IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA

ADVENTIST HEALTH SYSTEM/SUNBELT, INC. d/b/a ADVENTHEALTH ORLANDO, BOARD OF TRUSTEES OF THE UNIVERSITY OF ALABAMA for and on behalf of THE UNIVERSITY OF ALABAMA HOSPITAL, MEDICAL UNIVERSITY HOSPITAL AUTHORITY, UNIVERSITY OF IOWA, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, a body politic and corporate and an independent instrumentality of the State of Kansas, UNIVERSITY OF KENTUCKY, and ALEXANDER BERRIOS, JR.,	)	CIVIL ACTION NO. 3:20-cv-101
Plaintiffs,	)	
v.	)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR II in his official capacity as Secretary of the United States Department of Health and Human Services, HEALTH RESOURCES AND SERVICES ADMINISTRATION, THOMAS J. ENGELS, in his official capacity as Administrator of the Health Resources and Services Administration, UNITED NETWORK FOR ORGAN SHARING,	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. It is a uniquely terrible time to throw out thirty years of established practice and implement a complex new nationwide policy on the allocation of life-saving organs while the United States is recording its single-worst daily death tolls since the pandemic began and with COVID-19 hospitalizations hitting all-time highs. Indeed, the Centers for Disease Control has warned that this winter may be the "most difficult time" in U.S. public health history.[1] Implementing a sweeping new organ allocation policy now would be especially hard if it heavily relies on severely-impacted commercial air travel and would be even worse if the policy were developed by self-interested individuals looking to maximize their own profit even at the cost of American lives. To implement such a policy while bypassing important procedural and regulatory safeguards and without giving any consideration to how the pandemic will affect the new policy—which was developed and modeled pre-COVID—would be unfathomable. Yet that is exactly what the U.S. Department of Health and Human Services ("HHS") and its contractor, United Network for Organ Sharing ("UNOS"), seek to do. The potential consequence of this rushed, poorly-timed policy implementation are enormous.

2. The number of Americans who need a transplanted kidney far exceeds the supply. This results in a waiting list of nearly 100,000 Americans and an ongoing challenge in how to develop and administer an efficient and fair method to allocate donated kidneys. While not exclusively limited to kidneys—although patients on the kidney waitlist outnumber all other wait-listed organ recipients by more than a 5-to-1 ratio—20 Americans die each day because an organ transplant remains out of reach.[2]

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[1] Sabrina Taverine, *Grim Day in U.S. as Covid-19 Deaths and Hospitalizations Set Records*, N.Y. TIMES, *available at* https://www.nytimes.com/live/2020/12/02/world/covid-19-coronavirus.

[2] *See* Press Release, U.S. Dep't of Health & Human Serv., *Trump Administration Proposes New Rules to Increase Accountability and Availability of the Organ Supply* (Dec. 17, 2019), *available at* https://www.hhs.gov/about/news/2019/12/17/trump-administration-proposes-new-rules-increase-accountability-availabilityorgansupply.html#:~:text=media%40hhs.gov,Trump%20Administration%20Proposes%20New% 20Rules%20to%20Increase%20Accountability%20and%20Availability,of%20whom%20die%20each%20day.

3. Against this backdrop, the unlawful kidney allocation policy will benefit a select group of hospitals and patients on the East and West Coasts in densely populated areas—a group that aligns with the regional biases of UNOS's leadership—by diverting donated kidneys from less populated areas of the country to large metropolitan centers. The policy falls far short of the federally mandated goal of achieving the best use of organs. Indeed, the government's own data predicts that the new policy will result in *fewer* kidney transplants and *more* patients dying on the waitlist. The new policy is also expected to result in more post-surgical failures for those who fortunate enough to receive a transplant.

4. The development of a policy such as this one by self-interested parties is unfortunate but hardly unimaginable. That is why there is an extensive regulatory scheme to make sure that HHS provides thorough oversight of such significant policies changes, in furtherance of its "mission . . . to enhance the health and well-being of all Americans."[3] But this time, unfortunately, HHS abdicated its critical role atop the watchtower. The resultant unconscionable outcome demonstrates why HHS cannot be permitted to shirk regulatory safeguards; those procedures are essential to developing organ allocation policies that are the product of sound medical judgment rather than biased opinions and incomplete analysis. The failure to abide by those safeguards and the adoption and implementation of the new kidney allocation policy is unlawful, arbitrary, and capricious.

5. Plaintiffs respectfully request that the Court declare the new kidney allocation policy unlawful and enjoin its implementation.

[3] *Introduction: About HHS*, U.S. Dep't of Health & Human Servs., https://www.hhs.gov/about/strategic-plan/introduction/index.html (last accessed Dec. 4, 2020).

PARTIES

6. Plaintiffs operate kidney transplant programs across the country that serve transplant candidates on waitlists for kidneys, patients with kidney disease, and individuals who become living and deceased kidney donors.

7. Plaintiff Adventist Health System/Sunbelt, Inc. d/b/a AdventHealth Orlando ("AdventHealth") operates a kidney transplant program in Orlando, which is in Orange County, Florida.

8. Plaintiff Board of Trustees of the University of Alabama for and on behalf of the University of Alabama Hospital operates a kidney transplant program in Birmingham, which is in Jefferson County, Alabama.

9. Plaintiff the Medical University Health Authority ("MUHA") is an affiliate of the Medical University of South Carolina and operates a kidney transplant program in Charleston, which is in Charleston County, South Carolina.

10. Plaintiff the University of Iowa operates a kidney transplant program in Iowa City, which is in Johnson County, Iowa.

11. Plaintiff the University of Kansas Hospital Authority d/b/a the University of Kansas Health System ("University of Kansas Hospital") operates a kidney transplant program in Kansas City, which is in Wyandotte County, Kansas.

12. Plaintiff the University of Kentucky operates a kidney transplant program in Lexington, which is in Fayette County, Kentucky.

13. Plaintiff Alexander Berrios, Jr., is a patient on the kidney transplant waitlist at the University of Kentucky.

14. Defendant United States Department of Health and Human Services ("HHS") is a federal agency of the United States. Under the National Organ Transplant Act ("Transplant Act"),

HHS is responsible for establishing and operating the Organ Procurement and Transplantation Network ("OPTN"). 42 U.S.C. §§ 274(a), 274c. HHS is headquartered at 200 Independence Avenue, S.W., Washington, DC 20201.

15. Defendant Alex M. Azar II is the Secretary of HHS and is sued in his official capacity. As Secretary of HHS, Secretary Azar oversees HHS's activities and is responsible for operating the OPTN in accordance with the Transplant Act. 42 U.S.C. §§ 274(a), 274c.

16. Defendant Health Resources and Services Administration ("HRSA") is a federal agency of the United States within HHS. HRSA currently provides oversight of U.S. organ transplant policies on HHS's behalf. *See* 42 U.S.C. § 274c (directing the HHS Secretary to designate "an identifiable administrative unit"); FDA, *Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products*, 69 Fed. Reg. 29,786-01, 29,788 (May 25, 2004) (noting the statute requires "Federal oversight of the nation's [OPTN]" and that HRSA "currently administers" it). HRSA is headquartered at 5600 Fishers Lane, Rockville, Maryland 20857.

