IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

RANDALL CALLAHAN, KATRYNA GRISSON, CANDICE SEAMAN, MICHAEL WINGATE, EMORY UNIVERSITY D/B/A EMORY UNIVERSITY HOSPITAL, HENRY FORD HEALTH SYSTEM, INDIANA UNIVERSITY HEALTH, OREGON HEALTH & SCIENCE UNIVERSITY, PIEDMONT HEALTHCARE, THE RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA on behalf of its Medical Center, THE REGENTS OF THE UNIVERSITY OF MICHIGAN on behalf of its academic medical center, Michigan Medicine, SAINT LUKE'S HOSPITAL OF KANSAS CITY, 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, VANDERBILT UNIVERSITY MEDICAL CENTER, VIRGINIA COMMONWEALTH UNIVERSITY HEALTH SYSTEM AUTHORITY, THE WASHINGTON UNIVERSITY, and BARNES-JEWISH HOSPITAL, Plaintiffs, v.	)	CIVIL ACTION NO. _____

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES through ALEX M. AZAR II in his official capacity as Secretary of the United States Department of Health and Human Services, and UNITED NETWORK FOR ORGAN SHARING,

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. The Department of Health and Human Service ("HHS") is on the brink of implementing an unlawful liver allocation policy that will result in hundreds of liver transplant candidates needlessly dying, as donated organs are misdirected and tossed away under the new policy, rather than being used for the life-saving purpose intended by their generous donors.

2. Defendants inexplicably adopted this policy in obvious and unwarranted haste, based on demonstrably faulty assumptions, and without due consideration of applicable law.

3. HHS has failed to follow legally-required procedures in developing the policy, instead choosing to defer virtually all decision-making to a private government contractor, United Network for Organ Sharing, acting in its capacity as the Organ Procurement and Transplantation Network. Federal law does not allow HHS to abdicate its responsibility of determining whether critical organ allocation policies—which directly impact thousands of lives—are legally compliant.

4. Because these actions violate the Administrative Procedure Act as well as the Due Process Clause of the Fifth Amendment, Plaintiffs respectfully request that the Court declare this policy unlawful and enjoin its implementation.

PRELIMINARY STATEMENT

5. Patients suffering from end-stage liver disease have a single option for survival—a liver transplant. As of April 16, 2019, there were 13,144 individual candidates on the liver "waitlist." Ex. 1. Approximately 11,000 candidates are added to the waitlist each year, while only 7,000 deceased donors gift livers for transplant.

6. The waitlist currently includes Plaintiffs Randall Callahan, Katryna Grisson, Candice Seaman, and Michael Wingate (collectively "Patient Plaintiffs") and many other patients served by Plaintiffs Emory University d/b/a Emory University Hospital, Henry Ford Health System, Indiana University Health, Oregon Health & Science University, Piedmont Healthcare, The Rector and Visitors of the University of Virginia, The Regents of the University of Michigan, Saint Luke's Hospital of Kansas City, University of Iowa, University of Kansas Hospital Authority d/b/a University of Kansas Health System Authority, University of Kentucky, Vanderbilt University Medical Center, Virginia Commonwealth University Health System Authority, and The Washington University with Barnes-Jewish Hospital, each of which operates a liver transplant program (collectively, "Transplant Center Plaintiffs").

7. The National Organ Transplant Act ("NOTA"), enacted in 1984, established an infrastructure for oversight of the then-new field of transplant medicine. NOTA created the Organ Procurement and Transplantation Network ("OPTN") and required that HHS engage a non-profit contractor to operate the OPTN. Defendant United Network for Organ Sharing ("UNOS") serves in this role. *See* Ex. 2. UNOS, in its capacity as the OPTN, manages the national system that matches donated organs with recipients and develops allocation policies that prioritize recipients and determine which candidates are offered which organs.

8. Through NOTA and its implementing regulations, Congress and HHS imposed several legal requirements for how organ allocation policies must be developed, how the public is to be informed of and given opportunity to comment on policy proposals, and how HHS must oversee the policy development. This process was designed so that allocation policies would reflect the OPTN's expertise in organ transplant matters, but would be adopted and approved only after a full and transparent public debate and authorization by HHS to ensure significant policies complied with the law. In this case, HHS completely failed to follow these procedural mandates.

9. In December 2017, following a careful, multi-year deliberative process, the OPTN Board adopted a new liver allocation policy and announced it would take

effect one year later, in December 2018. But this policy was never implemented. In May 2018, a New York plaintiffs' attorney submitted a statement in opposition to the policy and subsequently filed suit against HHS and UNOS. In response, HHS's Health Resources and Services Administration ("HRSA") division, which oversees the OPTN, made the abrupt decision to abandon that policy. Instead, HRSA directed the OPTN to adopt a new liver allocation policy in accordance with the attorney's demands and set an unreasonable deadline of four months later.

10. HRSA's directive to develop a new policy within this incredibly limited timeframe resulted in an unlawful decision-making process and illegal allocation policy that was adopted by the OPTN Board of Directors in December 2018. This wholly non-compliant policy is set to take effect on April 30, 2019.

11. Organ allocation policies are required to "seek to achieve the best use of donated organs," "be designed to . . . promote patient access to transplantation," 42 C.F.R. § 121.8(a), and to be reformed "based on assessment of their cumulative effect on socioeconomic inequities." 42 C.F.R. § 121.4(a)(3)(iv). The OPTN's policy at issue in this case does none of these things. It will result in at least 20% fewer liver transplants being performed in the most socioeconomically disadvantaged regions in the country, which are served in part by Transplant Center Plaintiffs' liver transplant programs. Based on the government's own data,

Transplant Center Plaintiffs will perform 256 fewer transplants per year—leaving 256 candidates at risk of imminent death absent the transplant they would have otherwise received. Notably, this reduced number does not even account for the increased air transportation of organs and other system inefficiencies, which are expected to further decrease the number of transplants performed nationally under the new policy.

12. This unlawful policy was the product of an opaque, reckless process that failed to allow for full public comment and transparent discussion and deprived Plaintiffs of adequate due process. The OPTN's expert liver committee did not have sufficient time to review, and was not even sent, public comments by key constituencies before voting on a policy to recommend to the OPTN Board. Then, without any public notice, the OPTN Board made the exceptionally rare decision to reject the committee's recommended policy and instead adopt a wholly different policy that is now set to be implemented on April 30, 2019.

13. HHS, meanwhile, stood idly by and failed to take required action in multiple instances. HHS—not the OPTN—is charged with "determin[ing] whether the proposed policies are consistent with the National Organ Transplant Act and this part." 42 C.F.R. § 121.4(b)(2). But HHS has thus far failed to do so, even in the face of the looming April 30, 2019 implementation deadline. Remarkably, the

Secretary has suggested that his "cards are played out" and he cannot intervene, despite the fact that the Secretary has clear legal authority and the obligation to determine whether the policy complies with law. Ex. 3. The Secretary cannot delegate an inherently governmental function to the OPTN and then shirk his mandated oversight responsibility when the policy's legality is questioned.

14. HHS also failed to publish the policy proposal in the Federal Register and failed to seek input from the Advisory Committee on Organ Transplantation, as the law requires for "significant" policy proposals. *See* 42 C.F.R. § 121.4(b)(2); 54 Fed. Reg. 51,802 (Dec. 18, 1989). This is particularly troubling because the Secretary himself acknowledged during a recent Senate hearing that the disputed liver allocation policy is "significant." Indeed, there is simply no argument that a policy that will dictate the distribution of life-saving organs to over 13,100 waitlisted candidates is not significant. Under the Administrative Procedure Act, HHS must comply with these discrete and mandatory requirements set forth in the regulation.

15. To be clear, Plaintiffs are not asking to impose any one specific alternative policy, nor are they seeking preferential treatment. Rather, Plaintiffs simply ask that Defendants enforce the regulatory process requirements, and in doing so, develop a liver allocation policy that complies with the law.

16. Without judicial intervention, the unlawful new policy will have a devastating effect on Plaintiffs. Patient Plaintiffs are at grave risk of dying before they receive a liver transplant. This policy will result in fewer liver transplants performed nationally and considerably fewer liver transplants performed in the communities that the Transplant Center Plaintiffs serve. Dramatically longer travel times for available organs and logistical inefficiencies will cause an increased percentage of viable livers to go to waste. These cumulative effects and others create significantly increased costs for the national health care system and economic harm to Transplant Center Plaintiffs, threaten the long-term financial viability of Transplant Center Plaintiffs' liver transplant programs, and immediately endanger the lives of the Patient Plaintiffs. In short, these unlawful actions will greatly harm Plaintiffs. Most concerning, a significant number of liver transplant candidates, including Patient Plaintiffs, will very likely die if this policy is allowed to take effect.

PARTIES AND JURISDICTION

17. Randall Callahan is a retired school teacher who lives in Vidalia, Georgia. Mr. Callahan has served as a quarterbacks coach and advisor for the Fellowship of Christian Athletes for the Toombs County schools. Mr. Callahan suffers from non-alcoholic steatohepatitis and has been listed for a liver transplant at Emory University Hospital since December 2018.

18. Katryna Grisson is a 50-year-old mother of five from Morven, Georgia. She has autoimmune hepatitis and was listed for a liver transplant at Emory University Hospital in 2014. She was described by her local paper as "your typical Southern lady" and is an active member of her church.

19. Candice Seaman is a mother of two young children who has previously served as both a teacher and school counselor in Waverly, Kansas. She has biliary atresia, which is a serious condition that appears in infancy. She is on the liver transplant waitlist through the University of Kansas Health System.

20. Michael Wingate is a 58-year-old gentleman from Frankfort, KY with end-stage liver disease presumed to be caused by non-alcoholic steatohepatitis. He has been treated at the University of Kentucky since May 2018.

21. Emory University d/b/a Emory University Hospital ("Emory") operates a transplant center located in Atlanta, Georgia. Emory performed the first liver transplant in Georgia in 1987 and has performed approximately 2,500 liver transplants since then.

22. Piedmont Healthcare ("Piedmont") operates a transplant center in Atlanta, Georgia, which has performed over 1,200 liver transplants since 1988. Piedmont and Emory are the only two adult liver transplant programs in the State of Georgia.

23. Henry Ford Health System ("Henry Ford") operates a transplant center in Detroit, Michigan, which has performed almost 1,900 liver transplants since 1989.

24. The Regents of the University of Michigan, through its academic medical center, Michigan Medicine ("Michigan Medicine") operates a transplant center in Ann Arbor, Michigan, which has performed nearly 2,500 liver transplants since 1985.

25. Indiana University Health ("Indiana University") operates the only transplant center in Indiana, which has performed over 2,800 liver transplants since 1988.

26. The University of Iowa operates the only liver transplant program in Iowa and has performed approximately 900 liver transplants.

27. The University of Kansas Hospital Authority d/b/a the University of Kansas Health System ("University of Kansas") operates the only liver transplant program in Kansas, and has performed nearly 1,600 transplants since 1990.

28. The University of Kentucky operates a liver transplant program in Kentucky and has performed over 850 liver transplants since 1995.

29. Saint Luke's Hospital of Kansas City ("Saint Luke's") operates a liver transplant program in Kansas City, Missouri. Saint Luke's has performed approximately 70 liver transplants in the past five years.

30. Oregon Health & Science University ("Oregon Health") operates a liver transplant program in Portland, Oregon, which has performed over 1,000 transplants since the program began in 1988.

31. Vanderbilt University Medical Center ("Vanderbilt") operates a liver transplant program in Nashville, Tennessee, which has performed more than 2,100 liver transplants since 1991.

32. Virginia Commonwealth University Health System Authority ("Virginia Commonwealth") operates a liver transplant program in Richmond, Virginia and has performed nearly 1,500 adult transplants since 1987.

33. The Rector and Visitors of the University of Virginia ("University of Virginia") operates a liver transplant program through its Medical Center in Charlottesville, Virginia, which has performed over 1,600 liver transplants since 1988.

34. The Washington University and Barnes-Jewish Hospital jointly operate a transplant center ("Barnes-Jewish") with a liver transplant program in St. Louis, Missouri, which has performed over 2,100 liver transplants since 1985.

35. Defendant Alex M. Azar II is the Secretary of HHS, located at 200 Independence Avenue, S.W., Washington, DC 20201. Defendant Azar is sued in his official capacity. The OPTN was established by NOTA. By congressional

mandate, the Secretary of HHS is responsible for contracting for the establishment and operation of the OPTN consistent with the requirements of NOTA. 42 U.S.C. § 274(a).

36. Defendant United Network for Organ Sharing ("UNOS") is a Virginia tax-exempt organization. HRSA has contracted with UNOS to operate and perform all activities of the OPTN, including the development of organ allocation policies. The UNOS Board of Directors is identical to that of the OPTN Board of Directors. In FY 2018, UNOS received over $5.5 million from HHS under the OPTN contract. UNOS received $40.4 million from OPTN registration fees, which are fees all transplant centers must pay to register each transplant candidate that the center places on the waiting list. *See* 42 C.F.R. § 121.5(c). As of September 30, 2018, UNOS had net assets of $50.8 million and FY 2018 revenues of nearly $59 million.

