GALLAGHER
EVELIUS & JONES LLP
ATTORNEYS AT LAW

December 16, 2019

VIA EMAIL & COURIER

Ms. Ruby Potter
ruby.potter@maryland.gov
Health Facilities Coordination Officer
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215

Re: MedStar Franklin Square
Establishment of Liver and Kidney Transplant Services
Matter Nos. 17-03-2405 & 17-03-2406

Dear Ms. Potter:

On behalf of interested party University of Maryland Medical Center ("UMMC"), I am submitting four copies each of (1) UMMC's Renewed Motion for Stay of Certificate of Need Review and (2) UMMC's Response to the Motion of Medstar Franklin Square Medical Center to Submit Additional Data and in Support of its Renewed Motion for Stay of Certificate of Need Review of Medstar Health, Inc.'s Applications Proposing the Establishment of Liver and Kidney Transplant Services. WORD versions of the filings will also be provided to Commission Staff under separate email.

I hereby certify that a copy of this submission has been forwarded to the appropriate local health planning agencies as noted below. Thank you for your assistance.

Sincerely,

Ella R. Aiken

ERA/blr
Enclosures

#686748
006551-0239

cc: Paul Parker, Director, Center for Health Care Facilities Planning & Development, MHCC
Kevin McDonald, Chief, Certificate of Need, MHCC
Suellen Wideman, Esq., Assistant Attorney General, MHCC
William Chan, Health Policy Analyst, HSP&P/CON, MHCC
Jenelle Mayer, MPH, Health Officer, Allegany County
Nilesh Kalyanaraman, MD, Health Officer, Anne Arundel County
Letitia Dzirasa, MD, Health Commissioner, Baltimore City
Gregory Branch, M.D., Health Officer, Baltimore County Health Department
Laurence Polsky, M.D., Health Officer, Calvert County
Scott LeRoy, MPH, MS, Health Officer, Caroline County
Edwin Singer, L.E.H.S., Health Officer, Carroll County
Lauren Levy, Health Officer, Cecil County
Roger L. Harrell, MHA, Health Officer, Dorchester County
Barbara Brookmyer, MD, MPH, Health Officer, Frederick County
Robert Stephens, MS, Health Officer, Garrett County
Russell Moy, MD, Health Officer, Harford County
Maura Rossman, MD, Health Officer, Howard County
William Webb, MD, MPH, Health Officer, Kent County
Joseph Ciotola, MD, Health Officer, Queen Anne's County
Meenakshi Brewster, MD, MPH, Health Officer, St. Mary's County
Lori Brewster, MS, APRN/BC, LCADC, Acting Health Officer, Somerset County
Fredia Wadley, MD, Health Officer, Talbot County
Earl E. Stoner, MPH, Health Officer, Washington County
Lori Brewster, MS, APRN/BC, LCADC, Health Officer, Wicomico County
Rebecca Jones, RN, MSN, Health Officer, Worcester County
David C. Tobin, Esq.
Conor B. O'Croinin, Esq.
Thomas C. Dame, Esq.
Hannah L. Perng, Esq.

IN THE MATTERS OF	*	
	*	
MEDSTAR FRANKLIN SQUARE KIDNEY TRANSPLANT SERVICE	*	
	*	BEFORE THE MARYLAND
Docket No. 17-03-2405	*	HEALTH CARE
-and-	*	COMMISSION
MEDSTAR FRANKLIN SQUARE LIVER TRANSPLANT SERVICE	*	
	*	
Docket No. 17-03-2406	*	

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MEMORANDUM OF UNIVERSITY OF MARYLAND MEDICAL CENTER IN RESPONSE TO MOTION OF MEDSTAR FRANKLIN SQUARE MEDICAL CENTER TO SUBMIT ADDITIONAL DATA AND IN SUPPORT OF RENEWED MOTION FOR STAY OF CERTIFICATE OF NEED REVIEW

University of Maryland Medical Center ("UMMC"), by its undersigned counsel, submits this Memorandum in response to the November 12, 2019 motion of MedStar Health, Inc. ("MedStar") to submit additional data in connection with the reviews of its applications for Certificates of Need ("CON") proposing to establish liver and kidney transplant services at Franklin Square Hospital Center *d/b/a* MedStar Franklin Square Medical Center ("MFSMC"). UMMC also submits this Memorandum in support of UMMC's renewed motion for stay of the MFSMC CON reviews.

As described more fully below, UMMC requests that the Commission defer review of MedStar's applications until the United Network for Organ Sharing implements recently approved organ allocation policies for livers and kidneys. UMMC does not oppose the substantive request of MedStar to submit additional data into the record of these reviews, and indeed requests that the Commission require MedStar to update its analyses of its compliance with the applicable State

Health Plan chapter and review criteria based on the new organ allocation policies. However, UMMC believes such submissions would be untimely at this stage, and requests that such submissions be made after the new organ allocation policies are implemented and the requested stay, if granted, is lifted.

Introduction

In October of 2018, UMMC filed Interested Party comments in the pending reviews of MedStar's applications for CON proposing to establish liver and kidney transplant programs at MFSMC (the "MedStar organ transplant applications") together with a motion requesting that the reviews be stayed. As described more fully in UMMC's motion for stay and related briefing, UMMC requested that the Commission stay the review of MedStar organ transplant applications because the applications and applicable State Health Plan chapter assume the existence of Donation Service Areas for organ procurement ("DSAs") that will soon be obsolete. The liver and kidney allocation policies currently in effect are not compliant with federal regulation, and will soon be replaced with new, recently approved policies. Once implemented, the new policies will allocate livers and kidneys on a larger geographic scale beyond the current, artificial boundary lines of existing DSAs and will prioritize allocation to the most acute adult and pediatric patients. These changes render much of MedStar's analyses of its compliance with the applicable review standards and criteria moot, and undermine MedStar's justification for new programs at MFSMC.

Significantly, under the organ allocation policies in effect at the time of MedStar's applications, proposed efforts to create more donor organs in the Baltimore-area DSA would benefit patients waitlisted with UMMC or The Johns Hopkins Hospital ("JHH") more than patients waitlisted with MedStar Georgetown Transplant Institute at the MedStar Georgetown University Hospital ("MGTI"), because MGTI is in a different DSA. By opening a new program at MFSMC,

which is in the same DSA at UMMC and JHH, MedStar would increase the benefit of MedStar's Baltimore-area efforts to MedStar patients, assuming those patients join the MFSMC waitlist. Under the new allocation policies, however, MedStar's efforts to increase the donor organ supply in the Baltimore area will benefit patients waitlisted at MGTI, JHH, and UMMC equally, because of the geographic proximity of the hospitals and the removal of artificial DSA boundaries. Simply put, once the new policies are implemented, MedStar will not need a program at MFSMC for its patients to receive the maximum benefit from its proposed efforts to increase the organ supply in Maryland.

The Commission should defer review of MedStar's applications until the new allocation policies are implemented. At that time, UMMC agrees it will be appropriate for MedStar to update its application, as much of MedStar's analyses will be rendered moot by the allocation policy changes.

I. DONATION SERVICE AREAS WILL SOON BE OBSOLETE FOR KIDNEY AND LIVER ALLOCATION

A. Organ allocation policy background

Organ allocation policy in the United States is governed by the Final Rule issued by the U.S. Department of Health and Human Services ("HHS") and codified at 42 C.F.R. Part 121. The Final Rule establishes a regulatory framework for the structure and operations of the Organ Procurement and Transplantation Network ("OPTN"). 42 C.F.R. Part 121. Within HHS, the Health Resources and Services Administration ("HRSA") oversees organ donation. OPTN is responsible for developing organ transplantation policy in the United States, including how donor organs are distributed to transplant recipients. Id.; see also COMAR § 10.24.15.03, pp. 5-6. HRSA operates the OPTN through a contract with the United Network for Organ Sharing ("UNOS"). Id., p. 6.

As was true at the time the CON applications were docketed, UNOS currently divides the United States into 11 organ allocation regions. Id., p. 7. OPTN's organ allocation policy utilizes 58

distinct Donation Service Areas ("DSAs") within these 11 regions in order to determine who will receive a donor organ. An Organ Procurement Organization ("OPO") operates in each DSA to facilitate organ procurement and transplantation within that service area. HRSA July 31, 2018 Letter to OPTN, Exhibit A,[1] p. 1. Two OPOs provide organ procurement and allocation services in Maryland: the Washington Regional Transplant Community ("WRTC") and the Living Legacy Foundation ("LLF"). COMAR § 10.24.15.03, pp. 7-8.

MGTI is in the WRTC DSA. MFSMC, UMMC, and JHH are in the LLF DSA. The geographic boundaries of the DSAs play a significant role in the current allocation of organs because most organs are offered to categories of recipients (based on acuity of illness and organ compatibility, among other factors), first within a DSA, then within a region, and then nationally. The result of the DSAs and allocation policies currently in effect for both livers and kidneys is that patients outside the geographic boundary of a DSA do not have equal access to an organ as a patient of a similar acuity level on the other side of the boundary. For example, a donor organ that becomes available at Anne Arundel Medical Center, which is in the LLF DSA, could under current allocation policy be offered to a patient at UMMC who has a lower but similar range MELD or PELD[2] score than a patient at MGTI, because UMMC is in the LLF while MGTI is in the WRTC. Had the same

[1] Exhibits A through H are attached to UMMC's October 15, 2018 Motion for stay. Exhibits I through M are attached to UMMC's November 26, 2018 Reply in further support. UMMC incorporates those filings together with their exhibits as if set forth in full. Exhibits N through Z are attached to this Memorandum.

[2] MELD is an acronym for Model for End-Stage Liver Disease, a model for "prioritizing candidates waiting for liver transplants based on statistical formulas that are designed for predict who needs a liver transplant most urgently." UNOS, *Questions and Answers for Transplant Candidates about Liver Allocation*, Exhibit E. MELD scores are used for candidates 12 and older. Id. PELD (Pediatric End-Stage Liver Disease Model) scores are used for patients 11 and younger. Id.

donor organ become available at UM Capital Region Medical Center, which is just one county away but in the WRTC, the organ would be allocated to the higher acuity patient at MGTI.

B. UNOS has approved a new liver allocation policy.

As described more fully in UMMC's October 2018 Motion for stay and related briefing, HRSA determined that the reliance on DSAs does not comply with applicable regulation, and directed OPTN to develop new allocation policy.[3] In response, OPTN committed to approve new liver allocation policy in December 2018, and implement it by April, 2019. August 13, 2018 UNOS Letter regarding Plan for Amending Organ Allocation Policies, Exhibit E.