17. Defendant Thomas J. Engels is the Administrator of HRSA and is sued in his official capacity.

18. Defendant United Network for Organ Sharing ("UNOS") is a non-profit organization headquartered in Richmond, Virginia. Under a contract with HHS and HRSA, UNOS operates and "serves as" the Organ Procurement and Transplantation Network (the "OPTN").[4] The OPTN is a statutorily mandated entity that is structured by regulation. 42 U.S.C. § 274; 42 C.F.R. § 121.3. Among other responsibilities, the OPTN is responsible for establishing "policies for the equitable allocation of cadaveric organs among potential recipients," based on "sound medical judgment," to "achieve the best use of donated organs," "to avoid wasting organs, to avoid futile transplants, to promote patient

[4] *See* OPTN Charter, U.S. DEP'T OF HHS, https://optn.transplant.hrsa.gov/governance/about-the-optn/optn-charter/.

access to transplantation, and to promote the efficient management of organ placement." 42 C.F.R. § 121.8(a).

JURISDICTION AND VENUE

19. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331, 28 U.S.C. § 2201, and 5 U.S.C. § 706 because this action for declaratory and injunctive relief arises under the Transplant Act, 42 U.S.C. § 274 *et seq.*, and the Administrative Procedure Act ("APA"), 42 C.F.R. part 121 *et seq.*

20. Venue is proper in this District under 28 U.S.C. § 1391(e)(1) because it is where one of the plaintiffs currently resides, there is no real property involved in the action, and at least one defendant is sued in his official capacity as an officer of a United States agency.

BACKGROUND

A. The Statutory and Regulatory Framework

21. The comprehensive regulatory framework governing organ transplantation in the United States is somewhat byzantine but also essential to understanding what has happened in this case—and why it is unlawful. Congress created a national organ transplant infrastructure in 1984 by enacting the Transplant Act. The Transplant Act directed HHS to establish and operate the OPTN, an organization that would have critical responsibilities in the national transplant system. 42 U.S.C. § 274(a). Under the Transplant Act and subsequent amendments, the OPTN must comply with important statutory mandates, including establishing a national waitlist of individuals who need organs and "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list." *Id.* § 274(a)(2)(A). The Transplant Act also requires the OPTN "to establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria." *Id.* § 274(a)(2)(B).

22. HHS retains a supervisory role for the OPTN's operation under the Transplant Act. For example, the Transplant Act mandates that the HHS Secretary establish procedures for "(1) receiving from interested persons critical comments relating to the manner in which the [OPTN] is carrying out [its] duties" as set forth in the Transplant Act and (2) "the consideration by the Secretary of such critical comments." 42 U.S.C. § 274(c). The Transplant Act also tasks HHS with developing and maintaining a scientific data registry of organ transplant recipients. 42 U.S.C. § 274a.

23. In 1986, HHS and HRSA (collectively, "HHS") awarded the initial contract to operate the OPTN to UNOS, and UNOS has served as the OPTN ever since.[5] Indeed, according to UNOS, the OPTN is not a separate legal entity from UNOS. *See* Letter to Judge Torres, *Cruz v. HHS*, No. 1:18-cv-6371 (S.D.N.Y. Aug. 17, 2018), ECF No. 28 ("UNOS takes this opportunity to inform the Court that Defendant OPTN is not a proper party to this action because it is not a separate legal entity."). Therefore, UNOS, acting as the OPTN (collectively "OPTN"), is responsible for managing the national system that governs organ transplants.[6]

24. As required by the Transplant Act, HHS contracted with a separate entity to maintain a scientific data registry of organ transplant recipients: the Scientific Registry of Transplant Recipients (the "SRTR").[7] The SRTR provides "statistical and other analytical support" to OPTN and HHS.[8]

25. HHS also promulgated regulations, known as the "Final Rule" (42 C.F.R. Part 121), that govern the national transplant system and OPTN, with organ allocation policies principally governed by 42 C.F.R. §§ 121.4 and 121.8. Section 121.4 sets forth that the OPTN is responsible for

[5] *See History of UNOS*, UNOS, https://unos.org/about/history-of-unos/.

[6] *See* OPTN Charter, U.S. DEP'T OF HHS, https://optn.transplant.hrsa.gov/governance/about-the-optn/optn-charter/.

[7] *Mission, Vision, and Values*, SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS, https://www.srtr.org/about-srtr/mission-vision-and-values/.

[8] *Id.*

> developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in [the Transplant Act] and the Secretary's contract for the operation of the OPTN, including:
>
> (1) Policies for the equitable allocation of cadaveric organs in accordance with § 121.8;
> * * *
> (3) Policies that reduce inequities resulting from socioeconomic status, including, but not limited to:
>
> * * *
> (iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;
> [and]
> (6) Policies on such other matters as the Secretary directs.

Id. § 121.4(a). Allocation policies are listed as the first category of required OPTN policies because "establish[ing] . . . medical criteria for allocating organs" is central to the OPTN's role. 42 U.S.C. § 274(b)(2)(B). Socioeconomic inequities had not been addressed in the proposed version of the rule, but in response to public concerns, the Final Rule requires that "the OPTN modify or issue policies to reduce inequities resulting from socioeconomic status to help patients in need of a transplant be listed and obtain transplants without regard to ability to pay or source of payment." *Organ Procurement and Transplantation Network*, 63 Fed. Reg. 16,296, 16,309 (Apr. 2, 1998). Finally, § 121.4(a)(6) requires the OPTN to develop policies on other matters "as the Secretary directs."

26. In developing these policies, the OPTN must comport with certain procedures set forth in § 121.4(b). First, under paragraph (b)(1), the OPTN Board of Directors ("OPTN Board") must "[p]rovide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN." 42 C.F.R. § 121.4(b)(1). Second, under paragraph (b)(2), the OPTN Board shall provide to the Secretary at least two categories of proposed policies: (1) those the OPTN "recommends to be enforceable" and (2) those "on such other matters as the Secretary directs." *Id.* § 121.4(b)(2).

27. Section 121.4 further establishes review procedures as part of HHS's oversight role. Paragraph (b)(2) mandates that, for "significant" proposed policies, the Secretary "will refer" such proposals to the Advisory Committee on Organ Transplantation ("Advisory Committee") and publish them in the Federal Register for public comment. *Id.* The HHS Secretary must then "determine whether the proposed policies are consistent with the National Organ Transplant Act and this part, taking into account the views of the Advisory Committee and public comments," and may provide comments to the OPTN or direct the OPTN to revise the policies. *Id.* (In contrast, if the proposed policies are not "significant," the Secretary has discretion in deciding whether to refer the proposed policies to the Advisory Committee and publish the policies for public comment. *Id.*)

28. In developing organ allocation policies, the OPTN must not only comport with those procedures, but it must also develop allocation policies that satisfy additional specific requirements in 42 C.F.R. § 121.8. That section provides that allocation 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 paragraphs (a)(1)–(5) of this section.

