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The Short Circuit: Privatized Organ Allocation Policymaking Violates Fundamental Fairness

Sean F. Driscoll

THE SHORT-CIRCUIT: PRIVATIZED ORGAN ALLOCATION POLICYMAKING VIOLATES FUNDAMENTAL FAIRNESS

ABSTRACT

The successful development of organ transplantation brought with it a new challenge—how to share the scarce organs that are donated. To resolve this challenge, Congress contracted out to the United Network for Organ Sharing, a non-profit corporation composed of transplantation stakeholders, the responsibility of developing, implementing, and administering organ allocation policies under the oversight of the Department of Health and Human Services. However, increased scrutiny due to ongoing litigation between transplantation stakeholders has called into question the accountability and objectivity of this quasi-governmental agency.

This Comment argues that the delegation of organ allocation policymaking to the United Network for Organ Sharing violates the Fifth Amendment Due Process Clause. When private actors are delegated regulatory authority that rises to state action, the protections of the U.S. Constitution apply. The Supreme Court has further recognized that due process is violated where self-interested state actors are delegated regulatory authority without sufficient agency oversight. This Comment argues that (1) the United Network for Organ Sharing should be considered a state actor subject to constitutional constraints, (2) the individual members of its Board of Directors are self-interested, and (3) the Department of Health and Human Services does not have sufficient oversight over the United Network for Organ Sharing to mitigate potential self-interest.

To ensure fundamental fairness, this Comment proposes relegating the United Network for Organ Sharing to an advisory committee for the purposes of developing organ allocation policies. Such a proposal empowers the Secretary of the Department of Health and Human Services to maintain substantive control of organ allocation policymaking, thus satisfying the due process inquiry. This proposal also balances mitigation of perceived conflicts of interest and maintenance of stakeholder participation in policymaking.

INTRODUCTION

The moment a man is declared dead by a medical professional, the deceased has the opportunity to save the lives of up to eight people.[1] If he has consented to donating his organs, a federally designated organ procurement organization (OPO) will harvest and preserve his viable organs.[2] The OPO will then enter the donor's information into a computer algorithm maintained by the United Network for Organ Sharing (UNOS), which compares the donor's organs against the patients on organ waitlists.[3] The algorithm first screens out all waitlisted patients that are ineligible to receive the donor's organs due to blood type, height, and weight.[4] The algorithm then ranks the remaining potential organ donation recipients based on UNOS-approved metrics of medical urgency, distance between the donor and recipient, and other organ-specific factors.[5] Finally, the OPO offers the organ to the top-ranked patient and that patient's transplant hospital.[6]

After the top-ranked patient receives his or her life-saving operation, over 109,000 patients in the United States will still be waiting for an organ transplant as of September 2020.[7] Of those 109,000 people, approximately seventeen will die each day.[8] Patients on organ transplant waitlists may also be surpassed by one of the new patients added every nine minutes.[9] Although organ donation more than doubled between 1991 and 2018,[10] the patients waiting for an organ

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[1] *Organ Donation Statistics*, HEALTH RES. & SERVS. ADMIN., https://www.organdonor.gov/statistics-stories/statistics.html (last visited Feb. 14, 2021).

[2] *OPO Services*, ASS'N OF ORGAN PROCUREMENT ORGS., https://www.aopo.org/opo-services/ (last visited Feb. 14, 2021).

[3] *Donor Matching System*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/learn/about-transplantation/donor-matching-system/ (last visited Feb. 14, 2021).

[4] *How Organ Allocation Works*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/learn/about-transplantation/how-organ-allocation-works (last visited Feb. 14, 2021).

[5] *Donor Matching System*, *supra* note 3. Certain organ allocation algorithms weigh additional factors, such as the degree of survival benefit. *Id.*

[6] *Id.* If the top ranked patient's doctors were to deny the organ, the OPO would offer it to the next-in-line patient and replicate that process until the organ is accepted. *Id.*

[7] *Organ Donation Statistics*, *supra* note 1. An organ transplant is "to transfer (an organ or tissue) from one part or individual to another." *Transplant*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/transplant (last visited Feb. 14, 2021). For the purposes of this Comment, "organ transplantation" will specifically refer to "deceased donor" transplantation, in which organs are harvested from deceased individuals who consented to donating their organs. *See generally Deceased Donation*, DONATE LIFE AM., https://www.donatelife.net/types-of-donation/deceased-donation/ (last visited Feb. 14, 2021) (describing the deceased organ donation process).

[8] *Organ Donation Statistics*, *supra* note 1.

[9] *Id.*

[10] *Id.*

in the same time period nearly quintupled.[11] The number of patients waiting for an organ transplant continues to exceed the number of organs donated, thus creating an organ shortage.[12]

Unless organ shortages are resolved, organ rationing is unavoidable.[13] Organ rationing forces the difficult process of selecting which patients receive the few organs available for transplant.[14] This selection "becomes literally a question of pronouncing a death sentence upon those to whom organ transplantation is denied."[15] To make this difficult decision, Congress contracted out the role of "distribut[ing] organs equitably among transplant patients" at the federal level to UNOS, a private non-profit entity.[16]

UNOS balances competing factors to determine which patient deserves a specific organ before every other patient on the waitlist.[17] Most controversial among these factors is the role of geography because patients who are less sick, but closer in proximity to a donated organ, receive priority in allocation.[18] Geographic boundaries have caused "radically different chances of receiving an organ even though [patients have] comparable medical conditions—livers [can] go to relatively healthy candidates while a much sicker patient continue[s] waiting in another locale."[19] For example, a patient living in Kentucky or Tennessee has a better chance of obtaining a liver transplant within a year than a patient living in California or New York.[20]

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[11] *Id.*

[12] *Id.*

[13] Resolving the organ shortage itself will not be the focus of this Comment. For more information, see generally Adam Crepelle, *A Market for Human Organs: An Ethical Solution to the Organ Shortage*, 13 IND. HEALTH L. REV. 17 (2016) (proposing presumed consent, a national organ market, and better preventative medicine); Sara Krieger Kahan, Note, *Incentivizing Organ Donation: A Proposal to End the Organ Shortage*, 38 HOFSTRA L. REV. 757 (2009) (proposing financial incentives to increase organ donation); Raymond Pollak, *Cadaver Donors Are the Best Solution to the Organ Shortage*, 55 DEPAUL L. REV. 897 (2006) (proposing increased use of cadaver organs).

[14] *See generally Ethical Principles in the Allocation of Human Organs*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/ (last updated June 2015) (identifying "1) utility; 2) justice; and 3) respect for persons" as the primary criteria).

[15] Frank P. Grad, *Legislative Responses to the New Biology: Limits and Possibilities*, 15 UCLA L. REV. 480, 497 (1968).

[16] 42 U.S.C. § 274(b)(2)(D).

[17] *How Organ Allocation Works*, *supra* note 4.

[18] David L. Weimer, *Public and Private Regulation of Organ Transplantation: Liver Allocation and the Final Rule*, 32 J. HEALTH POL., POL'Y & L. 9, 23 (2007).

[19] *Id.*

[20] Brendan Parent & Arthur L. Caplan, *Fair Is Fair: We Must Re-allocate Livers for Transplant*, 18 BMC MED. ETHICS, Apr. 5, 2017, at 2, https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-017-0186-9.

The delegation of authority to develop organ allocation policies to private parties questions the notion of fundamental fairness.[21] UNOS, which is composed of transplant hospitals, transplant doctors, waitlist patients, OPOs, and other transplantation stakeholders, develops—with minimal federal oversight—the metrics that determine who receives a lifesaving procedure.[22] Although it is sensible to involve subject matter experts in making these decisions, each stakeholder has a vested interest in maximizing their access to the few organs available: patients seek to survive, transplant hospitals seek to profit, and transplant doctors seek to both help their patients and further their professional careers. Due to the scarcity of available organs, the members of UNOS actively compete to advance their own personal or organizational interests.[23] These competing interests have aligned into two coalitions of transplantation stakeholders that use UNOS as a means to develop and promulgate favorable organ allocation policies to the detriment of the other coalition.[24]

This Comment argues that the existing public-private framework for organ policymaking violates the Fifth Amendment Due Process Clause. The due process analysis rests on three prongs. First, UNOS must be a state actor subject to constitutional constraints. Second, the individuals delegated regulatory power, the members of UNOS's Board of Directors, must be self-interested parties. Third, the delegated regulatory power must lack effective government oversight. A court finding these three prongs satisfied would short-circuit the existing organ allocation algorithm by invalidating the delegation of organ allocation policymaking to UNOS. To prevent such a short-circuit, this Comment proposes that UNOS be relegated to an advisory committee for the purposes of developing organ allocation policies.

Part I of this Comment explains the current organ transplantation framework and its relation to due process in the context of private delegations. To do this, Part I first examines the scope of UNOS's authority to develop and implement

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[21] *See, e.g.*, Anicka Slachta, *Do Hospitals Have Too Much Control over Who Receives Heart Transplants?*, CARDIOVASCULAR BUS. (Nov. 13, 2019), https://www.cardiovascularbusiness.com/topics/coronary-intervention-surgery/hospitals-have-control-who-receives-heart-transplants (questioning hospital control and noting competition among transplant hospitals).

[22] *See* 42 C.F.R. § 121.3 (2019) (describing the membership of the Organ Procurement and Transplantation Network).

[23] *See, e.g.*, Brett Kelman, *Vanderbilt: Patients Will Wait Longer for Liver Transplants Due to Federal Policy*, TENNESSEAN (Apr. 23, 2019, 12:42 PM), https://www.tennessean.com/story/news/health/2019/04/23/vanderbilt-university-medical-center-liver-transplants/3549341002/ (discussing regional competition between transplant centers).

[24] *Id.*

organ allocation policies. Part I then discusses how geography and scarcity have caused stakeholders to form two coalitions and compete for scarce organs. It concludes by analyzing Supreme Court and appellate court precedent where private industry stakeholders are delegated regulatory authority. Part II asserts that UNOS is a state actor, thus requiring constitutional constraints, under both the public function and nexus tests. Part III then argues that a majority of the Board of Directors of UNOS have strong personal and financial interests in how UNOS allocates donated organs by demonstrating how stakeholders act upon their own self-interest to ensure more favorable organ allocation for themselves at the expense of other stakeholders.

Part IV argues that the Secretary of the Department of Health and Human Services' scope of oversight over UNOS is inadequate to ensure due process. To this end, Part IV first concludes that the Secretary has no statutory authority to substantively override UNOS. It then argues that the Secretary's oversight is otherwise inadequate to mitigate the conflicts of interest inherent to the existing system. Part V proposes that relegating UNOS to an advisory capacity subject to the Secretary's approval for the purposes of organ allocation policymaking will both ensure fundamental fairness and maintain many of the advantages of quasi-governmental delegations.

I. ORGAN SCARCITY & DUE PROCESS

The organ allocation policymaking framework starts with federal legislation and ends with individual patients. In between lies a complex web of interconnected private and governmental stakeholders. To understand the implications for due process in organ allocation policymaking, this Part provides contextual background. Section A explains the development of the existing organ transplantation framework, UNOS's organ allocation policymaking power, and UNOS's administrative functions. Section B examines how the Organ Procurement and Transplantation Network (OPTN) functionally operates in the distribution of organs, and how scarcity exacerbates competition among stakeholders. Section C concludes by providing an overview of due process case law in the context of congressional delegations to private entities.

A. The Development of the Organ Procurement and Transplantation Network

The first successful organ transplant occurred in 1954, and medical advancements have since rapidly expanded the scope and capabilities of

transplantation.[25] Private networks of regional hospitals responded to medical advances by developing their own methods to share transplantable organs and exchange information.[26] As organ transplantation became a more commonplace medical procedure,[27] and as organ transplantation received greater media attention,[28] Congress passed the National Organ Transplant Act (NOTA) in 1984.[29] NOTA established, by contract from the Department of Health and Human Services (HHS) to a private entity, the OPTN, a national organ transplantation network.[30]

The OPTN sought to articulate a national policy for organ transplantation, determine a way to equitably distribute donated organs, and increase organ donation rates nationally.[31] Practically, these goals meant (1) creating a federal organ rationing regime and (2) delegating the governance of that regime from Congress to a private contractor. Congress and HHS achieved these goals by subsuming the private infrastructure previously created by regional networks into a singular national network.[32]

To create a federal organ rationing regime, Congress banned the private sale of organs, which created a monopoly on how organs are allocated[33] and made donated organs a public resource.[34] Congress then required that transplant

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[25] *History*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/transplant/history (last visited Feb. 14, 2021).

[26] DAVID L. WEIMER, MEDICAL GOVERNANCE: VALUES, EXPERTISE, AND INTERESTS IN ORGAN TRANSPLANTATION 44 (2010).

[27] *See generally* Clyde F. Barker & James F. Markmann, *Historical Overview of Transplantation*, COLD SPRING HARBORS PERSPS. MED. (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3684003/pdf/cshperspectmed-TRN-a014977.pdf (explaining development of organ transplantation).

[28] WEIMER, *supra* note 26, at 46.

[29] 42 U.S.C. § 274.

[30] *Id.* § 274(a).

[31] Gail L. Daubert, Note, *Politics, Policies, and Problems with Organ Transplantation: Government Regulation Needed to Ration Organs Equitably*, 50 ADMIN. L. REV. 459, 463 (1998).

[32] *See* Barker & Markmann, *supra* note 27, at 12 ("[Regional coalitions] served as the template for the resultant national entity . . . .").

[33] 42 U.S.C. § 274(a). Congress enacted NOTA in part to prevent brokers from recruiting living organ sellers from developing countries to meet demand in the United States. *See* Ellen Goodman, *Life for Sale*, WASH. POST, Oct. 1, 1983, at A15 (discussing the fledgling organ brokerage business).

[34] *See* TASK FORCE ON ORGAN TRANSPLANTATION, ORGAN TRANSPLANTATION: ISSUES AND RECOMMENDATIONS, DEP'T HEALTH & HUM. SERVS. 86 (1986) ("[T]he Task Force recommends that donated organs be considered a national resource to be used for the public good[.]"); Alexandra K. Glazier, *The Lung Lawsuit: A Case Study in Organ Allocation Policy and Administrative Law*, 14 J. HEALTH & BIOMEDICAL L. 139, 143 (2018) ("The founding principle under the federally established framework is that donated organs are a national resource[.]"); Lawrence P. McChesney & Susan S. Braithwaite, *Expectations and Outcomes in Organ Transplantation*, 8 CAMBRIDGE Q. HEALTHCARE ETHICS 299, 302 (1999) ("The reality is that the donor organ is not a resource that belongs to the transplant community but rather to society as a whole."); Emanuel D. Thorne, *When Private Parts Are Made Public Goods: The Economics of Market-Inalienability*, 15 YALE J. REG. 149,

hospitals and other transplantation stakeholders become members of the OPTN as a prerequisite to receiving federal Medicare and Medicaid reimbursements.[35] By eliminating the unregulated private market, and through financial coercion, the government built a federal organ rationing regime through the OPTN.

