thereby predict their tier ranking in advance of CMS's final certification decisions in 2026. However, errors compounded and CMS's release of this data was delayed. *Compare* 85 Fed. Reg. at 77,911–12 ("OPOs would be assessed annually on these outcome measures . . . [in published] interim reports"), *with Organ Procurement Organization (OPO) Conditions for Coverage – Reporting Data Related to Pancreata Procured for Research* at 2, (Aug. 29, 2024), https://www.cms.gov/files/document/qso-24-19-opo.pdf (requiring that OPOs "resubmit[]" 2022 data such that CMS could "re-run the 2024 OPO Annual Individual Performance Reports"). This delay highlights how CMS's reliance is an inadequate cure for the problems its own arbitrary methodology created. Further, interim reports providing OPOs with data nearly two-years old under the auspice of helpful performance insight is not a legitimate effort to support meaningful change. Organizations engaged in quality improvement efforts need close to real-time data to drive real improvement.

4. CMS Ignored Critical Evidence Showing that Its Methodology Privileges Some OPOs over Others

106. CMS ignored statistical evidence and peer-reviewed research showing that CMS's chosen outcome measures will systemically privilege OPOs with smaller DSA populations over others.

107. The Outcome Rule imposes its Tier-ranking system on the basis of one-sided 95% confidence intervals. 85 Fed. Reg. at 77,914. Mathematically, confidence intervals reflect the margin of error around a parameter (like donation rate or transplantation rate within a DSA). This means that each OPO will be evaluated based not on their raw donation and transplantation rates but rather on a calculated cushion surrounding those rates. *Id.* But when

a population size increases, the statistical margin of error decreases—and the confidence interval narrows. As a result, OPOs that serve DSAs with smaller populations will have wider confidence intervals: a bigger cushion added to their numbers. And because CMS judges all OPOs based on the *upper tail* of their one-sided 95% confidence intervals for donation rate and transplantation rate, the values that CMS will use for smaller OPOs—with wider confidence intervals—will tend to exceed the OPO's true numbers (i.e., donation or transplantation rate) by an amount greater than the values used for OPOs with larger DSAs. This necessarily gives OPOs with smaller DSAs a boost in the competition.

108. Commenters explained this problem to CMS. In response, CMS asserted it did "not concur . . . [that its] methodology is biased against large OPOs" while simultaneously emphasizing that the purpose of the 95% confidence intervals was to protect small OPOs. *Id.* at 77,914. On its face, this explanation was self-contradictory and failed to meaningfully engage with the underlying problem. Years later, analysis has proven what was already clear: peer-reviewed studies identified this mathematical bias as a significant flaw in the outcome measures. *E.g.,* Rocio Lopez, et al., *Association of organ procurement organization volume with Centers for Medicare and Medicaid Services performance evaluations*, 25 Am. J. Transplant. 1013, 1016–17 (2025), available at https://pubmed.ncbi.nlm.nih.gov/39608573/. Predictably, the data now show that a disproportionate number of the smallest OPOs are projected to be in Tier 1. 2025 OPO Interim Performance Report ("2025 Assessment" Tab). Larger OPOs, handling larger and more diverse populations, are disadvantaged.

5. CMS Failed to Consider the Natural Consequences of Its Outcome Rule

109. Finally, CMS failed to give due regard to the massive disruptions that its Rule will set in motion. Prior to the promulgation of this Rule, CMS's own analysis showed demonstrated improvements in OPO performance. 85 Fed. Reg. at 77,913. Yet, CMS's own estimates showed that, for the first recertification cycle nearly 40% of OPOs would fall into

Tier 3, and nearly 20% would fall into Tier 2. *Id.* at 77,911. Thus, close to 60% of DSAs nationwide would be opened to competition. *Id.*

110. Implementation of the outcome measures will result in unprecedented disruption to the safe and stable organ donation and transplantation system. CMS dismissed the impact of transitioning nearly 60% of the nation's DSAs and the resulting interference with OPOs, their communities, and the donor hospitals and transplant centers that they serve. Instead, CMS blithely, and without evidentiary support or explanation, "assume[d] that regardless of the precise reform or takeover option involved in a particular DSA," OPOs "would undertake careful measures to maintain the integrity and performance of ongoing organ procurement and placement functions with minimal or no disruption." *Id.* at 77,941.