Id. § 121.8(a). Accordingly, allocation policies must be calibrated "to achieve the best use of donated organs," "to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placements"—which will

sometimes require consideration of a candidate's place of residence due to logistical realities of organ transplants. *See id.*

29. The regulations set forth allocation performance goals, which aim "to achieve equitable allocation of organs among patients," and allocation performance indicators that aim to measure how well each policy achieves those goals. *See id.* § 121.8(b),(c). These performance indicators must include baseline data reflecting how closely the current allocation policy meets the established goals as well as "the amount of projected improvement" with respect to any proposed change. *Id.* § 121.8(c)(2). All revisions to policies towards that aim, however, must be accomplished consistently with § 121.8(a)'s separate requirements. *See id.* § 121.8(b). Allocation policies must thus seek to distribute "organs over as broad a geographic area as feasible . . . in order of decreasing medical urgency" while still achieving the "best use of donated organs" and not "wasting organs." *Id.* § 121.8(a)(2), (a)(5), (b)(3). The regulatory priority—and mandate—remains complying with § 121.8(a)(1)-(5)'s requirements.

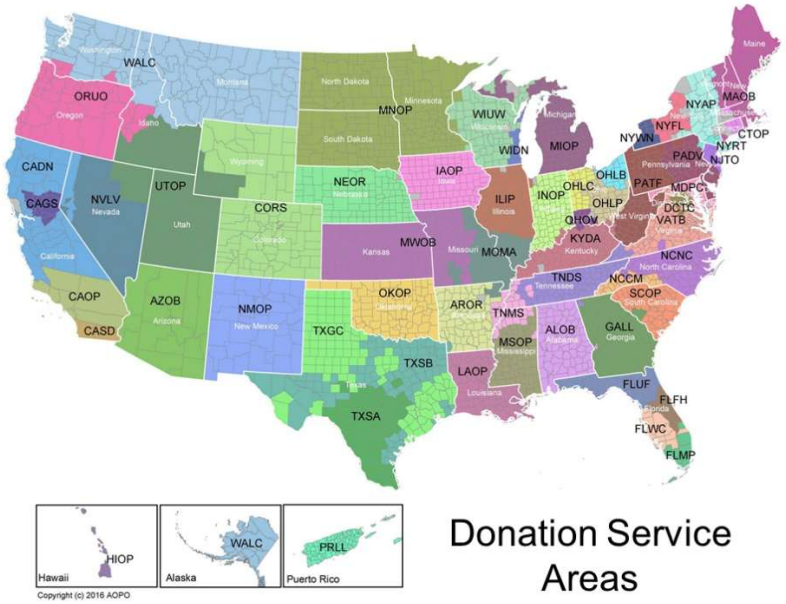
30. The OPTN must also comport with various requirements that it study the effects of its policies and provide data to the Secretary to facilitate HHS's oversight. For example, the OPTN must "collect, analyze, and publish data concerning organ donation and transplants," 42 U.S.C. § 274(b)(2)(J), and "shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, [and] the effect of allocation policies on programs performing different volumes of transplants," 42 C.F.R. § 121.8(c)(3). Moreover, when the OPTN revises organ allocation policies, it must consider, *inter alia*, how the new policy will affect potential organ recipients already on the waitlist and whether such individuals should effectively be grandfathered into the prior policy. *See id.* § 121.8(d)(1) ("shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated

under the previous policies"). And the OPTN must transmit "[t]he transition procedures . . . to the Secretary for review together with the revised allocation policies." *Id.* The OPTN must also provide the Secretary with the "proposed allocation policies and performance indicators," along with "such supporting material, including the results of model-based computer simulations, as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators and transition procedures." *Id.* § 121.8(f).

B. How Donor Organs Have Been Allocated Historically

31. Historically, organs, including kidneys, have been distributed under allocation policies that have used two geographic boundaries: (1) "Regions" and (2) Donation Service Areas or "DSAs." There are 11 Regions, which are groupings of states as depicted by the map below.

32. There are 58 DSAs, as reflected in the map below.



Donation Service Areas

Each DSA is serviced by one organ procurement organization ("OPO"), which is certified by HHS and responsible for engaging with donor families and obtaining donor organs within that area. OPOs vary significantly in their effectiveness. Indeed, the Centers for Medicare and Medicaid Services recently acknowledged as much while revising the rules under which OPOs are qualified. It noted that its "historical approach to measuring OPO performance has resulted in a wide range of performances" and that "[t]his variability is unacceptable to patients."[9] Unfortunately, poorly performing OPOs cost lives. They also sacrifice revenue for transplant hospitals in their DSA because those hospitals are not able to perform as many transplants as they might otherwise perform.

33. The DSAs and Regions have largely served as a proxy for various geographical and logistical considerations, such as relationships and policies among OPOs, transplant programs, and hospitals, for decades. Taking relationships among the different entities into account has been considered important, because different entities have different procedures and preferences, including how organs are maintained during transport, which affects whether organs are accepted for transplant

[9] Centers for Medicare & Medicaid Services, Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule, https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf (Nov. 20, 2020).

and post-transplant outcomes. Geographical factors must also be considered in allocating organs to avoid organ wastage and futile transplants, because once organs are removed from the body, there is a small window of time that the organs remain viable for transplant. When an organ remains outside the body, referred to as cold ischemic time, the tissue damage to the organ increases and the risks of poor post-transplant outcomes increase.[10] Accordingly, kidney allocation policies have traditionally sought to equitably distribute organs based on a variety of factors, including blood type, estimated post-transplant survival, length of time on the waitlist, and medical urgency, while also considering a candidate's residence in a DSA or Region to minimize cold ischemic time and benefit from long-standing working relationships among entities.

34. Over the years, the OPTN, has tweaked the allocation policies and the factors that are evaluated in matching organs as medical advancements have been made and knowledge has increased regarding outcomes for organ transplants in various scenarios, such as different stages of disease progression. *See* 42 C.F.R. § 121.4(3)(2) (requiring the OPTN to update policies "to accommodate scientific and technological advancements").

C. Abrupt Change in the Allocation of Organs

35. More recently, the transplant community explored various liver allocation models. In December 2017, after careful, multi-year deliberations among transplant experts, the OPTN approved a modified liver allocation policy, which relied on DSAs and Regions less heavily. The policy was slated to take effect one year later, in December 2018, but it never did. Instead, HHS and UNOS abruptly changed course.

[10] *See, e.g.*, Claudio E. Ponticelli, *The impact of cold ischemia time on renal transplant outcome*, 87 KIDNEY INT'L 272, 273 (2015), https://www.kidney-international.org/article/S0085-2538(15)30070-3/pdf (explaining that "even a short lengthening of CIT [cold ischemic time] may worsen the outcome of renal transplantation"); *id.* at 274 ("The French report demonstrated that even short differences in CIT may influence not only the survival of the graft but also that of the patient.").