To govern the OPTN, NOTA required HHS contract with "a private nonprofit entity that has an expertise in organ procurement and transplantation" and oversee that contractor's management of the OPTN.[36] UNOS has continuously held the OPTN contract since NOTA was enacted.[37] The bidding process for the contract further guarantees that UNOS will hold the contract indefinitely, and thus UNOS effectively is the OPTN's permanent contractor.[38] Congress thus explicitly delegated by statute to UNOS the power to (1) develop organ allocation policies through private rulemaking and (2) manage the day-to-day administrative functions of the OPTN.[39] Each power is discussed in turn.

1. Policymaking Power

Congress directed UNOS (as the OPTN's contractor) to construct "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list,"[40] subject

150 (1998) ("An essential feature of market bans is that they make the good or service at issue into common property[.]").

[35] Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, 100 Stat. 2009 (codified as amended at 42 U.S.C. § 274).

[36] 42 U.S.C. § 274(a)–(b)(1)(A).

[37] *History of UNOS*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/about/history-of-unos/ (last visited Feb. 14, 2021); Press Release, United Network for Organ Sharing, UNOS Wins Contract to Continue as National Transplant Network (Nov. 7, 2018) (available at https://unos.org/news/unos-wins-contract-to-continue-as-national-transplant-network/).

[38] *See* Lenny Bernstein, *For the First Time in Years, New Groups May Vie to Run Organ Transplant Network*, WASH. POST (Apr. 23, 2018), https://www.washingtonpost.com/national/health-science/for-the-first-time-in-years-new-groups-may-vie-to-run-organ-transplant-network/2018/04/23/a8b7eb3c-44ad-11e8-ad8f-27a8c409298b_story.html. The government gave challengers for the bid thirty-one days to devise a plan to manage organ allocations nationally. *Id.* The federal government now requires "three years of experience managing transplant projects of similar complexity." *Id.* Finally, a new provider would not inherit UNOS's software or hardware that currently administers the allocation algorithms. *Id.* This seemingly monopolistic practice has received growing criticism from politicians whose constituents stand to lose organs from recent policy changes. *See, e.g.*, Susannah Luthi, *New Liver Transplant Distribution System Has Senators Demanding Answers*, MOD. HEALTHCARE (Sept. 9, 2019, 4:57 PM), https://www.modernhealthcare.com/politics-policy/new-liver-transplant-distribution-system-has-senators-demanding-answers (noting that Congress is seeking "to make sure the [contract] is viable for other contractors to compete" (internal quotation marks omitted)).

[39] *See* 42 U.S.C. § 274(b)(2).

[40] *Id.* § 274(b)(2)(A)(ii); *About the OPTN*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/governance/about-the-optn/ (last visited Feb. 14, 2021). The OPTN "is a unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system." *Id.*

to HHS oversight. HHS implemented this directive by promulgating the final rule entitled "Organ Procurement and Transplantation Network" ("Final Rule"), which provides the "framework within which the transplant system would operate."[41] The Final Rule includes general guidelines for organ allocation criteria, requiring that UNOS's policies:

> (1) Shall be based on sound medical judgment;
> (2) Shall seek to achieve the best use of donated organs;
> (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);
> (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
> (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
> (6) Shall be reviewed periodically and revised as appropriate;
> (7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and
> (8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by [the metrics above].[42]

Based on these guidelines, the Board of Directors of UNOS formulates "medical criteria for allocating organs," which are incorporated into the computer algorithm that ultimately matches donated organs with patients.[43]

The Board of Directors of UNOS, as specified in NOTA[44] and the Final Rule,[45] is composed of organ transplantation stakeholders who hold private rulemaking power.[46] The Board of Directors relies on various internal committees to produce allocation policies in accordance with NOTA, the Final Rule, the OPTN Bylaws, and the contract between HHS and UNOS.[47] First,

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41 INST. OF MED. COMM. ON ORGAN PROCUREMENT & TRANSPLANTATION POL'Y, ORGAN PROCUREMENT AND TRANSPLANTATION: ASSESSING CURRENT POLICIES AND THE POTENTIAL IMPACT OF THE DHHS FINAL RULE 2 (2000).

42 42 C.F.R. § 121.8(a) (2019).

43 42 U.S.C. § 274(b)(2)(A)–(B).

44 *Id.* § 274(b)(1)(B)(i).

45 *See* 42 C.F.R. § 121.3(a)(1) (2019). The Final Rule requires that 50% of the Board of Directors be doctors; 25% be patients, donors, or family members; and the remainder be "[r]epresentatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public." *Id.*

46 *See* WEIMER, *supra* note 26, at 12 (describing private rulemaking and how it applies to UNOS).

47 *Making OPTN Policy*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.

subject matter experts at an organ-specific committee level have the ability to develop policy proposals based on scientific research.[48] The policy proposal is then either approved or rejected by the OPTN Executive Committee.[49] If approved, the policy plan is distributed on the OPTN website[50] for comment. During the comment period, the organ-specific committee may revise the policy based on feedback provided.[51] Finally, the policy may be amended and approved by the Board of Directors, after which it is implemented throughout the OPTN.[52]

Congress mandates that the Secretary of HHS provide procedural oversight over UNOS by establishing procedures for "receiving from interested persons critical comments relating to the manner in which [UNOS] is carrying out the duties of [UNOS]."[53] UNOS is therefore "authorized to promulgate binding organ allocation policies"[54] subject only to agency review relating to the manner in which UNOS develops and implements those policies.[55]

2. Administrative Power

In addition to developing organ allocation policies, UNOS assists in both facilitating and improving the transplantation process. NOTA requires that UNOS coordinate the transportation of organs with OPOs,[56] maintain the national system that determines organ recipients, adopt quality standards for the acquisition and transportation of organs, and work to increase the supply of donated organs.[57]

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hrsa.gov/governance/policies/making-optn-policy/ (last visited Feb. 14, 2021).

[48] *See, e.g.*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, BYLAWS 37 (2020), https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (providing guidelines for organ allocation policies and data analysis); *Data That Drives Development: The SRTR Database*, SCI. REGISTRY TRANSPLANT RECIPIENTS, https://www.srtr.org/about-the-data/the-srtr-database/ (last visited Feb. 14, 2021) (summarizing the data analysis and publication apparatus that support the OPTN).

[49] *Making OPTN Policy*, *supra* note 47.

[50] *Public Comment*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/governance/public-comment/ (last visited Feb. 14, 2021).

[51] *Making OPTN Policy*, *supra* note 47.

[52] *Id.*

[53] 42 U.S.C. § 274(c).

[54] Daniel M. Bruggebrew, *The Administrative Law Implications of Quasi-Governmental Organ Allocation*, 41 SETON HALL LEGIS. J. 1, 11 (2016).

[55] 42 U.S.C. § 274(c).

[56] *Id.* § 274(b)(2)(D). OPOs are the nonprofit entities solely responsible for harvesting deceased-donor organs within their donation service area (DSA). *About OPOs*, *supra* note 2. OPOs are also responsible for increasing the number of registered donors within their DSA. *See generally Local Organ Procurement Organizations*, HEALTH RES. & SERVS. ADMIN., https://www.organdonor.gov/awareness/organizations/local-opo.html (last visited Feb. 14, 2021) (specifying each OPO by DSA and describing their functions).

[57] 42 U.S.C. § 274(b)(2)(A), (D), (E), (G) & (K).

UNOS is thus a privately run organization of stakeholder-members that oversees the harvesting, transportation, allocation, and transplantation of organs. Together, these industry stakeholders govern the day-to-day functions of the OPTN,[58] subject to limited oversight by a politically accountable administrative agency, HHS.[59] Exclusion from the OPTN precludes participation in a monopolized market, which coerces compliance with OPTN policies.[60] However, the emergence of a national network under NOTA means that organs are no longer voluntarily shared amongst transplant hospitals but rather rationed by the OPTN.[61]

B. Geography, Scarcity, and Competition

The existing allocation system has a practical benefit: transplant hospitals are still largely free to coordinate organ distributions among themselves. However, this system is complicated by geography and scarcity. Congressional federalization of organ allocation came during a period in which (1) medical technology permitted more transplants than ever before, (2) medical technology permitted farther transportation of organs than ever before, and (3) newly built transplant hospitals began siphoning away donated organs from established centers.[62] These developments made geography—how far organs should be shared—the central debate in determining organ allocation policies because geography heavily influences which patient and transplant hospital received a donated organ.[63] As a result of this strong influence, transplantation stakeholders use the geographic metrics in organ allocation metrics to pursue their own self-interest.

Although UNOS purports to create a system of national distribution, geography still plays a central role. UNOS divided the United States into eleven geographic regions along state lines.[64] At a more local level, UNOS divided the United States into fifty-eight donation service areas (DSAs) based on the jurisdiction of OPOs to procure and transport organs.[65] Once harvested, a

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[58] *See id.* § 274(b)(2).

[59] *See id.* § 274(c).

[60] *See* Emily Hammond, *Double Deference in Administrative Law*, 116 COLUM. L. REV. 1705, 1719 (2016).

[61] Weimer, *supra* note 18, at 20.

[62] *See id.* at 23.

[63] *Id.* at 23–24.

[64] *Regions*, HEALTH RES. & SERVS. ADMIN., https://optn.transplant.hrsa.gov/members/regions/ (last visited Feb. 14, 2021).

[65] *How UNOS, OPOs and Transplant Programs Work Together to Save Lives*, UNOS, https://unos.org/about/national-organ-transplant-system/ (last visited Feb. 14, 2021).

transplantable organ is first offered to the sickest patient in a local DSA, "then to patients in the same [DSA] with less medically urgent conditions if a patient with an urgent medical need is not available."[66] If the organ cannot be used at the DSA level, this offering process is repeated in the broader geographic region that contains the DSA, and then finally at the national level.[67]

Due to a recent lawsuit,[68] this traditional system has been thrown into disarray. A court-ordered review of this tiered system for lungs led UNOS to adopt a new geographic metric: transplantable lungs would be offered to the sickest patient within a 250-mile concentric circle around the donor hospital.[69] This Acuity Circle Policy would have the effect of more broadly sharing organs than the traditional tiered system.[70] Two weeks after it adopted the new rule, UNOS began implementing this metric across other organs,[71] prompting yet another lawsuit in which certain transplant hospitals sought to set aside the Acuity Circle Policy in favor of the previous tiered system.[72] This lawsuit, which remains ongoing, will determine the future of organ allocation.[73]

The disagreement between transplantation stakeholders over how UNOS should incorporate geography into organ allocation metrics is a proxy for inter-stakeholder competition. Competition for organs is exacerbated by the currently inequitable distribution of viable organs for transplantation across the United States.[74] The Southeast,[75] due to higher rates of strokes and deaths from motor vehicles, is believed to have more organs readily available for transplantation.[76]

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66 Clifford H. Van Meter, *The Organ Allocation Controversy: How Did We Arrive Here?*, 1 OCHSNER J. 6, 9 (1999).

67 *Id.*

68 *See* Emma Yasinski, *Woman's Lawsuit Put Emphasis on 'Urgency' in Deciding Organ Transplants in US*, CYSTIC FIBROSIS NEWS TODAY (Jan. 22, 2019), https://cysticfibrosisnewstoday.com/2019/01/22/lawsuit-forced-changes-ranking-urgency-for-organ-transplant-above-location-in-us/ (discussing the patient's lawsuit).

69 Glazier, *supra* note 34, at 146.

70 *See* Yasinski, *supra* note 68.

71 U.S. DEP'T HEALTH & HUM. SERVS., ENHANCING LIVER DISTRIBUTION 1 (2017), https://optn.transplant.hrsa.gov/governance/public-comment/enhancing-liver-distribution.

72 *See* Callahan v. U.S. Dep't of Health & Hum. Servs., 939 F.3d 1251, 1256 (11th Cir. 2019).

73 *See id.* at 1257 ("So here we are . . . the nation's policy for allocating donated livers hang[ing] in the balance.").

74 *See* David Goldberg, Seth Karp, Malay B. Shah, Derek Dubay & Raymond Lynch, *Importance of Incorporating Standardized, Verifiable, Objective Metrics of Organ Procurement Organization Performance into Discussions About Organ Allocation*, 19 AM. J. TRANSPLANTATION 2973, 2973 (2019).

75 Florida, Georgia, Alabama, Mississippi, Louisiana, Arkansas, and Puerto Rico collectively make up the Southeast Administrative Region for UNOS. *See generally Region 3*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/members/regions/region-3/ (last visited Feb. 14, 2021).

76 Lenny Bernstein, *Liver Transplant Distribution Changed After Years of Debate*, WASH. POST (Dec. 4, 2017), https://www.washingtonpost.com/national/health-science/liver-transplant-distribution-changed-after-years-of-

In 2016, southeastern states, composing one UNOS region, collectively obtained 1,336 livers from deceased donors, while New York and part of Vermont, composing a different UNOS region, collectively obtained just 327 livers.[77] Due to the current geographic disparity in readily transplantable organs, two coalitions of transplantation stakeholders have developed in response; however, they share a common theme—"the primary stakeholders, transplant surgeons, seek to secure as many organs as possible for their own patients."[78]

The first coalition of stakeholders in comparatively "organ-scarce" regions asserts that broader sharing is necessary to allocate organs to the sickest person.[79] This argument emphasizes that allocation policies "shall not be based on the candidate's place of residence or place of listing," while de-emphasizing geographic limitations that may be necessary "to the extent required by" sound medical judgment, avoiding organ waste, and achieving the best use of organs.[80] This coalition further asserts that the use of administrative regions with varying populations creates "inherent differences in the ratio of donor supply and demand across the country."[81]

By contrast, the second coalition of stakeholders in comparatively "organ-rich" regions of the United States emphasize the need for more localized organ sharing.[82] These transplantation stakeholders contend that sending organs far away from where they are harvested will increase transplant costs and decrease organ quality to the point of potentially wasting them.[83] Moreover, simply broadening organ sharing fails to consider that the groups responsible for promoting organ donation, OPOs, have varying success in obtaining organs, which also causes low organ supply within a given region.[84] By way of example,

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debate/2017/12/04/fedefc0e-d92c-11e7-b859-fb0995360725_story.html.

[77] *Id.*

[78] Weimer, *supra* note 18, at 15.