37. This action arises under NOTA, 42 U.S.C. § 274 *et seq.*, the Administrative Procedure Act ("APA"), 42 C.F.R. part 121 *et seq.*, and the U.S. Constitution. As a result, jurisdiction is present under 28 U.S.C. § 1331 because "district courts have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." The APA additionally provides that a reviewing court is to "decide all relevant questions of law, interpret

constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action." 5 U.S.C. § 706.

38. Venue is proper before this Court pursuant to 28 U.S.C. § 1391(e)(1) because at least one plaintiff currently resides in this district, there is no real property involved in the action, and at least one defendant is an officer of the United Sates or agencies thereof and acting in his official capacity.

FACTS

A. Liver Transplant Background

39. The first liver transplants were performed by Dr. Thomas Starzl at the University of Colorado during the early 1960s. For the first five liver transplant attempts, no patient survived more than 23 days, largely due to deficiencies in immunosuppression therapy. In 1967, Dr. Starzl performed the first successful liver transplant, which enabled a patient with a common type of liver cancer (hepatocellular cancer) to survive for more than one year with preserved liver function.

40. In 1968, the National Conference of Commissioners on Uniform State Laws drafted the Uniform Anatomical Gift Act, which, when enacted by the states, enabled anyone over the age of 18 to legally donate his or her organs upon death. That same year, the Southeast Organ Procurement Foundation was formed as an

organization for transplant professionals. In 1977, the Southeast Organ Procurement Foundation implemented the first computer-based organ matching system, which became the basis of the system used today. Before this system, if a donated organ could not be used at local hospitals, the organ was likely to go to waste because there was no systematic way to identify a compatible recipient in a timely manner.

41. During the 1960s and 1970s, advances in immunosuppression treatment improved transplant survival rates, with Dr. Starzl reporting in 1981 in the *New England Journal of Medicine* that the one-year survival for liver transplant recipients was nearly 70%.

42. During the early 1980s, although the medical science continued to advance and result in more lives saved, the number of donated organs fell far short of demand. The Senate estimated that organs were recovered from fewer than 15 percent of persons who might have been suitable organ donors. S. Rep. No. 98-382, at 2 (1984). Media coverage of the organ shortage and individuals' pleas for donations made organ transplantation one of the most widely discussed and publicized health issues in 1983 and 1984. At the time, there were 120 organ procurement organizations ("OPOs") primarily focused on kidney procurement, which was funded by Medicare. While recognizing the work of these groups,

Congress concluded that more needed to be done to encourage organ donation and improve procedures for efficient organ procurement.

B. The National Organ Transplant Act

43. In 1984, Congress passed NOTA, which created the entity known as the OPTN and launched a national framework for organ transplantation. 42 U.S.C. § 274.

44. In 1986, HHS contracted with UNOS, which had been formerly affiliated with the Southeast Organ Procurement Foundation, to operate the OPTN. That same year, Congress amended the Social Security Act to make OPTN membership and compliance with the OPTN's rules and requirements mandatory for Medicare-participating hospitals and all OPOs. Act of Oct. 21, 1986, 42 Pub. L. No. 99–509, § 9318, 100 Stat 1874 (1986).

45. In 1987, the OPTN developed the first liver allocation model suggesting how UNOS would prioritize the distribution of organs to waiting candidates. In light of the new requirement that transplant hospitals must comply with the OPTN's rules to participate in Medicare, many within the community debated whether compliance with the first proposed liver allocation model was mandatory.

46. In 1989, HHS published a *Federal Register* Notice clarifying that "OPTN rules and requirements which are mandatory upon Medicare and Medicaid

participating hospitals performing transplants and OPOs are subject to the Administrative Procedure Act (APA) requirements." Further, "the Secretary must review and approve matters proposed by the OPTN contractor to be rules and requirements of the OPTN in order for them to be binding upon hospitals and OPOs." Medicare and Medicaid Programs; Organ Procurement and Transplantation Network Rules and Membership Actions, 54 Fed. Reg. 51,802 (Dec. 18, 1989).

47. The OPTN's original focus under NOTA was to establish a national system to match donated organs with recipients and assist OPOs in distributing organs that they could not otherwise match within their respective service areas. In 1988, NOTA was amended so that the statutory language did not unintentionally limit the distribution of organs to the OPO's service area. As part of this amendment, the OPTN was also tasked with establishing "medical criteria for allocating organs and provid[ing] to members of the public an opportunity to comment with respect to such criteria." *See* Act of Nov. 4, 1988, Pub. L. No. 100-607, § 403, 102 Stat. 3048 (1988) (codified at 42 U.S.C. § 274(b)(2)(B)). In addition, the HHS Secretary was required to 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 NOTA and (2) "the consideration by the Secretary of such critical comments." *Id.* (codified at 42 U.S.C. § 274(c)).

48. In 1990, another amendment was passed to reflect that the OPTN should assist OPOs with the potential distribution of organs nationwide. At the same time, Congress added that the OPTN "shall . . . work actively to increase the supply of donated organs." *See* Transplant Amendments of 1990, Pub. L. No. 101-616, § 202, 104 Stat. 3279 (1990) (codified at 42 U.S.C. § 274(b)(2)(K)). Congress recognized that there was a "wide gap between the need for organs and the supply of donors," and the OPTN had a significant role to play to increase donations. S. Rep. 101-530, § 401, at 4626-27 (1990).

49. In 2000, NOTA was again amended, this time to require the OPTN to "carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and *attempt to increase transplantation among populations with special needs*, including children and *individuals who are members of racial or ethnic minority groups*." *See* Children's Health Act of 2000, Pub. L. No. 106-310, § 2101, 114 Stat. 1101 (2000) (codified at 42 U.S.C. § 274(b)(2)(N)) (emphases added).

50. In addition to the OPTN, NOTA established a data registry of organ transplant recipients, which is also operated by a government contractor. 42 U.S.C. § 274a. This registry is known as the Scientific Registry of Transplant Recipients

("SRTR"). The SRTR performs statistical modeling of various allocation policies and publishes annual data reports on organ donation, transplantation, and transplant programs. The computer model that evaluates liver allocation policies, known as the Liver Simulated Allocation Model, uses historical data to simulate one year of liver transplants and provide an estimate of how organs might be distributed to different candidates under various allocation models.

C. The Transplant Waiting List

51. Today, UNOS, in its capacity as the OPTN, manages the national system that matches donated organs with recipients, as contemplated by NOTA. *See* 42 U.S.C. § 274(a)(2)(A) (setting forth that the OPTN shall establish "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list"). Patients with end-stage liver disease who meet the medical criteria are eligible to be added to the liver transplant "waitlist."

52. Unlike most areas of health care, where patients may transfer to another hospital or physician and still generally receive the same medical services, organ transplantation ties patients to a specific program through the waitlist. Although the waitlist is national in the sense that UNOS lists all transplant candidates in one

computer system, to be included on the list, a patient must be registered by an individual transplant program.

53. Before a program can register and add a patient to the waitlist, the patient must first be referred to the hospital with the liver transplant program. For sick individuals who live in remote areas without high-quality healthcare, this referral often does not occur as early in the disease's progression as it would for those who live in more urban areas with better access to specialists and quality healthcare.

54. After the referral, the patient must be evaluated to determine if the patient is an appropriate candidate for a liver transplant based on that particular transplant program's selection criteria. This evaluation process includes assessments by the program's hepatologists, surgeons, licensed social workers, dietitians, psychologists, and pharmacists. Clinically, the evaluation process includes blood tests, ultrasound scans of the liver, chest x-rays, electrocardiogram, and pulmonary function tests. Once the tests and evaluations are complete, the transplant center's selection committee will meet to discuss whether the patient is an appropriate candidate for that center's program. The selection criteria may differ across various programs.

55. If a patient is selected to be added to the waitlist, the transplant program that submitted the patient for registration on the list carefully follows the transplant candidate, with regular follow-up appointments and correspondence with the transplant program physicians. When the candidate becomes eligible for an organ "offer" from UNOS, only programs that have formally registered and waitlisted the candidate are able to accept the organ on behalf of the candidate and perform the transplant surgery. If the candidate relocates or decides to seek care elsewhere, he or she must be re-evaluated at the new transplant program and must be approved based on the new program's selection criteria. Although occasionally patients seek and are approved for listing at multiple transplant centers, it is well-recognized within the transplant community that when transplant programs close, many patients do not get relisted elsewhere and are likely to die without a transplant.

D. The Final Rule

56. In 1994, HHS published a proposed rule governing the operation of the OPTN, the final version of which, as amended, is referred to within the transplant community simply as the "Final Rule." Organ Procurement and Transplantation Network, 59 Fed. Reg. 46,482 (Sept. 8, 1994). Among other things, the proposed rule required the OPTN Board of Directors to provide an opportunity for members of the OPTN to comment on proposed allocation policies, while "[c]oncurrently, the

Secretary would publish the proposed policies or a notice about the proposed policies in the Federal Register to give the public an opportunity to comment." 59 Fed. Reg. 46,482 at 46,486. Moreover, the proposed rule provided:

> [T]he Secretary shall review final allocation policies and provide comments and/or objections. The OPTN must consider the Secretary's comments before the policies are finalized. If the Secretary objects to a policy, the OPTN may be directed to revise the policy consistent with the Secretary's direction.

Id.

57. HHS further acknowledged that there was tension in then-existing allocation policies, specifically as they affected ethnic minorities or individuals in certain geographic regions:

> [S]ome policies intended to maximize transplant outcomes and based on sound scientific data may have adverse implications for one ethnic group in particular, or for residents of particular geographic areas. *The Department is committed to a full public debate on these and related issues that arise in the context of organ allocation policies*.

Organ Procurement and Transplantation Network, 59 Fed. Reg. at 46,486 (emphasis added).

58. In 1998, HHS published the Final Rule with a comment period. Organ Procurement and Transplantation Network, 63 Fed. Reg. 16,296 (Apr. 2, 1998). The preamble to the rule stated that NOTA "vested in the [HHS] Secretary oversight of the OPTN and responsibility for ensuring public benefit." *Id.* at 16,299. "Working

in partnership with the transplant community, the Secretary has final authority over OPTN policies and procedures." *Id.*

59. HHS recognized that the comment process administered by the OPTN was "invaluable in obtaining technical advice," but "it does not reach all of the affected public—including potential donors and interested persons who are not OPTN members and have no access to the OPTN—or otherwise provide the functions and protections accorded by the impartial review by the Secretary." *Id.* at 16,310. For this reason, the rule required that the OPTN:

> Provide, at least 30 days prior to their proposed implementation, proposed policies to the Secretary, who may provide comments and/or objections within a reasonable time, or may publish the policies in the Federal Register to obtain comments from the public.

Id. at 16,334. The rule further provided that the Board of Directors "shall indicate which of the proposed policies it recommends to be enforceable under § 121.10," which is a provision that allows for termination of a transplant hospital's participation in Medicare based on non-compliance with OPTN policies.

60. Based primarily on issues raised at a public hearing, HHS included in the Final Rule a new requirement, which had not been included in the proposed rule, 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 regarding to ability to pay or source of payment." *Id.* at 16,309;

see 42 C.F.R. § 121.4(a)(3). HHS further noted that "the Secretary has an affirmative obligation to make sure that policies and actions of the OPTN do not violate the civil rights of candidates for organ transplants." *Id.*

61. Shortly after the April 1998 rule was published, Congress intervened and suspended the rule's implementation until October 1999, because of concerns from the transplant community as well as the general public.

62. During the congressionally-imposed stay, Congress conducted hearings on the matter, in which legislators and witnesses expressed concerns about the so-called "green screen," which was a term used to describe the inability of low-socioeconomic status individuals to access the waiting list, particularly for non-renal transplantation that was not necessarily covered by Medicare.[1] As part of the public debate, Congress asked the Institute of Medicine ("IOM") to conduct a study on the potential impact of the Final Rule. Ex. 4. Among other things, Congress asked the IOM to examine "access to transplantation services for low-income populations and racial and ethnic minority groups." *Id.* at 3.

63. In its report, the IOM expressly considered both access to the waiting list as well as access to organs once candidates were waitlisted. Under the heading

[1] *See* Joint Hearing Before the House of Representatives Subcommittee on Health and Environment of the Committee on Commerce and the Senate Committee on Labor and Human Resources, 105th Cong., 2nd Sess., June 18, 1998.

"Factors Affecting Access," the IOM began by referring to "[f]actors that might influence waiting list entry." *Id.* at 41. According to the report, in the late 1990s, once a patient was placed on the waiting list, socioeconomic status had little influence on whether that candidate received a transplant. Rather, the "primary barrier" in access to transplantation "for poor people as a group was gaining access to the waiting list." *Id.*

64. More specifically, the IOM explained:

> Lower access by African Americans to kidney transplantation is well documented. Much of the disparity appears to be due to the fact that African Americans are not placed on waiting lists as quickly, or in the same proportion, as their white counterparts.

Id. at 40. For liver transplants, the IOM reported that "African Americans enter the list and receive liver transplants when they are sicker, relative to other racial groups." *Id.* This IOM Report concluded that "initial access to health care and to referrals for transplant evaluation is an important impediment for African Americans with liver disease." *Id.*

65. After reviewing the IOM Report, at the end of the congressionally-imposed suspension of the Final Rule, HHS released a new "Final Rule," which became effective on November 19, 1999. Organ Procurement and Transplantation Network, 64 Fed. Reg. 56,650 (Oct. 20, 1999). One addition to the Final Rule was a provision that required the OPTN to develop allocation policies that "seek to

promote patient access to transplants," in response to the issue Congress had asked the IOM to address. *Id.* at 56,656; 42 C.F.R. § 121.8(a)(5).