36. On May 30, 2018, a plaintiff's attorney, funded by New York hospitals to represent liver transplant candidates in New York, sent HHS a comment that criticized the revised liver allocation policy for relying on DSAs and Regions at all.[11] Unsurprisingly, eliminating the use of DSAs and Regions would benefit New York hospitals financially by allowing them to perform more transplants by effectively transferring more organs from rural and low-income communities with well-performing OPOs to populous areas with poor-performing OPOs, including New York.

37. In response to the critical comment, the then-HRSA Administrator, George Sigounas, acting on behalf of HHS directed UNOS to consider the critical comment and to provide a responsive comment addressing whether DSAs and Regions should continue to be used as units of allocation.[12]

38. On June 25, 2018, UNOS responded by half-heartedly defending the revised liver policy (while declining to defend the use of DSA or Regions in general) before nevertheless committing to a "plan to eliminate DSA or OPTN Regional boundaries as a component of distribution" for donated livers by December 2018.[13]

39. Unsatisfied with that response, the New York law firm filed suit challenging the liver allocation policy on July 16, 2018.[14]

40. In light of the lawsuit and the UNOS's refusal to defend the continued use of DSAs and Regions, HRSA concluded that UNOS had not justified the use of DSAs and Regions in the allocation of donated livers.[15] In a July 31, 2018 letter (the "July 31, 2018 Directive"), HRSA directed

[11] *See* Letter from George Sigounas, HRSA Administrator, to Yolanda Becker, President, OPTN (June 8, 2018), https://transplantpro.org/wp-content/uploads/sites/3/OPTN_letter_6.8.2018.pdf, at 1.

[12] *See id.* at 2–3.

[13] *See* Letter from Yolanda Becker, OPTN President, and Brian Shepard, OPTN Executive Director and UNOS CEO, to George Sigounas, HRSA Administrator (June 25, 2018), https://optn.transplant.hrsa.gov/media/2582/becker_shepard_sigounas_optn_liver_policy_20180625.pdf, at 1–2, 6.

[14] *See* Compl., *Cruz v. HHS*, No. 1:18-cv-6371 (S.D.N.Y July 16, 2018), Doc. 4.

[15] *See* Letter from George Sigounas, HRSA Administrator, to Sue Dunn, OPTN President (July 31, 2018), https://unos.org/wp-content/uploads/unos/HRSA_to_OPTN_Organ_Allocation_20180731.pdf, at 1.

the OPTN "to adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions and that is compliant with [regulations]" by December 2018.[16] As particularly relevant to this action, HRSA also concluded that "the use of DSAs and Regions in all other (non-liver) organ allocation policies has not been and cannot be justified under the OPTN final rule."[17] Accordingly, it further directed OPTN "to submit a detailed report by August 13, 2018, for review by HRSA outlining the OPTN's plans to eliminate DSAs and Regions from other (non-liver) organ-specific allocation policies."[18]

41. UNOS then proceeded to rush the development of new allocation policies that eliminated the use of DSAs and Regions altogether in accordance with the July 31, 2018 Directive. Indeed, the very same day, UNOS staff informed the OPTN Kidney-Pancreas Workgroup of the "recent HRSA letter" that "calls on the OPTN and UNOS to remove DSA and region from distribution models."[19] The next week, UNOS staff reminded the Workgroup "of [its] task: to remove DSA and regions from kidney allocation policy."[20]

D. Development of the Fixed Circle Policy

42. Following HHS's directive, UNOS developed a proposed kidney policy that eliminated the use of DSAs and Regions. The Kidney Transplantation Committee (the "Committee") published its policy proposal (the "Proposal") on the OPTN website and scheduled public comment from August 2, 2019 to October 2, 2019.[21] The Committee proposed exchanging reliance on DSAs and

[16] *See id.* at 3, 5.

[17] *See id.* at 5.

[18] *See id.*

[19] OPTN/UNOS Kidney-Pancreas Workgroup, Meeting Minutes (July 31, 2018), https://optn.transplant.hrsa.gov/media/3347/20180731_kp-meeting-meeting-summary.pdf.

[20] OPTN/UNOS Kidney-Pancreas Workgroup, Meeting Minutes (Aug. 7, 2018), https://optn.transplant.hrsa.gov/media/3348/20190807_kp-workgroup-meeting.pdf

[21] Public Comment Proposal: Eliminate the Use of DSA and Region from Kidney Allocation Policy, OPTN Kidney Transplantation Committee, https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf.

Regions "in favor of a single fixed distance circle encompassing 500 nautical miles (NM) with the donor hospital at its center."[22] Under the Proposal, waitlist candidates could receive between four and eight "proximity points" (thus increasing their chances of receiving an organ) depending on whether they fell inside or outside the fixed circle.[23]

43. On October 2, 2019, plaintiffs submitted comments on the Proposal.[24] One of the comments, which was obviously submitted before COVID-19, explained that the Proposal would lead to a host of negative consequences and did not comply with federal regulations.[25] Specifically, it noted that, according to the modeling from the government's data contractor (SRTR), the Proposal would: (1) "decrease the number of kidney transplants performed annually," (2) "increase or leave unchanged the waitlist mortality rate," and (3) "increase the graft failure rate per patient year."[26] The comment further explained that "the increased logistical complexity" of the Proposal "will inevitably increase the cold ischemic time and cost of procuring kidneys," create a greater waste of donated organs due to increased reliance on inconsistent and frequently delayed commercial flights, and would "disproportionately affect those in non-metropolitan areas without access to major airports."[27]

44. Plaintiffs' comment raised not only substantive issues with the Proposal, but also procedural issues regarding the manner in which the Proposal was developed. For example, the OPTN/UNOS justified the elimination of DSAs as necessary to address different transplant rates

[22] *See id.* at 1–2.

[23] *See id.* at 2, 11.

[24] *See* Transplant Centers' Comment regarding OPTN's Public Comment Proposal: Eliminate the Use of DSA and Region form Kidney Allocation Policy (Oct. 2, 2019).

[25] *See id.* at 1.

[26] *Id.*; *see also id.* at 3 (noting the "waitlist mortality and graft failure rates will *increase* under the Proposal's preferred 500nm policy" (citing SALLY GUSTAFSON ET AL., SCI. REGISTRY OF TRANSPLANT RECIPIENTS, ANALYSIS REPORT: UPDATE 10 (June 21, 2019), https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf)). The "graft failure rate" is the rate of transplants in which the transplanted organ does not function properly and the patient dies, requires dialysis, or needs a re-transplant. Longer cold ischemic time or improperly matched organs typically have a higher failure rate.