[79] *Id.* at 23; *see also Our Mission*, NAT'L COAL. FOR TRANSPLANT EQUITY, https://www.transplantequity.org (last visited Feb. 14, 2021) (supporting wider geographic organ allocation policies).

[80] *See* 42 C.F.R. § 121.8(a)(8) (2019).

[81] CHAD SOUTHWARD & MATTHEW PRENTICE, GEOGRAPHIC ORGAN DISTRIBUTION PRINCIPLES AND MODELS RECOMMENDATIONS REPORT, OPTN/UNOS AD HOC COMM. ON GEOGRAPHY 3 (June 2018), https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf.

[82] *See generally* KEEP TRANSPLANTS FAIR, https://keeptransplantsfair.org (last visited Feb. 14, 2021) (supporting more restrictive geographic organ allocation policies).

[83] *Id.*; Weimer, *supra* note 18, at 24 (identifying costs and transplant success as central arguments for local priority).

[84] *See* Goldberg et al., *supra* note 74, at 2973, 2977. In 2018, 169 patients in the New York City metropolitan area died waiting for a transplant. *Id.* at 2977. If New York City's OPO had performed at the same level as Philadelphia's OPO, it "would have had an additional 303 organ donors, which would have dramatically decreased the number of patients who died waiting for a liver (and kidney, heart, or lung) transplant in the region." *Id.* New York City's OPO has performed so poorly it risks being decertified. Ted Alcorn, *New York*

New York has the lowest organ donation registration rate of any state[85] and its OPO performs below the national median,[86] leading to the conclusion that efforts to increase donation rates within the DSAs in New York "would save more lives, increase the number of transplants, and potentially cost much less than efforts to more broadly share organs across the nation."[87] Broader organ sharing therefore results in organs being sent from areas with high-performing OPOs to areas with under-performing OPOs.[88]

Both coalitions of transplantation stakeholders have merit under the guidelines set forth in the Final Rule.[89] However, the organ allocation policies both groups espouse directly benefit their respective interests in obtaining a greater share of transplantable organs at the expense of the other group. Stakeholders are therefore incentivized to elect individuals to the Board of Directors that will support their coalition's preferred organ allocation outcomes. Moreover, UNOS's bylaws require that the Board of Directors include only one board member selected by each administrative region, while the remaining members of the Board of Directors are elected by a majority vote of UNOS's general members.[90] Thus, each of the eleven geographic regions is guaranteed only one of the forty-one positions available on the Board of Directors,[91] which allows the two coalitions of voting members to vie for the remaining thirty positions available. Given UNOS's power to develop metrics and regulate organ allocation throughout the United States,[92] competing interests raise due process concerns where one self-interested coalition is empowered to regulate another.

Has World-Class Hospitals. Why Is It So Bad for People in Need of Transplants?, N.Y. TIMES (July 11, 2018), https://www.nytimes.com/2018/07/11/nyregion/organ-donation-is-desperate-in-new-york.html.

[85] Maggie Koerth, *Our Organ Donation System Is Unfair. The Solution Might Be Too.*, FIVETHIRTYEIGHT (Apr. 3, 2019, 5:21 PM), https://fivethirtyeight.com/features/our-organ-donation-system-is-unfair-the-solution-might-be-too/.

[86] David S. Goldberg, Benjamin C. French, Peter L. Abt & Richard K. Gilroy, *Increasing the Number of Organ Transplants in the United States by Optimizing Donor Authorization Rates*, 15 AM. J. TRANSPLANTATION 2117, 2120 (2015).

[87] *Study Reveals Wide Variability in Organ Donation Rates Across the United States: Midwest Leads the Nation in Highest Rates of Lifesaving Donations*, PERELMAN SCH. OF MED. UNIV. OF PA. (May 26, 2015, 1:05 PM), https://www.newswise.com/articles/study-reveals-wide-variability-in-organ-donation-rates-across-the-united-states-midwest-leads-the-nation-in-highest-rates-of-lifesaving-donations.

[88] *See* Goldberg et al., *supra* note 74, at 2976. This finding led the authors to conclude that "unmet need may best be addressed with critical reassessment of local effort rather than reliance on the efforts of others." *Id.* at 2977.

[89] 42 C.F.R. § 121.8 (2019).

[90] *Bylaws*, *supra* note 48, at 13. The voting members who elect the Board of Directors consist of the stakeholders of the OPTN, including transplant hospitals, OPOs, transplant doctors, and patients. *Id.* at 1–2.

[91] *Board Q&A*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/members/board-of-directors/board-q-a/ (last visited Feb. 14, 2021).

[92] *See supra* notes 40–55 and accompanying text (describing policymaking power).

C. Delegation & Due Process

To establish whether the delegation of policymaking power to the OPTN violates the Fifth Amendment, this section examines the elements of a due process violation. The Due Process Clause of the Fifth Amendment of the U.S. Constitution guarantees that a state actor may not abridge one's "life, liberty or property without due process of law."[93] Due process claims against private entities "[are] less commonly encountered, [are] more unsettled, and raise[] questions of the source of constitutional limits upon delegation to private parties."[94] Courts have struck down private delegations when Congress delegates (1) to a state actor (2) that is self-interested (3) the power to regulate the affairs of other competitors without sufficient oversight.[95] However, the federal government may interfere with one's rights so long as it engages in procedures that are fundamentally fair.[96]

Fundamental fairness in the context of private delegations is predicated on concerns of self-interested bias.[97] "[D]ue process addresses the threat of arbitrary agency lawmaking by imposing substantive, procedural, and structural constraints on Congress's delegation of lawmaking functions."[98] The U.S. Supreme Court has "consistently concluded the delegation of coercive power to

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[93] U.S. CONST. amend. V.

[94] Calvin R. Massey, *The Non-Delegation Doctrine and Private Parties*, 17 GREEN BAG 2D 157, 157 (2014); *see* CONG. RSCH. SERV., 7-5700, ANALYSIS OF CONSTITUTIONAL ISSUES ARISING FROM A PROPOSAL TO AUTHORIZE A FEDERALLY CHARTERED PRIVATE CORPORATION TO PROVIDE AIR TRAFFIC CONTROL SERVICES 19 (2015) (concluding that it is "unclear" how a hypothetical reviewing court would approach a due process claim to a board-managed private entity delegated regulatory power by Congress).

[95] Carter v. Carter Coal Co., 298 U.S. 238, 278 (1936); Ass'n of Am. R.Rs. v. Dep't of Transp., 821 F.3d 19, 37 (D.C. Cir. 2016). However, courts have struggled to distinguish between adjudication and rulemaking for this analysis. *See* Alexander Volokh, *The New Private-Regulation Skepticism: Due Process, Non-Delegation, and Antitrust Challenges*, 37 HARV. J.L. & PUB. POL'Y 931, 952–53 (2014) (finding Supreme Court precedent "suggest[s] that potential pecuniary bias in adjudication is easier to challenge than potential pecuniary bias in rulemaking"); *Ass'n of Am. R.Rs.*, 821 F.3d at 32–33 (applying *Carter Coal* to the development of industry metrics); Hans A. Linde, *Due Process of Lawmaking*, 55 NEB. L. REV. 197, 248 (1976) (extending adjudicatory precedent to rulemaking); David N. Wecht, Note, *Breaking the Code of Deference: Judicial Review of Private Prisons*, 96 YALE L.J. 815, 825 n.58 (1987) (characterizing the distinction as "murky").

[96] Hurtado v. California, 110 U.S. 516, 535–36 (1884); Daniel G. Stoddard, *Falling Short of Fundamental Fairness: Why Institutional Review Board Regulations Fail to Provide Procedural Due Process*, 43 CREIGHTON L. REV. 1275, 1291–92 (2010).

[97] *See Ass'n of Am. R.Rs.*, 821 F.3d at 28 ("[I]t becomes clear that what *primarily* drives the Court to strike down this provision is the self-interested character of the delegatees[.]" (internal quotation marks omitted)); *see also* Hammond, *supra* note 60, at 1723–24 (explaining role of arbitrariness and accountability in terms of due process).

[98] *See* Evan J. Criddle, *When Delegation Begets Domination: Due Process of Administrative Lawmaking*, 46 GA. L. REV. 177, 124 (2011). The Court also noted that "bicameralism, presentment, judicial independence and life tenure" also serve the same purpose. *Ass'n of Am. R.Rs.*, 821 F.3d at 30.

private parties can raise . . . due process concerns."[99] The Due Process Clause is violated when Congress enables biased private parties to regulate the affairs of other competitors without sufficient oversight.[100]

The Court articulated this biased review for due process in *Carter v. Carter Coal*.[101] In the midst of the Great Depression, Congress enacted the Bituminous Coal Conservation Act of 1935 to stabilize prices and create a cooperative market.[102] The Act delegated the ability to fix industry wages to "the producers of more than two-thirds the annual national tonnage production . . . and a majority of the miners."[103] Each policy adopted was binding on all other mines, including the dissenting producers and miners.[104]

The Court invalidated the delegation, concluding that "[t]he delegation is . . . clearly a denial of rights safeguarded by the [D]ue [P]rocess [C]lause of the Fifth Amendment."[105] This reasoning heavily weighed on the potential for self-interested policymaking, focusing on the fact that this was "not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business."[106] The Court found that "[t]o 'accept' in these circumstances, is not to exercise a choice, but to surrender to force."[107] The Act granted the majority "the power to regulate the affairs of an unwilling minority."[108]

In reaching its conclusion, the Court distinguished between the production and regulation of coal.[109] The production of coal "is a private activity," whereas its regulation is "necessarily a governmental function, since, in the very nature of things, one person may not be entrusted with the power to regulate the business of another, and especially of a competitor."[110] By placing regulatory

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99 *Ass'n of Am. R.Rs.*, 821 F.3d at 31; *see also* Volokh, *supra* note 95, at 944 (explaining that "the due process rationale for striking down delegations of regulatory authority to private parties—in particular competitors—remain[s] alive and well").

100 *See Carter*, 298 U.S. at 311.

101 *Id.*

102 *Id.* at 278; *see* Bituminous Coal Conservation Act of 1935, 49 Stat. 1001.

103 *Id.* at 310 (quoting Bituminous Coal Conservation Act of 1935, 49 Stat. 1001) (internal quotation marks omitted).

104 *Id.* at 311.

105 *Id.*

106 *Id.*

107 *Id.*

108 *Id.*

109 *Id.*

110 *Id.*

power in the hands of private actors to govern one another, the statute "[undertook] an intolerable and unconstitutional interference with personal liberty and private property."[111] *Carter Coal* thus stands for the proposition that Congress may not delegate mandatory control of coercive power to self-interested parties.[112]

The Court's review for self-interest in due process claims focuses on pecuniary interests.[113] In *Tumey v. Ohio*, the mayor of North College Hill, Ohio, sat as a judge and was paid only if he convicted defendants.[114] The Court held that the mayor's involvement violated the Due Process Clause because the mayor "had a direct, personal, pecuniary interest in convicting the defendant who came before him for trial."[115] In *Gibson v. Berryhill*, the Court reviewed the adjudicatory process of the Alabama Board of Optometry.[116] The Alabama Board of Optometry was composed of optometrists who were self-employed, rather than employed through a company or by another individual.[117] The self-employed optometrists attempted to use the Board to revoke the licenses of optometrists employed by corporate entities.[118] The Court held that the Board's adjudicatory process violated the corporate-employed optometrists' due process rights because "those with substantial pecuniary interest . . . should not adjudicate these disputes."[119] The Court also noted that the "financial stake *need not be as direct or positive* as it appeared to be in *Tumey*."[120] The Court thus acknowledged that pecuniary interests may be found where inferential steps are necessary.[121]

Courts have, however, recognized an exception and upheld congressional delegations where private, self-interested parties are not delegated rulemaking power, but instead hold a subordinate role subject to disinterested government

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111 *Id.*

112 *Id.*

113 *See* Ward v. Vill. of Monroeville, 409 U.S. 57, 60 (1972) (noting the "possible temptation" for the mayor to maintain high levels of fines when he sat as judge because the village income was derived from fines); *see also* Pittston Co. v. United States, 368 F.3d 385, 394 (4th Cir. 2004) (explaining that delegations "to private persons whose interests may be and often are adverse to the interests of others in the same business is disfavored" (internal quotation marks omitted)).

114 273 U.S. 510, 520 (1927).

115 *Id.* at 523.

116 411 U.S. 564, 571–73 (1973).

117 *Id.* at 578.

118 *Id.* The self-employed optometrists asserted that optometrists accepting employment with a corporation constituted "unprofessional conduct" under Alabama law. *Id.* at 567.

119 *Id.* at 579.

120 *Id.* (emphasis added).

121 *See id.*

oversight. In *Currin v. Wallace*, the Court upheld a regulatory framework in which Congress authorized the Secretary of Agriculture to impose tobacco sales standards in markets with the approval of two-thirds of cultivators in the affected markets.[122] The Court distinguished the regulatory framework in *Currin* from *Carter Coal* because in *Currin*, the Secretary of Agriculture developed the standards, and therefore "[t]his [was] not a case where a group of producers may make the law."[123] In *Sunshine Anthracite Coal Co. v. Adkins*, the Court upheld a similar regulatory framework in which industry stakeholders acted in an advisory capacity.[124] Industry stakeholders would propose metrics for a government commission's approval, thus placing the substantive decision-making power in the hands of the commission.[125]

The degree and nature of sufficient oversight remains somewhat unclear in the context of private delegations because Supreme Court precedent predates the modern administrative state.[126] Recently, in *Association of American Railroads v. United States Department of Transportation*,[127] the D.C. Circuit struck down on due process grounds a regulatory scheme in which Amtrak and the Federal Railroad Administration (FRA) jointly set industry standards.[128] Amtrak and the FRA occupied "positions of equal authority" in developing industry standards and in the event of disagreement a private arbitrator would resolve the dispute.[129] Applying *Carter Coal*, the D.C. Circuit limited its review of the agency oversight to whether the FRA had the ultimate power to overrule the standards, concluding that the FRA was "powerless to overrule Amtrak."[130] Rather than providing a more functional review of internal procedures of the arbitration itself, the court instead emphasized fundamental fairness and accountability, reasoning that,

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122 306 U.S. 1, 15 (1939).

123 *Id.* (citing Carter v. Carter Coal Co., 298 U.S. 238, 310, 318 (1936)). The *Currin* Court further explained that "[Congress] may leave the determination of such time to the decision of an [e]xecutive, or, as often happens in matters of state legislation, it may be left to a popular vote of the residents of a district to be [a]ffected by the legislation." *Id.* at 16.

124 310 U.S. 381, 388–89 (1940).

125 *Id.* at 399.