111. In keeping with this Pollyannaish view, CMS put forth no plan for how it will accommodate the expected transitions and rearrangement in over half of the nation's DSAs. Instead, CMS was content to leave OPOs, hospitals, patients, and communities to figure out for themselves how to solve the problems CMS's Outcome Rule creates, deciding, without cited support, that it could "reasonably expect another OPO to take over [a decertified OPO's] service area, retaining the original staff of the OPO that is being taken over, but changing the leadership and many of the organ procurement practices." *Id.* at 77,942. Such a conclusion is particularly striking given that CMS itself recognized that its proposed "aggressive threshold rate could result in too many OPOs being decertified, particularly in the first recertification cycle, without enough OPOs with organizational capacity and interest to assume responsibility for those open DSAs." *Id.* at 77,911 (justifying the changes between the 2019 proposed rule and the Outcome Rule).

112. Nor did CMS meaningfully engage with the logical endpoint of the calamitous culling process it was so intent on setting in motion. As commenters noted, the inevitable result of CMS winnowing out OPOs that fall outside the top 25% performance threshold is an ever-shrinking pool of OPOs. CMS admitted that it has "no current statutory authority to add new OPOs." *Id.* at 77,898. Nevertheless, it dismissed these concerns, asserting that its

goal in promulgating the Outcome Rule was "not necessarily [to] reduc[e] the number of OPOs or forc[e] consolidation[,]" and implausibly suggesting that the downward spiral would stop once all OPOs "cluster near the top" in performance. *Id.* at 77,913. CMS's irresponsible conclusion ran contrary to all the data before the agency. *E.g., id.* at 77,926 (Table 1—OPO Donor Rate for 2018 With Top 25% and Median Cutoff Levels); *id.* at 77,927 (Table 2—OPO Transplant Rate for 2018 With Top 25% and Median Cutoff Levels).

113. Given the inherent variability in DSAs' donation characteristics and MCOD data, the most likely outcome is that the culling of OPOs will subside only after the total number of OPOs has shrunk enormously. Even using the most conservative estimate for Tier 3 OPOs, after four recertification cycles fewer than half the currently-existing OPOs would remain. After another four recertification cycles, only eleven OPOs would remain. Given the interim data, it is far more likely that there would be even fewer OPOs.

114. At that point, most of the nation's DSAs will likely be operated by just the few large OPOs left standing and they will face little, if any, competitive pressure. Ironically, the competitive mechanism that CMS imposed as a means of improving OPO performance will have ceased to work.

115. Instead of incentivizing continuous improvement, CMS's approach merely threatens to unleash chaos for a number of years, leaving large swaths of the county without the OPO that spent years (often decades) building trusted relationships within the community. CMS failed to address this gaping hole in the logic of its methodology.

IV. The Outcome Rule Will Harm Plaintiffs, Patients, and the Public

116. The Plaintiff OPOs, the national healthcare system, transplant patients, donor families, and the public writ large will face irreparable injury if the 2020 Outcome Rule is not held unlawful and set aside. The first recertification cycle under the Outcome Rule looms large and will conclude July 31, 2026. At that time, Tier 3 OPOs will be automatically decertified—and CMS will open the DSAs of all but Tier 1 OPOs for competition.

117. When it enacted the Rule, CMS estimated that this convulsive process could disrupt nearly 60% of all DSAs across the country. *See* 85 Fed. Reg. at 77,911. But, showcasing the unpredictability of the underlying data, this estimate has shifted each subsequent year, ranging from just below 50 percent at the low end to nearly 75 percent. *See* 2025 OPO Interim Performance Report. That interim-tier rankings fluctuate so significantly from year to year is emblematic of the broader instability created by this Outcome Rule. For the vast majority of OPOs to be potentially deemed underperforming and thus face extermination is shocking by any measure. This has already created instability and incentivized competitive behavior contrary to the public-health purpose of OPOs and the operation of a safe and stable organ donation and transplantation system.

118. Among other things, CMS has already started to rely on OPO's interim Tier rankings to make decisions about whether to grant hospitals' requests to work with OPOs other than those designated for their service areas. *See HonorBridge v. Carlton*, No. 4:25-CV-00050-M, (E.D.N.C. Mar. 31, 2025) (challenging CMS's grant of a hospital waiver on the basis of OPOs' interim Tier ratings); *Donor Network W. v. Kennedy*, No. 3:25-CV-00140-ART-CSD, 2025 WL 973914, at *1 (D. Nev. Mar. 31, 2025) (same). And that is just the beginning.