[27] *Id.* at 1; *see id.* at 6–8.

seen across different DSAs, which the OPTN blamed on the use of DSA in allocation and hospitals in different DSAs having varying access to donated organs. The OPTN, however, did not consider alternative explanations for the variation in transplant rates—despite the fact that variations also existed in transplant rates *within the same DSA*, suggesting other factors were responsible for the transplant rate disparities.[28] Moreover, the OPTN "inexplicably" did not ask for SRTR data regarding the Proposal's effect on underserved areas even though waitlist "candidates in rural and low socioeconomic communities are most likely to be negatively impacted by the Proposal."[29]

45. Even worse, Plaintiffs pointed out that the OPTN manipulated the data and modeling in an effort to minimize the negative consequences that would flow from the Proposal. SRTR's "initial data model raised significant red flags about the Proposal," including that it "would result in 1,000 fewer kidney transplants performed nationally each year" and "possibly almost 2,000 fewer transplants."[30] But the OPTN did not reconsider its suggested policies in response to these alarming predictions; it instead "directed that the data model . . . be changed to produce the results it wanted."[31] Significantly, the revised model did not consider how far an organ would travel between the donor and the recipient,[32] and the OPTN knew that selecting that revised model would be "[l]ess likely to predict a decrease in transplant[s]."[33]

[28] *Id.* at 1.

[29] *Id.*

[30] *Id.* at 1, 9.

[31] *Id.* at 1; *see id.* at 9–11 (detailing how the model was changed).

[32] *See id.* at 10–11.

[33] Minutes, OPTN/UNOS Kidney Transplantation Committee, (Mar. 25, 2019), https://optn.transplant.hrsa.gov/media/2935/20190325_kidney_meeting_minutes.pdf.

46. After the public comment period ended, the Kidney Committee submitted a briefing paper to the OPTN Board of Directors in November 2019.[34] Although the Committee had previously proposed replacing the DSAs and Regions with a fixed circle of 500 nautical miles, it now proposed a radius of 250 nautical miles even though it had not published a policy proposing a 250-mile circle for public comment.[35]

47. Accordingly, some of the plaintiffs submitted a comment to the OPTN Board on November 27, 2019 regarding the revised policy proposal.[36] In the comment, plaintiffs outlined that: (1) the revised proposal would hurt patients and failed to comply with federal regulations; (2) the Committee and the OPTN failed to provide scientific justification for the decision to switch models after the first model raised red flags with the Proposal; and (3) the Committee failed to properly solicit public comments on the revised proposal that relied on a radius of 250 nautical miles.[37] Specifically, the comment explained that, with the revised proposal, "[a]t best, there will be 300 *fewer* kidney transplants performed annually . . . , and there may be a decrease of as many as nearly 1,800 transplants annually."[38] Furthermore, the comment noted that the waitlist mortality count and graft failure rates would increase, meaning "more patients will surely die" under the revised policy because that is the natural consequence of "fewer transplants, increased waitlist mortality, and increased failed transplants."[39]

[34] Briefing to the OPTN Board of Directors on Elimination of DSA and Region from Kidney Allocation Policy, OPTN Kidney Transplantation Committee (Nov. 2019), https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf.

[35] *See id.* at 1.

[36] *See* Transplant Center Letter to OPTN Board Members (Nov. 27, 2019).

[37] *See id.* at 1.

[38] *Id.* at 1.

[39] *Id.* at 1–2.

48. Nevertheless, the OPTN Board approved the revised policy on December 3, 2019.[40] Under the approved new kidney allocation policy (the "Fixed Circle Policy"), DSAs and Regions will no longer be "units of allocation."[41] Instead, the allocation of kidneys will rely on "a 250 nautical mile (NM) fixed-distance circle with the donor hospital at its center" and "proximity points."[42] Waitlist candidates inside the 250-mile circle "can receive a maximum of 2 proximity points" to their total score, which increases their chance of receiving an organ.[43] If the kidney will be allocated outside of that circle, "proximity points are then awarded to candidates outside of that circle" based on how close a candidate is to the donor hospital.[44]

49. The Fixed Circle Policy does not consider logistical factors affecting transportation between the donor hospital and the candidate: It does not consider the number of direct flights available, the average flight times, or the average travel time by roadways; it only considers the distance in "nautical miles."[45] And, although the OPTN recognized that the new policy will require OPOs to work with certain transplant hospitals "for the first time" and may require those entities to "develop[] working relationships to address issues such as sharing donor information and coordinating recoveries," it failed to consider how the lack of pre-existing relationships may lead to increased operational difficulties and poor post-transplant outcomes.[46]

50. The Fixed Circle Policy also fails to consider the effect on racial disparity, as it is required to do. Black Americans are three times as likely to suffer from kidney failure as white

[40] Notice of OPTN Policy Changes: Eliminate the Use of DSA and Region form Kidney Allocation Policy, OPTN (Dec. 2019), https://optn.transplant.hrsa.gov/media/3452/kidney-removal-of-dsa-policy-notice.pdf.

[41] *Id.* at 2.

[42] *Id.*

[43] *Id.*

[44] *Id.*

[45] *Id.*

[46] *Id.*

Americans, yet are significantly less likely to be put on the transplant waitlist, as well as less likely to receive a lifesaving transplant even once they are. This is in part because OPOs do not prioritize organ recovery from Black patients. Since same-ethnicity donors and recipients are more likely to be clinical matches for transplant, fewer Black donors means fewer Black recipients, which means more Black deaths. UNOS failed to consider this problem and instead exacerbated it. The five states with the highest burden of end-stage kidney disease are Louisiana, Mississippi, Alabama, Georgia, and South Carolina. But the state that is projected to benefit the most from the Fixed Circle Policy is New York, which will see a 124% increase in transplants (e.g., 497 additional kidney transplants) even though it serves a population that is only 14% African American and has a disease burden that is a third lower than Louisiana, Mississippi, Alabama, Georgia, and South Carolina.

51. At a virtual board meeting in June 2020, UNOS indicated that it would implement new policies related to medical urgency and donors in Alaska, along with the Fixed Circle Policy, in late 2020.[47] On October 20, 2020, UNOS announced an implementation date of December 15, 2020.[48]

52. Neither HHS nor UNOS has not evaluated the impact of COVID-19 on the Fixed Circle Policy nor has it publicly considered the need to delay the policy's implementation in light of the current pandemic.

E. Plaintiffs Request that HHS Take Action

53. On December 1, 2020, Plaintiffs submitted a comment to Secretary Azar that detailed several shortcomings of the Fixed Circle Policy, the unlawful manner in which UNOS developed it, and the dangers of fundamentally changing an organ allocation policy during a global pandemic. Plaintiffs thus requested that HHS (1) suspend the implementation of the Fixed Circle Policy;

[47] *Additional Provisions Adopted to Upcoming Kidney, Pancreas Distribution System*, HHS, https://optn.transplant.hrsa.gov/news/additional-provisions-adopted-to-upcoming-kidney-pancreas-distribution-system/.