126 *See* Ass'n of Am. R.Rs. v. Dep't of Transp., 821 F.3d 19, 27 (D.C. Cir. 2016) (explaining that the *Carter Coal* decision "predates the Administrative Procedure Act and the birth of the Court's modern administrative law jurisprudence"); James M. Rice, Note, *The Private Nondelegation Doctrine: Preventing the Delegation of Regulatory Authority to Private Parties and International Organizations*, 105 CALIF. L. REV. 539, 540 (2017) ("Supreme Court jurisprudence has not clearly defined the extent to which the Constitution permits the delegation of regulatory power to entities outside the federal government.").

127 821 F.3d 19 (2016).

128 *Id.* at 23.

129 *Id.* at 35.

130 *Id.*

> the Government argues the Constitution does not prohibit Congress from empowering Amtrak to develop metrics and standards because Congress itself could have developed the metrics and standards or could have directed FRA to develop them alone. Perhaps. But notice that, in either of these alternative scenarios, the power to regulate [market participants] would be in the hands of "official bod[ies], presumptively disinterested." Pointing to Congress or FRA's capacity to develop these metrics is nothing but a red herring—the due process question *Carter Coal* and the freight operators put before us in this appeal centers on the propriety of self-interested actors exercising regulatory power.[131]

The D.C. Circuit's formalistic focus on agency approval suggested that private parties must obtain the approval of a government agency prior to exercising regulatory power.[132] This interpretation was later confirmed when the D.C. Circuit explained that the delegation violated the Fifth Amendment because "[u]ltimate control over the regulatory standards did not rest with a neutral government agency," thus distinguishing the delegation of regulatory power from the frameworks considered in *Currin* and *Sunshine Anthracite Coal Co*.[133]

Synthesizing this case law, the due process analysis is not a per se bar to private delegations, but instead relies on three elements to determine whether there has been a constitutional violation. As a threshold matter, the private entity must be subject to constitutional constraints as a state actor.[134] Next, self-interested market participants must be delegated the power to regulate one another.[135] Finally, the government itself must lack effective oversight over the private entity with regulatory authority.[136]

II. UNOS IS A STATE ACTOR SUBJECT TO THE DUE PROCESS CLAUSE

"[T]he public-private distinction is primary—all other legal distinctions are subsumed beneath this first-order division of legal life."[137] This distinction is essential because due process claims challenging UNOS require that organ allocation policymaking be considered acts of the state.[138] State action does not

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131 *Id.* at 35–36.

132 *Id.*

133 Ass'n of Am. R.Rs. v. Dep't of Transp., 896 F.3d 539, 546 (D.C. Cir. 2018).

134 Brentwood Acad. v. Tenn. Secondary Sch. Athletic. Ass'n, 531 U.S. 288, 295 (2001).

135 Carter v. Carter Coal Co., 298 U.S. 238, 278 (1936); *Ass'n of Am. R.Rs.*, 821 F.3d at 36.

136 *See Ass'n of Am. R.Rs.*, 896 F.3d at 546.

137 William J. Novak, *Public-Private Governance: A Historical Introduction*, *in* GOVERNMENT BY CONTRACT: OUTSOURCING AND AMERICAN DEMOCRACY 23, 25 (Jody Freeman & Martha Minow eds., 2009).

138 L. Higginbotham, *Due Process in the Allocation of Scarce Lifesaving Medical Resources*, 84 YALE L.J.

arise merely because the government is connected with a private entity's actions, nor does it arise merely because of extensive rulemaking authority.[139] As applied here, the state action doctrine turns on whether the organ allocation policymaking "resulted from the exercise of a right or privilege having its source in state authority" and whether UNOS can "be described in all fairness as a state actor."[140] The Court has applied several tests to determine state action,[141] which in turn have created inconsistent results with respect to private entities.[142]

This Part asserts that UNOS is a state actor under both the (1) public function test and (2) nexus test, which are the "two central theories for recognizing private activities as state actions."[143] If a reviewing court determines that the state action requirement is satisfied by either test, the inquiry is complete.[144] Both tests are fact-specific inquiries because "[o]nly by sifting facts and weighing circumstances can the nonobvious involvement of the State in private conduct be attributed its true significance."[145] Section A demonstrates that UNOS satisfies the public function test, while section B shows that there is a sufficient nexus between HHS and UNOS to satisfy the nexus test.

1734, 1736 (1975); The Civil Rights Cases, 109 U.S. 3, 11 (1883).

[139] Richard L. Stone, *Not Just a Private Club: Self-Regulatory Organizations as State Actors When Enforcing Federal Law*, 2 COLUM. BUS. L. REV. 453, 467 (1995).

[140] Edmonson v. Leesville Concrete Co., 500 U.S. 614, 620 (1991); *see also* Callahan v. U.S. Dep't of Health & Hum. Servs., 939 F.3d 1251, 1265 (11th Cir. 2019) (suggesting same standard in the context of UNOS).

[141] Robert S. Gilmour & Laura S. Jensen, *Reinventing Government Accountability: Public Functions, Privatization, and the Meaning of "State Action"*, 58 PUB. ADMIN. REV. 247, 250 (1998).

[142] *See Edmonson*, 500 U.S. at 632 (admitting that "[the Supreme Court] cases deciding when private action might be deemed that of the state have not been a model of consistency"); Julie K. Brown, *Less Is More: Decluttering the State Action Doctrine*, 73 MO. L. REV. 561, 581 (2008) ("The state action doctrine is slowly descending into utter confusion, where private parties remain unaware of what conduct subjects them to Constitutional restrictions, and courts are unclear as to the appropriate state action standard."). For information in the context of UNOS, see generally Benjamin Mintz, *Analyzing the OPTN Under the State Action Doctrine - Can UNOS's Organ Allocation Criteria Survive Strict Scrutiny*, 28 COLUM. J.L. & SOC. PROBS. 339, 367–76 (1995) (concluding UNOS is not a state actor under the nexus and public function tests, but is a state actor under the compulsion test); Jeffrey A. McDaniel, *A Decent Proposal - Fundamental Fairness in an Un-Commercial Organ System*, 19 J.L. & COM. 327, 341–43 (2000) (concluding UNOS should be a state actor); Bruggebrew, *supra* note 54, at 33–41 (concluding that (1) it is "perhaps impossible" to categorize UNOS as a state actor under the entwinement test and "unlikely" under the control test, and (2) it would require "tolerance of high-level generality" under the public function test).

[143] Daphne Barak-Erez, *A State Action Doctrine for an Age of Privatization*, 45 SYRACUSE L. REV. 1169, 1174 (1994).

[144] *See* Mintz, *supra* note 142, at 359 (concluding "state action is justified when any of these tests is satisfied").

[145] Burton v. Wilmington Parking Auth., 365 U.S. 715, 722 (1961).

A. UNOS Serves a Public Function

UNOS is a state actor under the public function test. To be considered a state actor under the public function test, a private entity must exercise "powers traditionally exclusively reserved to the State."[146] Although medical care is not a power traditionally or exclusively reserved to the State,[147] organ allocation falls into an ancillary function exclusively held by the State: public health regulation.[148]

The power to regulate is "necessarily a government function,"[149] and the regulation of public health is a "traditional area[] of police power regulation" dating back to the colonial era.[150] The government has involved medical professionals in public health responses because "[d]isease control and nuisance abatement were a primary focus in the colonial governments."[151] At the founding of the United States, the government "had plenary power to impose restrictions on property and persons" due to public health concerns, and this power "belonged to the states, subject to concurrent regulation for national purposes."[152] The regulation of public health is therefore a traditional State function[153] because UNOS's ability to create organ allocation policies is regulatory[154] and responds to a public health issue.[155]

Congress made organ allocation the "exclusive prerogative of the sovereign" by eliminating other markets.[156] UNOS, as the administrator of the singular

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146 Jackson v. Metro. Edison Co., 419 U.S. 345, 352 (1974).

147 *See* Wheat v. Mass, 994 F.2d 273, 275–76 (5th Cir. 1993) (concluding that the hospital was not a state actor). The plaintiff asserted that the hospital was a government actor by virtue of its membership in UNOS but did not challenge whether UNOS itself was a state actor. *Id.*

148 In the alternative, this concept could be viewed as management of a public resource, another traditional State function. Bruggebrew, *supra* note 54, at 40–41.

149 Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936).

150 Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 202 (1999).

151 *Id.* at 203. Concerns of disease "permeated society, affecting legislators, judges, and the drafters of the Constitution." *Id.* at 205.

152 *Id.* at 205.

153 *See id.*; 4 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND 162 (Oxford Univ. Press 1978) (1769) ("A species of offences, more especially affecting the commonwealth, are such as are against the public health of the nation; a concern of the highest importance.").

154 Weimer, *supra* note 18, at 11 (describing private rulemaking).

155 *See* Howard K. Koh, Marsha D. Johnson, Anne Marie Lyddy, Kevin J. O'Connor, Sean M. Fitzpatrick, Milly Krakow, Christine M. Judge, Hillel R. Alpert & Richard S. Luskin, *A Statewide Public Health Approach to Improving Organ Donation: The Massachusetts Organ Donation Initiative*, 97 AM. J. PUB. HEALTH 30, 30 (2007) (describing the organ disparity as "a major public health crisis").

156 Flagg Brothers, Inc. v. Brooks, 436 U.S. 149, 160 (1978).

federal market and developer of allocation policies, is tasked with enacting this "exclusive prerogative."[157] Therefore, UNOS serves a public function because the government traditionally has regulated public health and exclusively regulates organ allocation.[158] As a result, UNOS is a state actor and subject to the Due Process Clause.

B. The UNOS-HHS Nexus Is Sufficient

UNOS is also a state actor under the nexus test. For a private entity to be considered a state actor under nexus test, there must be "a sufficiently close nexus between the [s]tate and the challenged action."[159] Courts determine the sufficiency of this nexus by analyzing three prongs: (1) the mutuality of benefits arising from the private-government relationship,[160] (2) the degree of government regulation of the private actor,[161] and (3) the degree of funding provided by the government to the state actor.[162]

Applying these factors, UNOS, and therefore the OPTN, is a state actor. The OPTN operates for the mutual benefit of private transplantation stakeholders and the federal government. Congress enacted NOTA precisely because of the need to articulate a national organ rationing scheme,[163] and, as a result, gave UNOS, by contract, the sole responsibility of articulating this plan as the OPTN.[164] UNOS develops this organ rationing scheme subject to NOTA and the Final Rule, which impose restrictions on Board of Directors composition,[165] as well as its public comment procedures,[166] executive committees,[167] and statutory goals.[168] In terms of oversight, the Secretary is required to submit bi-yearly reports to Congress regarding transplantation.[169] Finally, the Secretary maintains

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157 *See id.* at 160; *see also* 42 U.S.C. § 274e (banning the sale of organs).

158 *See* Jackson v. Metro. Edison Co., 419 U.S. 345, 352 (1974).

159 *Id.* at 351.

160 Burton v. Wilmington Parking Auth., 365 U.S. 715, 722 (1961).

161 Blum v. Yaretsky, 457 U.S. 991, 1011 (1982); *see also* Dep't of Transp. v. Ass'n of Am. R.Rs., 575 U.S. 43, 52 (2015) (analyzing the extent of government regulation).

162 *Ass'n of Am. R.Rs.*, 575 U.S. at 52. *But see* S.F. Arts & Athletics, Inc. v. U.S. Olympic Comm., 483 U.S. 522, 544 (1987) (concluding that "[t]he Government may subsidize private entities without assuming constitutional responsibility for their actions").

163 *See* S. REP. NO. 98-382, at 13 (1984) (concluding that "the Committee believes it is timely to direct the development of a national policy regarding the appropriate federal and private sector roles in organ transplantation").

164 42 U.S.C. § 274.

165 *Id.* § 274(b)(1)(B)(i); 42 C.F.R. § 121.3(a)(1) (2019).

166 42 C.F.R. § 121.4(d) (2019).

167 42 U.S.C. § 274(b)(1)(B)(ii).

168 *See id.* § 274(b)(2).

169 *See, e.g.*, *id.* § 274f–4(a) ("rate of organ donation and recovery"); *id.* § 274d (scientific and clinical

procedures for receiving and considering critical comments regarding OPTN activity.[170]

UNOS is both privately and federally funded. The federal government paid approximately $5,000,000 in appropriations for the 2016 fiscal year.[171] Meanwhile, transplant hospitals are paying registration fees to place patients on the organ donation waitlist.[172] UNOS, acting as the OPTN, is state actor under the nexus test because the OPTN operates for the benefit of the government and transplant stakeholders, subject to limited oversight with government funding.[173] Therefore, UNOS must comply with the demands of the due process.

Ultimately, UNOS should be considered a state actor in due process challenges because in satisfying both the public function and nexus tests, it "dominate[s] [organ allocation] to such an extent that its participants must be deemed to act with the authority of the government and, as a result, be subject to constitutional constraints."[174]

III. SELF-INTEREST IN THE ORGAN PROCUREMENT & TRANSPLANTATION NETWORK

The delegation of organ allocation policymaking to UNOS violates the Due Process Clause because Congress both (1) granted regulatory power to self-interested members of the Board of Directors of UNOS and (2) failed to empower HHS with the authority to effectively mitigate the board members' self-interests.[175] This Part examines the first prong by considering the ways in which stakeholders in the OPTN are self-interested. To achieve this goal, this

status of organ transplantation); *id.* § 273b (long-term health effects of donation).

170 *Id.* § 274(c).

171 *See* UNITED NETWORK FOR ORGAN SHARING, INCREASING THE NUMBER OF TRANSPLANTS IN THE UNITED STATES: 2016 IN REVIEW, https://unos.org/about/annual-report/2016-annual-report (last visited Feb. 14, 2021).

172 *Id.*; *see also* 42 C.F.R. § 121.5(c) (2019) (requiring that "[t]he amount of such fee shall be calculated to cover (together with contract funds awarded by the Secretary) the reasonable costs of operating the OPTN and shall be determined by the OPTN").

173 *See* Jackson v. Metro. Edison Co., 419 U.S. 345, 351 (1974).

174 Edmonson v. Leesville Concrete Co., 500 U.S. 614, 620 (1991).

175 *Cf.* Gibson v. Berryhill, 411 U.S. 564, 579 (1973) (invalidating State Board of Optometry hearings due to the "substantial pecuniary interest" of board members); Eubank v. City of Richmond, 226 U.S. 137, 144 (1912) (invalidating a city ordinance that gave property owners authority to prevent future construction); Washington *ex rel.* Seattle Title Tr. Co. v. Roberge, 278 U.S. 116, 122 (1928) (invalidating a city ordinance that allowed two-thirds of neighboring landowners to prevent construction of an elderly home); Carter v. Carter Coal Co., 298 U.S. 315, 316–17 (1936) (invalidating a law that granted a supermajority of coal stakeholders the regulatory power to fix wages and hours).