As projected, OPTN's board approved a new, acuity circle based liver allocation policy at its December 2018 meeting.[4] OPTN News Dec. 4, 2018, "Board approves updated liver distribution system," attached as Exhibit N. Following that approval, several medical centers and individual plaintiffs filed a lawsuit challenging the new allocation policy. [5] As a result of that lawsuit, HRSA

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[3] HRSA found that OPTN "has not justified and cannot justify the use of donation service areas (DSAs) and OPTN Regions in the current liver allocation policy." HRSA July 31, 2018 Letter to OPTN, Exhibit A, p. 1. HRSA noted that under the final rule, OPTN was required to "develop policies for the equitable allocation of cadaveric organs among potential recipients" that, among other things, "[s]hall not be based on the candidates' place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."(Id., p. 2, citing 42 C.F.R § 121.8(a)). HRSA ultimately directed OPTN to "approve liver allocation policy, consistent with the terms described in this letter and the OPTN final rule, by its December 2018 meeting." Id., p. 4.

[4] The acuity circle based policies considered by OPTN's board are discussed more fully in UMMC's 2018 briefing.

[5] Several medical centers and individual plaintiffs filed a lawsuit seeking a temporary restraining order and preliminary and permanent injunctions preventing UNOS from implementing the new liver allocation policy, based in part on the theory that HHS failed to follow legally required procedures in developing the policy, and deferred too greatly to UNOS, a private government agent. Callahan v. HHS, 939 F.3d 1251, 1256-7 (11th Cir. 2019), attached as Exhibit O. Plaintiffs further allege that the new policy is arbitrary and capricious, in violation of the Administrative Procedures Act ("APA"), and that it deprives plaintiffs of due process, in violation of the Fifth Amendment. Id. The United Stated District Court for the Northern District of Georgia denied plaintiffs' motion, finding, in part, that plaintiffs had not met their burden of establishing their likelihood of success on the merits. Id., 939 F.3d at 1257. However, the following day, the Court issued a temporary

directed OPTN to defer implementation of the new liver allocation policy and the National Liver Review Board ("NLRB") [6] until May 14, 2019. OPTN News, April 23, 2019, "Liver distribution policy, NLRB implementation deferred until May 14." Exhibit Q.

On May 14, 2019, OPTN implemented the new acuity circle based liver allocation policy and the NLRB. OPTN News, May 14, 2019, "New national liver transplant system takes effect," attached as Exhibit R. The use of the new policy, however, was short lived. On May 17, 2019, HRSA instructed UNOS to "revert to the liver distribution policy in place prior to May 14, 2019, utilizing boundaries based on donation service areas and regions, consistent with a federal court order." OPTN News, May 20, 2019 "Work in Progress to revert to DSA based system due to court order," attached as Exhibit S. UNOS implemented the reversion to the DSA based allocation policy on May

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injunction pending plaintiffs' appeal of its decision, reasoning, in part, that the burden if demonstrating the likelihood of success on the merits for an injunction pending appeal is lesser than the burden imposed on the same factor for the denied relief. Callahan v. HHS, No. 19-CV-1783-AT, Order (N.D.G.A. May 15, 2019), attached as Exhibit P. This Order effectively kept the recent status quo (prior to the May 14, 2019 implementation of the new policy), allowing the plaintiffs to seek appellate court review of the denial.

Ultimately, the Eleventh Circuit affirmed the District Court's finding that plaintiffs had failed to show likelihood of success on the merits with respect to the HHS's alleged failure to follow required procedures, but remanded the remainder of plaintiffs' motion for a temporary restraining order and preliminary injunction to the District Court for consideration of the APA and Fifth Amendment claims. Callahan et al. v. HHS et al., 939 F.3d 1251. The matter is now again pending before the District Court.

[6] The new policy contemplates reliance on a National Liver Review Board that would replace the individual review boards used in each of the 11 OPTN regions. This move to a national scoring body was intended to increase the consistency of MELD, PELD, and exception scores nationally. See generally OPTN December 2018 Briefing Paper, "Liver and Intestine Distribution Using Distance from Donor Hospital," *available at* https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (last accessed Dec. 14, 2019). The OPTN had previously approved the NLRB, but not yet implemented it.

23, 2019. OPTN News, May 23, 2019, "System notice: OPTN liver allocation policy revered to DSA and regions," attached as Exhibit T. The NLRB remains in effect. Id.[7]

Subsequent to the court order halting implementation of the new policy, the court denied a motion for a preliminary injunction seeking to prevent implementation of the new policy, finding that the plaintiffs had failed to demonstrate a likelihood of success on the merits. Callahan v. HHS, 939 F.3d 1251, 1256-7 (11th Cir. 2019), Exhibit N. The Order was upheld on appeal. Id. However, the district court will consider a new motion for preliminary injunction on additional grounds at an evidentiary hearing on December 17, 2019. Callahan et al. v. HHS et al., No. 19-CV-1783 AT, Order (N.D.G.A. Dec. 3, 2019), attached as Exhibit V.

Meanwhile, UNOS has agreed "to a voluntary stay in connection with implementation of the Acuity Circles Policy through January 17, 2020 and to refrain from proceeding with implementation of the Acuity Circles Policy through that date." Callahan et al. v. HHS et al., No. 19-CV-1783 AT, Stipulation (N.D.G.A. Dec. 9, 2019), attached as Exhibit W. Thus, in five weeks, there will be additional clarity regarding whether UNOS will implement the new, acuity circle based allocation policy. Even if UNOS does not implement the new policy, it will still need to cease allocating livers based on DSAs, based on HRSA's finding that reliance on DSAs does not comply with the Final

[7] While the NLRB continues to remain in effect, "the median MELD at transplant (MMaT) scores for liver candidates with exception scores are now based on recent liver transplants performed at liver transplant hospitals within the donation service area (DSA) where the candidates are listed." OPTN News, May 24, 2019, "NLRB update – MMaT calculation now based on DSA of transplant hospital," attached as Exhibit U. As OPTN explains, "When the National Liver Review Board (NLRB) was implemented on May 14, 2019, at the same time as the acuity circles distribution model, the basis of the MMaT calculation was recent transplants at all liver transplant hospitals included in a 250 nautical mile radius of the hospital listing the exception candidate. With the reversion to a donation service area (DSA) and region-based liver allocation system effective May 23, some DSAs had different MMaT scores among liver programs within their area. This in turn could create disparities affecting candidates' transplant access within the local DSA of the donor." Id.

Rule. Thus, regardless of the result of the December 17, 2019 hearing, the justification for MedStar's program relies on a policy that will necessarily change in the near future.

B. UNOS will implement its newly approved kidney allocation policy in 2020.

At the time UMMC filed its comments and motion for stay, kidney allocation policy changes were also imminent.[8] OPTN projected that a final policy change for kidney allocation would be submitted to the OPTN Board for approval in December 2019. UNOS Letter regarding Plan for Amending Organ Allocation Policies, Aug. 13, 2018, Exhibit E, p. 5. UNOS has met this timing.

Since UMMC filed its motion for stay, the OPTN Kidney Transplantation and Pancreas Transplantation Committees presented proposals for public comment in August, 2019 that "eliminate donation service area (DSA) and region from policy and replace them with a system that allocates kidneys and pancreata based on distance between the hospital listing the transplant candidate and the donor hospital." OPTN News, Oct. 28, 2019, "Kidney and pancreas allocation proposals modified to advance 250 nautical mile distribution circle, fewer proximity points," ("OPTN Oct. 28 News Release") attached as Exhibit X. The proposed policies first considered well-matched candidates nationally, then made offers to candidates based on a 500 nautical mile radius from the donor hospital and candidates' "proximity points," which are assigned based on the location of candidates' intended transplant program and the location of the donor organ's hospital. Id. Following public

[8] As described more fully in UMMC's initial motion and related briefing, HRSA notified the OPTN that "the use of DSAs and Regions in all other (non-liver) organ allocation policies has not been and cannot be justified under the OPTN final rule." HRSA July 31, 2018 Letter to OPTN, Exhibit A, p. 5. HRSA further directed the OPTN to "submit a detailed report by August 13, 2018, for review by the Health Resources Services Administration outlining OTPN's plans to eliminate DSAs and Regions from other (non-liver) organ-specific allocation policies." Id. In November, 2018, OPTN acknowledged that "HRSA has directed the OPTN to develop policies to replace the donor service area (DSA) and region as units of organ distribution with areas that meet provisions of the OPTN Final Rule." See OPTN, "Updates from kidney and pancreas committees regarding geographic distribution issues," Nov. 5, 2018, Exhibit M at pp. 1-2.

comment, OPTN released modified proposals on November 17, 2019. OPTN News, Nov. 17, 2019 "Modifications made to kidney and pancreas allocation proposals," attached as Exhibit Y. Key changes in the modified proposed policies include a reduction in the radius of the distribution circle from 500 nautical miles to 250 miles, and a reduction in the number of proximity points. Id.

The OPTN Board of Directors considered and approved the modified proposals at a December 3, 2019 meeting. OPTN News, Dec. 5, 2019 "OPTN board adopts new policy to improve kidney, pancreas distribution," ("OPTN Dec. 5 News Release") attached as Exhibit Z. OPTN states that "Additional clarifying policy components will be circulated for additional public comment early in 2020 and implemented along with the policies as approved by the board." OPTN Oct. 28 News Release, Exhibit X. OPTN expects to implement the new policy in 2020. OPTN Dec. 5 News Release, Exhibit Z.

II. MEDSTAR'S REQUEST TO SUPPLEMENT THE DATA IN THE RECORD IS PREMATURE.

The forthcoming policy changes described in UMMC's motion for stay have progressed, and OPTN has so far met its timing projections. While the court challenge to the new liver allocation policy has at least temporarily halted implementation of that policy, even if the lawsuit is ultimately successful, OPTN will still need to replace the old policy, as OPTN has acknowledged that the use of DSAs does not comply with federal regulation. New kidney allocation policy has been approved and will be implemented in 2020. MedStar's motion is thus premature. If MedStar determines to proceed with its application, it will certainly need to update the data and analyses, but should do so only once these policy issues are resolved.

III. MEDSTAR MUST, BUT CANNOT, DEMONSTRATE THAT ITS ORGAN TRANSPLANTATION PROGRAMS ARE NEEDED BECAUSE IT RELIES ON OUTDATED ALLOCATION POLICIES.

The State Health Plan Chapter for Organ Transplant Services, COMAR § 10.24.15, defines "the health planning regions for CON review of an application to establish or relocate organ transplant services in Maryland" to be "consistent with the OPO [Organ Procurement Organizations] designations." COMAR § 10.14.15.03, p. 8. Need for a new project is based in part, on "[t]he ability of the general hospital to increase the supply or use of donor organs for patients served in Maryland through technology innovations, living donation initiatives, and other efforts." 10.24.15.04B(1).