66. Organ allocation policies today are principally governed by two sections of the Final Rule: 42 C.F.R. Sections 121.4 and 121.8. The first regulation sets forth that the OPTN Board of Directors is responsible for developing policies that further the OPTN's mission, including "policies that reduce inequities resulting from socioeconomic status." 42 C.F.R. § 121.4(a)(3). Specifically, such policies include the "[r]eform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities." *Id.* § 121.4(a)(3)(iv).

67. Section 121.4 also sets forth the regulatory process for developing "policies within the mission of the OPTN." Specifically, the OPTN Board of Directors shall:

> (1) Provide 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; and
>
> (2) Provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies it recommends to be enforceable under § 121.10 *(including allocation policies)*.

Id. § 121.4(b) (emphasis added). As compared to the 1998 rule, this language was modified in part "[i]n response to comments asking which OPTN policies are to be submitted to the Secretary." 64 Fed. Reg. at 56,656. HHS explained in the

preamble that the "Board of Directors is required to provide the Secretary with proposed policies that the OPTN recommends to be enforceable under § 121.10 *(including allocation policies)* and others as specified by the Secretary." *Id.* (emphasis added).

68. The Final Rule was further revised based on recommendations from the IOM to create "an independent scientific review board for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible." *Id.* at 56,652 (internal quotation marks omitted). The regulation instructs the Secretary to seek input from this "Advisory Committee on Organ Transplantation" for "significant" policy proposals, in addition to publishing such proposals in the *Federal Register* for public comment.

> The 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. The Secretary may also seek the advice of the Advisory Committee on Organ Transplantation established under § 121.12 on other proposed policies, and publish them in the Federal Register for public comment.

42 C.F.R. § 121.4(b)(2).

69. Moreover, the regulation makes clear that the Secretary has oversight of the OPTN's policymaking process to ensure compliance with the law. "The Secretary will 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." *Id.* As explained in the preamble, the rule was "revised to emphasize that the Secretary's review is intended to ensure consistency between OPTN policies and the National Organ Transplant Act and this regulation." 64 Fed. Reg. at 56,652. Thus, the Secretary has the responsibility and authority to determine whether an OPTN policy is consistent with federal law.

70. Organ allocation policy development is further governed by 42 C.F.R. § 121.8(a), which states:

> (a) **Policy development**. The Board of Directors established under § 121.3 shall develop, ***in accordance with the policy development process described in § 121.4***, policies for the equitable allocation of cadaveric organs among potential recipients.

Notably, this provision begins by explicitly incorporating the guidance in section 121.4, which, among other things, includes the consideration of socioeconomic inequities and publication of significant policies in the Federal Register. Section 121.8(a) then goes on to set forth additional specific requirements for allocation policies:

> Such 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***.

71. Importantly, the Final Rule requires that allocation policies "seek to achieve the best use of donated organs" and "be designed . . . to promote patient access to transplantation." Moreover, in sub-paragraph (8), the Final Rule expressly permits consideration of a transplant candidate's place of residence to the extent necessary to achieve the best use of donated organs, to avoid wasting organs, and to promote patient access to transplantation.

72. The Final Rule establishes performance goals for allocation policies, which include "distributing organs over as broad a geographic area as feasible under

paragraphs (a)(1) – (5) of this section, and in order of decreasing medical urgency." 42 C.F.R. § 121.8(b)(3). Therefore, although wide geographic distribution of organs may be a goal, any such effort to achieve this goal must take place within the context of the regulatory requirements to avoid organ wastage and promote patient access to transplantation, among other factors.

E. How Donor Livers Are Allocated Under Three Recently Approved Liver Allocation Policies

73. In recent years, at the direction of HRSA, UNOS has developed and approved for implementation three relevant liver allocation policy models: (1) the current policy, which has been in place since 2013 ("Current Policy"), (2) the policy that was approved by the OPTN in December 2017 but never took effect ("December 2017 Policy"), and (3) the rewritten policy that was approved by the OPTN in December 2018 and is set to take effect on April 30, 2019 ("April 2019 Policy").

74. All policies consider a candidate's severity of illness using a calculation known as the Model for End-Stage Liver Disease or "MELD" score, with scores ranging from 6 (least ill) to 40 (gravely ill). A special medical urgency category (Status 1) is reserved for a subset of candidates who are most likely to die within 7 days if they do not receive a liver transplant.

75. MELD scores are based primarily on certain laboratory values that are intended to reflect the severity of liver disease. However, some candidates may have

conditions where the lab value might not adequately capture the severity of the illness. For certain conditions, the physician may request "exception points" so the candidate is given a higher MELD score than would otherwise be warranted based on the lab tests. Currently, regional boards of physicians assess whether or not to award these points.

76. The OPTN has acknowledged that "exception point" approvals vary by OPTN Region (as defined below), with some Regions approving as few as 75% of exception requests while other Regions approve up to 93% of requests. Ex. 5 at 2. In fact, research has demonstrated that Region 9 (New York and western Vermont) has a statistically significant higher rate of exception approvals when compared to other Regions. Ex. 6. For certain conditions, a hypothetical candidate listed by a transplant program in New York would have a higher MELD score than the same candidate would have if he or she were listed in Georgia because the New York regional board approves exception points under circumstances where the Georgia regional board does not. This contributes to New York transplant programs having a higher "median MELD at transplant," or the average MELD score of candidates at the time they receive the transplant.

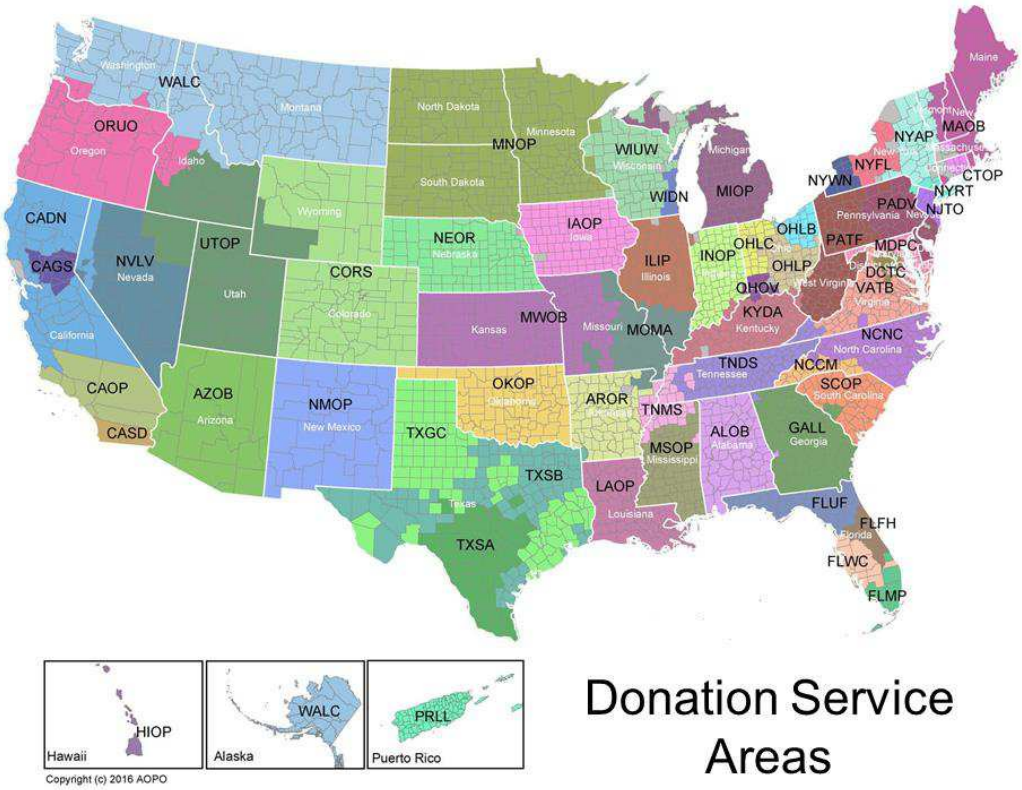
77. In addition to MELD scores, the various liver allocation policies all consider donor and recipient blood type as well as the length of time a candidate has

been on the waiting list. Each of the three policies weighs blood type and waitlist time slightly differently, but the crux of the differentiation among the policies is how the recipient's MELD scores and the location of the donor affect the prioritization of the recipient.

78. Historically, allocation policies have used two OPTN-defined 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.

79. There are 58 DSAs, some of which follow state lines but others of which do not, as shown by the map below. Each DSA is serviced by one OPO, which is responsible for engaging with donor families and obtaining donor organs within that area. OPOs vary significantly in their effectiveness, with liver donation

rates ranging from 50% of eligible decedents donating the organ (in Hawaii and parts of New York) to 80% of eligible decedents donating (in Iowa, Pennsylvania, and Utah, among others).



80. Under the Current Policy, a donated liver is first offered to Status 1 candidates within the donor's Region. If no such candidate accepts the organ, then the organ is offered to candidates with a MELD score of 40 (including any exception points) first within the donor's DSA and then within the Region. From there, the organ is offered to candidates with a MELD score of 39 within the donor's DSA and then within the Region. The offers continue to go down to a MELD score of 35.

After that, if the organ still has not been accepted, then the organ is offered to candidates with a MELD score of at least 15 within the donor's DSA and then to candidates with a MELD score of at least 15 within the donor's Region. If the organ is still not accepted, the organ is offered to Status 1 candidates anywhere across the country followed by candidates with a MELD score of at least 15 anywhere in the country.

Priority	**Candidate**
1	Status 1 within the Region
2	MELD of 40 within DSA
3	MELD of 40 within Region
4	MELD of 39 within the DSA
…	…
14	MELD of at least 15 within DSA
15	MELD of at least 15 within Region
16	Status 1 anywhere in the nation
17	MELD of at least 15 anywhere in the nation

81. Under this policy, a hypothetical candidate with a MELD score of 37 in the donor hospital's Region who is not also in the donor hospital's DSA would receive the organ ahead of a candidate with a MELD score of 36 in the donor hospital's DSA. But a candidate with a MELD score of 36 who is in the donor hospital's DSA would receive the organ offer ahead of a candidate with MELD score of 37 who is outside of the donor hospital's Region.

82. For several years, the transplant community explored various allocation models that did not rely as heavily on DSAs and Regions, which the OPTN claimed were not designed specifically for organ allocation. In December 2017, after careful, multi-year deliberations among transplant experts, the OPTN Board approved a modified policy, which was to take effect one year later, in December 2018.

83. As the December 2017 Policy was nearing implementation, HRSA abruptly directed UNOS to scrap the December 2017 Policy. On July 31, 2018, HRSA instructed UNOS "to adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions and that is compliant with the OPTN final rule" by the next OPTN Board of Directors meeting, just four months later, on December 3-4, 2018. Ex. 7 at 5; Ex. 8 at 5-6. As the OPTN explained, Ex. 8 at 3, the policy revision's limited timeline was established in the immediate aftermath of a critical comment filed by a New York plaintiffs' attorney, which challenged the use of DSAs in liver allocation.

84. The April 2019 Policy, currently slated to go into effect on April 30, 2019, uses circles and clusters of MELD scores to allocate organs. The policy draws three circles, known as "acuity circles," around the donor hospital: small (150 nautical miles), medium (250 nautical miles), and large (500 nautical miles). First, Status 1 candidates within the large circle are offered the organ. Next, candidates

with a MELD score of 37 or higher within the small circle are offered the organ, followed by candidates with a MELD score of 37 or higher within the medium circle and then within the large circle. If the organ is still available, it is offered to candidates with MELD scores ranging from 33 to 36 within the same sequence of circles (small, medium, large) and then for candidates with MELD scores ranging from 29 to 32, followed by scores from 15 to 28.

Priority	Candidate
1	Status 1 within 500nm
2	MELD of at least 37 within 150nm
3	MELD of at least 37 within 250nm
4	MELD of at least 37 within 500nm
5	MELD of 33 to 36 within 150nm
6	MELD of 33 to 36 within 250nm
7	MELD of 33 to 36 within 500nm
8	MELD of 29 to 32 within 150nm
	etc…

85. Under this proposed policy, a transplant candidate with a MELD of 37 who is 490 nautical miles away from the donor's hospital would always be offered the organ before a candidate with a MELD score of 36 who lives down the street from the donor's hospital, regardless of which patient has the greater mortality risk. A candidate with a MELD score of 37 who is 501 nautical miles away from the donor's hospital would not be offered the organ unless all other candidates (of any MELD score) within 500 nautical miles had declined the organ.

F. The Rushed And Unlawful Process Of Developing And Adopting The April 2019 Policy

86. Following HRSA's direction to approve a new policy by December 2018, the OPTN Liver and Intestine Transplantation Committee (the "Committee") published a policy proposal on the OPTN website (not the Federal Register) available for public comment from October 8 to November 1, 2018. The proposal reflected the SRTR's analysis of two frameworks under the Liver Simulated Allocation Model—acuity circles and broader 2-circle distribution. Ex. 9. As part of the proposal's publication, the Committee sought public comment regarding both frameworks, but the proposal noted that the Committee "preferred" the broader 2-circle model. The Committee meeting to discuss the public comments and vote on a policy recommendation was scheduled for November 2, 2018.