Part considers the stakeholders that constitute 75%[176] of the individuals sitting on the Board of Directors of UNOS: transplant doctors, transplant hospital representatives, and patients.[177] Section A explains how transplant doctors and hospitals pursue their own pecuniary interests through lobbying, gaming allocation metrics, and litigating preferential allocation outcomes. Section B explains how patients pursue their own self-interest in survival through litigating preferential treatment and placing themselves on multiple waitlists.

A. Transplant Doctors and Hospitals

Pecuniary interests "conflict with decisions about the patients who should undergo transplantation, the best matching of organs with recipients, and, therefore, the best allocation of this scarce resource."[178] The scarcity of donated organs has caused a geopolitical battle for supply among transplant hospitals. Transplant doctors and hospitals have an acute pecuniary interest in how UNOS allocates organs because transplant procedures are "one of the most profitable types of surgery for hospitals."[179] As one transplant doctor noted, "[f]inancial interests can rule the day in trying to move forward or to block [allocation changes]."[180] A single heart transplant generates nearly $1.4 million in bills charged per member per month, with an aggregate total of approximately $3.8 billion per year for all heart transplants performed nationally.[181] Liver transplants generate an aggregate of approximately $5 billion in total billings per member per month.[182] Transplant centers need to not only perform enough transplants to preserve their market share and meet fixed costs,[183] but also expand their market share to remain profitable.[184]

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[176] Pursuant to UNOS's bylaws, the Board of Directors can approve organ allocation policies as long as more than 25% of its members approve the policy. *Bylaws*, *supra* note 48, at 14.

[177] 42 C.F.R. § 121.3(a). "Patients" as used here refers to "transplant candidates, transplant recipients, organ donors and family members" collectively. *Id.* § 121.3(a)(ii). The remainder of the Board of Directors is composed of "voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public." *Id.* § 121.3(a)(iii).

[178] Jeffrey B. Halldorson, Harry J. Parsch, Jennifer L. Dodge, Alberto M. Segre, Jennifer Lai & John Paul Roberts, *Center Competition and Outcomes Following Liver Transplantation*, 19 LIVER TRANSPLANTATION 96, 97 (2013).

[179] WEIMER, *supra* note 26, at 61.

[180] Jordan Michael Smith, *The Gross Inequality of Organ Transplants in America*, NEW REPUBLIC (Nov. 8, 2017), https://newrepublic.com/article/145682/gross-inequality-organ-transplants-america.

[181] *See* T. SCOTT BENTLEY & STEVEN J. PHILLIPS, 2017 U.S. ORGAN AND TISSUE TRANSPLANT COST ESTIMATES AND DISCUSSION, MILLIMAN RESEARCH 3 (2017), http://www.milliman.com/uploadedFiles/insight/2017/2017-Transplant-Report.pdf.

[182] *See id.*

[183] Halldorson et al., *supra* note 178, at 97.

[184] *See* P.S. Cho, R.F. Saidi, C.J. Cutie & D.S.C. Ko, *Competitive Market Analysis of Transplant Centers and Discrepancy of Wait-Listing of Recipients for Kidney Transplantation*, 6 INTL. J. ORGAN TRANSPLANTATION

How UNOS allocates organs has substantial financial consequences for transplant hospitals.[185] The transplant hospitals that "lose" in these situations face grave repercussions.[186] After recent allocation policy changes, University of Louisville Health - Jewish Hospital experienced an 86% reduction in heart transplants, a 56% reduction in kidney transplants, and a 29% reduction in liver transplants, even though the national number of transplants for all three organs only decreased 11%.[187] An interruption in a hospital's transplant center can also undermine the hospital's revenue streams, reputation, ancillary medical services, and residency placements.[188] Organ allocations similarly affect doctors because their financial benefits "depend on how the organs are allocated," namely "to what degree the procured organs are common property available to other transplant centers."[189]

As members of the Board of Directors, transplant doctors and hospital representatives are motivated to pursue allocation policies that prioritize their financial interests and contradict "the best allocation of this scarce resource."[190] The financial bias of transplant doctors and hospitals necessary to violate due process can be inferred[191] from three practices: (1) lobbying for advantageous allocation policies, (2) gaming allocation metrics, and (3) litigating for preferential treatment.

1. Lobbying for Preferential Organ Allocation Policies

Transplant doctors and hospitals have lobbied for advantageous organ allocation policies since NOTA's passage. Consider the University of Pittsburgh Medical Center (UPMC), one of the early leaders in liver transplantation.[192]

MED. 141, 146 (2015).

185 Weimer, *supra* note 18, at 12.

186 *See, e.g.*, May Ortega, *Transplant Rules Leave NM Behind*, KUNM (July 30, 2019), https://www.kunm.org/post/transplant-rules-leave-nm-behind (explaining how the only transplant hospital in New Mexico closed due to allocation policy changes).

187 Al Cross, *As Jewish Hospital Struggles, so Does Its Organ-Transplant Program, with Bad Implications for U of L and Regional Health Care*, KY. HEALTH NEWS (July 15, 2019), https://ci.uky.edu/kentuckyhealthnews/2019/07/15/as-jewish-hospital-struggles-so-does-its-organ-transplant-program-with-bad-implications-for-u-of-l-and-regional-health-care/ (citations omitted).

188 *Id.* The University of Louisville ultimately took over Jewish Hospital to prevent it from closing down. Chris Otts, *University of Louisville to Take Over KentuckyOne Health Properties in Bid to Save Jewish Hospital*, WRDB (Aug. 14, 2019), https://www.wdrb.com/in-depth/university-of-louisville-to-take-over-kentuckyone-health-properties-in/article_f90decee-be96-11e9-9799-67667ac2e209.html.

189 Weimer, *supra* note 18, at 16.

190 Halldorson et al., *supra* note 178, at 2.

191 *See* Gibson v. Berryhill, 411 U.S. 564, 579 (1973) (explaining that pecuniary interests can be inferred).

192 *See generally History and Experience*, UNIV. PITT. MED. CTR. TRANSPLANT SERVS., https://www.upmc.com/-/media/upmc/services/transplant/documents/history.pdf?la=en (last visited Feb. 14, 2021)

Between 1990 and 1996, UPMC's total number of liver transplants performed per year declined from 471 to 177,[193] resulting in a $60 million decrease in revenue.[194] The decrease in transplants performed was caused by the opening of new transplant hospitals, which diverted organs away from established centers like UPMC.[195] To stop this trend, UPMC spent over $260,000 in lobbying fees in two years to push for broader organ allocation rules[196] that would increase UPMC's market share of organs at the expense of newer transplant hospitals.[197]

UPMC is not unique in promoting its financial interests through lobbying.[198] Hospitals and doctors have formed advocacy groups that seek to further their geographically preferred organ allocation outcome.[199] Transplant hospitals support or oppose allocation policies based on how the policies affect the center's market share of allocated organs.[200] Transplant hospitals that support broader allocation policies, like UPMC, have seen a decrease in their market share.[201] In contrast, the transplant centers that oppose broader allocation policies have seen a net increase in transplants performed due to advantageous regional allocation policies.[202] This distinction corroborates "the proposition that self-interest influence[s] the position that transplant hospitals took on the issue of the national allocation."[203]

(explaining history and scope of liver transplantation at UPMC).

193 Weimer, *supra* note 18, at 23.

194 *Putting Patients First: Resolving Allocation of Transplant Organs: Joint Hearing Before the Subcomm. on Health & Env't of the H. Comm. on Com. and the S. Comm. on Labor & Hum. Res.*, 105th Cong. 98 (1998) (hereinafter *Putting Patients First*) (testimony of John Greg Ganske, Rep., U.S. House of Representatives).

195 *See* Weimer, *supra* note 18, at 20.

196 *Id.* at 27. UNOS itself also lobbied its stakeholders during the debate over the Final Rule. *Id.* at 33–34. In response, then-Secretary of HHS Donna Shalala criticized UNOS, stating: "[UNOS] has launched a cynical political lobbying campaign against the [Final Rule]. This campaign has been characterized by misinformation and outright falsehoods. The essence of the UNOS campaign has been to create phantom policies and use scare tactics that have hospital administrators and patients around the country up in arms. UNOS has sent form letters, part of a self-described 'legislative action kit,' to surgeons and patients across the country. UNOS has been loud and vociferous in its lobbying and is working with some of the highest priced public relations and lobbying firms in town." *Putting Patients First*, *supra* note 194, at 77 (statement of Donna Shalala, Secretary, Department of Health and Human Services).

197 *See* Weimer, *supra* note 18, at 24 (explaining how national allocation policies "would threaten the survival of smaller transplant centers").

198 *See Putting Patients First*, *supra* note 194, at 99 (statement of Donna Shalala, Secretary, Department of Health and Human Services) ("I have been lobbied on every part of this issue[.]").

199 *Compare* NAT'L COAL. FOR TRANSPLANT EQUITY, *supra* note 79 (supporting wider geographic organ allocation policies), *with* KEEP TRANSPLANTS FAIR, *supra* note 82 (supporting smaller geographic organ allocation policies).

200 *See* Weimer, *supra* note 18, at 29–30.

201 *Id.* at 29.

202 *Id.* at 30.

203 *Id.* at 32; *see also id.* at 12 (noting that allocation policies have direct implications for transplant hospitals "to promote their own professional and financial interests"); John Howser, *Transplant Centers,*

2. Gaming the System for Financial Advantage

Transplant hospitals and doctors manipulate the transplant waitlist to benefit financially, enhance hospital reputation, and decrease scrutiny for underperformance.[204] Hospitals can manipulate organ allocations through a bait and switch technique in which a center registers a sick patient for transplant but then uses the organ for a different, less sick patient.[205] Hospitals also artificially increase their patients' severity of illness, which gives them priority under the OPTN relative to other patients.[206] Patients are generally scored by doctors using objective metrics to determine how sick they are compared to other patients waiting for an organ donation.[207] In addition to the objective score, doctors may obtain "exception points,"[208] which inflate a patient's score, and therefore increase the quantified severity of their illness.[209] Doctors have increasingly used exception points,[210] and patients who receive exception points are more likely to receive a transplant.[211] By inflating the score of their less sick patients, transplant doctors benefit financially by keeping organs locally rather than

Patients Unite to Stop New Organ Sharing Policy That Threatens Longer Waits for a Liver, VAND. UNIV. MED. REP. (Apr. 23, 2019, 1:46 PM), http://news.vumc.org/2019/04/23/transplant-centers-patients-unite-to-stop-new-organ-sharing-policy-that-threatens-longer-waits-for-a-liver/ (characterizing a national organ allocation policy as the "lobbying efforts by large hospitals in the Northeast and on the West Coast, where organ donation rates are among the lowest in the nation, so they can gain greater access to donor livers").

[204] ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, MANIPULATION OF THE ORGAN ALLOCATION SYSTEM WAITLIST PRIORITY THROUGH THE ESCALATION OF MEDICAL THERAPIES 15 (June 2018), https://optn.transplant.hrsa.gov/media/2526/ethics_boardreport_201806.pdf.

[205] *Id.* at 18; *see also* Press Release, United Network for Organ Sharing, University of Pittsburgh Medical Center Released from Probation (Sept. 30, 2016) (available at https://unos.org/news/university-of-pittsburgh-medical-center-released-from-probation/) (finding that UPMC had "an unusually high number of instances where they accepted lung offers for one transplant candidate, then transplanted another candidate at the program").

[206] *See* Dennis P. Scanlon, Christopher S. Hollenbeak, Woolton Lee, Evan Loh & Peter A. Ubel, *Does Competition for Transplantable Hearts Encourage 'Gaming' of the Waiting List?*, 23 HEALTH AFFS. 191, 197 (2004) (finding that "transplant hospitals facing greater competition for cadaveric organs will game the system").

[207] *See generally Questions & Answers for Transplant Candidates About MELD and PELD*, UNITED NETWORK FOR ORGAN SHARING, https://unos.org/wp-content/uploads/unos/MELD_PELD.pdf (last visited Feb. 14, 2021). These scores use routine lab tests to determine severity of sickness "from 6 (less ill) to 40 (gravely ill)." *Id.* at 1. Patients are regularly tested for re-scoring to offer organs to the most-ill person locally, then regionally, then nationally. *Id.* at 2.

[208] "Exception points" are additional points added to a patient's objective score based on certain qualifying medical ailments. *What Is the MELD Score for Liver Disease?*, WEBMD, https://www.webmd.com/hepatitis/meld-score-for-liver-disease#2 (last visited Feb. 14, 2021).

[209] Therese Bittermann, George Makar & David Goldberg, *Exception Point Applications for 15 points: An Unintended Consequence of the Share 15 Policy*, 18 LIVER TRANSPLANTATION 1302, 1305 (2012).

[210] *Id.* at 1307.

[211] A. B. Massie et al., *MELD Exceptions and Rates of Waiting List Outcomes*, 11 AM. J. TRANSPLANTATION 2362, 2365 (2011).

sending them to other hospitals with sicker patients.[212] Therefore, transplant waitlist manipulation further supports the inference that transplant doctors and hospitals are self-interested for the purposes of a due process analysis.

3. Litigating Preferential Organ Allocation Policies

The OPTN framework assumes that members of the Board of Directors have aligned interests and will resolve differences internally through committee procedures.[213] When these interests diverge due to self-interest, processes break down at the committee and board levels, which in turn causes transplant hospitals to litigate their way to a preferred allocation policy outcome.[214] In *Callahan v. United States Department of Health & Human Services*, fourteen transplant hospitals and four individual patients located in "organ-rich" states sued UNOS and HHS because UNOS had adopted liver allocation policies that broadened the geographic range of liver allocation.[215] The plaintiffs in this ongoing case assert that (1) the Secretary violated the APA by failing to publish new allocation policies in the Federal Register, (2) the adoption of new organ allocation policies was otherwise arbitrary and capricious, and (3) the broader allocation policies adopted by UNOS violated the plaintiffs' due process rights.[216] UNOS itself alleged, during oral arguments, that the plaintiff-transplant centers were motivated by financial considerations rather than medical concerns[217] because each plaintiff-transplant hospital expected to perform fewer transplants due to the broader allocation policy that was adopted.[218] The plaintiff-transplant centers meanwhile asserted that the UNOS Board of Directors was "concoct[ing] a plan to gerrymander donated livers away from [the plaintiffs] and toward their favored transplant centers."[219] The

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[212] *See* Bittermann et al., *supra* note 209, at 1307–08.