MedStar's need analysis is based in significant part upon its supposed ability to increase the organ supply in the Baltimore area. MedStar June 1, 2018 Completeness Response, p. 18.[9] Under the organ allocation policy framework at the time MedStar submitted its applications, efforts by MedStar to increase the availability of organs in the Baltimore area, which is in the LLF, would not benefit MedStar patients at MGTI as much as patients at JHH and UMMC, because the increased organ volume would first be made available to patients in the LLF before MGTI patients. Thus, while MedStar certainly could take efforts to increase organ supply in the Baltimore area even without establishing organ transplant programs, the unstated assumption in MedStar's applications is that MedStar would not take such efforts unless it establishes programs at MFSMC. With such programs, MedStar claims, it would be able to increase the organ supply in the LLF.

As a result, MedStar's need analysis is premised upon the existence of DSAs. Under new liver and kidney organ allocation policies, however, organ allocation will be determined not based on

[9] In its June 1, 2018 Completeness Response, MedStar states that it is the "shortfall of donor organs, and MGTI's ability to increase the supply of donor organs, that forms the basis of MFSMC's case for its proposed liver transplant program."

DSAs, but on larger geographic circles from the donor hospital to the transplant hospital. Because the smallest circle considered by both liver and kidney allocation policy will, if starting at MFSMC, or any hospital in the current LLF, include MGTI, there is no need for MedStar to establish a program at MFSMC in order to benefit its patients. Any increase in the supply of organs in the Baltimore area will benefit all patients waitlisted at programs within 150, 250, or 500 nautical miles (for liver, depending on additional factors), or 250 nautical miles (for kidney).

The new policies eliminate the benefit a patient would obtain by being waitlisted at both MFSMC and MGTI, thus seriously undermining MedStar's justification for its proposed program. OPTN Board President, Maryl Johnson, recognizes this reality in describing the new kidney allocation policy:

> 'Under the current system, candidates listed at two different hospitals just a short distance apart from each other, and a short distance from a donor hospital, can appear much higher or lower on a match just because their hospitals are in different DSAs or regions,' Johnson said. 'The new policy will remove those artificial distinctions for candidates who are much the same as each other in terms of distance and medical need.'

OPTN Dec. 5 News Release, Exhibit Z.

CONCLUSION

OPTN has approved new liver and kidney allocation policies since MedStar filed its applications. Both policy changes eliminate DSAs as the basis for organ allocation decisions. For these reasons and the additional reasons set forth in UMMC's October 2018 motion for stay and related briefing, UMMC respectfully requests that the Commission stay the CON review of MedStar's applications proposing to establish liver and kidney transplant services at MedStar Franklin Square Medical Center until these allocation policy changes are passed, and then request that MedStar update its analyses to be consistent with those changes.

Respectfully submitted,

Thomas C. Dame
Ella R. Aiken
Hannah L. Perng
Gallagher Evelius & Jones LLP
218 North Charles Street, Suite 400
Baltimore MD 21201
(410) 727-7702

Attorneys for University of Maryland Medical Center

December 16, 2019

Table of Exhibits

Exhibit	Description
N	OPTN News Dec 4, 2018, "Board approves updated liver distribution system"
O	*Callahan v HHS*, 939 F.3d 1251 (11th Cir 2019)
P	*Callahan v. HHS*, No. 19-CV-1783-AT, Order (NDGA May 15, 2019)
Q	OPTN News, April 23, 2019, "Liver distribution policy, NLRB implementation deferred until May 14"
R	OPTN News, May 14, 2019, "New national liver transplant system takes effect"
S	OPTN News, May 20, 2019, "Work in Progress to revert to DSA based system due to court order"
T	OPTN News, May 23, 2019, "System notice - OPTN liver allocation policy revered to DSA and regions"
U	OPTN News, May 24, 2019, "NLRB update – MMaT calculation now based on DSA of transplant hospital"
V	*Callahan v. HHS*, No. 19-CV-1783 AT, Order (NDGA Dec. 3, 2019)
W	*Callahan v HHS*, No 19-CV-1783 AT, Stipulation (NDGA Dec 9, 2019)
X	OPTN News, Oct. 28, 2019, "Kidney and pancreas allocation proposals modified to advance 250 nautical mile distribution circle, fewer proximity points"
Y	OPTN News, Nov. 17, 2019, "Modifications made to kidney and pancreas allocation proposals"
Z	OPTN News, Dec. 5, 2019, "OPTN board adopts new policy to improve kidney, pancreas distribution"

CERTIFICATE OF SERVICE

I hereby certify that on the 16th day of December 2019, a copy of University of Maryland Medical Center's Memorandum in response to MedStar's Motion, and in support of University of Maryland Medical Center's Renewed Motion for stay of Certificate of Need Review was sent:

via email and first-class mail to

Suellen Wideman, Esq.
Assistant Attorney General
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215-2299
suellen.wideman@maryland.gov

Conor B. O' Croinin, Esq.
Zuckerman Spaeder LLP
100 E. Pratt Street, Suite 2440
Baltimore MD 21202-1031
cocroinin@zuckerman.com

David C. Tobin, Esq.
Jennifer Concino, Esq.
Tobin, O'Connor & Ewing
5335 Wisconsin Ave. NW Suite 700
Washington DC 20015
dctobin@tobinoconnor.com
jcconcino@tobinoconnor.com

---

via email to

Jenelle Mayer, MPH
Health Officer
Allegany County
12501 Willowbrook Road SE
P.O. Box 1745
Cumberland, MD 21502
jenelle.mayer@maryland.gov

Gregory Wm. Branch, MD, MBA, CPE
Health Officer & Director, Department of Health & Human Services
Baltimore County
6401 York Road. 3rd Floor
Baltimore, MD 21212-2130
gbranch@baltimorecountymd.gov

Nilesh Kalyanaraman, MD
Health Officer
Anne Arundel County
3 Harry S Truman Parkway
Annapolis, MD 21401
hdkaly00@aacounty.org

Letitia Dzirasa, MD
Health Commissioner
Baltimore City
1001 E. Fayette Street
Baltimore, MD 21202
letitia.dzirasa@baltimorecity.gov

Laurence Polsky, M.D.
Health Officer
Calvert County
975 Solomons Island Road North
P.O. Box 980
Prince Frederick, MD 20678
laurence.polsky@maryland.gov

Scott LeRoy, MPH, MS
Health Officer
Caroline County
403 S. 7Th Street
P.O. Box 10
Denton, MD 21629
scott.leroy@maryland.gov

Edwin Singer, L.E.H.S.
Health Officer
Carroll County
290 South Center Street
Westminster, MD 21157
ed.singer@maryland.gov

Lauren Levy, JD, MPH
Health Officer
Cecil County
401 Bow Street
Elkton, MD 21921
lauren.levy1@maryland.gov

Roger L. Harrell, MHA
Health Officer
Dorchester County
3 Cedar Street
Cambridge, MD 21613
roger.harrell@maryland.gov

Barbara Brookmyer, MD, MPH
Health Officer
Frederick County
350 Montevue Lane
Frederick, MD 21702
bbrookmyer@frederickcountymd.gov

Robert Stephens, MS
Health Officer
Garrett County
1025 Memorial Drive
Oakland, MD 21550
robert.stephens@maryland.gov

Russell Moy, MD
Health Officer
Harford County
120 S. Hays Street
P.O. Box 797
Bel Air, MD 21014-0797
russell.moy@maryland.gov

Maura Rossman, MD
Health Officer
Howard County
8930 Stanford Blvd.
Columbia, MD 21045
mrossman@howardcountymd.gov

William Webb
Health Officer
Kent County
125 S. Lynchburg Street
P.O. Box 359
Chestertown, MD 21620
william.webb@maryland.gov

Joseph Ciotola, MD
Health Officer
Queen Anne's County
206 N. Commerce Street
Centreville, MD 21617-1118
joseph.ciotolamd@maryland.gov

Meenakshi Brewster, MD, MPH
Health Officer
St. Mary's County
21580 Peabody Street
P.O.Box 316
Leonardtown, MD 20650
meenakshi.brewster@maryland.gov

Lori Brewster, MS, APRN/BC, LCADC
Acting Health Officer
Somerset County
7920 Crisfield Highway
Westover, MD 21817
lori.brewster@maryland.gov

Fredia Wadley, MD
Health Officer
Talbot County
100 S. Hanson Street
Easton, MD 21601
fredia.wadley@maryland.gov

Earl E. Stoner, MPH
Health Officer
Washington County
1302 Pennsylvania Avenue
Hagerstown, MD 21742
earl.stoner@maryland.gov

Lori Brewster, MS, APRN/BC, LCADC
Health Officer
Wicomico County
108 E. Main Street
Salisbury, MD 21801-4994
lori.brewster@maryland.gov

Rebecca Jones, RN, MSN
Health Officer
Worcester County
6040 Public Landing Road
P.O. Box 249
Snow Hill, MD 21863
rjones@maryland.gov

Ella R. Aiken

EXHIBIT N

OPTN/UNOS Board approves updated liver distribution system

UNOS News Bureau

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

Dallas – The OPTN/UNOS Board of Directors, at its meeting December 3, approved a new liver distribution policy to establish greater consistency in the geographic areas used to match liver transplant candidates with available organs from deceased donors and reduce geographic differences in liver transplant access.

Access a recording of the liver distribution policy proposal discussion (https://unos.wistia.com/medias/rjjlpm5mjv). (http://www.hrsa.gov/exitdisclaimer/hrsaexitdisclaimer.html)

“The Board carefully weighed a number of options, with the ultimate goals of best honoring the gift of organ donation and helping those in greatest need,” said Sue Dunn, president of the board. “This model represents a necessary step forward to address long-existing differences in transplant in various areas of the country.”

The 42-member board represents transplant clinical and professional disciplines throughout the United States, as well as views of transplant candidates and recipients, their family members, family members of deceased donors and living donors. “As a donor mom, I’m proud of the board’s decision to pass the new liver

policy," said Deanna Santana, the board's vice president for patient and donor affairs. "When my family was approached about donation when my son died, my only thought was that I wanted to spare other families the heartache we were experiencing. This policy has the potential to better assure liver candidates are transplanted in a similar way around the country."