87. On October 30, at 2:02 p.m. CT, four of the Transplant Center Plaintiffs submitted a public comment to the OPTN public comment email address. Several other Transplant Center Plaintiffs also submitted comments during the public comment process, but none of the Patient Plaintiffs commented. Indeed, most patients were not even aware that a change to the liver allocation policy was being considered.

88. At 11:10 p.m. CT on November 1, 2018, UNOS staff circulated to the Committee an Excel spreadsheet with approximately 1,200 public comments in a

format that made it near-impossible to read. The staff also provided a summary analysis of the comments that had been received, which identified some themes from commenters, but largely included irrelevant statistical information, such as what percentage of comments were received from which states. The UNOS document also stated the percentage of commenters who supported or opposed a particular policy but without providing any context for the percentage, such as whether the support was accompanied by a substantive, reasoned opinion or if the commenter's support was merely one of a large number of "copied and pasted" stock responses.

89. At 7:56 a.m. CT on November 2, UNOS staff circulated to the Committee in a PDF (and thus more readable format) the public comment submitted by four of the Plaintiffs as well as a comment from the Attorneys General of New York and California. The Committee meeting started in Chicago at 8:30 a.m. CT, the morning after the comment period and just 9 hours after UNOS first circulated the public comments and analysis.

90. On November 7, 2018, UNOS staff notified the Committee that there were 17 comments that had not been provided to the Committee in advance of the meeting, even though such comments were timely submitted during the public comment period. One such comment was submitted by Dr. Timothy Schmitt, who

is a transplant surgeon at one of the Transplant Center Plaintiffs and a member of the UNOS Board of Directors.

91. During the November 2 Committee meeting, one of the UNOS staff members acknowledged that the OPTN had never previously held a Committee meeting the day after the public comment period had closed. In addition, on information and belief, the Committee chair admitted several times that she had not yet read comments submitted by key constituencies, such as the American Society of Transplant Surgeons. Various members of the Committee repeatedly lamented the fact that the process for such a critical topic was so rushed, noting that they had to make a decision without the same kind of data they usually had for issues of this import.

92. Nonetheless, acknowledging pressure from HRSA, the Committee acted by a narrow vote to recommend the broader 2-circle distribution model to the OPTN Board.

93. After the Committee meeting, OPTN/UNOS posted a "Briefing Paper" recommending that the Committee's recommendation be supported because it "strikes an appropriate balance" of the Final Rule's requirements "by distributing organs as broadly as feasible while promoting the efficient management of organ placement by mitigating the logistical issues associated with distributing organs

across further distances, and avoiding organ wastage." Ex. 10 at 4. The Briefing Paper expressed concerns with the significant increased number of flights that would be required by the acuity circle model (which was ultimately adopted in the April 2019 Policy), given the increasing scarcity of pilots and flights available for procurement teams. *Id.* at 15. The Briefing Paper observed that "[s]ignificant increase in the need for flights could lead to an increase in organ offers that were unable to be accepted because flights or pilots were not available." *Id.*

94. The Briefing Paper's proposed resolution and delineated changes to the OPTN liver allocation policy solely included language incorporating the broader 2-circle model and did not propose an option for incorporating the acuity circle model.

95. On December 3, 2018, the Board met in Dallas, Texas to discuss the Committee's recommendation. During the Board meeting, several members requested that the vote be delayed, but both the Committee chair and the CEO of UNOS urged the Board to make a decision because of the pressure from HRSA to adopt a new policy by the close of the Board meeting. Ex. 11 at 129-130. Representatives from HRSA were in attendance at the Board meeting and reiterated that HRSA's July 2018 letter had directed the OPTN to approve a new policy "by this meeting." *Id.* at 11.

96. Despite the Liver Committee's recommendation, the OPTN Board voted to approve an "amendment" that changed the policy from the broader 2-circle distribution to the acuity circle framework. There had been no notice to the public that the OPTN Board was considering the acuity circle model. Although general members of the transplant community could attend the Board meeting, only Board members were given the opportunity to speak.

97. The immediate past president of UNOS, Dr. Yolanda Becker, stated at the Board meeting that "setting [the] precedent of not following our expert committees is not a good precedent to set." Ex. 11 at 145.

98. In a statement that flatly contradicted the Final Rule's requirements, UNOS Policy Director, James Alcorn, acknowledged at the Board meeting that the policy did not seek to achieve the best use of donated organs because "that wasn't the goal of this specific allocation policy." Ex. 11 at 83-84; *see* 42 C.F.R. § 121.8(a)(2).

99. The policy adopted by the Board of Directors is set to take effect on April 30, 2019. The Secretary did not publish the policy in the Federal Register or submit it to the Advisory Committee on Organ Transplantation. 42 C.F.R. § 121.4(b)(2).

100. In a letter to the OPTN on December 19, 2018, HRSA stated that the "OPTN Board analyzed the policy adopted in light of each of the regulatory requirements," but HRSA itself did not opine as to the legality of the policy. Nonetheless, HRSA endorsed the OPTN's actions by stating that it "expect[ed] the OPTN to proceed expeditiously in implementing" the policy. Ex. 12 at 4.

101. On February 13, 2019, a group of Transplant Center Plaintiffs submitted a critical comment to HHS Secretary Azar detailing several legal shortcomings of the April 2019 Policy ("Plaintiffs' Critical Comment"). Plaintiffs' Critical Comment requested that Secretary Azar "suspend implementation of the [April 2019 Policy] and [ ] develop a legally compliant policy." Ex. 13 at 19.

102. On March 14, 2019, HRSA Administrator George Sigounas requested the OPTN's views on the issues raised in Plaintiffs' Critical Comment "[t]o assist HHS in its consideration of the critical comment." Ex. 14 at 1. Specifically, HRSA requested the OPTN's views regarding:

> (1) the cumulative impact of the policy on socioeconomic inequities, in light of 42 C.F.R. § 121.4(a)(3); (2) patient access to transplantation per 42 C.F.R. § 121.8(a)(5); (3) the predicted number of liver transplants and deaths under this policy; and (4) the use of median model for end-stage liver disease score at transplant.

Id. HRSA also asked the OPTN to respond to the Plaintiffs' Critical Comment's discussion of the OPTN's public comment process. HRSA "recognize[d] that the

OPTN's evaluation of these comments may likely take additional time beyond April 30, 2019, the implementation date of the new Acuity Circles Policy." *Id.* at 2.

103. Administrator Sigounas then noted that the role of "HRSA Administrator is one of oversight," and stated that he would "review the OPTN's comments in light of the requirements of NOTA and the OPTN Final Rule." *Id.*

104. On March 26, 2019, the OPTN responded to HRSA's inquiry regarding the Plaintiffs' Critical Comment. The OPTN Executive Committee, acting on behalf of the OPTN Board, concluded that the April 2019 Policy "is compliant with the OPTN Final Rule and will result in more equitable distribution of livers for all liver candidates on the waiting list." Ex. 15 at 2.

105. As of the date of this filing, HRSA has not responded to the OPTN's comments. UNOS, acting in its capacity as the OPTN, informed Plaintiffs' counsel that it intends to implement the policy as scheduled on April 30, 2019.

106. As discussed above, *supra* ¶ 68, under 42 C.F.R. § 121.4(b)(2), "[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" (emphasis added). When Defendant HHS Secretary Azar was asked during a recent Senate hearing if he agreed that the liver allocation

policy "has consequences, and it's significant," Secretary Azar replied, "Yes, the issue of liver transplants are very important to all of us, absolutely." Ex. 3 at 67.

107. This policy critically affects all 58 organ procurement organizations and 145 liver transplant centers in the United States, their transplant physicians and employees, and the approximately 13,100 candidates on the UNOS liver waitlist. Secretary Azar acknowledged that this policy is "significant," but he nevertheless failed to comply with the Final Rule. The proposal was not formally presented to the Advisory Committee on Organ Transplantation and was never published in the Federal Register, as is required for "significant proposed policies" under the regulation. 42 C.F.R. § 121.4(b)(2).

108. When asked whether he would request the OPTN to delay implementation of the April 2019 Policy, Secretary Azar told Senators, "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 but I am happy to work with the committee on any other solutions here to look at and ensure that the fair and scientifically valid treatment has been given here." Ex. 3 at 11.

109. But the role of the OPTN as set forth by Congress in NOTA is more limited than the Secretary implied. Under NOTA, with respect to organ allocation, the OPTN is tasked simply with establishing "medical criteria for allocating organs

and provid[ing] to members of the public an opportunity to comment with respect to such criteria," 42 U.S.C. § 274(b)(2)(B), as well as "carry[ing] out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation," *id.* § 274(b)(2)(N). The April 2019 Policy goes far beyond establishing "medical criteria for allocation" and has never been purported to be a demonstration project. For example, nautical miles are certainly not "medical criteria," and there is no clinical or medical distinction between 501 nautical miles and 500 nautical miles. Thus, the choice to allocate organs based on the acuity circles in the April 2019 Policy exceeds the bounds of the OPTN's statutory purview under NOTA.

110. Rather, it is the Secretary, through the Final Rule, not Congress, who established that the OPTN would be responsible specifically for developing organ allocation policies. And under the Final Rule, the Secretary has the responsibility to "determine whether the [OPTN's] proposed policies are consistent with National Organ Transplant Act" and the Final Rule. 42 C.F.R. § 121.4(b)(2). The Secretary is vested with this authority because the determination of whether an organ allocation policy complies with federal law is an "inherently governmental function." Federal Activities Inventory Reform Act, Pub. L. No. 105-270, § 5, 112 Stat 2382 (1998). The law defines such functions as those that are "so intimately

related to the public interest as to require performance by Federal Government employees." *Id.* Inherently governmental functions include "among other things, the interpretation and execution of the laws of the United States so as– . . . (iii) to significantly affect the life, liberty, or property of private persons." *Id.* As a private government contractor, UNOS acting as the OPTN, cannot interpret the laws of the United States in a way that significantly affects the lives of individuals on the liver transplant waiting list.

111. Perhaps recognizing this limitation, around the time the Final Rule was implemented, the Secretary publicly declared that the Advisory Committee on Organ Transplantation would "provide independent review and advice to HHS concerning revised organ allocation policies being developed" by the OPTN. Moreover, the Secretary explained that "HHS review and approval is needed to make these policies binding on OPTN members." Ex. 16. Thus, despite Secretary Azar's recent statements, his office in 2000 recognized that HHS had a necessary role in reviewing and approving organ allocation policies.

112. If the Secretary does not exercise his authority under 42 C.F.R. § 121.4(b), then he is unlawfully permitting a private contractor to exercise an inherently governmental function by policing itself, interpreting federal law, and (not surprisingly) concluding that its own policy proposal is compliant with such

law. Such abdication of the Secretary's responsibility is unlawful, arbitrary, and capricious. *See* 48 C.F.R. § 7.503(a) ("Contracts shall not be used for the performance of inherently governmental functions."); *id.* § 7.503(c)(3) (listing as an inherently governmental function "[t]he determination of agency policy, such as determining the content and application of regulations, among other things").

G. The April 2019 Policy Does Not Comply With NOTA

1. The OPTN's Flawed Consideration of Waitlist Mortality Will Result In Increased Patient Deaths Nationwide.

113. In the Liver Committee's policy proposal, the OPTN stated that it "could not support an allocation plan that would be very likely to decrease the number of organs transplanted," Ex. 8 at 8, but the OPTN's executive summary of the April 2019 Policy ("Executive Summary") acknowledges that the approved policy does just that and will result in "a slight reduction in the number of transplants overall." Ex. 17. According to the SRTR data models, there will be 57 fewer transplants each year under the April 2019 Policy. As explained below, the actual reduction in the number of transplants performed nationally will likely be much greater because the policy significantly increases the number of organs that must be flown to reach their intended recipient, which will result in additional organs being discarded and unusable.

114. In the OPTN's Executive Summary, the OPTN states, "[t]he reduction of deaths on the waitlist was considered a measure of best use of transplanted organs, and was an influencing factor in the Board's ultimate decision to adopt the [April 2019 Policy]." Similar opinions were expressed during the December OPTN Board meeting. For example, in presenting slides on waitlist mortality, Committee Chair Julie Heimbach stated that all proposals moved waitlist mortality "in the right direction though with different degrees," but the April 2019 Policy made "a bigger difference on this important end point." Another OPTN Board member, Charles Miller, stated that the April 2019 Policy performed the "best . . . with respect to waiting list mortality[; i]t is in the data." Therefore, a fundamental principle driving the OPTN's decisionmaking was an understanding based on simulation modeling data that the April 2019 Policy would reduce mortalities.

115. This understanding is not consistent with more refined data models. As part of the data released on actual transplant candidates and centers (contrasted with the simulated modeled numbers), the SRTR publishes the waitlist mortality rates of each DSA. These rates vary significantly, from a low of .074 to a high of .355 (a nearly fivefold difference). However, the SRTR does not consider these varying mortality rates in its calculations to predict waitlist mortalities under a proposed

allocation policy. Rather, the SRTR model assumes that waitlist mortality rates are roughly the same across the country for patients with the same MELD score.