[48] Dec. 15 Implementation Date Set for Changes to Kidney, Pancreas Allocation, UNOS (Oct. 20, 2020), https://unos.org/news/dec-15-implementation-date-set-for-changes-to-kidney-pancreas-allocation/.

(2) instruct UNOS to present HHS with the policy at least sixty days before implementation; (3) submit the policy to the Advisory Committee for review; (4) publish the policy to the Federal Register; and (5) implement any change in a kidney allocation policy only after it has been carefully evaluated by neutral parties considering all the comments and evidence, along with the pandemic's impact.

54. In support of this request, Plaintiffs explained that "a subset of individuals within the transplant community, many of whom stand to benefit financially from a change in allocation policy that eliminates DSAs, successfully captured control of the entity that operates the OPTN."[49] And Plaintiffs cited to evidence to support that claim.[50] In litigation challenging the revised liver allocation policy, the court found that there was "certainly colorable evidence of animosity and even some measure of regional bias against transplant community professionals who advocated for continued use of DSAs or Regions."[51] The court concluded the materials "show[ed] that some of the major players within the transplant community," who "enjoyed particularly close access to the ear of UNOS's executives during the volatile events of 2018 and 2019," "had strongly held views in favor of new allocation policies [that removed reliance on DSAs or Regions] that aligned with their locations and institutional interests."[52] It is thus unsurprising that UNOS adopted a policy that was projected to give "[a]reas such as New York State, with greater urban populations" and higher rates of insurance coverage a greater number of organs,[53] while disregarding the evidence that the policy would increase

[49] *See id.* at 2.

[50] *See id.*

[51] *See* Mem. Op., No. 1:19-cv-01783 (Jan. 16, 2020), Doc. 261, at 77.

[52] *Callahan v. HHS*, 434 F. Supp. 3d 1319, 1363 (N.D. Ga. 2020); *see id.* at 1364 (noting the plaintiffs "proffered evidence of bad faith, undisclosed ex parte communications, and improper predetermination by [UNOS]").

[53] *Id.* at 1335.

organ waste, poor post-transplant outcomes, and waitlist mortality, and would decrease the overall number of kidney transplants performed.[54]

55. Citing UNOS'sbad faith, Plaintiffs urged HHS to exercise its regulatory authority and request that the OPTN provide the Fixed Circle Policy to HHS sixty days before implementation so HHS could review the policy, publish it to the Federal Register, solicit public comments, and determine whether that policy is consistent with the Transplant Act and regulations, taking into account Plaintiffs' comment and public comments.[55]

56. Plaintiffs further noted that HHS was responsible for the ill-conceived policy, because it specifically directed, in its July 31, 2018 Directive, removal of DSAs and Regions from all organ allocation policies without regard to what the data, modeling, or future analyses would show regarding contemplated revisions to allocation policies for other organs.[56] That directive was troubling enough to the extent it departed from regulatory requirements and sound scientific practices, but it has become even more egregious given what the subsequent data showed and the emergence of the COVID-19 pandemic.[57]

57. Plaintiffs then proceeded to elaborate on the reasons that it is unlawful and dangerous to change the kidney allocation policy during the COVID-19 pandemic. *First*, it is arbitrary, capricious, and an abuse of discretion to fundamentally change an organ allocation policy, which would require hospitals to overhaul operations and explain complex policy changes to patients and staff, while those hospitals are attempting to care for an increasing number of patients due to an ongoing pandemic.[58] That is especially true given that implementation is scheduled to occur as COVID-19 cases are spiking

[54] *See* Dec. 1, 2020 Comment, at 12.

[55] *See id.* at 2–3 (citing 42 C.F.R. § 121.4(b)(2), (d)(2)).

[56] *See id.* at 3.

[57] *See id.* at 3–4.

[58] *See id.* at 4–6.

and epidemiologists are projecting a record number of deaths.[59] *Second*, implementing a policy change during this pandemic will prevent HHS and UNOS from complying with the regulatory mandate that changes in allocation policies be measured to assess whether performance goals are being achieved.[60] Indeed, SRTR is already reporting that "COVID-19 has had a large impact on the transplant system,"[61] and "research has shown that 'COVID-19 has affected virtually all aspects of kidney transplantation."[62] Further complicating matters, COVID-19 has had different effects in different parts of the country, which would make it impossible to ascertain how any new kidney allocation policy affects the geographic equity of kidney transplants.[63] And this impossibility has been borne out in the liver allocation context: SRTR has not been able to determine the "true impact" of the policy change due to COVID-19 although it knows that the number of liver transplants has declined.[64] *Third*, HHS must evaluate the Fixed Circle Policy in light of the pandemic because COVID-19 has impacted both the transplant system generally and the commercial airline industry on which the Fixed Circle Policy so heavily relies to transport donated kidneys farther distances.[65] Plaintiffs cited the decreased flight availability, including the cancellation of all direct flights between certain cities, the increased

[59] *See id.* at 1 (citing Reed Abelson, *Covid Overload Pushes Hospitals to the Brink*, N.Y. Times (Nov. 28, 2020)).

[60] *See id.* at 6–9.

[61] *See id.* at 6 (quoting *COVID-19 Changes: Upcoming Adjustments to Transplant Program and OPO Evaluation Metrics*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS (Aug. 6, 2020), https://www.srtr.org/news-media/news/news-items/news/#covid19psrosrchanges)

[62] *See id.* at 6–7 (quoting Brian J. Boyarsky, *Early National & Center-Level Changes to Kidney Transplantation in the United States During the COVID-19 Epidemic* 3132 (June 28, 2020), available at https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.16167)

[63] *See id.* at 7–9 (explaining, for example, that the waitlist mortality "was 2.2-fold higher than expected in the 5 states with highest COVID-19 burden" (quoting Boyarsky, at 3136))).

[64] *See id.* at 7–8).

[65] *See id.* at 9–11.

wait times between connecting flights, and the increased flight cancellations as factors that "could significantly increase [cold ischemic time] while worsening recipient posttransplant outcomes."[66]

58. Plaintiffs next set forth the various ways that the Fixed Circle Policy would be detrimental to patients, even setting aside the negative repercussions of COVID-19, and was adopted in a procedurally improper manner based on flawed modeling. *First*, the Fixed Circle Policy will increase patient deaths by (1) reducing the number of kidney transplants by at least 250 transplants, (2) increasing waitlist mortality, and (3) increasing graft failure rates.[67] *Second*, the Fixed Circle Policy relies on flawed modeling that understates the reduction in kidney transplants and failed to even account for the distance an organ would travel.[68] SRTR's first analysis demonstrated that the proposed allocation changes would result in "*at least 1,000 fewer kidney transplants* performed nationally each year" and "possibly 2,000 fewer transplants" so UNOS directed SRTR to approach the model differently.[69] SRTR did so and gave UNOS two new model options that would change the acceptance rate of the donated kidneys, making the predicted reduction in the number of transplants lower.[70] Out of those two new options, UNOS chose the model that was known to be less likely to predict a decrease in transplant rates, with no explanation, and ignored "the distance the organ must travel to reach the transplant center (as an approximation of time)," which "is absolutely a factor that surgeons take into consideration when determining whether or not to accept an organ."[71] *Third*, the Fixed Circle Policy does not properly account for disparities in transplant rates for low socioeconomic status candidates.[72]

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[66] *See id.* at 10 (quoting Alexandra T. Strauss, et al., *Impact of the COVID-19 Pandemic on Commercial Airlines in the United States and Implications for the Kidney Transplant Community* 3129 (Aug. 19, 2020), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16284).