The policy will replace fixed, irregular local and regional geographic boundaries historically used to match liver candidates based on the donor location. It initially prioritizes liver offers from most deceased adult donors in the following sequence:

- candidates with highest medical urgency (Status 1A and 1B) listed at transplant hospitals within a radius of 500 nautical miles of the donor hospital
- candidates with a MELD or PELD score of 37 or higher listed at transplant hospitals within a radius of 150 nautical miles from the donor hospital
- candidates with a MELD or PELD score of 37 or higher listed at transplant hospitals within a radius of 250 nautical miles from the donor hospital
- candidates with a MELD or PELD score of 37 or higher listed at transplant hospitals within a radius of 500 nautical miles from the donor hospital
- a similar, continuing sequence of progressive offers (candidates at transplant hospitals within 150, 250 and 500 nautical miles of the donor hospital) for candidates with ranges of MELD or PELD scores from 33 to 36, from 29 to 32, and from 15 to 28

Livers from deceased donors older than age 70, and/or those who die as a result of cardiorespiratory failure, will be distributed differently. After consideration of Status 1A and 1B candidates within a 500 nautical mile radius of the donor hospital, they will next be offered to candidates with a MELD or PELD score of 15 or higher at transplant hospitals within 150 miles of the donor location. Most of these organs are accepted for local candidates, since they are most viable when the preservation time between recovery and transplantation is short.

In addition, livers from deceased donors younger than age 18 will first be offered to any pediatric candidates (younger than age 18) listed at any transplant hospital within a 500 nautical-mile radius of the donor hospital. This will give additional priority to pediatric transplant candidates compared to the current distribution system.

Simulation modeling of the approved system indicates it will reduce variation in transplants by MELD score that exist in various areas of the country under the current liver distribution system. Modeling further suggests it will reduce pre-transplant deaths and increase access for liver transplant candidates younger than age 18.

Published on: Tuesday, December 4, 2018

EXHIBIT O

939 F.3d 1251
United States Court of Appeals, Eleventh Circuit.

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, Barnes-Jewish Hospital, Plaintiffs - Appellants,
v.
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, United Network for Organ Sharing, Defendants - Appellees,
Susan Jackson, Charles Bennett, Intervenor Appellees.

No. 19-11876
|
(September 25, 2019)

Synopsis

Background: Liver-transplant candidates and transplant hospitals brought action against Department of Health and Human Services (HHS) challenging policy for allocating donated livers promulgated by private nonprofit entity tasked by HHS with coordinating nation's organ-transplant system. The United States District Court for the Northern District of Georgia, No. 1:19-cv-01783-AT, Amy Totenberg, J., 2019 WL 3539815, denied plaintiffs' motion for preliminary injunction, and they filed interlocutory appeal.

Holdings: The Court of Appeals, Newsom, Circuit Judge, held that:

plaintiffs failed to demonstrate substantial likelihood of success on merits of their claim that HHS was obligated to refer new policy to Advisory Committee on Organ Transplantation or publish it in Federal Register, and

regulation permitting, but not requiring, HHS to refer new policies to Advisory Committee did not violate Federal Activities Inventory Reform (FAIR) Act or Federal Acquisition Regulation.

Affirmed in part and remanded in part.

Procedural Posture(s): Interlocutory Appeal; Motion for Preliminary Injunction.

Attorneys and Law Firms

***1253** Peter Canfield, Atlanta, GA, Courtney A. Carrell, Dallas, TX, Glenn Lorin Krinsky, Los Angeles, CA, John M. Majoras, Washington, DC, Jones Day, William Roquemore Taylor, Blank Rome LLP, Houston, TX, for Plaintiffs-Appellants.

Jason Scott Alloy, Robbins Ross Alloy Belinfante & Littlefield, LLC, Atlanta, GA, for Intervenors-Appellees.

Bradley Hinshelwood, U.S. Department of Justice, Civil Division, Appellate Staff, Michael Drezner, U.S. Department of Justice, Civil Division, Martin Totaro, U.S. Securities & Exchange Commission, Office of the General Counsel, Washington, DC, for Defendant-Appellee 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.

Jay S. Blumenkopf, Gordon Rees Scully Mansukhani, New York, NY, Lauren Gailey, Washington, DC, Linda T. Coberly, Melanie Laiyee Lee, Daniel D. Rubinstein, Sean H. Suber, Thomas G. Weber, Chicago, IL, Winston & Strawn, LLP, Sara Anderson Frey, Trujillo Rodriguez & Richards, LLC, Philadelphia, PA, for Defendant-Appellee United Network for Organ Sharing.

Josh Belinfante, Attorney, Matthew T. Parrish, Robbins Ross Alloy Belinfante & Littlefield, LLC, Atlanta, GA, Evelyn

Fruchter, Mordechai Shulman, Boies Schiller & Flexner, LLP, Armonk, NY, for Intervenor Appellees.

Appeal from the United States District Court for the Northern District of Georgia, D.C. Docket No. 1:19-cv-01783-AT

Before WILSON and NEWSOM, Circuit Judges, and COOGLER, * District Judge.

Opinion

NEWSOM, Circuit Judge:

The liver is one of the human body's most vital and versatile organs. Among its 500-some-odd functions, the liver cleans the blood, regulates amino acids, produces critical proteins, manages blood clotting, and facilitates digestion. But that's when things go right. Far too often—and due to a variety of causes—things can go wrong, and when they do modern medicine has to step in. For minor liver complications, medication and dietary changes will usually do the trick. When liver failure sets in, though—when things go *really* wrong—there is often only one long-term solution: transplant.

This case centers on the high-stakes rules that determine which patients—among the more than 12,000 currently on the national waiting list—receive the liver transplants they need. In December 2018, a private nonprofit entity tasked by the Department of Health and Human Services (HHS) with coordinating the nation's organ-transplant system adopted a new policy for allocating donated livers. This suit followed. Plaintiffs, four liver-transplant candidates and more than a dozen transplant hospitals, challenged the policy in federal district court on a variety of grounds and moved for preliminary injunctive relief barring the policy's implementation. The district court denied the motion, and plaintiffs filed an interlocutory appeal.

***1254** The central question we face is one of regulatory construction. In particular, we must determine whether 42 C.F.R. § 121.4(b) required the Secretary of HHS to take two procedural steps that all agree he did not: (1) referral of the new liver-allocation policy to an entity called the Advisory Committee on Organ Transplantation and (2) publication of the new policy in the Federal Register for public comment. We hold that the Secretary was not required to do so, and we therefore affirm—at least in that regard—the district court's denial of plaintiffs' preliminary-injunction motion. Because the district court failed to address two of plaintiffs' claims, however, we remand for consideration of them in the first instance.

I

Before diving into the merits, we first need to canvass the statutory and regulatory landscape, some factual background, and the case's procedural posture. Fair warning: This gets complicated.

A

In the United States, organ transplants are a public-private affair. The National Organ Transplant Act of 1984 requires HHS to appoint and oversee the Organ Procurement and Transplant Network (OPTN)—a private nonprofit responsible for coordinating foundational aspects of the nation's organ-transplant system. *See* 42 U.S.C. § 274. Under the Act, the OPTN must maintain a list of transplant candidates, implement a system for allocating donated organs, and ensure the organs' equitable distribution. *See id.* § 274(b).

While the Act describes the OPTN's duties in broad strokes, HHS's implementing regulation—the "Final Rule"—covers the nitty-gritty, from the OPTN's Board of Directors to its record-maintenance policy. *See* 42 C.F.R. §§ 121.1–.13. Most importantly for present purposes, the Final Rule prescribes the procedures that the OPTN must follow when developing new organ-transplant policies, as well as the circumstances under which—and extent to which—HHS must review those policies. *See id.* § 121.4.

We'll get *way* down into the regulatory weeds in due time, complete with a dense block quote of the Final Rule's pertinent text—but for now it's enough to summarize the Rule's key features. As an initial matter, the Final Rule states that whenever the OPTN proposes any new policy, its Board of Directors must give OPTN members and other "interested parties" an opportunity to comment on it, and the Board must "take [those comments] into account" in developing and adopting the policy. *Id.* § 121.4(b)(1). Separately, the Rule requires the OPTN to provide the Secretary of HHS with two types of proposed policies at least 60 days prior to their intended implementation: (1) those that the OPTN Board "recommends to be enforceable" [1]; and (2) those that relate to "such other matters as the Secretary directs." *Id.* at § 121.4(b)(2). Finally, as part of the same subsection—and

as you'll see soon enough, this is where the debate hinges—the Final Rule requires the Secretary to refer "significant ***1255** proposed policies" to the Advisory Committee on Organ Transplantation and to publish those policies in the Federal Register for "public comment." *Id*.

B

An organization called the United Network for Organ Sharing has served as the OPTN for the past 35 years. In 2013, United Network approved and implemented the liver-allocation policy that remains in place today. The current policy distributes livers based on two geographic criteria: "Regions"—11 groups of states—and "Donation Service Areas" (DSAs)—58 smaller, geographically irregular areas (within and among states) that surround the entities that United Network has tasked with collecting donated organs. [2]

In recent years, the use of DSAs has come under fire. Critics of the DSA-based system contend that because DSAs are neither geographically uniform nor designed to minimize transit of donated organs, reliance on them can lead to bizarre allocation results. They argue, for instance, that organs can end up traveling greater distances to less-sick patients. [3] Defenders of the DSA-based system, by contrast, insist that aligning organ allocation with the organ-procurement organizations encourages communication between the entities that collect organs and those that perform transplants.

By 2016, United Network had decided that things needed to change. After more than a year of exploring alternatives, United Network approved a new liver-allocation policy in December 2017. That policy—which retained DSAs but reduced their impact on allocation decisions—was set to take effect in December 2018. In May 2018, however, a group of patients awaiting liver transplants filed a comment with the Secretary pursuant to 42 C.F.R. § 121.4(d) [4] criticizing *any* continued use of DSAs in liver-allocation determinations. Two months later, in July 2018, the Secretary instructed United Network's Board to scrap the December 2017 policy and adopt a new one that eliminated the use of Regions and DSAs altogether.

United Network went back to the drawing board, but it faced an extremely tight timeline. The Secretary's July 2018 instruction imposed a December 3, 2018 deadline for promulgating the new liver-allocation policy. By September, the Liver and Intestinal Transplantation Committee—a specialized group within United Network that makes recommendations to the Board—had homed in on two alternative, ***1256** DSA-less approaches for allocating livers: the "Acuity Circles" model and the "Broader 2-Circle" model. [5] When the Committee published its policy proposal on October 6, it identified the Broader 2-Circle model as the "preferred" policy, but it sought public comment on both options. At the Committee meeting on November 2, the Broader-2 Circle model prevailed by a narrow 11-9 vote.

United Network's Board, however, went the other way. On December 3, 2018—the HHS-imposed deadline—the Board adopted the Acuity Circles model. This model, the Board found, would result in "lower waitlist mortality rate[s]" and "more equity in access" for liver-transplant candidates. United Network later set the policy's implementation date for April 30, 2019.

Up to this point, HHS had remained on the sidelines. Of course, the Secretary had initiated the process by directing United Network to adopt a new, DSA-less allocation policy. But once the new policy's development began, HHS didn't actively intervene. As particularly relevant here, consistent with HHS's treatment of prior organ-allocation policies, the Secretary didn't refer the new policy to the Advisory Committee on Organ Transplantation or publish it in the Federal Register for public comment.