119. The most recent data released by CMS in 2025 (which uses 2023 data) places 26 OPOs in Tiers 2 and 3. This includes Plaintiffs NEDS, Gift of Life Michigan, and DNA, which are all ranked in Tier 2. Attach. A ¶¶ 11-12; Attach B ¶¶ 32, 34; Attach. D ¶ 14. Plaintiff SHSC is ranked in Tier 3. Attach. C ¶¶ 9-10.

120. Plaintiffs in Tier 2, like NEDS, Gift of Life Michigan, and DNA, who "must compete to retain [their] DSA," will suffer immediate and irreparable injury. 42 C.F.R. § 486.316(a). Merely being forced to compete in this manner (despite performance above the median on both rates) undermines OPOs' reputational interests in being seen by the public and by their clinical partners as high performing, reliable and stable community partners. Indeed, CMS itself has previously recognized the harms of such competition. S*ee* 70 Fed. Reg. at 6,094 (noting need to avoid competition for partial service areas).

121. Further, because maintaining a DSA is vital for OPOs' economic survival, those OPOs will have no choice but to expend time and resources to participate in that competition and submit whatever information and data CMS demands. *See* 42 C.F.R. § 486.316(d) (describing the information that CMS will require). Doing so will require OPOs to divert resources from their primary work and undermine their efforts to build stable relationships with the community.

122. These harms will be magnified for any OPOs that lose this existential competition. Those OPOs will be unable to continue working in the service area where they have built extensive ties and invested innumerable resources. Even if CMS awards those OPOs a new service area—which is highly unlikely for OPOs that the agency determines should not retain their existing areas—taking over that new service area will be challenging and require extensive effort. CMS appears to have contemplated precisely this burden, empowering itself to unilaterally command OPOs to take over an open DSA if OPOs do not choose to compete for it. 42 C.F.R. § 486.316(e). Meanwhile, OPOs that are not assigned to any service area will be stripped of their hospital partners, and immediately lose access to all Medicare and other reimbursement sources. Those OPOs will not survive.

123. OPOs ranked in Tier 3, like Plaintiff SHSC, will suffer all these harms even more immediately. Those OPOs will be automatically decertified and lose any ability to continue their work even despite substantial performance improvement and donation growth. Because Congress has precluded any hospital receiving federal funding from working with non-certified OPOs, and because OPOs that are not certified by CMS cannot operate as OPOs, Tier 3 OPOs will have no economic future and will be driven out of existence.

124. These disruptions will inevitably extend to the OPOs' communities. Hospitals and patients in DSAs of decertified OPOs will be deprived of trusted partners who have unique experience and relationships in those communities. Over 108,000 people in the United States await the possibility of a lifesaving organ transplantation. *See* Organ Procurement & Transplantation Network, *National Data*,

https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/# (last visited Dec. 12, 2025) ("Waiting List" registrations overall report). But the system for procuring organs for donation relies upon public trust that is built slowly and intentionally. Potential organ donors and their families must make the difficult decision to donate organs, often at emotionally fraught periods of their lives. Few would be willing to make such a decision if they feared that donation decisions were being urged on the basis of commercial or competitive need. This is particularly true in communities with historically low donation rates. The entire organ donation and transplant system rests upon this delicate balance of public trust; for it to succeed, people must believe that the transplantation system operates in an ethical, just, and efficient manner. *See* Boulware LE, et al, *Perceived transparency and fairness of the organ allocation system and willingness to donate organs: a national study*, 7 AM. J. OF TRANSPLANTATION, 1778–1787 (2007), available at https://pubmed.ncbi.nlm.nih.gov/17524080/. CMS's new policy misunderstands the fundamental nature of organ donation and paramount importance of public trust in facilitating the system that enables these life-saving transplants. Indeed, CMS's Outcome Rule uses the term "competition" eighty-four times and the word "aggressive" seven times—but the term "donor family" only appears twice (and only in regard to OPOs obtaining permission) and there are zero references to "donor safety."