[67] *See id.* at 11–12.

[68] *See id.* at 14–15.

[69] *See id.* at 14.

[70] *See id.* at 14–15.

[71] *See id.*

[72] *See id.* at 16–17.

Indeed, the SRTR specifically did not model the impact of the Fixed Circle Policy based on cumulative community risk scores.[73]

F. HHS Fails to Act, Necessitating this Lawsuit

59. Despite Plaintiffs' critical comment and the impending implementation date of the unlawful Fixed Circle Policy, HHS has not acceded to Plaintiffs' request or otherwise responded. This suit thus became necessary to compel Defendants to comply with the statutory and regulatory framework governing kidney transplants, which has significant consequences for Plaintiffs, including life-or-death consequences for their patients.

60. If this unlawful kidney allocation policy is implemented, Plaintiffs will be harmed by the administrative burden of redirecting resources from addressing the pandemic to overhauling their systems and educating staff and patients about the new policy.

61. Plaintiffs will also suffer financial hardship due to the Fixed Circle Policy. Plaintiffs' patients will be allocated fewer donated organs, which will lead to fewer kidney transplants, and the costs of kidney transplants will increase due to additional transportation costs and administrative burdens. The decreased volume of transplants and increased costs could threaten the long-term viability of Plaintiffs' transplant programs, as well as make it difficult to retain qualified medical specialists.

62. Plaintiffs' patients will also suffer greatly under the Fixed Circle Policy. Many of Plaintiffs' patients will not receive organs that they would have otherwise received under the previous policy. What is more, Plaintiffs' patients, as well as other waitlist patients, will be harmed by the increased costs of kidney transplants, the increased waitlist mortality rates, and the increased graft failure rates.

[73] *See id.* at 16.

CAUSES OF ACTION

COUNT I: APA, 5 U.S.C. § 706(2)(A)
HHS'S JULY 31, 2018 DIRECTIVE WAS ARBITRARY AND CAPRICIOUS, AN ABUSE OF DISCRETION, AND OTHERWISE NOT IN ACCORDANCE WITH LAW

63. Plaintiffs repeat and incorporate by reference the allegations contained in prior paragraphs.

64. The APA authorizes suit by "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute," 5 U.S.C. § 702, and mandates that "a reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *id.* § 706(2).

65. HHS acted arbitrarily, capriciously, and unlawfully by issuing the July 31, 2018 Directive that instructed OPTN to remove DSAs and Regions from *all* organ allocation policies in response to a critical comment that addressed the use of DSAs and Regions in the *liver* allocation policy. This directive deprived interested parties of the opportunity to submit critical comments related to whether non-liver organ allocation policies should retain the use of DSAs and Regions and precluded HHS's consideration of such comments, violating regulatory provisions that require the availability of such an opportunity. *See* 42 C.F.R. § 121.4(d); *see also* 42 U.S.C. § 274(c).

66. Moreover, HHS failed to consider important aspects of the problem before issuing this directive and failed to "supply a reasoned analysis for the change." *See Motor Vehicle Mfs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983). Indeed, it never even considered evidence and arguments relating to the use of DSAs and Regions to allocate other organs; it simply assumed the use of DSAs and Regions could not be justified under any circumstances for those policies based on evidence regarding the liver allocation policy. This was arbitrary and

capricious, especially given the requirement that allocation policies "be specific for each organ type." 42 C.F.R. § 121.8(a)(4).

67. Additionally, HHS's directive was arbitrary and capricious because it was based on a legally erroneous view that the use of DSAs or Regions was necessarily inconsistent with the regulations.[74] *See Safe Air for Everyone v. EPA*, 488 F.3d 1088, 1101 (9th Cir. 2007) (concluding an agency's determination violates 5 U.S.C. § 706(2)(A) when it is based on a legally erroneous premise). In reality, regulations allow—and require—geographic factors to be considered when necessary to enable an allocation policy to achieve other criteria, such as "the best use of donated organs" and avoiding organ wastage and futile transplants. *See* 42 C.F.R. § 121.8(a)(2), (5).

68. The July 31, 2018 Directive constitutes a final agency action, because it was the "consummation of the agency's decisionmaking process" with legal consequences. *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S.Ct. 1807, 1813 (2016) (quotation omitted). HHS's conclusion that the use of DSAs and Regions was legally impermissible and its mandate that organ allocation policies not rely on DSAs and Regions was a final decision. Indeed, HHS has refused to take further action required by the regulations, such as publishing the Fixed Circle Policy in the Federal Register, demonstrating HHS's view that it has acted with finality in prohibiting the use of DSAs and Regions. And "legal consequences" flowed from HHS's action, *id.*, Plaintiffs cannot rely on the use of DSAs or Regions in operating their kidney transplant programs if they wish to continue participating in the Medicare program, *see* 42 U.S.C. § 1320b-8(a)(1)(B).

69. This directive has serious and detrimental consequences for Plaintiffs and their patients. As a result of the elimination of the use of DSAs and Regions in the kidney allocation policy, there will be fewer kidney transplants nationally and significantly fewer transplants in the Plaintiffs' communities, which severely impacts Plaintiffs as they will experience economic harm due to

[74] *See* July 31, 2018 Directive, at 3.

decreased volume and increased costs. Plaintiffs' patients will also be injured, because many patients will not receive organs that they would have received under a policy that used DSAs and Regions. Furthermore, Plaintiffs' patients, as well as all waitlisted patients, will be harmed by increased waitlist mortality rates and increased graft failure rates.

COUNT II: APA, 5 U.S.C. § 706(1)
HHS UNLAWFULLY FAILED TO ACT

70. Plaintiffs repeat and incorporate by reference the allegations contained in prior paragraphs.

71. Where an agency action has been "unlawfully withheld or unreasonably delayed," the APA provides that "[t]he reviewing court shall . . . compel [such] agency action." 5 U.S.C. § 706(1).

72. When OPTN proposes significant policies, the regulations dictate that "[t]he Secretary *will refer* significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and *publish them* in the Federal Register for public comment." 42 C.F.R. § 121.4(b)(2) (emphases added). The regulations further dictate that the Secretary "*will* determine whether the proposed policies are consistent with [the Transplant Act] and this part, taking into account the views of the Advisory Committee and public comments." *Id.* (emphasis added).