The new policy's detractors, however, brought HHS into the mix. Just as critics of the December 2017 policy had done, a group of hospitals that opposed the new policy filed a comment with the Secretary asking him to suspend the new policy's implementation until something better could be developed. This time, though, the policy survived the challenge. Acting on the Secretary's behalf, the Administrator of HHS's Health Resources and Services Administration responded to the comment, announcing that no further action was warranted and that the new policy would take effect as scheduled.

C

On April 22, 2019—eight days before the new policy's official implementation date—a collection of hospitals and individual patients sued HHS and United Network in the United States District Court for the Northern District of

Georgia.[6] Plaintiffs' complaint challenged the new liver-allocation policy on three grounds: (1) that HHS failed to follow legally required procedures during the development of the new policy, in violation of the Administrative Procedures Act (APA); (2) that HHS's and United Network's actions were —both substantively and procedurally—arbitrary, capricious, and otherwise not in accordance ***1257** with the law, also in violation of the APA; and (3) that HHS's and United Network's conduct violated the Due Process Clause of the Fifth Amendment. Asserting the same grounds, plaintiffs also filed a motion for a temporary restraining order, asking the district court to prevent the new policy's impending implementation.[7]

Following HHS's agreement to delay implementation by two weeks, the district court received expedited briefing and held a hearing on plaintiffs' TRO motion. On May 13, 2018, the district court—in an order that addressed only plaintiffs' first claim—denied the motion. The following day, the new liver-allocation policy went into effect for the first time. Its force, however, was short lived. Plaintiffs immediately noticed this appeal and sought an injunction pending its disposition, which the district court granted. As a result, HHS reinstated the prior (and once again current) policy.

So here we are. After years of development, thousands of public comments, and several revisions, the nation's policy for allocating donated livers hangs in the balance.

II

The standard for obtaining preliminary injunctive relief is a familiar one. Such relief is appropriate if—but only if—the movant shows "(1) substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998). Because a preliminary injunction "is an extraordinary and drastic remedy," relief may not be granted "unless the movant clearly established the burden of persuasion as to the four requisites." *Id.* (internal quotation marks and citation omitted).[8]

Our task on appeal is to determine whether the district court erred in concluding that plaintiffs failed to satisfy their burden and were therefore ineligible for preliminary injunctive relief. We begin (and for now find that we can end) with plaintiffs' first claim—the only one that the district court addressed. In particular, the district court concluded that plaintiffs had failed to demonstrate a substantial likelihood of success on the merits of their contention that HHS neglected to follow legally required procedures during the new liver-allocation policy's development. We hold that the district court was right in so concluding, if not quite for the right reasons. As for plaintiffs' second and third claims—respectively, that defendants' actions in adopting the new policy were arbitrary and capricious and deprived plaintiffs of due process—we will remand so that the district court can consider them in the first instance.

A

Now, for the promised deep dive into 42 C.F.R. § 121.4(b)—the section of the Final Rule that we summarized earlier. Section 121.4(b) contains two subsections; its relevant text is as follows:

> ***1258** (b) 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). These policies will not be enforceable until approved by the Secretary. The Board of Directors shall also provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. ***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 also may 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) (emphasis added).

Plaintiffs' first claim centers on a single sentence of § 121.4(b)(2)—which we've italicized and which, to keep matters straight here, we'll call the "significant proposed policies" sentence. Plaintiffs' contention is simple and straightforward: Clearly, they say, a policy that fundamentally alters liver-allocation procedures throughout the country is "significant." And because it's undisputed that the Secretary neither referred the new liver-allocation policy to the Advisory Committee nor published it in the Federal Register—as, on plaintiffs' reading, the significant-proposed-policies sentence requires—it follows that the Secretary violated § 121.4(b)(2).

Defendants see it differently. They argue that, properly understood, § 121.4(b)(2)'s significant-proposed-policies sentence doesn't apply here at all. Under defendants' reading, the significant-proposed-policies sentence's referral and publication requirements are triggered *only* in the two circumstances specified in § 121.4(b)(2)'s opening clauses: (1) when the policy at issue is one that the OPTN's Board "recommends to be enforceable"—we'll call this (more than a little clunkily) the "recommends to be enforceable" sentence—or (2) when the policy at issue is one that relates to "such other matters as the Secretary directs"—here, the "as the Secretary directs" sentence. Because it's undisputed that neither of those two conditions obtained here, defendants contend, the Secretary wasn't required to refer the policy to the Advisory Committee or publish it in the Federal Register.

Boiled to its bare essence, then, the interpretive question we face is whether § 121.4(b)(2)'s referral and publication requirements apply to *all* "significant proposed policies" (plaintiffs' reading) or, instead, only to those "significant proposed policies" that (1) the OPTN's Board has "recommend[ed] to be enforceable" or (2) pertain to a matter that the Secretary has "direct[ed]" (defendants' reading). In short: Does § 121.4(b)(2)'s significant-proposed-policies sentence stand alone, such that it applies universally, or is it modified and limited by § 121.4(b)(2)'s recommends-to-be-enforceable and as-the-Secretary-directs sentences?

The district court answered this question in defendants' favor. Deferring to HHS's interpretation of § 121.4(b)(2), that court held that plaintiffs had not demonstrated ***1259** a substantial likelihood of success on their claim that the Secretary was legally obligated to refer the new liver-allocation policy to the Advisory Committee or publish it in the Federal Register. *See* Amended Dist. Ct. Order at 10–11. We agree with the district court's bottom-line conclusion—and we therefore affirm that court's decision that plaintiffs haven't shown the requisite substantial likelihood of success on their first claim—but we arrive at that conclusion by a different route. As the Supreme Court recently held in *Kisor v. Wilkie*, deference "is not the answer to every question of interpreting an agency's rules." —— U.S. ——, 139 S. Ct. 2400, 2414, 204 L.Ed.2d 841 (2019). [9] This case illustrates the truth and wisdom of that observation. Here, we hold that the "traditional tools of construction"—which *Kisor* directs reviewing courts to "exhaust" before resorting to principles of deference, *id.* at 2415—provide a clear answer: Defendants' reading of § 121.4(b)(2) is the better one.

1

a

We begin, as always—and as *Kisor* reiterates we should—with "text [and] structure." *Id.*; *see also* *Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195, 204, 131 S.Ct. 871, 178 L.Ed.2d 716 (2011). To orient ourselves, let's start with the big(ish) picture—a bird's-eye view. Section 121.4(b)'s two subsections lay out two possible paths for the review and development of proposed organ-transplant policies. Path number one—§ 121.4(b)(1)—provides for the usual, baseline OPTN-administered notice-and-comment review. Subsection (b)(1) places no limitation on the "proposed policies" to which it applies—it requires OPTN's Board to give both "OPTN membership and other interested parties" an opportunity to comment on *all* proposed policies, irrespective of substance, and then directs the Board to consider those comments in developing and adopting the policies for implementation. Path number two—§ 121.4(b)(2), which governs the Secretary's involvement in and review of proposed policies—is different, right off the bat. Unlike subsection (b)(1), subsection (b)(2) immediately narrows in on two subsets of policies: (1) those that OPTN's Board "recommends to be enforceable" and (2) those that relate to "other matters as the Secretary directs." Those two types of proposed policies—and *only* those—must be provided to the Secretary at least 60 days prior to their intended implementation. 42 C.F.R. § 121.4(b)(2).

Even before getting into the details—and addressing the significant-proposed-policies sentence and its placement in

subsection (b)(2)—we should pause to consider what § 121.4(b)'s two-path architecture indicates. It seems, we think, to imply a "default-and-extra"-style regime, with subsection (b)(1) being the "default" and subsection (b)(2) being the "extra." In other words, it suggests—not definitively so, but ***1260** presumptively—that the baseline (b)(1) requirements apply to all proposed organ-allocation policies, while the additional (b)(2) requirements apply only to a subset of those policies.

With that structural context in mind, let's zoom back in to take a closer look at § 121.4(b)(2) itself—and in particular, the way in which its several constituent sentences interact. A careful reading, we think, confirms that defendants' interpretation is the better one—subsection (b)(2), including the significant-proposed-policies sentence and its referral and publication requirements, applies only to two specific types of proposed policies: those that OPTN's Board "recommends be enforceable" and those pertaining to matters that the "Secretary directs." That is so for at least three reasons.

First, and most fundamentally, there's the "scope-of-subparts" canon, pursuant to which, at least as a general proposition, "[m]aterial within an indented subpart relates only to that subpart." Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 156 (2012); *see also, e.g.*, *Lary v. Trinity Physician Fin. & Ins. Servs.*, 780 F.3d 1101, 1105–06 (11th Cir. 2015) ("Ordinarily, the scope of a subpart is limited to that subpart ...."). Under this interpretive principle, the significant-proposed-policies sentence's placement within subsection (b)(2) indicates that it goes with, relates to, and is limited by the other sentences in that subsection, including the recommends-to-be-enforceable and as-the-Secretary-directs sentences. [10]

Second, we think that is the most natural—and most coherent—reading of § 121.4(b)(2). Subsection (b)(2) operates like a flow chart—or, as it was described at oral argument, a "funnel" that begins wide and narrows as it goes. The first few sentences mark out the universe of proposed policies to which § 121.4(b)(2) applies—at the risk of repetition, those that OPTN's Board "recommends to be enforceable" and those that relate to "matters [that] the Secretary directs." Subsection (b)(2) expressly requires that such proposed policies be provided to the Secretary for his review 60 days in advance of their implementation. Having received a proposed policy that fits one of those two descriptions, the Secretary must then determine whether it constitutes a "significant proposed polic[y]." 42 C.F.R. § 121.4(b)(2). If he concludes that it does, he "will"—must—refer it to the Advisory Committee and publish it in the Federal Register for public comment. *Id.* With respect to "other proposed policies"—*i.e.*, those that he determines are not "significant"—the Secretary "may," but need not, refer and publish them. *Id.* On defendants' reading, therefore, the significant-proposed-policies sentence slots in comfortably with the sentences that come before and after it—all links in a continuous chain of administrative review.

Finally, defendants' reading isn't just natural, it's also sensible. As just explained, § 121.4(b)(2) requires that two particular types of policies be sent to the Secretary at least 60 days prior to their "proposed implementation"—*i.e.*, before they are slated to go into full force and effect. Presumably, there's a reason that those two—and no others—are singled out that way. If we read the ensuing significant-proposed-policies sentence as applying—as § 121.4(b)'s text and structure ***1261** indicate—only to those two, the reason becomes clear: For "significant proposed policies" that either OPTN's Board has "recommend[ed] to be enforceable" or pertain to a matter that the Secretary has "direct[ed]," the Secretary *must* take certain action—in particular, he must refer them to the Advisory Committee and publish them in the Federal Register. Of course, doing so—all in advance of the date of "proposed implementation," *id.*—requires *time*. Under defendants' reading of § 121.4(b)(2), the recommends-to-be-enforceable and as-the-Secretary-directs sentences work hand-in-hand with the significant-proposed-policies sentence: they operate, together, to ensure that the Secretary will have enough time to do what needs to be done.