116. But a candidate with a MELD score of 19 living in the Bronx, NY is more likely to survive than a candidate with a MELD score of 19 living in rural Georgia. If the Bronx candidate experiences confusion, jaundice, or internal bleeding related to worsening liver condition, he will go to any number of local hospitals and be seen by experienced hepatologists. If the rural Georgia patient experienced the same symptoms, he would likely be treated at a critical access hospital without a hepatologist, without physicians who know how to treat end-stage liver disease, and thus is much less likely to receive the care he needs to survive. Because the SRTR model does not account for these differences, the model underestimates the deaths that will result from the April 2019 Policy, particularly in areas with higher waitlist mortality rates.

117. Further, the OPTN Board acknowledged during its December 2018 meeting that the SRTR models had not taken into consideration transplant candidates who were removed from the waitlist because they had become too sick to transplant. Of course, because these individuals will inevitably die without receipt of a liver, they should be treated as deaths when evaluating whether an allocation policy "achieves the best use of donated organs," as required by regulation. *See* 42 C.F.R.

§ 121.8(a)(2). The SRTR representative at the Board meeting explained that the SRTR has the ability to perform a simulated calculation that accounts for deaths following removal from the waitlist, but the analysts had been unable to provide this calculation to the Liver Committee before the policy vote because of the "short time line." As with the DSA waitlist mortality rates, the SRTR also makes publicly available data from actual transplant experience that identifies the number of transplant candidates who were removed from waitlists because they were too sick to transplant. This data could be used in the liver simulation model to enhance the accuracy of the model's calculation of expected deaths resulting from any proposed policy.

118. On information and belief, when the SRTR simulation model is appropriately refined by taking into account the data regarding variations in mortality rates across DSAs and candidates who are too sick to transplant, the model shows a very different picture than the OPTN Board assumed to be true. Instead of decreasing the number of deaths, preliminary results from a refined model show the April 2019 Policy *increases the number of deaths across the country*.

2. The April 2019 Policy Fails To Reduce Inequities Resulting From Socioeconomic Status As Required By Law.

119. Under the Final Rule, the OPTN Board "shall be responsible for developing" policies that further the OPTN's mission, including "policies that

reduce inequities resulting from socioeconomic status." 42 C.F.R. § 121.4(a)(3). Such policies must include the "[r]eform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities." *Id.* § 121.4(a)(3)(iv) (emphasis added).

120. The OPTN failed to reform the liver allocation policy based on an assessment of the policy's effect on socioeconomic inequities, as required by the Final Rule. *See* 42 C.F.R. § 121.4(a)(3). In response to Plaintiffs' Critical Comment, the OPTN told HRSA that the liver allocation policy "is designed to help medically urgent candidates, regardless of whether those candidates are of low or high socioeconomic status," disregarding the mandate to specifically consider the effect of allocation policies on socioeconomic inequities. Ex. 15 at 8.

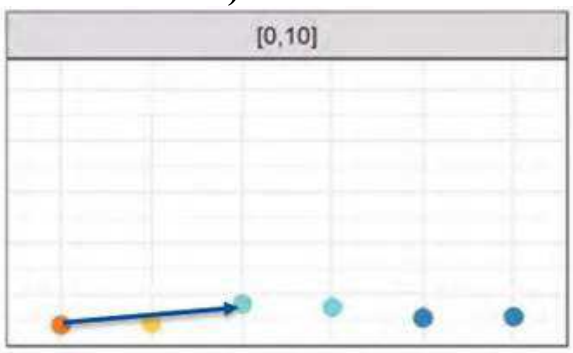
121. In the December 2018 HRSA Letter, HRSA stated that "the OPTN analyzed the impacts of the [April 2019 Policy] on various demographic groups, including racial and ethnic minorities, [and] those disadvantaged by lower socioeconomic status" and notes that the OPTN "found these groups would not be disadvantaged by the policy changes." Ex. 12 at 4. But HRSA's assertion is not supported by the facts. The only time socioeconomic status was mentioned during the December Board meeting was when OPTN Board members suggested that the

development process for the April 2019 Policy *failed* to consider socioeconomic inequities.

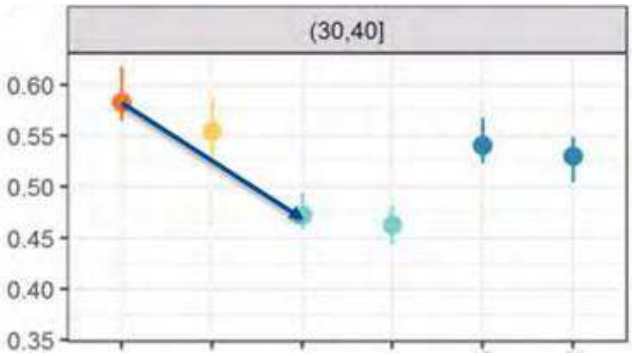
122. In fact, the OPTN disregarded the SRTR model's analysis of the April 2019 Policy's impact on impoverished areas. As part of its analysis, the SRTR predicted how the various allocation models would affect communities as ranked by an indicator designed specifically to evaluate socioeconomic and environmental risk factors that may affect transplant recipients—a metric known as Cumulative Community Risk Scores ("CCRS"). This scoring system evaluates communities based on a variety of health factors, including birth weights, number of poor health days, obesity rates, preventable hospital stays, illiteracy rates, and median household income, among others. Community scores range from 0 to 40, with 0 being the lowest risk (and highest socioeconomic status) and 40 being the highest risk (and lowest socioeconomic status). According to the SRTR's analysis, the April 2019 Policy will have significant detrimental effects on transplant candidates in high-risk communities with low socioeconomic status. When compared to the current and the December 2017 Board-approved policies, the April 2019 Policy *decreases* transplant rates for *the highest risk* communities (with CCRS scores from 30 to 40) and *increases* transplant rates for *the lowest risk* communities (with CCRS scores from 0 to 10). Ex. 9 at 287. The image below shows the data model that was included

the SRTR Report and was available to the OPTN Liver Committee and OPTN Board. The orange data points reflect the current policy, the yellow data points reflect the December 2017 Policy, and the light blue data points reflect the April 2019 Policy.

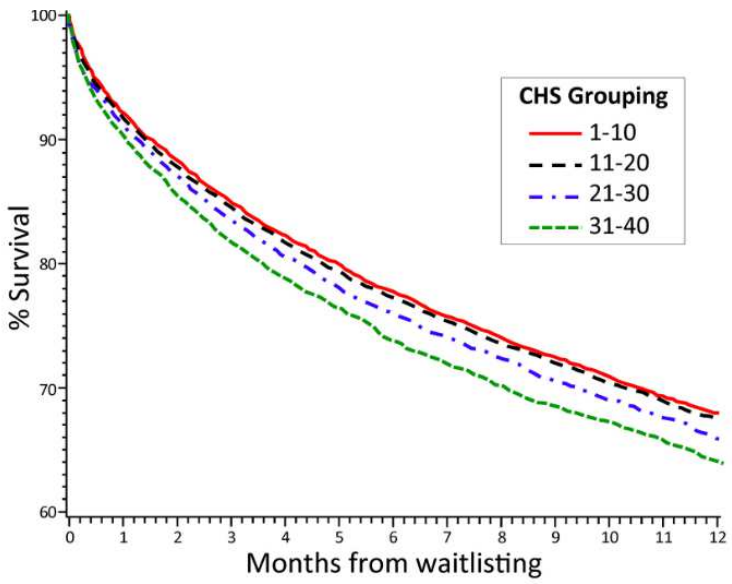
Low Risk (high socioeconomic status) Communities



High Risk (low socioeconomic status) Communities



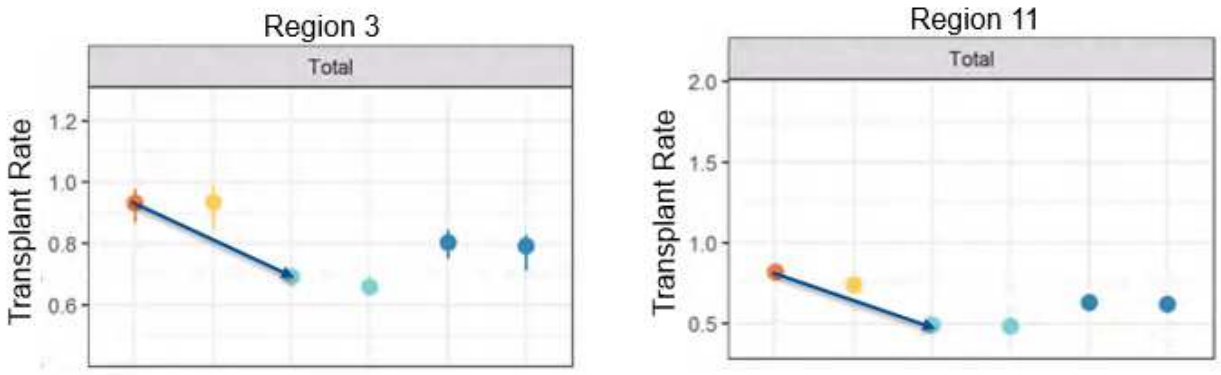
123. Patients in high-risk communities do not have the same access to quality healthcare as patients in low-risk communities. Even though not every transplant candidate in a high-risk community is individually "high-risk" (or of low socioeconomic means), they are still affected by the circumstances of their community, including a decreased access to specialists. The *American Journal of Transplantation* published that candidates from higher-risk communities (groupings 31 to 40) have a greater likelihood of mortality on the waitlist than candidates in lower-risk communities (groupings 1 to 10), as shown below.



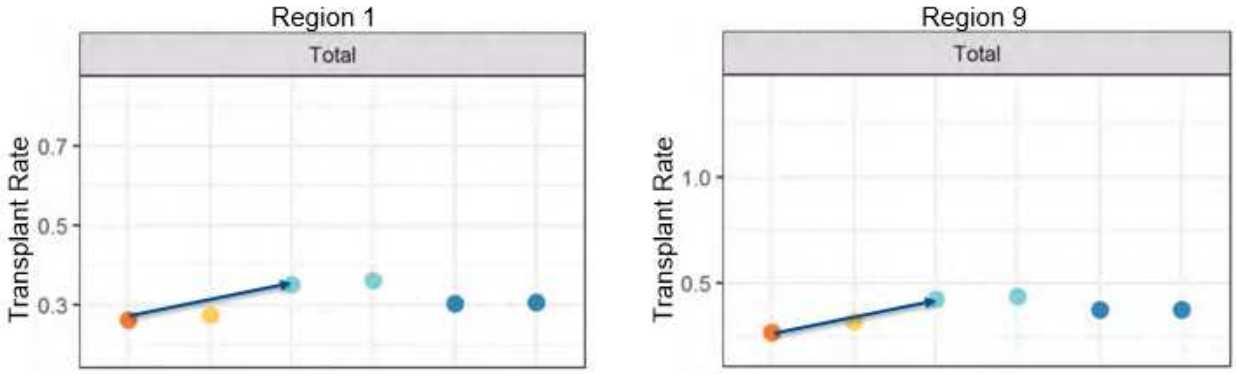
This difference in survival rate is present even though the communities did not have a statistically significant different MELD score at the time of listing (ranging from 17.3 in the low-risk communities to 17.8 in the high-risk communities).

124. The April 2019 Policy's negative effects on candidates with lower socioeconomic status are further illuminated by analyzing the models from a regional perspective. The states with the highest mean CCRS risk scores (i.e., the states with the greatest number of high-risk communities) are in Regions that will have their number of transplants *reduced* by the April 2019 Policy. Region 3 and Region 11 (collectively, Virginia, Tennessee, Kentucky, North Carolina, South Carolina, Louisiana, Arkansas, Mississippi, Alabama, Georgia, and Florida) have some of the highest average CCRS risk scores in the country (that is, some of the most at-risk, low-socioeconomic-status communities); yet, the transplant rates and

number of transplants decrease for both of these Regions under the April 2019 Policy.



By contrast, transplant rates and the number of transplants increase for Regions 1 and 9, which encompass states with the lowest CCRS risk scores: Connecticut, Massachusetts, New Hampshire, Rhode Island, Maine, New York, and Vermont.



125. During the OPTN Board meeting, the Liver Committee Chair erroneously stated that the Committee looked at "community risk score" and other demographic factors and found that the only area where there was a difference was age. Ex. 11 at 98. In fact, the Committee's meeting minutes indicate that Committee

members found that "concerns about socio-economic status are legitimate." Ex. 18 at 8. Moreover, as shown above, the April 2019 Policy *increases* socioeconomic inequities regarding access to transplantation as evidenced by the CCRS data.

126. The adverse impact to low-income, high-risk communities may be even worse than the SRTR model predicts because, as discussed above at ¶¶ 115-118, the LSAM illogically treats the waitlist mortality rate as the same across all communities.