[213] Oral Argument at 26:50, Callahan v. U.S. Dep't of Health & Hum. Servs., 939 F.3d 1251 (11th Cir. 2019) [hereinafter *Callahan* Oral Argument] (available at http://www.ca11.uscourts.gov/oral-argument-recordings?title=&field_oar_case_name_value=callahan&field_oral).

[214] *See generally* Complaint, Callahan v. U.S. Dep't of Health & Hum. Servs., No. 1:19-cv-01783 (N.D. Ga. filed Apr. 22, 2019) [hereinafter *Callahan* Complaint].

[215] *See id.* at 1, 3–4, 6–7.

[216] *See id.* at 79–89. The due process challenge in *Callahan* related to the inadequacy of notice-and-comment procedures for the new allocation policy, rather than the delegation of policymaking power itself. *Id.* at 88–89.

[217] *Callahan* Oral Argument, *supra* note 213, at 27:05. Implied in this accusation is that transplant hospitals who support UNOS in this case seek to gain organs in connection with the new Acuity Circle Policy. *Cf. id.*

[218] *Callahan* Complaint, *supra* note 214, at 67–69.

[219] Supplemental Brief in Support of Preliminary Injunction of Plaintiff at 2, Callahan v. U.S. Dep't of Health & Hum. Servs., No. 1:19-cv-01783 (N.D. Ga. filed Dec. 31, 2019).

transplant hospitals are seeking to ensure their "long-term financial viability" through litigation.[220]

Due to the acute financial pressures of organ transplantation,[221] transplant hospitals and doctors are incentivized to pursue their own pecuniary interests at the expense of other transplant centers and doctors, which can be inferred from lobbying, gaming, and litigating. These interests are not only inconsistent with Final Rule[222] but also inconsistent with due process because Congress delegated regulatory power to "private persons whose interests . . . are adverse to the interests of others in the same business."[223]

B. Transplant Patients

Instead of finding motivation in pecuniary interests, transplant patients serving on UNOS's Board of Directors are motivated by their own personal welfare.[224] Patients are "essentially in competition with one another through transplant centers."[225] Patients therefore will not advance a common objective—a national, equitable organ sharing scheme—when it directly contradicts their personal welfare.[226] This section considers the two ways in which patients have instead promoted their own self-interest. First, patients litigate their way to advantageous outcomes relative to other patients. Second, patients manipulate waitlists in their favor through "transplant tourism."

1. Litigating Preferential Transplant Outcomes

Patients have used litigation as a means of gaining an individual, temporary advantage in obtaining a donated organ. In *Murnaghan v. United States Department of Health & Human Services*,[227] Sarah Murnaghan, a ten-year-old severely ill with cystic fibrosis, sued HHS because—pursuant to a UNOS policy referred to as the "Under-12 Rule"—children under twelve years of age were

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220 *Callahan* Complaint, *supra* note 214, at 7.

221 *See supra* notes 179–89 and accompanying text (describing the financial incentives).

222 *See* 42 C.F.R. § 121.4(a)(1) (2019) (requiring the OPTN Board of Directors to develop policies for "equitable allocation").

223 Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936).

224 Although reviewing courts emphasize pecuniary biases, other sources of bias are still relevant. *See* Volokh, *supra* note 95, at 953 n.108 (collecting cases); Ernest Gellhorn & Glen O. Robinson, *Rulemaking "Due Process": An Inconclusive Dialogue*, 48 U. CHI. L. REV. 201, 220–21 (1981) (examining inconsistencies of distinguishing between personal and pecuniary interests).

225 Halldorson et al., *supra* note 178, at 96.

226 *See* MANCUR OLSON, THE LOGIC OF COLLECTIVE ACTION: PUBLIC GOODS AND THE THEORY OF GROUPS 2 (1965).

227 No. 2:13-cv-03083 (E.D. Pa. filed June 05, 2013).

placed behind adults on the waitlist for adult lungs.[228] On the same day the complaint was filed, a temporary restraining order was granted in favor of Miss Murnaghan.[229] However, the temporary restraining order lifted the Under-12 Policy only as it applied to Miss Murnaghan.[230] Through litigation, she had temporarily placed herself in an advantageous position relative to other children under twelve years old on the waitlist, as she would have a better chance of receiving adult lungs as long as the temporary restraining order remained effective.[231] Because Miss Murnaghan ultimately did receive a lung transplant, the case was voluntarily dismissed,[232] and the substantive issues raised by her claim were left unanswered.[233]

Patients have also used litigation to force organ allocation policy changes that benefit their geographic region. Without any judicial intervention, UNOS took ten years to revise its kidney allocation policy through its standard procedures.[234] In response to the legal challenge in *Holman v. United States Department of Health & Human Services*,[235] UNOS's lung allocation policy changed in just five days.[236] After HHS failed to respond to her critical comment, Miriam Holman asserted that the geographic focus of the tiered organ allocation system[237] was unconstitutional because "it threaten[ed] to deprive [her] of her life without due process of law in violation of the Fifth Amendment."[238] Due to a court-ordered review, UNOS replaced the traditional tiered system with the Acuity Circle Policy.[239] As a resident of New York, Ms. Holman benefited from

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228 Complaint at 1–2, Murnaghan v. U.S. Dep't of Health & Hum. Servs., No. 2:13-cv-03083 (E.D. Pa. filed June 05, 2013) [hereinafter *Murnaghan* Complaint].

229 Order Granting Temporary Restraining Order, Murnaghan v. U.S. Dep't of Health & Hum. Servs., No. 2:13-cv-03083 (E.D. Pa. filed June 5, 2013) [hereinafter *Murnaghan* Order Granting TRO].

230 *See id.* (requiring OPTN to "immediately cease application of the Under 12 Rule *as to Sarah Murnaghan* so that she can be considered for receipt of donated lungs from adults" (emphasis added)).

231 *See id.*

232 Notice of Dismissal Without Prejudice, Murnaghan v. U.S. Dep't of Health & Hum. Servs., No. 2:13-cv-03083 (E.D. Pa. July 8, 2013).

233 *See Murnaghan* Complaint, *supra* note 228, at 16–18 (alleging violations of due process and equal protection).

234 HEALTH RES. & SERVS. ADMIN., THE NEW KIDNEY ALLOCATION SYSTEM (KAS) FREQUENTLY ASKED QUESTIONS 4, https://optn.transplant.hrsa.gov/media/1235/kas_faqs.pdf (last visited Feb. 14, 2021).

235 No. 1:17-cv-09041 (S.D.N.Y. filed Nov. 19, 2017).

236 Yasinski, *supra* note 68.

237 *See supra* notes 64–67 and accompanying text (explaining the tiered allocation system).

238 Complaint at 20, Holman v. U.S. Dep't of Health & Hum. Servs., No. 1:17-cv-09041 (S.D.N.Y. filed Nov. 19, 2017) [hereinafter *Holman* Complaint].

239 Letter from George Sigounas, Adm'r, Health Res. & Servs. Admin., to Yolanda Becker, President, OPTN (Nov. 24, 2017) (available at https://optn.transplant.hrsa.gov/media/2399/hrsa_letter_to_optn_20171124.pdf). The policy was implemented on a one-year interim basis subject to more comments from stakeholders. *Id.* This policy later prompted the transplant hospitals' lawsuit in *Callahan*. *Callahan* Complaint, *supra* note 214, at 79–89.

the Acuity Circle Policy more than the tiered organ allocation system due to the broader geographic sharing of donated organs.[240] Because UNOS implemented an advantageous organ allocation policy, Ms. Holman voluntarily dismissed the case.[241]

Ms. Holman and Miss Murnaghan both pursued their respective personal interests through litigation. In *Murnaghan*, a patient proved that she could litigate her way to an advantageous position relative to other individuals abiding by waitlist procedures.[242] In *Holman*, the inaction of UNOS in considering the plaintiff's critical comment to an existing allocation policy ultimately led the plaintiff to force the issue in court and achieve a preferred organ allocation policy.[243] In response to the court order, UNOS quickly promulgated new rules that favored broader organ sharing for lung and liver allocation.[244] The two patients thus placed their interests "ahead of other patients similarly situated, but who lacked the necessary legal and political clout to compromise an organ distribution system that best represents broader societal interests."[245] Transplant patients pursue their personal interests rather than the equitable sharing NOTA espouses, and therefore they can be considered self-interested for the purposes of a due process analysis.

2. Transplant Tourism

In addition to political and legal clout, transplant patients can use wealth to undermine broader societal interests. Due to the geographic differences in organ

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[240] *See supra* notes 64–73 and accompanying text (comparing the tiered system with the Acuity Circle Policy).

[241] Notice of Voluntary Dismissal, Holman v. U.S. Dep't of Health & Hum. Servs., No. 1:17-cv-09041 (S.D.N.Y. filed Nov. 28, 2017). Alexandra Glazier, an OPTN Board Member, implied that this emergency action prevented credibility damage because there was no "[j]udicial precedent of a court-ordered organ distribution policy." Glazier, *supra* note 34, at 147. This fails to consider, however, that Ms. Holman filed a critical comment regarding the policy with UNOS and HHS. *Holman* Complaint, *supra* note 238, at 18–19. UNOS and HHS failed to act upon her request, justifying inaction due to administrative burden. *Id.* at 19. Ms. Holman then sued because of UNOS and HHS's inaction, and therefore this was in some sense a "court-ordered organ distribution policy." Glazier, *supra* note 34, at 147. This failure undermines the credibility of private entities as efficient, subject-matter experts for rulemaking purposes. Hammond, *supra* note 60, at 1718–19.

[242] *See Murnaghan* Order Granting TRO, *supra* note 229 (requiring OPTN to "immediately cease application of the Under 12 Rule *as to Sarah Murnaghan* so that she can be considered for receipt of donated lungs from adults" (emphasis added)).

[243] *See* Order Denying Temporary Restraining Order at 1, Holman v. U.S. Dep't of Health & Hum. Servs., No. 1:17-cv-09041 (S.D.N.Y. filed Nov. 20, 2017) (ordering denial of TRO and emergency review of policy).

[244] *See* Yasinski, *supra* note 68 ("Five days after her lawsuit was filed in a U.S. District Court, UNOS changed its policy to strengthen organ sharing over greater distances, removing DSA from the 'first tier' in allocation decisions.").

[245] Roger W. Evans, *The Sarah Murnaghan Debacle: A Health Policy Perspective on Transplant Candidate Selection*, 32 J. HEART & LUNG TRANSPLANTATION 868, 868 (2013).

distribution, patients on the transplant waitlist have pursued their own self-interest through domestic "transplant tourism."[246] Transplant tourism occurs when a transplant patient registers himself or herself with multiple transplant centers across more than one UNOS region, which improves that individual's chance of receiving a transplant.[247] By registering with multiple transplant centers across the United States,[248] a transplant patient can simultaneously take advantage of the local preference for organ allocations in more than one UNOS region.[249]

However, not all patients have the ability to place themselves on multiple organ waitlists. If a patient is too sick to travel, multiple listing is not possible.[250] There are also financial considerations. The costs associated with traveling to a distant transplant hospital are not covered by insurance, and state-run Medicaid programs will not allow an out-of-state listing.[251] As a result, multiple listings "advantage[] candidates who have more financial resources but are objectively less sick than their [single listing] counterparts."[252] Steve Jobs famously traveled from his home in Northern California to Tennessee to obtain a transplant,[253] which received widespread criticism for unfairness.[254]

Transplant patients are incentivized to pursue their personal welfare rather than engage in equitable sharing, which is demonstrated from recent litigation and transplant tourism. Furthermore, patients' interests likely align with their representative organ transplant hospitals and doctors because of the geographical factionalism of organ transplantation—transplant policies that favor a patient's local hospital also favor the patient because of the increased

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246 Eitan Neidich, Alon B. Neidich, David A. Axelrod & John P. Roberts, *Consumerist Responses to Scarcity of Organs for Transplant*, 15 AM. MED. ASS'N J. ETHICS 966, 967 (2013).

247 *Id.*

248 To be listed, a patient must be referred to a transplant hospital that then accepts or denies the patient for listing. UNOS, FREQUENTLY ASKED QUESTIONS ABOUT MULTIPLE LISTING AND WAITING TIME TRANSFER 2, https://unos.org/wp-content/uploads/unos/Multiple_Listing.pdf (last visited Feb. 14, 2021).

249 *See* Parent & Caplan, *supra* note 20, at 4 (explaining that local organs are often transplanted locally, but on out-of-state residents flown in); *supra* notes 64–67 (explaining the tiered allocation system).

250 Parent & Caplan, *supra* note 20, at 4.

251 Raymond C. Givens, Todd Dardas, Kevin J. Clerkin, Susan Restaino, P. Christian Schulze & Donna Mancini, *Outcomes of Multiple Listing for Adult Heart Transplantation in the United States: Analysis of OPTN Data from 2000 to 2013*, 3 JACC HEART FAILURE 933, 934 (2015).

252 *Id.*

253 Neidich et al., *supra* note 246, at 966.

254 *See* Ava Jones, *Steve Jobs Liver Highlights the Problem of US Organ Allocation*, UNIV. HERALD (Mar. 31, 2017), https://www.universityherald.com/articles/71222/20170331/steve-jobs-liver-highlights-problem-organ-allocation.htm (asserting that "only the rich and the powerful can have access in organs available in far off places").

possibility of obtaining an organ.[255] Due to this alignment of interests, larger coalitions have the means, through UNOS, to implement more advantageous allocation policies at the expense of smaller coalitions. Therefore, due process is violated unless there is a means to effectively mitigate the self-interest of this larger coalition.

IV. HHS'S OVERSIGHT OVER UNOS IS INSUFFICIENT

Self-interest, pecuniary or otherwise, is insufficient to succeed on a due process claim if there is adequate oversight. If "[u]ltimate control over the regulatory standards [did] rest with a neutral government agency," due process would be satisfied notwithstanding the fact that self-interested parties initially developed the standards.[256] To prove that HHS's oversight over UNOS is inadequate, this Part analyzes the scope of the Secretary's substantive and procedural oversight. Section A asserts that as a matter of statutory interpretation, the Secretary does not have the authority to substantively override allocation policies developed by UNOS. Section B then asserts that the constraints imposed on UNOS by NOTA, the Final Rule, and judicial review fail to limit members of the Board of Directors from promoting their own interests.