If (as plaintiffs insist) HHS had meant for the significant-proposed-policies sentence to apply beyond the two types of policies flagged at the outset of subsection (b)(2), surely it would have given *some* textual indication. HHS could, for instance, have placed the significant-proposed-policies sentence *before* the recommends-to-be-enforceable and as-the-Secretary-directs sentences. That might have signaled that the significant-proposed-policies sentence applied to *all* proposed policies, rather than only a subset of them. HHS also could have created a separate subsection for the significant-proposed-policies sentence. A clear break from the recommends-to-be-enforceable and as-the-Secretary-directs sentences would have communicated that the significant-proposed-policies sentence embodies a distinct, stand-alone requirement. It might (?) even have been possible for HHS to keep the significant-proposed-policies sentence in its current location but to say, straight out, that its referral and publication requirements apply to

proposed policies beyond those identified in the recommends-to-be-enforceable and as-the-Secretary-directs sentences—something like, "The Secretary will consider all policies proposed by the OPTN and will refer those that he deems significant ...."

But HHS didn't do any of those things. Instead, it chose to place the significant-proposed-policies sentence immediately following the recommends-to-be-enforceable and as-the-Secretary-directs sentences. Given that choice, the significant-proposed-policies sentence is read most naturally—and in accordance with the scope-of-subparts canon and common sense—as being modified and limited by those two preceding sentences.

b

Against all of this, plaintiffs raise two textual arguments—neither of which convinces us. First, plaintiffs point out that when the significant-proposed-policies sentence is read alone, it more naturally supports their reading than defendants'. Maybe so—there's nothing within the four corners of the significant-proposed-policies sentence itself that clearly limits its application to the policies referenced in the recommends-to-be-enforceable and as-the-Secretary-directs sentences. But as enticingly straightforward as plaintiffs' argument may be, it's just not how we read law—tidbits and fragments in isolation. *See, e.g.*, *Strickland v. Water Works & Sewer Bd. of City of Birmingham*, 239 F.3d 1199, 1204–05 (11th Cir. 2001) (refusing to construe regulatory terms "absent their context"); Scalia & Garner, *supra*, at 167 ("Context is a primary determinant of meaning."). And for reasons we've explained in detail already, when read in toto—and in context—§ 121.4(b)(2) is best understood as limiting the significant-proposed-policies sentence's referral and publication requirements to policies that fit ***1262** within the recommends-to-be-enforceable and as-the-Secretary-directs sentences.

Second, plaintiffs invoke the presumption of consistent usage. Under this canon of construction, a word or phrase is presumed to bear the same meaning throughout a text. *See* Scalia & Garner, *supra*, at 170. Plaintiffs assert that § 121.4(b)(1) uses the same term that § 121.4(b)(2)'s significant-proposed-policies sentence uses—"proposed policies"—to mean *all* proposed policies. According to plaintiffs, adopting defendants' interpretation would mean giving the term "proposed policies" a different, narrower meaning in § 121.4(b)(2)—one that it bears nowhere else in the text. The response to all of this is basically, "See above." Although the presumption of consistent usage has its place, it also "readily yields to context." *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 320, 134 S.Ct. 2427, 189 L.Ed.2d 372 (2014) (internal quotation marks and citation omitted) (holding that the Clean Air Act's definition of "air pollutant" includes greenhouse gases but that the term had a narrower, context-dependent meaning when it appeared in a section of the statute addressing permits). And here, read in context, the phrase "proposed policies" in § 121.4(b)(2) is most logically limited by the sentences that precede it within the same subsection.

* * *

Based on the preceding analysis, we hold that defendants' interpretation of § 121.4(b) is demonstrably superior to plaintiffs'. Not only is defendants' reading more natural, given the rule's format, but it also coherently harmonizes the rule's several constituent provisions. Plaintiffs' interpretation, by contrast, wrenches § 121.4(b)(2)'s significant-proposed-policies sentence out of context and depends on a wooden literalism that we cannot accept.

2

Because § 121.4(b)'s text is clear, we needn't consult extra-textual evidence concerning "history" and "purpose." We address these considerations briefly, however, because they featured so prominently in plaintiffs' briefing and because, given the circumstances, we think it prudent to cover the waterfront. *See* *NLRB v. SW Gen., Inc.*, —— U.S. ——, 137 S. Ct. 929, 941–42, 197 L.Ed.2d 263 (2017) (declaring the statutory text "clear," but nevertheless considering history- and purpose-based arguments to show why they were "not compelling").

The Final Rule (codified in relevant part at 42 C.F.R. § 121.4(b)) was first published in the Federal Register in 1998 and then amended—to its current language—in 1999. In conjunction with each of the Rule's two iterations, HHS published a statement that purported to describe the agency's motivations. The parties cite to these statements extensively, so we consider them in turn.

First, the 1998 Rule. Plaintiffs seize on language from HHS's 1998 statement, which they insist demonstrates an intent

to require broad agency review of OPTN policies: "The Secretary also recognizes the need for additional public participation in the development of some OPTN policies, such as fundamental revisions to organ allocation policies." 63 Fed. Reg. 16,301. And later: "While we believe that the comment process administered by the OPTN itself is invaluable in obtaining technical advice, it does not reach all of the affected public ... or otherwise provide the functions and protections accorded by the impartial review by the Secretary." *Id.* at 16,310.

But as defendants emphasize, the same HHS statement also appears to give the Secretary broad discretion to determine ***1263** how OPTN policies should be reviewed. Just after "recogniz[ing] the need for additional public participation," HHS's statement observes that the Final Rule accordingly "*enable[s]* the Secretary to seek comment from the public and to direct the OPTN to revise policies *if necessary*." *Id.* at 16,301 (emphasis added). What's more, the statement goes on to explain that there is often good reason for the Secretary to employ a more modest system of review: "A body of voluntary standards that can be rapidly revised, particularly for purely technical changes, is a crucial function of the OPTN system and one that the Secretary strongly supports." *Id.* at 16,310. If anything, then, the statement accompanying the 1998 Rule seems to weigh in favor of defendants' interpretation, which gives the Secretary the discretion—but does not impose an obligation—to refer proposed allocation policies to the Advisory Committee and publish them in the Federal Register.

What, then, of the 1999 amendments? Plaintiffs contend that increased oversight of OPTN policies was a primary motivation behind the new version of the Final Rule, and to be sure, there's evidence for that proposition in HHS's statement accompanying the amended rule. *See, e.g.*, 64 Fed. Reg. 56,656. The statement notes, for example, that HHS decided to establish "an independent scientific review board"—the Advisory Committee on Organ Transplantation—in order to "help [e]nsure that policies and procedures are evidence-based and guided by the best available scientific and medical precepts." *Id.* at 56,652. And, the statement continues, HHS amended § 121.4(b)(2) so that the Committee could "fulfill this ... responsibility." *Id.* According to plaintiffs, these statements prove that HHS intended the new Advisory Committee to have a broad role in policy development.

But if you keep reading, HHS's statement makes it clear that, even with the 1999 revisions, the Secretary's discretion remains largely intact—the Secretary is only *required* to consult the Advisory Committee in a few circumstances. When HHS's statement refers to Secretarial review of "recommend[ed] to be enforceable" policies—which, again, the new liver-allocation policy is not—it uses mandatory language that mirrors that in § 121.4(b)(2)'s promulgated text: "When the OPTN proposes enforceable policies, the Secretary *will* ask the Committee for its views on the proposals when the proposals are published in the Federal Register for public comment." *Id.* (emphasis added). Contrast that with HHS's statement regarding Secretarial review of "other" policies, which, again, tracks the enacted text: "A similar approach *may* also be used *should* the Secretary review other OPTN policies." *Id.* (emphasis added). Once again, Secretarial discretion looms large.

In the end, the regulatory history is—at best—a mixed bag for plaintiffs. There is, as plaintiffs point out, language in the 1998 and 1999 HHS statements that speaks generally about the importance of oversight of OPTN policies. But there is also language consistently recognizing that the Secretary has broad discretion when it comes to the review of non-"recommend[ed] to be enforceable" OPTN policies, like the liver-allocation policy at issue here. [11]

***1264**

* * *

In the end, to the extent they are discernible, § 121.4(b)(2)'s "purpose" and "history" provide no basis for second-guessing—let alone countermanding—what its text and structure clearly indicate.

3

There's one last interpretive issue for us to tackle. Plaintiffs contend that defendants' reading of § 121.4(b)(2) violates federal contracting law. In particular, plaintiffs point to the Federal Activities Inventory Reform (FAIR) Act, Pub. L. No. 105-270, 112 Stat. 2382 (1998), and the Federal Acquisition Regulation, 48 C.F.R. 7.503, which they say together embody a rule that "[c]ontracts shall not be used for the performance of inherently governmental functions." Appellants' Br. at 37–38. Plaintiffs assert that defendants' interpretation of § 121.4(b)(2) would "allow[ ] [United Network] to perform the inherently governmental function of determining a policy's consistency with federal law." *Id.* at 38. Plaintiffs' argument, as we understand it, is not that United Network violates

the FAIR Act and the FAR regulation simply by developing and proposing new organ-allocation policies, but rather that if defendants' interpretation of § 121.4(b)(2) is adopted, United Network (as the OPTN) would be given a new task —assessing whether its policies are consistent with federal law—which would violate the FAIR Act and the FAR regulation. [12] We don't see it that way, for two reasons.

First, it's not clear why the OPTN would have an affirmative obligation to ensure its policies' compliance with federal law under one reading of § 121.4(b)(2), but not another. The specific provision of § 121.4(b)(2) at issue prescribes the Secretary's duties, not the OPTN's. We don't think that interpreting the Secretary's duties in a way that does not require referral of the new liver-allocation policy to the Advisory Committee or its publication in the Federal Register would necessarily expand the OPTN's responsibilities, as plaintiffs' argument seems to suggest.

Second, even under defendants' more constrained reading of § 121.4(b)(2), the OPTN cannot unilaterally evade all Secretarial oversight. The Secretary maintains significant authority to review OPTN's proposed policies. As defendants point out—and as the regulation's plain text makes clear—the Secretary can always "direct" OPTN's Board of Directors to provide him with a proposed policy 60 days in advance of its implementation, thereby bringing it within § 121.4(b)(2)'s ambit. Or, wholly separately, under § 121.4(d) the Secretary can review and suggest revision to any OPTN policy that has been the subject of a critical comment. Indeed, ***1265** that's exactly what happened here; it was pursuant to the Secretary's § 121.4(d) authority that HHS decided that the current liver-allocation policy—the one that plaintiffs favor—"cannot be justified" under the Final Rule and must be replaced.