125. The Plaintiff OPOs have spent decades building trusted relationships with potential donors, donor hospitals, transplant centers, medical providers, and the communities they serve in their DSAs. These relationships have been cultivated with care through years of investment in education as well as innovative donation and transplantation technology, culturally sensitive outreach, and professional collaboration across the organ donation and transplantation system. CMS's disregard for its statutory constraints and failure to reasonably evaluate the information before it threatens these relationships and strikes at the very foundations of the system of organ donation and transplantation.

126. Tens of thousands of patients and doctors will be left in the wake of this devastating competition without their trusted partners. Without these relationships, an enormous

proportion of the system will face "growing pains" as operations are shifted from one OPO to another at countless hospitals and transplant centers. This will inevitably lead to massive loss and waste of organs and/or donor safety lapses, which in turn will wreak havoc upon public health. Not only will such chaos ensue in the immediate aftermath of the 2026 recertification cycle, but such chaos is all but promised every four years for as long as this Outcome Rule remains in place.

127. Vacatur of the 2020 Outcome Rule in advance of the 2026 final performance reporting and the conclusion of the recertification cycle is necessary to prevent these harms and preserve stability of the nation's expansive organ donation system.

CAUSES OF ACTION

COUNT I

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

128. Plaintiffs reallege and incorporate by reference the allegations set forth in the preceding paragraphs.

129. The APA directs courts to "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C). Because an agency, "'literally has no power to act' . . . unless and until Congress authorizes it to do so by statute," its actions and "regulation[s] cannot 'operate independently of' the statute that authorized" them. *Fed. Election Comm'n v. Cruz*, 596 U.S. 289, 301 (2022) (citations omitted).

130. CMS's Outcome Rule abdicates the agency's statutory responsibility to set meaningful standards for certification. In their place, CMS has established an ever-shifting competition, where certification is determined solely based on a comparative ranking between OPOs, an approach wholly inimical to the language, structure, and purposes of the PHSA and the SSA.

131. Neither the PHSA nor the SSA grants CMS authority to rank OPOs or force them to compete against each other for continued certification.

132. To the contrary, the PHSA ties certification to "outcome and process performance measures" that CMS is required to determine "based on empirical evidence . . . *in each service area*." 43 U.S.C. § 273(b) (emphasis added). This language requires CMS to conduct a wholly individual determination of an OPO based only on its performance. Nothing in section 273 authorizes CMS to also rely on evidence in *other* service areas. Nor does anything in that section authorize CMS to look to the performance of other organizations.

133. Further, CMS's approach contravenes the overall framework of the PHSA and SSA, which are specifically designed to *eliminate* competition between OPOs by granting them exclusive designated service areas. Congress explicitly required CMS to designate only one OPO per designated service area—and mandated all hospitals wishing to receive federal funds in the area sign an agreement *only* with the designated OPO. *See id.* § 1320b-8(a)(1)(C), (b)(2). This leveraging of federal funds to create DSA exclusivity for OPOs reflects a deliberate policy judgment by Congress that market competition runs counter to the work of organ procurement. *Cf. id.* § 274e (making it a criminal offense to "transfer any human organ for valuable consideration for use in human transplantation"). Congress provided only one narrow exception to that framework: in instances where an individual hospital asks for a waiver to work with a different OPO. *Id.* § 1320b-8(a)(2). In doing so, Congress confirmed the general principle that OPOs are not to be placed in competition with each other for any other purpose.

134. Tellingly, CMS has consistently understood the need to evaluate the Congressionally mandated "process performance measures" in section 273 based *solely* on an individual OPO's characteristics, not on a competitive basis. *See* 42 C.F.R. §§ 486.320–486.360. Yet its 2020 Outcome Rule inexplicably adopted a completely different approach to evaluating "outcomes"—despite that term being part of the same compound statutory phrase and subject to the same modifiers.

135. Because this approach is unauthorized by statutory language and contrary to the overall framework and purpose of the relevant statutes, the Outcome Rule must be held unlawful and set aside.

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

136. Plaintiffs reallege and incorporate by reference the allegations set forth in the preceding paragraphs.

137. CMS separately lacks authority to open an existing OPO's designated service area for competition.

138. The PHSA and the SSA establish a strict relationship between an OPO and its service area. Section 273 requires each OPO to have a "defined service area"—and directs CMS to evaluate the OPO's performance solely on the basis of that service area. 42 U.S.C. § 273(b)(1)(D)(ii)(II), (F). Section 1320b-8, in turn, provides that the "Secretary may not designate more than one [OPO] for each service area." *Id.* § 1320b-8(b)(2). Taken together, these provisions establish a statutory entitlement for OPOs to operate in their designated service areas unless they are decertified.