A. The Secretary Cannot Substantively Override UNOS's Allocation Policies

Congress did not empower the Secretary to substantively revise organ allocation policies promulgated by UNOS. Under NOTA, the Secretary only has the authority to develop procedures for "receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under [NOTA]."[257] The "manner in which" the OPTN carries out its duties unambiguously refers to process rather than substance.[258] To the extent that the

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[255] *See* Weimer, *supra* note 18, at 44 (finding that "the interests of transplant surgeons are closely aligned to those of patients"); *cf.* CONG. RSCH. SERV., 7-5700, ANALYSIS OF CONSTITUTIONAL ISSUES ARISING FROM A PROPOSAL TO AUTHORIZE A FEDERALLY CHARTERED PRIVATE CORPORATION TO PROVIDE AIR TRAFFIC CONTROL SERVICES 18 (2015) (noting that diverse stakeholders collectively serving on a board of directors can implicate due process when interests align).

[256] Ass'n of Am. R.Rs. v. Dep't of Transp., 896 F.3d 539, 546 (D.C. Cir. 2018).

[257] 42 U.S.C. § 274(c).

[258] *See id.*; *see also* Batterton v. Marshall, 648 F.2d 694, 707 (D.C. Cir. 1980) (finding that "[p]rocedural rules are those that relate to the method of operation"); Mendoza v. Perez, 754 F.3d 1002, 1023 (D.C. Cir. 2014) (finding that "[p]rocedural rules 'alter the manner in which' the parties present themselves or their viewpoints to the agency" (quoting *Batterton*, 648 F.2d at 707)); Bruggebrew, *supra* note 54, at 22 (reaching the same conclusion).

Final Rule purports to empower the Secretary with substantive control over allocation policies,[259] the Secretary acts beyond the statutory authority granted in NOTA.[260]

This interpretation is also consistent with congressional intent. Prior to NOTA's passage, the Senate Committee on Labor and Human Resources explained that development of allocation policies, "while stimulated by the federal government and this legislation, should nonetheless be located in the private sector rather than in the government."[261] During the promulgation of the Final Rule, then-Secretary Shalala reiterated UNOS's control of substantive policymaking by stating that "[HHS] does not have a preconceived notion of any allocation policies. We are relying on the transplant community to develop the policy."[262] Therefore, NOTA does not grant the Secretary the power to substantively intervene in UNOS policymaking,[263] and the UNOS Board of Directors maintains the sole responsibility for developing and maintaining organ allocation policies.[264]

B. The Secretary Otherwise Lacks Sufficient Oversight to Ensure Due Process

The HHS-UNOS framework lacks sufficient oversight over self-interested stakeholders vested with the power to develop organ allocation policies. Therefore, the delegation of regulatory power violates the Due Process Clause. This section first argues that the Secretary's oversight is limited with respect to the approval of allocation policies, the broadness of organ allocation guidelines, and the scope of response to critical comments. Second, this section asserts that once allocation policies are implemented by UNOS, there are considerable limitations to challenging them due to the inapplicability of the Administrative Procedure Act (APA).

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[259] *See, e.g.*, 42 C.F.R. § 121.4(b)(2) (2019) (purportedly granting the Secretary authority to "direct [UNOS] to revise the proposed policy consistent with the Secretary's direction").

[260] *See* 42 U.S.C. § 274(c); *see also* Bruggebrew, *supra* note 54, at 17 (asserting that "[the Final Rule's] provision purporting to authorize the Secretary to oversee the substance of the Network's allocation policies has no statutory foundation and is an example of impermissible self-aggrandizement by an agency").

[261] S. REP. NO. 98-382, at 15.

[262] *Organ Donations: Hearings Before a Subcomm. of the S. Comm. on Appropriations*, 105th Cong. 11, 13 (1998) (statement of Donna Shalala, Secretary, U.S. Department of Health & Human Services).

[263] *See* 42 U.S.C. § 274(c).

[264] Weimer, *supra* note 18, at 20; *see also* Brief for Appellee United Network for Organ Sharing at 35, Callahan v. U.S. Dep't of Health & Hum. Servs., 939 F.3d 1251 (11th Cir. 2019) (No. 19-11876) (asserting that "there is no requirement that the Secretary approve the [organ allocation policy], ratify it, engage in rulemaking, or make a determination about its appropriateness").

1. Limitations of Secretarial Oversight

The Secretary has never affirmatively approved an organ allocation policy adopted by the Board of Directors of UNOS,[265] and UNOS has never published an organ allocation policy in the *Federal Register* for public comment[266] as is typical with informal rulemaking.[267] The Secretary is required to approve or deny UNOS-adopted policies only if they are recommended by UNOS to be "enforceable,"[268] meaning that violation of the policy can result in a stakeholder's termination of Medicare and Medicaid participation.[269]

The HHS-UNOS framework is distinguishable from the private delegations upheld in Supreme Court cases. In *Currin*, the Secretary of Agriculture proposed and implemented tobacco sales standards in markets with the approval of two-thirds of cultivators.[270] With respect to organ allocation policies, HHS does not propose policies for UNOS to approve.[271] In *Sunshine Anthracite Coal Co*., industry stakeholders proposed industry standards "subject to [the government commission's] pervasive surveillance and authority," and standards became effective only upon government approval.[272] UNOS, by contrast, develops organ allocation policies internally for approval by its Board of Directors, after which they become effective as "voluntary" policies without any action required by the Secretary.[273] To the extent that organ allocation policies are only "voluntary," they must be followed because the OPTN is the only means of participating in transplantation due to the federal government's creation of a monopoly,[274] OPOs are the only organizations that can legally harvest organs,[275] and "voluntary" policies must be followed as a condition for maintaining membership in UNOS.[276] Moreover, transplant hospitals violate the UNOS bylaws if they do not perform a certain number of transplants per year,[277] which is dependent upon

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265 Bruggebrew, *supra* note 54, at 29.

266 Callahan v. U.S. Dep't of Health & Hum. Servs., 939 F.3d 1251, 1263 n.11 (11th Cir. 2019).

267 CONG. RSCH. SERV., R41546, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW 2 (2017).

268 42 C.F.R. § 121.4(b)(2) (2019).

269 *Id.* § 121.10(c)(1).

270 Currin v. Wallace, 306 U.S. 1, 15 (1939).

271 *See supra* Part I.A.1.

272 Sunshine Anthracite Coal Co. v. Adkins, 310 U.S. 381, 387–99 (1940).

273 *See 10-Step Policy Development Process*, *supra* note 47. This process has been characterized as "promulgating binding allocation policies." Bruggebrew, *supra* note 54, at 11, 29–30.

274 *See* 42 U.S.C. § 274e (banning the sale of organs).

275 *See id.* § 273.

276 *Bylaws*, *supra* note 48, at 4; *see also* Ass'n of Am. R.Rs. v. Dep't of Transp., 821 F.3d 19, 32–33 (D.C. Cir. 2016) (characterizing regulatory power as ability to "alter [industry stakeholders]" behavior). UNOS has the authority to "impose actions based on a member's failure to comply with [organ allocation policies]," which coerces stakeholder compliance with them. *Bylaws*, *supra* note 48, at app.L, 186.

277 *See Bylaws*, *supra* note 48, at app.D, 76. The Center for Medicare & Medicaid Services guidelines also

the allocation of organs. Therefore, a transplant hospital's options are either (1) to comply with what the UNOS Board of Directors—a body of self-interested stakeholders[278]—dictates, or (2) to be excluded from the only existing organ exchange. UNOS therefore "effectively functions as a legalized cartel"[279] without any mandatory approval process for organ allocation policies by the Secretary.

HHS's remaining means for inhibiting stakeholder bias in decision-making are insufficient. First, the guidelines for organ allocation set out in the Final Rule[280] allow for both sides of the allocation argument to promote their financial interest.[281] The stakeholders that benefit from broader organ allocation policies[282] emphasize the need for policies to "not be based on the candidate's place of residence or place of listing."[283] Meanwhile, the stakeholders that benefit from local organ allocation policies[284] emphasize that geography must be considered to achieve the best medical judgment, ensure the best use of donated organs, and avoid organ waste.[285] Members of the Board of Directors of UNOS may act in a self-interested manner while both complying with their fiduciary duties and satisfying the allocation principles of the Final Rule.[286] Therefore, the guidelines do not effectively mitigate stakeholders' self-interest in seeking preferential allocation outcomes.

Second, if stakeholders desire to challenge an organ allocation policy, they may submit a critical comment "related to *the manner in which* the OPTN is

require a certain number of transplants be performed by each transplant hospital to remain certified, which is required for reimbursements from the federal government and private insurers. Cross, *supra* note 187.

278 *See supra* Part III.

279 Weimer, *supra* note 18, at 15.

280 42 C.F.R. § 121.8 (2019).

281 *See supra* Part I.B.

282 For example, consider UPMC and its associated doctors and patients.

283 *See* 42 C.F.R. § 121.8(a)(8) (2019); *see also* Complaint for Declaratory, Injunctive and Mandamus Relief at 13, 39, Cruz v. U.S. Dep't of Health & Hum. Servs., No. 1:18-cv-06371 (S.D.N.Y. filed July 13, 2018) (alleging that "[a]t the heart of support for status quo allocation policies is the financial advantage enjoyed by transplant centers with short wait times that perform a substantial number of transplants on candidates from outside their local areas," and emphasizing "the need for OPTN policy to reflect broad sharing of organs based on medical urgency and not arbitrary geographic boundaries").

284 For example, consider University of Louisville Health - Jewish Hospital and its associated doctors and patients.

285 *See* 42 C.F.R. §§ 121.8(a)(1)–(5) (2019); *see also Callahan* Complaint, *supra* note 214, at 28, 79–89 (emphasizing that broader sharing "must take place within the context of the regulatory requirements to avoid organ wastage and promote patient access to transplantation, among other factors").

286 *Cf.* CONG. RSCH. SERV., 7-5700, ANALYSIS OF CONSTITUTIONAL ISSUES ARISING FROM A PROPOSAL TO AUTHORIZE A FEDERALLY CHARTERED PRIVATE CORPORATION TO PROVIDE AIR TRAFFIC CONTROL SERVICES 18 (2015) (raising the same concern where a Board of Directors controlling air traffic control services was considered by Congress).

carrying out its duties."[287] The limitation of this procedural review is problematic under the 2016 holding of *Association of American Railroads*,[288] where the reviewing court focused on who ultimately wielded the government's regulatory power.[289] The D.C. Circuit found that Amtrak's ability to set metrics was "constrained very partially" because a private arbitrator "may ultimately choose to side with Amtrak" regarding the substance of the metrics.[290] By framing the due process analysis in terms of bias,[291] sufficient oversight for private entities delegated regulatory power under the D.C. Circuit's interpretation would require a government agency to control the final substance of policies.[292]

Due to the Secretary's inability to substantively override UNOS policies,[293] the Secretary is similarly powerless.[294] Secretary Azar explicitly affirmed this limited position, stating that "[UNOS] said they went through the procedures . . . and [UNOS] remained steadfast in their conclusion . . . . *I do believe my cards are played out here. Congress deliberately set up the OPTN system to keep people like me from actually dictating the policy allocations.*"[295] If a reviewing court applies *Association of American Railroads* this formalistically, the Secretary's authority would be insufficient.[296]

To the extent that procedural mechanisms might be sufficient, a court's analysis would "center[] on the propriety of self-interested actors exercising regulatory power."[297] As a general matter, exclusively procedural constraints are insufficient because agencies rarely reject the private entity's decision-

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[287] 42 C.F.R. § 121.4(d) (2019) (emphasis added).

[288] *See* Ass'n of Am. R.Rs. v. Dep't of Transp., 821 F.3d 19, 35–36, 39 (D.C. Cir. 2016) (invalidating the joint policymaking framework).

[289] *Id.* at 33, 35–36, 39.

[290] *Id.* at 33, 35–36.

[291] *Id.* at 39 (explaining that "the Due Process Clause effectively guarantees the regulatory power of the government will be wielded by 'presumptively disinterested' . . . actors").

[292] *See id.* at 35. The D.C. Circuit found the government's non-substantive oversight and control over Amtrak insufficient because "subjecting the [industry stakeholders] to government oversight would not have cured a grant of regulatory power." *Id.* at 34.

[293] *See supra* Part IV.A.

[294] *Ass'n of Am. R.Rs.*, 821 F.3d at 35.

[295] *Health and Human Services Fiscal Year 2020 Budget Request Before the Appropriations Subcomm. on Lab., Health & Hum. Servs., Educ., & Related Agencies of the S. Comm. on Appropriations* at 23:10, 116th Cong. (2019) (statement of Alex Azar, Secretary, U.S. Department of Health & Human Services) (emphasis added) (available at https://www.c-span.org/video/?459340-1/hhs-secretary-azar-testifies-fiscal-year-2020-budget-request&start=1271).

[296] *See Ass'n of Am. R.Rs.*, 821 F.3d at 35 (explaining that the FRA is ultimately unable to constrain Amtrak and "therefore the requirement of joint development does not somehow sanitize the Act").

[297] *Id.* at 36.

making.[298] As applied here, HHS forwards the critical comment to UNOS asking for an explanation of its decision-making process and then adopts its conclusion.[299] The appeals process therefore does not mitigate the concern originally articulated in *Carter Coal* and later adopted in *Association of American Railroads*: self-interest.[300] By reducing the scope of critical comments to strictly procedural matters, individual members of the Board of Directors can still pursue their own interests[301] within the confines of UNOS's policymaking apparatus[302] at the expense of other stakeholders.[303] If the Secretary finds a procedural violation in the manner in which UNOS promulgates organ allocation policies, the same policies can simply be reimplemented in accordance with the Secretary's procedural directions. Therefore, the appeals process insufficiently prevents self-interest from dictating advantageous allocation policies.[304]

The Secretary is thus powerless to substantively overrule UNOS and fails to provide a procedural "independent check" in a way that limits the self-interest of independent members of UNOS. As a result, due process is violated because the delegation of regulatory power "empower[s] one set of competitors to regulate a rival set."[305]

2. *Limitations on Judicial Review*

After finding the Secretary's oversight limited, aggrieved stakeholders will turn to the courts for relief. Unlike *Holman* and *Murnaghan*, where the cases were voluntarily dismissed,[306] an adjudication on the merits against UNOS by a stakeholder is unlikely to succeed. The APA provides the procedures for agency rulemaking and scope of judicial review.[307] The APA allows judicial review of

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[298] *See* Hammond, *supra* note 60, at 1748. This result is a "departure from administrative law norms." *Id.*

[299] *See Health and Human Services Fiscal Year 2020 Budget Request Before the Appropriations Subcomm. on Lab., Health & Hum. Servs., Educ. & Related Agencies of the S. Comm. on Appropriations* at 23:10, 116th Cong. (2019) (available at https://www.c-span.org/video/?459340-1/hhs-secretary-azar-testifies-fiscal-year-2020-budget-request&start=1271).