127. Moreover, among the general population in high-risk CCRS communities, the death rate from end-stage liver disease is almost twice that of communities in the lowest risk tier, but fewer candidates are listed in high-risk CCRS communities for each person dying from liver disease, suggesting an inequity in access to the transplant waitlist. As Congress and HHS recognized when developing the Final Rule, access to the waitlist is a fundamental issue when considering how to promote patient access to transplantation. *See supra* ¶¶ 62-65.

128. Therefore, contrary to the representations made by HRSA, *see supra* ¶ 121, the April 2019 Policy will undoubtedly "disadvantage" and adversely impact lower-socioeconomic-status communities, in violation of the Final Rule. If the OPTN had seriously considered the cumulative effect of allocation policies on

socioeconomic inequities, as required by 42 C.F.R. § 121.4, it would not have approved the April 2019 Policy.

3. The April 2019 Policy Fails To Account For Patients Awaiting Access To The Transplant Waitlist.

129. Pursuant to the Final Rule, organ allocation policies "[s]hall be designed to . . . promote patient access to transplantation." 42 C.F.R. § 121.8(a)(5). The OPTN's proposal for the April 2019 Policy acknowledged this regulatory requirement, and presumably because it did not intend to actually abide by that requirement, the proposal then expressed an inexplicably narrow interpretation of "patient" by stating: "[T]he OPTN has interpreted these requirements to apply to patients who are registered for organ transplantation—as opposed to all patients with end stage organ failure, who may or may not be registered for organ transplantation." Ex. 8 at 31. Following this narrow interpretation, the April 2019 Policy has ***not*** been designed to promote "patient" access to transplantation, but rather has considered access to transplant only for those ***candidates*** already on the waiting list. Such an interpretation is wholly inconsistent with the plain language and intent of the Final Rule.

130. Although the term "patient" is not defined by the Final Rule, "transplant candidate" is defined to mean "an individual who has been identified as medically suited to benefit from an organ transplant *and has been placed on the waiting list by*

the individual's transplant program." 42 C.F.R. § 121.2 (emphasis added). If the Final Rule intended "patient access" to be limited to those already on the waitlist, it would have used the word "candidate" instead of "patient." In fact, the regulation uses the word "candidate" later in the same rule—in paragraph (a)(8), the text sets forth that allocation polices "[s]hall 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."

131. Moreover, as previously described, *supra* ¶¶ 62-65, the legislative and regulatory history make clear that the government intended the OPTN to develop policies that consider socioeconomic factors affecting access to the waitlist, not just candidates' access to organs once waitlisted. *See, e.g.*, 63 Fed. Reg. at 16,309 (stating that the Final Rule required the OPTN to "modify or issue policies to reduce inequities resulting from socioeconomic status to help patients in need of a transplant *be listed* and obtain transplants") (emphasis added).

132. The Final Rule requires allocation policies to "promote patient access to transplantation," which was understood to mean promoting access to transplantation for all end-stage organ disease patients, including those not yet on the waitlist, because the "primary barrier" to transplant access was access to the waitlist. Ex. 4 at 41, *supra* ¶ 63. The OPTN has admitted that it did not consider

access to the waitlist when evaluating the effect of the April 2019 Policy. Ex. 8 at 31.

133. When prompted by HRSA to respond to this criticism as identified in Plaintiffs' Critical Comment, the OPTN claimed that "[i]t is not possible for an organ allocation policy to improve access to transplant for patients who are not registered for a transplant on the waitlist by a transplant hospital." Ex. 15 at 9. However, in the same response, the OPTN referred to a prior kidney allocation policy change, which recognized that some candidates "had a more difficult time gaining access to a transplant hospital" and thus access to the waitlist. *Id.* at 8. In kidney allocation, the OPTN changed the policy to credit candidates with waiting time from the date they started dialysis rather than from the date they are accepted by a transplant center onto a waitlist. The OPTN cites this as an example of a policy intended to address socioeconomic inequities, but the kidney policy also serves as an example of an allocation policy that promotes overall patient access to transplantation by recognizing that it takes longer for some patients to be listed as transplant candidates because of their access to healthcare and structuring the allocation of organs accordingly.

4. The OPTN's Focus On A So-Called "Geographic Variance" Ignores The Varying Waitlist Mortality Rates That Suggest The April 2019 Policy Will Increase Deaths Nationwide.

134. The OPTN uses the term "geographic disparities" to refer to the idea that different DSAs have different "median MELD at transplant" or "MMaT" scores. One of the OPTN's stated primary goals for the liver allocation policy was to "reduce the variance in geographic disparities to access," Ex. 8 at 7, and "to have as little variance as possible, which would indicate that candidates with relatively similar levels of need are receiving organ offers at similar rates." Ex. 17 at 12.

135. UNOS tracks a substantial amount of data from transplant centers, including the MELD score of each liver recipient at the time of his or her transplant. UNOS then looks at all the MELD scores at the time of transplant for all recipients at all centers within each DSA and takes the average score to arrive at the MMaT. If the MMaT in Georgia is 28, which is lower than the MMaT of 30 in Illinois, then without any further analysis, the OPTN concludes that there is a problematic "geographic disparity" in organ allocation. To reach such a conclusion, the OPTN assumes that a lower MMaT in one region means that healthier candidates in that region who are less likely to die are unfairly being transplanted while sicker candidates who live in another part of the country and are more likely to die remain on the waitlist. But this assumption ignores fundamental realities of liver

transplantation, realties that the OPTN is keenly aware of, including variations in waitlist mortality and access to quality health care.

136. Mortality risk is not solely reflected in the MELD score, but rather, is affected by a combination of severity of illness as well as non-clinical factors (including socioeconomic status and the ability to access the waitlist and quality health care). For example, the waitlist mortality in South Carolina has been as much as five times higher than the waitlist mortality in New York, even though MMaT is higher in New York. The OPTN acknowledged this fact in its annual data report, noting that "[w]aitlist mortality rates varied geographically." Ex. 19 at 3. The report goes on to explain that mortality rates "did not necessarily mirror transplant rates, suggesting that *waitlist outcomes were not determined simply by organ availability*. Other potential factors may include access to healthcare in general and to high-quality specialty care for liver disease, referral and waitlist registration practices, and pretransplant patient management." *Id.* And yet, in approving the April 2019 Policy, the OPTN seeks to equalize MMaT variances across DSAs through a reallocation of donated organs (including moving organs from low-income communities to high-income communities) without regard to variations in waitlist mortality rates across DSAs, access to quality care, and other factors identified as outcome determinative *in the OPTN's own report*. Critically, this report explores

mortality rates and correlations using real-world, actual outcomes, not simulated data, and this report recognizes that mortality risk is affected by more than MMaT.

137. The OPTN cannot simply cherry pick a single criterion, such as MMaT, to consider in a vacuum and disregard other known factors that reflect a candidate's likelihood of mortality. As noted above, factoring in these varying waitlist mortality rates suggests that *the April 2019 Policy will increase deaths nationwide*, which is not consistent with the requirements of the Final Rule. The OPTN has disregarded the fact that an end-stage liver disease patient's medical urgency may be significantly affected by the individual's socioeconomic status and is not limited to his or her MELD score, particularly when that MELD score varies based on the patient's geography.

138. Further, an overemphasis on MMaT as the primary metric indicative of geographic equality ignores the reality that surgical practices are a significant factor in MMaT variances. Not all donated organs are of equal quality, and in addition to basic donor-recipient matching considerations, some transplant programs are disproportionately willing to use higher risk (or "marginal") organs. Transplant programs that are more aggressive usually use such marginal livers in lower MELD recipients because it is thought that those marginal organs may be successfully transplanted to healthier recipients who can better tolerate a poor initial function of

the liver graft. Programs that are successfully able to use these marginal organs may have a lower MMaT than those programs that use higher quality organs on higher MELD recipients, but this does not necessarily mean that there is an unfair allocation of organs.

139. The OPTN acknowledges the likelihood of marginal organs affecting MMaT but only in the context of organs that are accepted from donor hospitals more than 500 nautical miles away. The April 2019 Policy excludes these organs from MMaT calculations because they are likely "more aggressive transplants" and "including them in the MMaT calculation could potentially serve as a disincentive to use [] these organs." Ex. 8 at 24. However, the April 2019 Policy does not take into consideration that certain transplant centers may be effectively using such marginal organs regardless of where the donor was located, which affects the center's MMaT. If certain centers have developed expertise in using these otherwise discarded organs in lower MELD candidates, they will perform the transplant regardless of the distance from the donor organ. The April 2019 Policy wholly fails to account for such use of marginal organs. Moreover, under the new policy, patients who are eligible for exception points and enrolled at such transplant centers will be significantly disadvantaged, as explained below in paragraph 155.

140. Finally, MELD scores do not definitively capture the medical urgency of the candidate receiving the transplant. One well-known factor affecting regional variation in MMaT is the difference in regional approval rates for symptom-based exceptions, *see supra* at ¶ 76, which, if granted, increase the recipient's MELD score at transplant.

141. When organs were allocated based in part on DSAs and Regions, the regional exception variances were not as influential in determining which candidates received donated organs because all candidates within the same Region received exception points at the same rate. However, under the April 2019 Policy, organs may cross Regions and DSAs, and therefore candidates in Regions with arbitrarily higher rates of exception point approvals will be more likely to receive organs as compared to candidates in Regions with lower rates of approval.

142. To try to correct the regional variances, the OPTN was set to implement a National Liver Review Board ("NLRB") on January 31, 2019 to promote consistency in awarding exception points. Because of the impact of exception points under the new allocation model, the vast majority of the Liver Committee voted in favor of delaying the implementation of any change in allocation policy until at least three months after the NLRB was implemented to allow time for the national

reviewers to begin the effort to normalize some of the regional variation in exception point allocation. Ex. 18 at 12.[2]

143. This three-month gap was also discussed at the OPTN December Board meeting, where the Committee Chair noted that both the NLRB and allocation policy are "major changes" and "to put these two too close together, we felt, would be asking for significant trouble." Ex. 11 at 49, 67-68. During the Board's discussion of the April 2019 Policy, the Committee Chair explicitly stated that "[t]he NLRB is going live before this policy, at least three months before[; t]hat's the plan."

144. The NLRB had been scheduled to begin on January 31, 2019, three months before the go-live date of the April 2019 Policy on April 30, 2019. However, UNOS has now published that the NLRB will be implemented on April 30, the same date as the April 2019 Policy. By implementing both the NLRB and a new allocation policy simultaneously, the OPTN has again ignored the advice and recommendations of its liver transplant experts, which voted overwhelmingly in favor of delaying the allocation policy change until at least three months after the NLRB implementation. *See* Ex. 18 at 12. Instead, by launching both policies

[2] Each candidate with exception points is re-reviewed every three months, so after a three-month period nearly all of the candidates should have been reviewed under the new national review board.

simultaneously, in the words of the OPTN's Liver Committee Chair, the OPTN is "asking for significant trouble."[3]

145. Moreover, the way in which the NLRB will be implemented will now result in the location of a candidate's listing directly affecting his or her likelihood of being offered an organ without any legal basis for doing so. For candidates who are granted exception points, the exception points will now be based on the median MELD at transplant within a 250 nautical mile circle of the transplant hospital. This means that a single patient could have two different MELD scores, despite obviously identical health status, if he or she is eligible for exception points and is "multi-listed" as a candidate through two different transplant hospitals.[4] For example, suppose a hypothetical exception point patient from Rochester, NY is listed as a transplant candidate in his hometown at the University of Rochester Medical Center ("Rochester") as well as a transplant center where his parents live at UMass Memorial Medical Center ("UMass"). The patient will have a different MELD score as a candidate at Rochester than he will have as a candidate at UMass. At UMass,

[3] In addition, the NLRB, as proposed, is also reliant on the flawed metric of median MELD at transplant, and thus it may result in a further inequitable distribution of organs.

[4] As noted above, *supra* ¶ 55, it is rare for candidates to be registered and listed at more than one transplant center, but this is possible, so long as the candidate meets each transplant center's independent listing criteria.

the candidate would be listed as a MELD of 29 and at Rochester the exact same candidate would be listed as a MELD of 27.[5] Under the April 2019 Policy, if a donor liver became available in Rochester, it would be flown to UMass for the candidate's transplant surgery before being offered to the same candidate locally. This is the very definition of organ allocation being "based on the candidate's place of residence or place of listing," which is prohibited by 42 C.F.R. § 121.8(a)(8).

H. The April 2019 Policy Does Not Promote Efficient Management of Organs and Will Result in Significantly Wasted Resources, Additional Discarded Organs, and Economic Harm to the Transplant Center Plaintiffs

1. There Will Be Wasted Resources On Additional Air Travel For Organ Procurement.

146. In the April 2019 Policy Proposal, the Committee "concluded that transporting 70% of the organs by air was not feasible at the time." Ex. 8 at 20. However, the April 2019 Policy will result in over 70% of donated livers nationally being flown to the intended recipient's hospital, compared to the Current Policy, in which the SRTR model simulates only 50.7% of donated organs flying. Because the

[5] *See* Median MELD at Transplant by 250 Nautical Mile Circles Around Liver Transplant Programs and Median PELD at Transplant Within the Nation, Updated April 08, 2019, https://optn.transplant.hrsa.gov/media/2844/mts_distribution.pdf. Under the new NLRB model, exception point candidates are given MELD scores of the median MELD at transplant minus three, based on the median MELD at transplant for a 250 nautical mile circle around the transplant hospital.

increased flying will inevitably result in increased amounts of time the donated organs spend outside of a body, the April 2019 Policy may result in additional discarded livers or even an increase in unfavorable transplant outcomes.