139. Where Congress permitted CMS to deviate from that framework, it was explicit. Thus, Congress specified only a limited circumstance where one OPO can take over for another—and only with respect to individual hospitals, not an entire DSA. *Id.* § 1320b-8(a)(2). And it provided for an elaborate process, based on clearly articulated criteria and involving public input, that CMS must use to decide whether to grant such waivers. *Id.* § 1320b-8(a)(2)(A)-(D).

140. Congress created no similar authorization for CMS to re-compete an entire area that is already assigned to an OPO. Nor, by necessity, did it authorize CMS to determine the criteria for any such competition. CMS's opening of Tier 2 OPOs' service areas for competition—and the standards CMS prescribed for that competition—are thus wholly without statutory basis or authority. *See* 42 C.F.R. § 486.316(b)-(d).

141. In fact, CMS's standards are much more expansive and opaque than what Congress provided for individual hospital waivers. *Compare id. with* 42 U.S.C. § 1320b-8(a)(2)(A)-(B). And, unlike those individual waivers, CMS's re-competition of a whole service area

permits no public participation. It is implausible that Congress would strictly circumscribe CMS's discretion to reassign a hospital—yet grant CMS unbridled authority to reassign an entire service area where scores of hospitals reside.

142. Nor is there any statutory authority for CMS to designate a single OPO for multiple service areas. To the contrary, Congress required that each OPO have "a defined service area" on which certification is based. 42 U.S.C. §§ 273(b)(1)(D)(ii)(II), (b)(1)(F). CMS is therefore without authority to award a purportedly open service area to a Tier 1 or Tier 2 OPO that already has a service area assigned.

143. Accordingly, CMS's 2020 Rule is unlawful and should be set aside.

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

144. Plaintiffs reallege and incorporate by reference the allegations set forth in the preceding paragraphs.

145. Construing the PHSA and the SSA to authorize the approach CMS adopted in its 2020 Outcome Rule would create a severe constitutional problem.

146. By requiring OPOs to compete amongst each other for certification and for designated service areas, CMS has attached a string of new conditions to federal funding that was previously provided to OPOs. All OPOs must now compete against each other for certification. 42 C.F.R. § 486.316(a). And Tier 2 OPOs must compete for a designated service area. *Id.* § 486.316(b)-(d).

147. But the Constitution requires recipients to have fair notice of the conditions that apply to the funds they receive. *See Pennhurst*, 451 U.S. at 17-18; *NFIB*, 567 U.S. at 583-84. Thus, "if Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously" in advance—so participants are not later "surprise[ed] . . . with post-acceptance or retroactive conditions" that work "a major change in a program." *NFIB*, 567 U.S. at 583-85 (quotes and citations omitted); *see also Cummings*, 596 U.S. at 219.

148. For this reason, when Congress authorizes HHS to conduct competition for federal projects, it does so explicitly. *See, e.g.*, 42 U.S.C. § 1395kk-1(b)(1)(A) ("Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors . . . taking into account performance quality").

149. Congress created no such explicit authorization for CMS to force OPOs to compete against each other in either the PHSA or the SSA. To the contrary, it provided repeated protections in those statutes *against* OPOs facing such competition. *See, e.g.*, 42 U.S.C. § 1320b-8(a)(1)(C) (requiring hospitals to only work with a CMS-designated OPO). As a result, the statutes provide OPOs no notice that they could lose federal funding based on the kinds of criteria CMS's 2020 Outcome Rule now seeks to impose.

150. The constitutional vagueness problem is especially acute here because CMS is leveraging federal funds to exclude all but the designated OPOs from the market entirely. Hospitals that wish to receive federal funding are prohibited from working with a non-CMS designated OPO—even for procedures that would be entirely funded by private insurance. 42 U.S.C. § 1320b-8(a)(1)(C). Thus, OPOs that lose their designated service area stand to lose not only their Medicare reimbursement but *all* other reimbursement, as well. A lack of clear notice in the statute about the conditions on which those OPOs can be driven out of business is Constitutionally impermissible. This forms an additional basis to find CMS's 2020 Rule unlawful and to set it aside.