[300] Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936); *Ass'n of Am. R.Rs.*, 821 F.3d at 31.

[301] *See supra* Part III.

[302] *See supra* notes 46–55 and accompanying text (explaining the policymaking apparatus).

[303] *See, e.g.*, Ortega, *supra* note 186 (explaining how the only transplant hospital in New Mexico closed due to allocation policy changes).

[304] *Ass'n of Am. R.Rs.*, 821 F.3d at 35–36 (explaining that the analysis "centers on the propriety of self-interested actors exercising regulatory power").

[305] *Id.* at 27 (citing Carter v. Carter Coal Co., 298 U.S. 238, 311–12 (1936)).

[306] Notice of Dismissal Without Prejudice, Murnaghan v. U.S. Dep't of Health & Hum. Servs., No. 2:13-cv-03083 (E.D. Pa. July 8, 2013); Notice of Voluntary Dismissal Pursuant to F.C.R.P. 41(a)(1)(A)(i), Holman v. U.S. Dep't of Health and Hum. Servs., No. 1:17-cv-09041 (S.D.N.Y. filed Nov. 28, 2017).

[307] CONG. RSCH. SERV., R44965, A BRIEF OVERVIEW OF RULEMAKING AND JUDICIAL REVIEW 1–2 (2017).

only "final agency action."[308] Review under the APA necessarily requires an agency, meaning "each authority of the Government of the United States, whether or not it is within or subject to review by another agency."[309] UNOS itself is not a federal agency, but a private contractor, and therefore does not fall within the statute.[310]

The limitations on reviewing UNOS policymaking also constrain judicial review of HHS's oversight of UNOS. Although HHS is undoubtedly an agency for the purposes of the APA,[311] it does not approve or develop organ allocation policies,[312] and therefore there is no final agency action.[313] If a court were to find agency action, the agency action would be limited to the Secretary's response to a critical comment.[314] With respect to critical comments, any response by HHS is limited to the procedural development of any disputed policy rather than its substance,[315] which will not protect an "unwilling minority."[316] Moreover, a reviewing court would likely extend deference beyond administrative law norms by deferring to HHS,[317] which had already deferred to UNOS.[318]

NOTA and the Final Rule provide an incomplete means for HHS to provide meaningful oversight when UNOS implements organ allocation policies. The Due Process Clause "effectively guarantees the regulatory power of the government will be wielded by 'presumptively disinterested' . . . actors."[319] Here, the delegation violates due process by empowering the Board of Directors of UNOS with the power to regulate competitors "whose interests may be and often are adverse."[320]

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308 5 U.S.C. §§ 701, 704.

309 *Id.* § 551(1).

310 *See id.* § 701(b)(1).

311 *See id.* § 551(1).

312 Bruggebrew, *supra* note 54, at 29.

313 *See* Bennett v. Spear, 520 U.S. 154, 178 (1997) (requiring that for agency action to be final it must be an action "by which rights or obligations have been determined, or from which legal consequences will flow" (internal quotation marks omitted)).

314 42 C.F.R. § 121.4(d) (2019).

315 *See* 42 U.S.C. § 274(c); *see also* Batterton v. Marshall, 648 F.2d 694, 707 n.70 (D.C. Cir. 1980) (finding that "[p]rocedural rules are those that relate to the method of operation"); Mendoza v. Perez, 754 F.3d 1002, 1023 (D.C. Cir. 2014) (finding "[p]rocedural rules 'alter the manner in which' the parties present themselves or their viewpoints to the agency" (quoting *Batterton*, 648 F.2d at 707)); Bruggebrew, *supra* note 54, at 22 (reaching the same conclusion).

316 Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936); *see supra* Part IV.B.1.

317 *See* Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843–44 (1984); *supra* note 295 and accompanying text.

318 *See* Hammond, *supra* note 60, at 1749 (explaining "double deference" arising out of judicial review of a self-regulatory organization's actions).

319 Ass'n of Am. R.Rs. v. Dep't of Transp., 821 F.3d 19, 39 (D.C. Cir. 2016).

320 *Carter*, 298 U.S. at 311.

V. UNOS SHOULD BE RELEGATED TO AN ADVISORY CAPACITY TO ENSURE DUE PROCESS

To ensure due process, Congress should amend NOTA to relegate UNOS to an advisory capacity that would propose organ allocation policies for the Secretary's mandatory approval. Federal advisory committees retain a "strictly advisory" role and are "prohibited from creating policy or issuing regulations."[321] Instead, the advisory committee would propose allocation policies for the Secretary's approval, and the Secretary would be authorized to direct the advisory committee to internally review the efficacy of existing policies. UNOS should, however, maintain the day-to-day responsibilities of administering and implementing these Secretary-approved policies.

Two premises addressed in the following sections support this recommendation. Section A asserts that the advisory model is consistent with the Supreme Court's interpretation of the Due Process Clause and better achieves NOTA's statutory goal than other permissible public-private frameworks. Section B asserts that the advisory model is an adequate institutional design by analogizing the advisory model to the use of advisory committees in other fields requiring significant scientific expertise.

A. Advisory Committees Are Consistent with the Due Process Clause

Advisory committees satisfy the due process considerations raised in *Carter Coal*, *Sunshine Anthracite Coal Co.*, and their progeny.[322] Requiring the Secretary to approve all organ allocation policies gives the Secretary the ultimate decision-making power and addresses the primary concern of the due process analysis: bias. The Secretary, a public official appointed by the President, is "presumptively disinterested"[323] and does not have the financial interests implicating fundamental fairness that patients, doctors, and transplant hospitals do have.[324] Moreover, the "ethos of the advisory committee [is] for members to avoid conflicts of interest in giving advice" because the Secretary would be

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321 WENDY GINSBERG, CONG. RSCH. SERV., R44232, CREATING A FEDERAL ADVISORY COMMITTEE IN THE EXECUTIVE BRANCH 1 (2015).

322 *See supra* Part I.C.

323 *Carter*, 298 U.S. at 311.

324 *See* Ward v. Vill. of Monroeville, 409 U.S. 57, 60 (1972) (noting the "possible temptations" for the mayor to maintain high levels of fines when he sat as judge because the village income was derived from fines); *see also* Pittston Co. v. United States, 368 F.3d 385, 394 (4th Cir. 2004) (explaining that delegations "to private persons whose interests may be and often are adverse to the interests of others in the same business is disfavored" (internal quotation marks omitted)); *supra* Part IV (explaining stakeholder interests).

statutorily authorized to revise proposals.[325] This framework would also govern the internal procedures of UNOS under the Federal Advisory Committee Act,[326] which would improve transparency for intra-UNOS functions.[327] The Secretary would therefore not be powerless,[328] thus satisfying the due process inquiry.[329]

Furthermore, advisory committees are better suited for organ allocation policymaking than other public-private frameworks. Although a regulatory framework similar to that in *Currin* would satisfy the due process inquiry,[330] it is ill-suited for organ allocation policymaking. By requiring the Secretary to propose organ allocation policies for UNOS to approve, the public-private framework ensures that the Secretary has substantive control but fails to properly incorporate the expertise required to develop organ allocation policies. UNOS members have technical expertise that "is extremely useful in identifying potential issues to be addressed as well as in predicting the likely consequences of proposed rule changes."[331] By inverting the process, the *Currin* framework would not allow HHS to fully take advantage of subject matter experts. Similarly, amending the critical comment process[332] to ensure substantive review by the Secretary falls short of the intent of NOTA. First, aggrieved stakeholders file critical comments after new policies have been implemented.[333] This reactionary process fails to improve deliberative policymaking and will not provide stability due to post-implementation challenges to allocation policies. Second, if aggrieved stakeholders were to seek judicial intervention instead of filing critical comments, the limitations of judicial review still apply.[334] In contrast, "an agency's final action based on advisory committee advice—or taken in contravention of such advice—is agency action subject to review."[335]

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325 Weimer, *supra* note 18, at 44.

326 Pub. L. No. 92-463, 86 Stat. 770 (codified at 5 U.S.C. app. (1982)).

327 *See, e.g.*, 18 U.S.C. § 208 (creating a statutory penalty for financial conflicts of interest). This section would undoubtedly apply to transplant hospital representatives and surgeons, but not to patients themselves. *See id.*

328 Ass'n of Am. R.Rs. v. Dep't of Transp., 821 F.3d 19, 35 (D.C. Cir. 2016).

329 *See* Sunshine Anthracite Coal Co. v. Adkins, 310 U.S. 381, 388–99 (1940); Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936); *Ass'n of Am. R.Rs.*, 821 F.3d at 35.

330 Currin v. Wallace, 306 U.S. 1, 15 (1939) (upholding a regulatory framework in which Secretary of Agriculture proposed tobacco sales standards for approval by two-thirds of cultivators because the law did not "involve any delegation of legislative authority").

331 Weimer, *supra* note 18, at 44.

332 42 U.S.C. § 274(c) (providing the statutory basis for "receiving from interested persons critical comments relating to the manner in which [UNOS] is carrying out the duties of [UNOS]").

333 *See, e.g.*, *Callahan* Complaint, *supra* note 214, at 4 (filing a critical comment four months after the UNOS Board of Directors approved the Acuity Circle Policy).

334 *See supra* Part IV.B.2.

335 Frederick H. Degnan, *An Introduction to FDA Advisory Committees*, 45 FOOD, DRUG, COSM. L.J. 709, 712 (1990).

The relegation of UNOS to an advisory capacity would satisfy due process because "[u]ltimate control over the regulatory standards . . . [would] rest with a neutral government agency."[336] The Secretary would therefore serve as a disinterested buffer to prevent transplantation stakeholders from "regulat[ing] the affairs of an unwilling minority."[337] However, this new framework would also need to ensure that organ allocation policies are promulgated in a manner that best serves patients.

B. Advisory Committees Are Commonly Used in Fields Requiring Scientific Expertise

Even if due process is satisfied, an advisory committee is appropriate only if it achieves the goal NOTA espouses—providing a means to equitably allocate organs to sick patients. Achieving this goal requires stakeholder participation to ensure that scarce organs are allocated efficiently. This section asserts that organ transplant stakeholders will continue to participate in organ allocation policymaking for two reasons. First, there is a robust tradition of government agencies using advisory committees in scientific fields. Second, the transplantation community has recognized the need for greater government oversight.

Advisory committees are commonly used throughout the federal government where scientific expertise is needed. In 1939, over eighty advisory committees existed, most of which advised government agencies on scientific matters.[338] Today, over 900 advisory committees operate in conjunction with federal agencies, "including twenty advisory committees and eighteen device panels that meet several times per year to advise the Food and Drug Administration about product regulation issues."[339] As a general matter, advisory committees are pervasive in the scientific community.[340]

Relegation of UNOS to an advisory capacity has raised specific concerns that such a framework "might lead stakeholders to be less than forthcoming with their tacit knowledge" and would "probably be less than willing to participate in advisory panels than in [UNOS] committees."[341] This rationale is likely grounded in the pushback from transplant doctors during the comment period of

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336 Ass'n of Am. R.Rs. v. Dep't of Transp., 896 F.3d 539, 546 (D.C. Cir. 2018).

337 Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936).

338 Marshall J. Breger, *Thoughts on Accountability and the Administrative Process*, 39 ADMIN. L. REV. 399, 401 (1987).

339 Weimer, *supra* note 18, at 16–17.

340 *See id.* at 44–45.

341 *Id.* at 44.

the Final Rule.[342] However, current opinions tell a different story. Transplant stakeholders themselves have identified their own involvement in policymaking as "a potential conflict of interest."[343] In response, they proposed "higher accountability from government agencies[,] better mechanisms to ensure an informed opinion from all stakeholders[, and] a more proactive stance by governmental agencies to ensure new and established policies adhere to established laws."[344]

The problem identified and solutions proposed are all satisfied by, and compatible with, an advisory committee. The Secretary's role as the ultimate decision-maker on the substance of organ allocation policies would both mitigate the self-interest of members of the Board of Directors and improve the compatibility of organ allocation policies with established laws. Meanwhile, the use of traditional notice-and-comment procedures increases accountability and assists in ensuring informed opinions. Therefore, relegating UNOS to an advisory committee for the purposes of developing organ allocation policies satisfies both due process and the primary goal of NOTA.

CONCLUSION

For the dead man donating his organs, the process of organ allocation will be irrelevant, but for those who anxiously await a transplant, the process may carry with it their survival. The passage of NOTA marked a striking change in how donated organs are shared that raises constitutional implications. The federal government became the sole steward of donated organs and delegated regulatory power to transplantation stakeholders in a manner permitting them to promote their own interests.

The Fifth Amendment provides a means to strike down the delegation of organ allocation policymaking under the current HHS-UNOS framework. With a more formalistic interpretation of the Due Process Clause like in *Association of American Railroads v. United States Department of Transportation*,[345] reviewing courts may appear more willing to require greater substantive oversight over congressional delegations of private regulatory authority. Through NOTA, Congress granted to the UNOS Board of Directors "the power

342 *See* Bruggebrew, *supra* note 54, at 17–19. Weimer makes his assertions without citation. Weimer, *supra* note 18, at 44.

343 Marie Achille et al., *Current Opinions in Organ Allocation*, 18 AM. J. TRANSPLANTATION 2625, 2626 (2018).

344 *Id.*

345 821 F.3d 19, 35, 39 (D.C. Cir. 2016).

to regulate the affairs of an unwilling minority."[346] After forming a majority, self-interested members of the Board of Directors of UNOS have the authority to promulgate favorable allocation policies. Without a statutory grant for substantive review,[347] the Secretary is "powerless to overrule [UNOS]."[348]

Relegating UNOS to an advisory capacity is the best solution to this problem for three reasons. First, advisory committees are consistent with Supreme Court precedent.[349] Second, UNOS would continue its administrative functions that ensure lives are saved,[350] while the Secretary of HHS would counterbalance the coalitions of transplantation stakeholders that pursue their own self-interest within the Board of Directors of UNOS.[351] Third, this approach is common in other scientific fields and supported by the medical community.[352]

Disagreement among transplantation stakeholders has boiled over into legal battles and editorials. If this trend continues, the legitimacy of the HHS-UNOS relationship will be called into question, especially if policies too strongly favor one side of the organ transplantation argument. A minority of hospitals and doctors would be faced with a difficult question: close down due to the fundamental unfairness of organ allocation and stop providing services to patients or challenge the system itself and force a short-circuit.

SEAN F. DRISCOLL*

346 Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936).

347 *See supra* Part IV.A.

348 *Ass'n of Am. R.Rs.*, 821 F.3d at 35.

349 *See supra* Part V.A.

350 *See supra* Part I.A.2.

351 *See supra* Part V.

352 *See supra* Part V.B.

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