Contrary to plaintiffs' suggestions, therefore, defendants' interpretation of § 121.4(b)(2) does not give the OPTN—here, United Network—free reign over the country's organ-allocation policy. The Secretary maintains important—and significant—oversight over the process, as the facts of this case themselves demonstrate.

* * *

The bottom line: Defendants' interpretation of § 121.4(b) clearly makes the most sense of the regulation's text and structure, and none of the remaining tools of construction remotely displace that conclusion. We are confident, therefore —even without resorting to principles of agency deference —that defendants' interpretation should prevail. Accordingly, we hold that the district court did not err in concluding that plaintiffs failed to demonstrate a substantial likelihood of success on the merits of their claim that the Secretary neglected to follow legally required procedures during the new liver-allocation policy's development. [13]

B

What of plaintiffs' remaining claims? In its order denying plaintiffs' motion for temporary injunctive relief, the district court didn't address plaintiffs' alternative contentions that HHS's and United Network's actions in adopting the new liver-allocation policy (1) were both arbitrary and capricious and (2) violated the Fifth Amendment's Due Process Clause. We are wary of diving head-first into claims that the district court hasn't yet considered, and we are especially wary of doing so with respect to *these* claims—both of which will likely turn on fact- and context-intensive questions that the district court is better equipped to decide in the first instance.

Plaintiffs' arbitrary-and-capricious claim, for instance, depends in part on the premise that United Network constitutes an "agency" within the meaning of the APA. 5 U.S.C. § 701(b)(1). And that question—which, so far as we can tell, has yet to be addressed by any federal court—turns on whether United Network exercises "substantial independent [government] authority." *Dong v. Smithsonian Inst.*, 125 F.3d 877, 881 (D.C. Cir. 1997). Similarly, for plaintiffs to have a cognizable due process claim against United Network, its actions in adopting the new policy must be considered "state action"—a question that turns on whether United Network's conduct "resulted from the exercise of a right or privilege having its source in state authority" and whether United Network can "be described in all fairness as a state actor." *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 620, 111 S.Ct. 2077, 114 L.Ed.2d 660 (1991) (citation omitted).

And beyond those threshold issues, more fact-dependent questions await. For ***1266** plaintiffs' arbitrary-and-capricious claim: Was HHS's decision to direct the new policy's development based on sufficient evidence? Did United Network use the appropriate procedures in considering the new policy? Did it adequately consider public comments? What role, if any, did the expedited timeline play? Does the new policy substantively comply with statutory

and regulatory requirements? And for plaintiffs' due process claim: Do plaintiffs have a life, liberty, or property interest that has been affected by the new policy? If so, did United Network's policies adequately afford them an opportunity to be heard? Did HHS's?

We think that these questions, which are unavoidably fact-sensitive, should be addressed first by the district court. *See* *Access Now, Inc. v. Southwest Airlines Co.*, 385 F.3d 1324, 1331 (11th Cir. 2004) (noting that this Court is particularly hesitant to address "fact-bound issues" not considered by the district court). We are, after all, a court of review, not a court of first view. *See, e.g.*, *Bartholomew v. AGL Res., Inc.*, 361 F.3d 1333, 1341 n.5 (11th Cir. 2004). We therefore remand plaintiffs' remaining claims to the district court for its consideration.

III

For the foregoing reasons, we hold that plaintiffs have not shown a substantial likelihood of success on the merits of their first claim—their allegation that the Secretary failed to follow legally required procedures under 42 C.F.R. § 121.4(b) during the new liver-allocation policy's development. We also hold, however, that the district court should decide plaintiffs' remaining claims—their APA-based arbitrary-and-capricious claim and their Fifth Amendment Due Process claim—in the first instance. Accordingly, the district court's order denying plaintiffs' motion for a temporary restraining order is **AFFIRMED** in part and **REMANDED** in part.

All Citations

939 F.3d 1251, 28 Fla. L. Weekly Fed. C 383

Footnotes

* Honorable L. Scott Coogler, United States District Judge for the Northern District of Alabama, sitting by designation.

1 A bit of additional background: None of the OPTN's adopted policies are, in and of themselves, legally "enforceable" against members of the transplant community; rather, compliance is strictly voluntary. But the OPTN can recommend to the Secretary that he or she *make* a policy enforceable. If the Secretary does so, any entity that violates the policy risks an enforcement action to terminate its participation in Medicare or Medicaid. 42 C.F.R. § 121.10(c)(1). So far, that hasn't been necessary. The OPTN has never asked the Secretary to make one of its organ-allocation policies enforceable; voluntary compliance has been excellent.

2 Under the current policy, a donated liver is first matched and offered to patients who are Status 1A or 1B—the most gravely ill—*and* who reside in the DSA or Region where the liver is acquired. If there is no suitable match, the liver is then offered to patients—again, who reside in the same DSA or Region where the liver is acquired—based on their Model for End-Stage Liver Disease (MELD) score, which rates patients from 6 (least ill) to 40 (most ill). If there are no matching candidates in the DSA or Region with a MELD score of 15 or higher, the liver is then offered to outside candidates.

3 Consider the following example, used as an illustration at oral argument: Under the current, DSA-based policy, if a liver becomes available in Charleston, South Carolina, it would be offered to a moderately ill patient in Memphis, Tennessee (600 miles away) before a critically ill patient in Atlanta, Georgia (266 miles away)—and indeed, would have to be flown directly over Atlanta en route to Memphis.

4 "Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN." 42 C.F.R. § 121.4(d). The Secretary must then "seek, as appropriate, the comments of the OPTN on the issues raised in the comments" and must "consider the comments in light of the [Act] and the [Final Rule]." *Id*.

5 The Acuity Circles model draws concentric circular boundaries at 150, 250, and 500 nautical miles from the donor hospital. The model then offers the donated liver based on the following hierarchy: (1) Status-1 candidates within the 500-mile circle; (2) candidates with MELD scores of at least 37 within the 150-mile circle, then the 250-mile circle, then the 500-mile circle; (3) candidates with MELD scores between 33 and 36 within the 150-mile circle, then the 250-mile circle, then the 500-mile circle; (4) candidates with MELD scores between 15 and 28 within the 150-mile circle, then the 250-mile circle, then the 500-mile circle. The Broader 2-Circle model uses the same distance-based circles, but places a premium on proximity—it gives lower priority to candidates with greater medical urgency who are farther away from the donor hospital.

6 Shortly after the complaint was filed, two liver-transplant candidates—Susan Jackson and Charles Bennett—sought to intervene as defendants. Holding that Jackson and Bennett (who, in July 2018, had brought suit in the Southern District

of New York seeking to invalidate the current liver-allocation policy) had "established a significant interest in the subject matter of this litigation," the district court granted their motion to intervene under Federal Rule of Civil Procedure 24(b).

7 The district court construed plaintiffs' TRO motion as also requesting a preliminary injunction, in accordance with Federal Rule of Civil Procedure 65.

8 We review the district court's ultimate decision to deny plaintiffs' motion for abuse of discretion, but we examine any constituent legal conclusions *de novo*. *See United States v. Endotec, Inc.*, 563 F.3d 1187, 1194 (11th Cir. 2009).

9 *Kisor* was issued just before the close of briefing in this case—the day before plaintiffs' reply brief was due, in fact. In response to this Court's request, though, the parties filed supplemental briefs addressing the effect, if any, that *Kisor* should have on this case. We are confident, therefore, that the parties had full opportunity to litigate *Kisor*'s applicability. We are equally confident that a *Kisor*-based remand to the district court is unnecessary. Although the district court didn't have the benefit of the Supreme Court's decision, *Kisor* itself disclaims any groundbreaking. *See* 139 S. Ct. at 2410 ("You might view this Part"—describing the regime of regulatory interpretation and deference associated with *Auer v. Robbins*, 519 U.S. 452, 117 S.Ct. 905, 137 L.Ed.2d 79 (1997)—"as 'just background' because we have made many of its points in prior decisions."); *see also id.* at 2418 (noting that its articulation of *Auer* restated "longstanding doctrine").

10 To be sure, where it "makes no sense" to interpret language as being limited to the subpart in which it appears, the scope-of-subparts canon can give way. *Lary*, 780 F.3d at 1106. For reasons explained in the body, however, that isn't the case here. Quite the contrary, in fact.

11 To the extent it matters, the post-enactment regulatory history is decidedly *not* a mixed bag, but rather stands squarely against plaintiffs' interpretation of § 121.4(b)(2). In the nearly 20 years since the current version of the Final Rule was published, not a single organ-allocation policy has ever been referred to the Advisory Committee or published in the Federal Register. For all the opacity of HHS's 1998 and 1999 statements, then, its actions since have been clear, and they provide at least some evidence that HHS did not intend to subject non-enforceable organ-allocation policies to § 121.4(b)(2)'s enhanced review procedures. *Cf. Kisor*, 139 S. Ct. at 2426 (Gorsuch, J., concurring in the judgment) ("[T]he government's early, longstanding, and consistent interpretation of a statute, regulation, or other legal instrument could count as powerful *evidence* of its original public meaning.").

12 Although we reject plaintiffs' FAIR- and FAR-related argument on other grounds, it's worth noting at the outset that the FAIR Act, in particular, appears to be totally irrelevant to plaintiffs' claim. The FAIR Act does not, as plaintiffs repeatedly suggest, prohibit the use of contracts for the performance of inherently governmental functions. In fact, plaintiffs' argument seems to rest on an understanding of the FAIR Act that is 180° wrong. The FAIR Act is a reporting statute that requires federal agencies to annually publish lists of activities that are performed by *government employees* (not private contractors) and are *not* (rather than are) inherently governmental functions. *See* 112 Stat. 2382 (1998).

13 Because we hold that the district court correctly concluded that plaintiffs had failed to demonstrate a substantial likelihood of success, we need not consider whether the remaining factors weigh in favor of a preliminary injunction. *See GeorgiaCarry.Org, Inc. v. U.S. Army Corps of Eng'rs*, 788 F.3d 1318, 1329 (11th Cir. 2015) ("Because the plaintiffs have not shown a substantial likelihood of success on the merits, we need not consider the remaining factors in the preliminary injunction test."); *ACLU of Fla., Inc. v. Miami-Dade Cty. Sch. Bd.*, 557 F.3d 1177, 1198 (11th Cir. 2009) ("Failure to show any of the four factors [of the preliminary injunction test] is fatal, and the most common failure is not showing a substantial likelihood of success on the merits.").