147. Additionally, as described above, *supra* ¶ 93, because of the challenges of obtaining last-minute air transportation to any hospital where a donor might be at any hour of day (including the necessity of private chartered air travel), the OPTN Liver Committee observed that the increased need for flights to procure organs may result in fewer transplants. If an organ had to be declined because of air travel issues, "additional offers to candidates away from the donor hospital would only increase allocation time, and decrease efficiency of [the] offer." Ex. 8 at 20. As such, the increase in organ wastage that is already predicted in the SRTR data models (as reflected in the decreased number of transplants) is likely significantly underestimated.

148. Marginal organs are especially less likely to be accepted and transplanted when the length of time the organ is outside of the body is prolonged due to longer travel distances. *See* Briefing Paper at 24 (noting that "a more desirable liver can withstand" longer times outside of a body) and 41 (noting that organs from donors over 70 years old, which are considered less desirable, "have better outcomes with shorter" times outside of a body). Therefore, these organs are

more likely to go to waste under the new policy. Furthermore, as travel increases, more programs will be required to rely on unaffiliated surgical teams to procure organs, which could negatively affect clinical outcomes.

149. Greater travel also increases risks to the procurement teams that must travel to remote locations in small aircrafts, often in the middle of the night, regardless of weather conditions. A 2009 study reported that 27 members of procurement teams had died in procurement air travel in recent history and estimated that the risk of fatality while traveling on an organ procurement flight was 1000 times higher than traveling on a scheduled commercial flight.[6]

150. The predicted increase in air travel is significant and present for each of the Transplant Center Plaintiffs, as shown in the chart below. For Emory and Piedmont, while performing 31 fewer transplants each year, the number of organs transplanted that will be required to be flown from the donor hospital to Georgia will increase from 53.6% to 77.2%.

151. For Henry Ford and Michigan Medicine, while performing approximately 41 fewer transplants each year, the number of organs transplanted

[6] *See* M. Englesbe & R. Merion, *The Riskiest Job in Medicine: Transplant Surgeons and Organ Procurement Travel*, 9 Am. J. Transplantation 2406 (2009).

that will be required to be flown from the donor hospital to Michigan will increase from 46.8% to 82%.

152. For Indiana University Health, while performing approximately 27 fewer liver transplants per year, the number of organs transplanted that will be required to be flown from the donor hospital to Indiana will increase from 42.8% to 79.9%.

153. For University of Iowa, while performing approximately 4 fewer liver transplants per year, the number of organs transplanted that will be required to be flown from the donor hospital to Iowa will increase from 49.7% to 91.3%.

154. For University of Kansas, Saint Luke's, and Barnes-Jewish, while performing 33 fewer transplants, the number of organs that will be required to be flown from the donor hospital to Kansas or Missouri will increase from 47.7% to 79.2%.

155. For University of Kentucky, while performing 24 fewer liver transplants per year, the number of organs that will be required to be flown from the donor hospital to Kentucky increases from 53.8% to 85.2%.

156. For Oregon Health, while performing 18 fewer liver transplants each year, the number of organs that will be required to be flown from the donor hospital to Oregon increases from 51.1% to 74.3%.

157. For Vanderbilt, while approximately 44 fewer transplants will be performed, the percentage of organs that must be flown from the donor hospital to Tennessee increases from 57.7% to 79.6%.

158. For University of Virginia and Virginia Commonwealth, while 34 fewer liver transplants will be performed in Virginia, the percentage of organs that must be flown from the donor hospital to be transplanted in Virginia rises from 69.8% to 92.7%.

159. Increased travel, particularly air travel, will increase organ wastage over the Current Policy and thus is contrary to the Final Rule's requirement that allocation policies avoid wasting organs and promote the efficient management of organ placement. 42 C.F.R. § 121.8(a)(5).

Region and Transplant Center Plaintiffs	Current Number of Transplants	April 2019 Policy Number of Transplants	Current Percentage of Organs Flown	April 2019 Policy Percentage of Organs Flown
Georgia: Emory and Piedmont	261.3	230	53.6%	77.2%
Michigan: Henry Ford and Michigan Medicine	176.9	136	46.8%	82%
Indiana: Indiana University Health	114.5	87.9	42.8%	79.9%
Iowa: University of Iowa	26.6	22.5	49.7%	91.3%

Region and Transplant Center Plaintiffs	Current Number of Transplants	April 2019 Policy Number of Transplants	Current Percentage of Organs Flown	April 2019 Policy Percentage of Organs Flown
Kansas and Missouri: University of Kansas, Saint Luke's, Barnes-Jewish	236.6	203.3	47.7%	79.2%
Kentucky: University of Kentucky	92.1	67.9	53.8%	85.2%
Oregon: Oregon Health	63.6	46	51.1%	74.3%
Tennessee: Vanderbilt	152.3	108.1	57.7%	79.6%
Virginia: University of Virginia Virginia Commonwealth	110.8	76.4	69.8%	92.7%
Transplant Center Plaintiffs' Region Total or Average	1,234	978	52.5%	82.3%
National Total or Average	6,651	6,594	50.7%	71.4%

2. Plaintiffs' Estimated Transplant Costs Will Increase Significantly Under The April 2019 Policy.

160. In its policy proposal, the OPTN Committee observed that the economic impact of increased transportation costs for prior proposed changes to liver allocation models was significant. The Committee cited to one research study that concluded increased air travel for donated livers could lead to increased costs to the health care system of over $70 million a year. Ex. 8 at 19.

161. Similar to the situation here, the lung allocation policy was hastily changed in November 2017. Based on real-world data and experience following the lung allocation policy change, the April 2019 Policy will significantly increase the costs for transplants without bringing any material benefit to national patient health and safety.

162. Organ cost for transplantation is bundled into an organ acquisition fee that includes expenses related to the procurement team, preservation, and transportation of the organ. In one Transplant Center Plaintiff's experience, following the change to the lung allocation policy, the median organ acquisition cost more than doubled from $34,000 to over $70,000, largely because of the increase in flying and transportation costs.

163. In addition, in some instances, a transplant center's procurement team may fly to a remote donor hospital after accepting the organ on paper, but then upon seeing the donor or organ, the team may decline the organ. Such travel costs and the time of the procurement surgeons and other medical personnel is largely a non-reimbursed activity. These so-called "negative fly outs" are estimated to cost between $10,000 and $15,000 each, and are more likely to occur under the April 2019 Policy. These negative fly out costs are not included in the doubled median organ acquisition cost cited above.

164. Transplants performed with distant donor organs are also more likely to need nighttime coordination, requiring additional resources and presenting additional risks. In one Transplant Center Plaintiff's experience, before the lung allocation policy changed, 100% of its lung transplants were performed during the daytime, as opposed to 67% under the new policy.

165. The April 2019 Policy will likely present similar additional costs, including increased organ acquisition costs as well as administrative expenses, such as negative fly outs. Such costs theoretically could be the price to pay for significantly improved, life-saving allocation policies, but based on the lung allocation policy experience, that is not what the April 2019 Policy presents. Under the lung allocation policy, there has been an increase in the overall waitlist death rate, a decrease in the overall transplant rate, a decrease in donor utilization, and an increase in the number of discarded organs.

3. The April 2019 Policy Will Result in Fewer Liver Transplants Performed Nationally, Significantly Fewer Liver Transplants Performed in Plaintiffs' Regions, and Will Meaningfully Reduce Patient Plaintiffs' Likelihood of Receiving a Liver Transplant and Likelihood of Survival.

166. Under the Current Policy, the SRTR's simulated model predicts an average of 6,651 liver transplants per year. *See* SRTR Report at 7, Table 2. Under the April 2019 Policy, the model predicts there will be 6,594 transplants per year—

57 fewer liver transplants performed nationally each year, and this number may be an underestimate. Because certain regions of the country will experience heightened reductions in the number of transplants, this concerning trend will be compounded for the Patient Plaintiffs, Transplant Center Plaintiffs and their waitlisted candidates, as well as for the communities Transplant Center Plaintiffs serve, some of which have significantly diminished access to quality healthcare for those with end-stage liver disease and thus diminished access to the waitlist.

167. Over the past five years, Emory has performed approximately 750 liver transplant surgeries. Piedmont has performed approximately 500 liver transplants. Emory currently provides care to 141 candidates waiting for a liver transplant, while Piedmont treats 190 waitlist candidates. According to the SRTR data models, under the April 2019 Policy, there will be 31 fewer liver transplants performed each year, or 155 fewer transplants during the next five years, in Georgia.[7] Piedmont and Emory are the only two adult liver transplant programs in the State of Georgia.

[7] All transplant counts are based on the SRTR transplant counts by DSA under the Current Policy as compared to the April 2019 Policy. *See* Scientific Registry of Transplant Recipients, SRTR LI_2018_01 Data Request on Circle Based Allocation: DSA-Level Data Tables, Table 2, https://optn.transplant.hrsa.gov/media/2641/li2018_01_dsa_level_results.pdf.

168. Henry Ford has performed about 500 liver transplants during the past five years, and Michigan Medicine has performed about 390 liver transplants. Henry Ford provides care to 182 candidates waiting for a liver transplant, while Michigan Medicine treats 160 adult waitlisted candidates. According to the SRTR data models, under the April 2019 Policy, there will be about 41 fewer liver transplants performed each year, or 205 fewer transplants over five years, in Michigan.

169. Indiana University performed over 750 liver transplants during the past five years. It currently provides care to 89 candidates waiting for a liver transplant. According to the SRTR data models, under the April 2019 Policy, there will be about 27 fewer liver transplants performed each year in Indiana, or 135 fewer transplants over five years, all of which would have been performed at Indiana University Health.

170. The University of Iowa has performed almost 130 liver transplants during the past five years. It currently manages the care of 19 candidates waiting for a liver transplant. According to the SRTR data models, under the April 2019 Policy, there will be about four fewer liver transplants per year in Iowa, or 20 fewer transplants over the course of five years. The University of Iowa is the only liver transplant program in the state.

171. Over the past five years, the University of Kansas has performed nearly 460 liver transplants. The University of Kansas currently provides care to 106 candidates waiting for a liver transplant. Saint Luke's has performed about 60 liver transplants in the past five years. Saint Luke's currently provides care to 22 candidates waiting for a liver transplant. According to the SRTR data models, under the April 2019 Policy, there will be about 26 fewer liver transplants performed each year in Kansas and neighboring parts of Missouri, meaning 130 fewer transplants during the next five years.

172. Over the past five years, Barnes-Jewish has performed over 500 liver transplants. Barnes-Jewish currently provides care to 50 candidates waiting for a liver transplant. According to the SRTR data models, under the April 2019 Policy, there will be about 33 fewer liver transplants performed each year, or 165 fewer transplants over five years, across Kansas, Missouri, and southern Illinois.

173. The University of Kentucky has performed approximately 215 liver transplants in the past five years. The health system currently provides care for 119 candidates on the liver waitlist. According to the SRTR data models, under the April 2019 Policy, there will be approximately 24 fewer liver transplants per year, or 120 fewer transplants over five years, within Kentucky.

174. Over the past five years, Oregon Health has performed approximately 275 liver transplants. Oregon Health currently provides care to 95 candidates waiting for a liver transplant. According to the SRTR data models, under the April 2019 Policy, there will be about 18 fewer liver transplants performed each year, or 90 fewer transplants over five years, in Oregon and the immediate surrounding area in southern Washington and western Idaho. Oregon Health is the only liver transplant center that services these areas other than a Veterans Affairs Health program.

175. Over the past five years, Vanderbilt has performed over 700 liver transplants. Vanderbilt currently provides care to 165 candidates waiting for a liver transplant. According to the SRTR data models, under the April 2019 Policy, there will be approximately 44 fewer liver transplants performed each year, or 220 fewer transplants over five years, in central and eastern Tennessee and neighboring parts of Virginia.

176. Over the past five years, Virginia Commonwealth has performed approximately 320 transplants. The University of Virginia has performed over 350 transplants in the past five years. Virginia Commonwealth currently provides care to approximately 57 candidates waiting for a liver transplant. The University of Virginia is treating 107 waitlisted adults. According to the SRTR data models, under

the April 2019 Policy, there will be approximately 34 fewer liver transplants performed each year, or 170 fewer transplants over five years, in Virginia (excluding the region that borders Tennessee).

177. Collectively, Transplant Center Plaintiffs currently treat over 1,500 candidates awaiting liver transplants. Based on the SRTR modeling, if the April 2019 Policy takes effect, the collective number of transplants in the regions that Transplant Center Plaintiffs serve will go from 1,234 transplants per year down to 978 transplants per year, leaving 256 candidates—20% of the liver transplant candidates the Transplant Center Plaintiffs collectively would expect to serve in one year—without a transplant that they would have otherwise received.

178. This number may be an underestimate if more organs than the model predicts are discarded because of the increased need to fly organs to intended recipients under the April 2019 Policy or other inefficiencies in the system, which have been noted in the change to the lung allocation policy, as discussed above.