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

151. Plaintiffs reallege and incorporate by reference the allegations set forth in the preceding paragraphs.

152. The APA requires that a court "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

153. An agency action is arbitrary or capricious where it is not "reasonable and reasonably explained." *Prometheus,* 592 U.S. at 423. An agency must provide "a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made." *State Farm,* 463 U.S. at 43 (citation omitted).

154. An agency action is also arbitrary and capricious if the agency "failed to consider . . . important aspect[s] of the problem" before it. *Regents of the Univ. of Cal.,* 591 U.S. at 25 (quoting *State Farm,* 463 U.S. at 43).

155. CMS's 2020 Outcome Rule violates these cardinal principles in numerous fundamental ways.

156. *First*, CMS's Rule measures OPO performance on the basis of only two, highly correlated outcome measures: donation rate and transplantation rate. Both measures are calculated on the basis of a single value—donor potential—and thus do not accurately measure OPOs' relative performance. This is exacerbated by the inherent differences in health status and organ donation attitudes and rates across different demographics and regions of the country. These factors, which are outside OPOs' control, skew the underlying data—and make comparisons between OPOs a fundamentally inaccurate means of assessing their capability or performance.

157. *Second*, CMS ignored demonstrated flaws in the underlying data used to calculate the two performance measures. Among other things, the donor potential data CMS uses is (1) unreliable; (2) does not reflect the donor pool (e.g., it includes donors that are not eligible for organ donation); and (3) skewed by inconsistencies in state reporting and transplant practices.[8] CMS blithely and without evidence claimed that flaws in the data would equally

[8] Further, states have different approaches to covering transplants under Medicaid—which necessarily affects the statistics. *See, e.g.*, Ersilia M. DeFilippis, et al., *Medicaid Coverage for Heart Transplantation: the Role of State Policies in Improving Access to Heart Transplantation,* 83 J. of Am. College of Cardiology 573 (2024) available at https://www.jacc.org/doi/10.1016/S0735-1097(24)02563-4.

impact OPOs based on the incorrect and unsubstantiated assumption that these problems affect all DSAs equally.

158. *Third*, CMS ignores the fact that OPOs do not control whether an organ is ultimately transplanted, which directly impacts both the transplant rate and the donation rate (because a donor is only counted if at least one organ is transplanted). CMS itself has recognized that transplant centers' performance measures should be risk adjusted for certain donor characteristics that impact the viability of donor organs for transplant but are outside of the transplant centers' control. By refusing to make similar adjustments when measuring OPO performance, CMS arbitrarily treated analogous situations differently.

159. *Fourth*, the Rule compounds this problem by relying only on the most recent available twelve months of data for purposes of the certification decision. This means that CMS's certification decision ignores OPOs' performance over *three quarters* of the four-year certification cycle. Not only does doing so literally ignore a crucial aspect of the problem that Congress charged CMS with considering, but it also introduces even greater variability into the data—and arbitrarily punishes OPOs for environmental factors during that short time period that are outside their control.

160. *Fifth*, CMS ignored statistical evidence showing that CMS's chosen outcome measures will systemically, unfairly, and inappropriately privilege OPOs operating in smaller DSAs over others.

161. *Sixth*, CMS ignored the fact that the natural consequence of its methodology will be to cull the overall number of OPOs over the course of several certification cycles. While it is happening, this culling will lead to massive disruption in the organ donation system. Ultimately, it will lead to a consolidation of many different regions in the country under a few large OPOs—who will then not face any competitive pressure, thus vitiating the very policy framework CMS created.

162. *Finally*, CMS failed to adequately reckon with the fact that its chosen methodology will impose huge monetary and non-monetary costs on OPOs, hospitals, and patients,

while ultimately failing to achieve Congress's objectives. CMS failed to justify this self-defeating project, or to properly consider reasonable alternatives.

163. All of this renders the Outcome Rule arbitrary and capricious and requires it to be set aside.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

A. Declare pursuant to 28 U.S.C. § 2201 that the Outcome Rule is unlawful because it violates the APA, 5 U.S.C. § 706;

B. Set aside and vacate the Outcome Rule pursuant to 5 U.S.C. § 706;

C. Enjoin Defendants from enforcing the provisions of the 2020 Outcome Rule against Plaintiffs;

D. Award Plaintiffs costs, expenses, and attorneys' fees pursuant to 28 U.S.C. § 2412; and

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

Dated: March 19, 2026

Respectfully submitted,

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