73. Yet HHS failed to take these actions here even though the Fixed Circle Policy is a significant policy with enormous ramifications for the almost 100,000 Americans currently on the waiting list for kidneys and for Plaintiffs, which must implement the complex and inefficient policy that harms its patients. HHS did not refer the Fixed Circle Policy to the Advisory Committee, it did not publish the policy in the Federal Register so the proposal could benefit from full notice-and-comment procedure, and it did not determine whether the Fixed Circle Policy was consistent with the Transplant Act and the regulations. These failures to act were unlawful under a proper interpretation of the regulations.

74. What is more, even under alternative interpretations of the regulations, HHS's failure to take these actions would nevertheless be unlawful. *First*, even if the Secretary's requirement to take these actions is triggered only if he receives the proposed significant policy, the Secretary received the Fixed Circle Policy, thereby triggering his requirement to take these actions. The Secretary constructively received the Fixed Circle Policy through HRSA employees who attended the OPTN meetings discussing the policy and through two HRSA employees who are ex officio members of the OPTN's Kidney Transplantation Committee. *Second*, even if the Secretary was not required to take these actions unless the Secretary formally—and nonsensically—requests transmittal of a policy he already has, then the Secretary was implicitly required to "direct[]" transmittal of "significant proposed policies" under 42 C.F.R. § 121.4(b)(2). In that case, the Secretary simply failed to take yet another legally required action. *Third*, even if the Secretary is only required to refer a proposed policy to the Advisory Committee, publish it in the Federal Register, and determine whether it is consistent with the Transplant Act and regulations if (1) the OPTN recommends that the proposed policy be enforceable or (2) the proposed policy is significant and on a matter the Secretary directs, the Fixed Circle Policy falls in the latter category.

75. Accordingly, under any interpretation of the regulations, HHS failed to take legally required actions. These failures to act violated the APA and will have a severe and detrimental effect on Plaintiffs.

COUNT III: APA, 5 U.S.C. § 706(2)(A)
HHS'S AND OPTN'S ADOPTION AND IMPLEMENTATION OF THE FIXED CIRCLE POLICY WAS ARBITRARY AND CAPRICIOUS, AN ABUSE OF DISCRETION, AND OTHERWISE NOT IN ACCORDANCE WITH LAW

76. Plaintiffs repeat and incorporate by reference the allegations contained in prior paragraphs.

77. Under the APA, "a reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and "without observance of procedure required by law." 5 U.S.C. § 706(2).

78. The Fixed Policy is arbitrary, capricious, and unlawful because HHS and UNOS developed and adopted it in violation of the Transplant Act and regulations. The Transplant Act and the regulations mandate that, in developing an organ allocation policy, OPTN "[p]rovide opportunity for the OPTN membership and other interested parties to comment on proposed policies *and shall take into account the comments received* in developing and adopting policies for implementation by the OPTN." 42 C.F.R. § 121.4(b)(1) (emphasis added); *see* 42 U.S.C. § 274(a)(2)(B) (requiring OPTN to "provide to members of the public an opportunity to comment with respect to such criteria [for allocating organs]"). But UNOS failed to give Plaintiffs a meaningful opportunity to comment and it failed to take comments it received into account, because it had reached a pre-determined outcome: DSAs and Regions must be eliminated and the new policy needed to benefit certain areas, such as New York, that aligned with the institutional interests of certain major players within the transplant community.

79. The regulations also mandate, *inter alia*, that allocation policies (1) "be based on sound medical judgment"; (2) "seek to achieve the best use of donated organs"; and (3) "be designed to avoid wasting organs" and "futile transplants," and "promote the efficient management of organ

placement." *Id.* § 121.8(a)(1)-(2), (4)-(5). Once again, HHS and UNOS disregarded this mandate, making the adoption and implementation of the Fixed Circle Policy unlawful. As a preliminary matter, the Fixed Circle Policy could not "be based on sound medical judgment," because UNOS immediately rejected (at HHS's direction and at the behest of major players with regional biases) any policy that relied on DSAs or Regions without regard to what the evidence showed regarding whether reliance on DSAs or Regions for allocation of kidneys yielded a better policy. Such an approach stands at odds with science and sound medical judgment. It also precluded UNOS from developing an allocation policy that satisfied other § 121.8(a) factors, because UNOS chose the Fixed Circle Policy without determining that it would achieve a better use of donated organs or that it would better avoid wasted organs and futile transplants than a policy that relied on DSAs or Regions. Furthermore, UNOS failed to base the Fixed Circle Policy on "sound medical judgment" or design it to avoid wasting organs and unsuccessful transplants, because it selected a model that failed to consider the distance that organs would travel—an indisputably significant factor to the medical community that impacts organ waste and post-transplant outcomes.

80. The adoption and implementation of the Fixed Circle Policy was similarly arbitrary and capricious and an abuse of discretion, because HHS and UNOS failed to consider important aspects of the problem of developing an equitable and efficient allocation policy. *See State Farm*, 463 U.S. at 43. Not only did UNOS fail to consider regulatory factors that it was required to consider, but it also failed to consider the anticipated impact of the Fixed Circle Policy on underserved communities or racial disparity by having SRTR model the cumulative community risk score. *See* 42 C.F.R. § 121.4(3)(iv). It likewise failed to consider transportation and operational difficulties with the revised policy that will have a disproportionate impact on individuals in less-populated regions.

81. HHS's and UNOS's decision to schedule the implementation of the Fixed Circle Policy in the middle of a pandemic is also arbitrary and capricious and an abuse of discretion. The

COVID-19 pandemic has had dramatic effects on the U.S. health care system generally and on the transplant system specifically, making it unduly onerous and dangerous to make a fundamental change to a long-standing transplant policy unrelated to COVID-19 at this time. Moreover, COVID-19 has disrupted the commercial airline industry, making it especially arbitrary and capricious for HHS and UNOS to implement a new policy on December 15, 2020 that relies on commercial flights when that policy was developed without consideration of the pandemic's effects. What is more, the pandemic will prevent UNOS from complying with its obligations to evaluate the impact of the revised allocation policies and will prevent HHS from assessing allocation policies as required. This too demonstrates that HHS's and UNOS's decision to implement the Fixed Circle policy on December 15, 2020 is arbitrary and capricious.

82. Finally, it is arbitrary and capricious for HHS to implement the Fixed Circle Policy in light of UNOS's bad faith.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court:

A. enter a judgment declaring that the Fixed Circle Policy and July 18, 2018 directive violates the Transplant Act and federal regulations;

B. enter a judgment declaring that the Fixed Circle Policy and the July 18, 2018 directive violate the APA and setting them aside in their entirety;

C. enter a preliminary injunction enjoining Defendants from implementing the Fixed Circle Policy and postponing the implementation date until Plaintiffs' claims are resolved on the merits;

D. enter a permanent injunction enjoining Defendants from implementing the Fixed Circle Policy;

E. grant Plaintiffs such additional or different relief as the Court deems just and proper, including an award of reasonable attorneys' fees and the costs of this action.

Dated: December 9, 2020

Respectfully submitted,
/s/ Stephen H. Locher

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