179. Therefore, at least 256 candidates registered on the waitlist through Transplant Center Plaintiffs will not receive a transplant that they would have otherwise received, and they face irreparable harm—near certain death—if the April 2019 Policy is allowed to take effect. Although it is impossible to identify the exact 256 individuals who will likely die because of this policy change, all of the transplant

candidates registered for the liver waitlist at the Transplant Center Plaintiffs face a significantly increased risk of death if the April 2019 Policy is implemented.

180. Patient Plaintiffs are among those who will be significantly disadvantaged and face a grave risk of death if the April 2019 Policy is implemented. All four live in high-risk communities with limited access to quality medical care and in parts of the country that will see dramatically decreased rates of liver transplantation. These patients will further be impacted because the April 2019 Policy is set to take effect alongside of the flawed National Liver Review Board program, which will benefit candidates in parts of the country that have historically high exception point approvals. The Patient Plaintiffs will have a much greater risk of death on May 1, despite no change to their clinical condition, if the April 2019 Policy takes effect.

181. Several of the Transplant Center Plaintiffs participated in the OPTN Liver Committee's public comment process, but none had formal notice that the Board of Directors was considering an "amendment" that would significantly affect their likelihood of receiving a transplant. Moreover, many patients and likely most potential donors were not aware of the OPTN's process at all. Defendants failed to provide adequate notice and an opportunity for Plaintiffs, patients, and the public to be heard, as required by the Final Rule, before approving the April 2019 Policy.

182. As explained above, *see supra* ¶¶ 122-124, the SRTR's model shows that under the April 2019 Policy, organs will be taken away from the Transplant Center Plaintiffs' waitlisted candidates, including the Patient Plaintiffs, and will be given to waitlist candidates in communities of higher socioeconomic status, in which waitlist candidates already have a statistically better chance of continuing to survive while waitlisted. The movement of organs under the April 2019 Policy will make existing disparities in access to health care even greater.

183. This level of anticipated reduction in transplants, coupled with the additional effects detailed herein, will cause life-threatening harm to Patient Plaintiffs as well as other Transplant Center Plaintiffs' patients, result in economic harm to Transplant Center Plaintiffs, and will threaten the long-term viability of Transplant Center Plaintiffs' liver transplant programs.

CAUSES OF ACTION

COUNT 1 – ADMINISTRATIVE PROCEDURE ACT, 5 U.S.C. § 706(1) THE SECRETARY FAILED TO ACT IN ACCORDANCE WITH LAW

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

185. 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.

186. 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).

187. HHS failed to take multiple required actions in violation of the APA. First, the April 2019 Policy fails to substantively comply with the requirements of NOTA and the Final Rule, and HHS's failure to stop the unlawful April 2019 Policy from going into effect as scheduled on April 30, 2019 is a violation of the APA.

188. Section 121.4(b)(2) of the Final Rule provides that "[t]he Secretary ***will 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" (emphasis added). The OPTN claims in its March 26 letter to HRSA that the policy complies with NOTA and the Final Rule, but HHS has not made any such determination through the Secretary, HRSA, or otherwise. Nor has HHS discussed the April 2019 Policy with its Advisory Committee or published it in the Federal Register for public comment.

189. Federal employees cannot contract out inherently governmental functions, which include the interpretation of U.S. laws that will significantly affect the lives of private persons. Federal Activities Inventory Reform Act, Pub. L. No. 105-270, § 5, 112 Stat 2382 (1998).

190. Determining whether the allocation policy complies with NOTA and the Final Rule is an "interpretation" of federal law that significantly affects the lives of those Americans on the transplant waitlist list, and such action must be performed by federal employees.

191. Even if the OPTN is a semi-governmental entity, the OPTN does not have federal employees. Furthermore, under NOTA, Congress only authorized the OPTN to develop "medical criteria" for allocation. The other elements for allocation policies are set forth in the Final Rule, created and adopted by HHS, and require the Secretary's oversight. In short, neither NOTA nor any other statute authorizes HHS to defer to the OPTN, or UNOS acting in its capacity as OPTN, regarding what allocation policies are legally compliant.

192. HHS is obligated to interpret federal law and determine if the OPTN's policy is compliant with such law. Yet when asked about his authority to request that the OPTN delay implementation of the April 2019 Policy, Secretary Azar told the Senate Appropriations Committee, "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 but I am happy to work with the committee on any other solutions here to look at and ensure that the fair and scientifically valid treatment has been given here." Ex. 3 at 11. This statement and the Secretary's

corresponding failure to act demonstrates that HHS has failed to take required action in violation of the APA.

193. Second, HHS violated the APA when it failed to comply with the legal procedures required for adopting a significant policy.

194. Section 121.4(b)(2) of the Final Rule mandates that the Secretary "will" refer "significant" proposed policies to the Advisory Committee on Organ Transplantation and publish them in the *Federal Register* for public comment.

195. A policy that dictates how donor organs will be allocated to transplant waitlist patients is "significant." Indeed, the Secretary admitted in a recent Senate hearing that the April 2019 Policy is "significant." Yet HHS has failed to refer the policy to the Advisory Committee on Organ Transplantation and has failed to publish the policy in the *Federal Register*.

196. The April 2019 Policy fails to comply with the requirements of NOTA and governing regulations in numerous ways. The reform of the policy was not based on an assessment of its cumulative effect on socioeconomic inequities as required under 42 C.F.R. § 121.4, even though the OPTN must consider how organ allocation policies affect those who are socioeconomically disadvantaged and direct its Board to reform those policies in a way that reduces any inequities.

197. The April 2019 Policy is also not designed to avoid wasting organs or to promote efficient management of organ placement as required under 42 C.F.R. § 121.8. Instead, it will require over 70% of donor organs to be flown, which will result in increased organ wastage and discarded organs, fewer transplants nationwide, and inevitably more deaths of waitlisted transplant candidates.

198. The policy also must be designed to promote patient access to transplantation, but the April 2019 Policy uses a flawed metric to reduce geographic variance. The OPTN inexplicably focuses on median MELD at transplant variances as a proxy for "access to transplantation." But this metric only focuses on transplant "candidates" already waitlisted and does not adequately capture the likelihood of mortality of candidates who are not yet on the waitlist or those whose severity of illness is not fully captured by their MELD score.

199. These failures to act violated the APA and resulted in the adoption and imminent implementation of the April 2019 Policy, which will have a severe and detrimental effect on all Plaintiffs as well as Transplant Center Plaintiffs' other end-stage liver disease patients. The longer travel times will also result in fewer marginal organs being likely to be accepted and transplanted and greater reliance on unaffiliated teams to procure organs, which could result in fewer successful transplants and further negatively affect clinical outcomes. Greater travel also

increases risks to the procurement teams that must travel to remote locations in small aircrafts, often in the middle of the night, regardless of weather conditions.

200. There will also be significantly more wasted resources and also wasted organs due to unnecessary "flyouts" under the April 2019 Policy. Increased travel, particularly air travel, will increase organ wastage and thus is contrary to the Final Rule's requirement that allocation policies avoid wasting organs and promote the efficient management of organ placement. Moreover, this policy will result in fewer liver transplants performed nationally and significantly fewer liver transplants performed in the Regions where Plaintiffs live and work.

201. These cumulative effects will result in fewer transplants nationally and significantly fewer transplants in the Plaintiffs' communities, which severely impacts the Plaintiffs. Patient Plaintiffs and Transplant Centers Plaintiffs' other patients are at a dramatically increased risk of death because of their decreased likelihood of receiving an organ. The Transplant Center Plaintiffs will also experience economic harm due to decreased volume and increased costs, which could threaten the long-term viability of their liver transplant programs.

202. In short, these unlawful actions will significantly harm Patient Plaintiffs, Transplant Center Plaintiffs, and Transplant Center Plaintiffs' other end-stage liver disease patients—including a significant number of whom will die as a

result of not receiving a liver transplant that they would otherwise receive under the current policy.

COUNT 2 – ADMINISTRATIVE PROCEDURE ACT, 5 U.S.C. § 706(2)
THE SECRETARY'S ACTIONS VIOLATED THE LAW

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

204. The APA mandates that "a reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be—(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court." 5 U.S.C. § 706(2).

205. If, in the alternative to Count 1, HHS did not unlawfully abdicate its responsibility under the inherently governmental function law, then it ratified or otherwise acted in approval of the April 2019 Policy, despite its failure to comply with the law substantively and procedurally.

206. In response to the immediate aftermath of a critical comment filed by a New York plaintiffs' attorney, HRSA made the abrupt decision to abandon before it could be implemented the December 2017 Policy that was adopted after a multi-year deliberative and thoughtful process. HRSA instead directed the OPTN Board "to adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions" by the next OPTN Board of Directors meeting, just four months later. The directive to develop and choose a new policy within this incredibly limited timeframe was arbitrary and capricious, and otherwise not in accordance with the law.

207. HRSA's truncated timeline to adopt a new liver allocation policy resulted in a flawed and unlawful process that failed to adequately enforce the public comment period and resulted in approval of a policy that does not satisfy the statutory criteria for organ allocation under NOTA. The Liver Committee did not have sufficient time to review, and was not even sent, public comments by key constituencies before voting on which policy it would recommend for adoption to the OPTN Board. Then without any additional public comment or notice period, the OPTN Board made the exceptionally rare decision to reject the Liver Committee's recommended policy and instead adopt the April 2019 Policy.

208. HHS, through HRSA, then authorized or ratified the resulting unlawful April 2019 Policy. *See, e.g.*, HRSA December 2018 Letter at 1 (HRSA "continues

its longstanding practice of relying on the expertise of the OPTN and its members . . . to consider and address the requirements of the OPTN final rule as organ allocation policies are developed and revised"); *id.* ("HRSA has carefully monitored the OPTN's deliberations and is satisfied that the OPTN complied with HRSA's expectations outlined in the enclosed letter to the OPTN, dated July 31, 2018."); *id.* at 4 (praising the OPTN Board's process in adopting the April 2019 Policy and noting that it "expects the OPTN to proceed expeditiously in implementing the December 2018 liver allocation policy").

209. Although the HRSA March 2019 Letter requests that the OPTN review certain aspects of the April 2019 Policy, it expressly "does not mandate that the OPTN reach any particular conclusions," nor does it require a delay in implementation of the unlawful policy. There has not been any subsequent communication from HHS, through HRSA or otherwise, indicating that it will delay the April 30, 2019 implementation of the unlawful policy.

210. In light of the statements approving of the unlawful April 2019 Policy and HHS's decision not to mandate that the policy's implementation date be postponed, HHS has acted in violation of the APA.

COUNT 3 – U.S. CONST, AMEND. V
DEFENDANTS VIOLATED PLAINTIFFS' RIGHT TO DUE PROCESS

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

212. "Procedural due process imposes constraints on governmental decisions which deprive individuals of ['life,'] 'liberty' or 'property' interests within the meaning of the Due Process Clause of the Fifth . . . Amendment." *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976); *see also Grayden v. Rhodes*, 345 F.3d 1225, 1232 (11th Cir. 2003) ("There can be no doubt that, at a minimum, the Due Process Clause requires notice and the opportunity to be heard incident to the deprivation of life, liberty or property at the hands of the government.").

213. A party's procedural due process right is violated when constitutionally inadequate processes result in state action that deprives the party of a constitutionally protected liberty or property interest. *Grayden*, 345 F.3d at 1232.

214. An organ allocation policy change that substantially diminishes a waitlist patient's expectation of receiving a donor organ is, for that patient, a deprivation of a constitutionally protected "life" interest. Before a state action, such as a change in allocation policy, can deprive such a patient of that "life" interest, it must satisfy at least the minimum requirements of due process. *Mathews*, 424 U.S.

at 332; *Dew v. McLendon Gardens Assocs.*, 394 F. Supp. 1223, 1230-31 (N.D. Ga. 1975).

215. UNOS, acting in its capacity as the OPTN, is an instrumentality of the government. The OPTN's adoption of the April 2019 Policy is a state action that deprives Patient Plaintiffs and other patients at the Transplant Center Plaintiffs of a constitutionally protected life interest, which the OPTN adopted pursuant to a constitutionally inadequate process. Indeed, the OPTN failed to give Patient Plaintiffs and Transplant Center Plaintiffs' patients any notice or meaningful opportunity to be heard before adopting a policy that will have a life-or-death effect.

216. These actions and others are state actions that resulted in the adoption and imminent implementation of the April 2019 Policy, which will have a severe and detrimental effect on the Patient Plaintiffs and Transplant Center Plaintiffs' liver transplant programs and patients. These state actions have injured the life interests of Patient Plaintiffs and other candidates on the liver transplant waitlist who, as a direct result of this state action, now have a significantly increased risk of dying from failure to receive a liver that they would have otherwise been much more likely to receive.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that this Court:

A. declare that the April 2019 Policy violates NOTA and the regulations promulgated thereunder;

B. declare that the implementation of the April 2019 Policy violates the Due Process Clause of the Fifth Amendment of the U.S. Constitution;

C. enjoin the Secretary and UNOS, in its capacity as the OPTN, from implementing the April 2019 Policy;

D. order the Secretary to direct the OPTN not to allow the April 2019 Policy to go into effect; and

E. such other relief as is just and proper.

Dated: April 22, 2019

Respectfully submitted,

/s/ Peter C. Canfield

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