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EXHIBIT P

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

RANDALL CALLAHAN, *et al.*,	:	
Plaintiffs,	:	
v.	:	
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,	:	CIVIL ACTION NO. 1:19-CV-1783-AT
Defendants.	:	

ORDER

Plaintiffs, Randall Callahan, Katryna Grisson, Candice Seaman and Michael Wingate (the "Patient Plaintiffs") along with Emory University, Henry Ford Health System, Indiana University Health, Oregon Health and 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, University of Kentucky, Vanderbilt University Medical Center, Virginia Commonwealth University Health System Authority, The Washington University, and Barnes-Jewish Hospital (the "Transplant Center Plaintiffs") (collectively, the "Plaintiffs") filed the instant action against Defendants, the United States

Department of Health and Human Services ("HHS") and United Network for Organ Sharing ("UNOS") (collectively, the "Defendants")[1] alleging that "HHS has failed to follow legally-required procedures in developing the [April 2019 liver allocation] policy, instead choosing to defer virtually all decision-making to a private government contractor, ['UNOS'], acting in its capacity as the Organ Procurement and Transplantation Network ['OPTN']" and that "these actions violate the Administrative Procedure Act [5 U.S.C. Section 706(1), (2)] as well as the Due Process Clause of the Fifth Amendment." *See* Complaint ("Compl") (Doc. 1). Plaintiffs request that the Court find that the April 2019 Policy is violative of the National Organ Transplant Act ("NOTA") along with the regulations promulgated thereunder as well as the Due Process Clause of the Fifth Amendment of the U.S. Constitution. On this basis, Plaintiffs ask the Court to enjoin the April 2019 Policy from being implemented or otherwise taking effect. *Id*. (Prayer for Relief).

Presently before the Court is Plaintiffs' Motion for Injunction Pending Appeal in accordance with Fed. R. Civ. P. 62(d). [Doc. 76]. Specifically, Plaintiffs request that the Court "grant an injunction enjoining the U.S. Department of

[1] "Defendants" as used throughout this Order shall also include Intervenor-Defendants Susan Jackson and Charles Bennett. *See* (Doc. 38, granting motion to intervene). Intervenor-Defendants here are Plaintiffs in a similar lawsuit filed in the Southern District of New York – but they take an opposing view to the Plaintiffs here regarding the merits of the new allocation policy at issue which their legal filings helped to trigger. *See Cruz et al. v. U.S. Dep't of Health and Human Servs. et al.*, No. 18-cv-6371. Based upon administrative actions taken by HHS, the Organ Procurement and Transplantation Network and UNOS following the filing of the instant lawsuit, the *Cruz* action was subsequently stayed pending implementation of the April 2019 Policy, which is the subject of the instant litigation. *See id*.

Health and Human Services ["HHS"] and the United Network for Organ Sharing ["UNOS"] from implementing the new liver allocation policy (the "April 2019 Policy") pending Plaintiffs' appeal of this Court's May 13, 2019 Order denying Plaintiffs' Motion for Temporary Restraining Order (Doc. No. 74). In the alternative, Plaintiffs move that this Court temporarily enjoin implementation of the April 2019 Policy pending a decision by the Court of Appeals on an emergency application for an injunction pending appeal that Plaintiffs intend to file." *Id*. Defendants have submitted responses in opposition to the motion. (Docs. 80, 81).[2]

As an initial matter, the Court has previously set forth the expedited chain of events which necessitated its May 13, 2019 ruling on Plaintiffs' motion seeking a temporary restraining order ("TRO") and will not do so again here. *See* (Doc. 74 [Order], 79 [Amended Order]).[3] On May 14, 2019, following the Court's

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[2] Neither Defendant UNOS nor the Intervenor-Defendants submitted opposition by the 4 PM deadline set by the Court. *See* May 14, 2019 Electronic Docket Entry. Indeed, their opposition (Doc. 81) has a time stamp of "4:15 PM" as evidenced by a review of the electronic docket. Despite the untimely response and in view of the severely truncated timeframe in which the Court directed responses be filed due to the time sensitivity of the relief requested, the Court will, in its discretion, consider the arguments raised therein, to the extent they bear on the issues at hand.

[3] While the Court will not repeat the expedited procedural chain of events that took place since the filing of this lawsuit, the Court nevertheless finds it prudent to take a moment to review the major events which ultimately resulted in the filing of this action. On July 31, 2018, the Administrator of the Health Resources and Services Administration (the division of HHS charged with direct oversight of OPTN/UNOS) directed the "OPTN Board to approve a liver allocation policy, consistent with . . . the OPTN final rule, by its December 2018" and that failure to adopt a compliant policy may result in the "Secretary [ ] exercise[ing] further options or direct further action consistent with his authority under 42 C.F.R. 121.4(d). (Doc. 2-11). Following this directive, the OPTN Liver and Intestine Committee (the "Liver Committee") worked towards and ultimately published for comment on the OPTN website a policy proposal. (Doc. 2-11). Comments could be posted between October 8, 2018 and November 1, 2018." *Id*. On November

issuance of its ruling denying Plaintiffs' request for a TRO, Plaintiffs' filed the instant motion seeking an injunction pending their request for interlocutory appellate relief of the Court's Order. [Doc. 76]. Thus, the Court again finds itself thrust into maelstrom of this preliminary issue prior to the Court of Appeals having a chance to weigh in on the matter. Nevertheless, in light of the mechanism provided for in Rule 62(d), the Court will faithfully dispatch its obligation to weigh Plaintiffs' request in conjunction with the applicable standard of review.

2, 2018, the day after the close of the comment period, the Liver Committee voted as to which liver allocation policy should be recommended for review by the OPTN Board. (Doc. 2-12, Liver Committee Meeting Minutes). The two policies being voted on were the Broader-2-Circles ("B2C") or Acuity Circles ("AC") (a lengthy discussion of the intricacies of each competing model is beyond the scope of this Order). *Id*. Ultimately, the Liver Committee voted to recommend the B2C over the AC model by a vote of 11 to 9 with 0 abstentions. *Id*. On December 3, 2018, the OPTN Board met in order to discuss a number of issues, including whether to adopt the Liver Committee's recommendation. (Doc. 34-13, OPTN Board Meeting Transcript). Although there was vociferous debate over which liver allocation policy (B2C or AC) should be adopted as well as whether, in light of the serious issues and truncated timeframe as directed by HRSA, the proposal should be tabled, the OPTN Board ultimately voted to adopt the AC policy, which had a projected implementation date of April 30, 2019. *Id*.; *see* (Doc. 2-19, March 14, 2019 Letter from HRSA Administrator to OPTN Executive Director). The vote on this specific policy amendment was 24 in favor, 14 against and 0 abstentions. (Doc. 34-2 at 7). Subsequently, on February 13, 2019, Plaintiffs submitted a "critical comment" to Secretary Azar, consistent with NOTA and the OPTN Final Rule, *see* 42 U.S.C. § 274(c) (providing that Secretary shall establish procedures for submission of critical comments by interested persons); 42 C.F.R. 121.4(d) (setting forth process for submission and consideration of critical comments by the Secretary), to invoke Secretarial review over the proposed policy. That critical comment described why, in Plaintiffs' view, the policy adopted by the OPTN Board in December 2018 (and schedule for implementation on April 30, 2019) was unlawful and that its implementation should be suspended. (Doc. 2-18). On March 26, 2019, OPTN/UNOS provided a 16-page response to Plaintiffs' critical comment. (Doc. 2-20). Specifically, OPTN/UNOS stated that in its view, the adopted policy was "compliant with the OPTN Final Rule and will result in more equitable distribution of livers for all liver candidates on the waiting list." *Id*. at 2. For its part, HRSA did not respond to Plaintiffs' critical comment until April 23, 2019—one day following the filing of this action. (Doc. 34-2). In its response, HRSA's Administrator stated, in part, that "[w]e have carefully reviewed your critical comment, other correspondence shared concerning the Acuity Circles Policy, the OPTN's response, and the SRTR's response in light of the requirements of NOTA and the OPTN final rule [and that] [b]ased upon this review, I do not believe that further HHS actions are warranted." *Id*. at 1-2.

Federal Rule of Civil Procedure 62(d) provides, in relevant part, that "[w]hile an appeal is pending from an interlocutory order or final judgment that grants, continues, modifies, refuses, dissolves, or refuses to dissolve or modify an injunction, the court may suspend, modify, restore, or grant an injunction on terms for bond or other terms that secure the opposing party's rights. Fed. R. Civ. P. 62(d). The Supreme Court has stated although "[d]ifferent Rules of Procedure govern the power of district courts and courts of appeals to stay an order pending appeal[,] [u]nder both Rules, however, the factors regulating the issuance of a stay are generally the same: (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776, 107 S. Ct. 2113, 2119, 95 L. Ed. 2d 724 (1987); *see Nken v. Holder*, 556 U.S. 418, 426, 129 S. Ct. 1749, 1756, 173 L. Ed. 2d 550 (2009); *Garcia-Mir v. Meese*, 781 F.2d 1450, 1453 (11th Cir. 1986); *Georgia Muslim Voter Project v. Kemp*, 918 F.3d 1262, 1267 (11th Cir. 2019). In *Georgia Muslim Voter Project*, the Eleventh Circuit reiterated the contours for applying these factors stating that

> The first two factors are the "most critical." *Nken*, 556 U.S. at 434, 129 S. Ct. 1749. As to the first factor, "[i]t is not enough that the chance of success on the merits be better than negligible." *Id.* (internal quotation marks omitted).

> As to the second factor, irreparable injury, "even if [a party] establish[es] a likelihood of success on the merits, the absence of a substantial likelihood of irreparable injury would, standing alone, make [a stay] improper." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc). That is because "[a] showing of irreparable injury is the sine qua non of injunctive relief." *Id.* (internal quotation marks omitted). "[T]he asserted irreparable injury must be neither remote nor speculative, but actual and imminent." *Id.* (internal quotation marks omitted).

Georgia Muslim Voter Project, 918 F.3d at 1267. Notwithstanding this analytical framework, it is also true that "the movant may also have his motion granted upon a lesser showing of a 'substantial case on the merits' when 'the balance of the equities [identified in factors 2, 3, and 4] weighs heavily in favor of granting the stay.'" *Garcia-Mir*, 781 F.2d at 1453; *LabMD, Inc. v. Fed. Trade Comm'n*, 678 F. App'x 816, 819 (11th Cir. 2016) (same). In addition, "granting a stay that simply maintains the status quo[4] pending appeal 'is appropriate when a serious legal question is presented, when little if any harm will befall other interested persons or the public and when denial of the [stay] would inflict irreparable injury on the movant.'" *LabMD, Inc.*, 678 F. App'x at 819 (quoting *Ruiz v. Estelle*, 650 F.2d 555, 565 (5th Cir. 1981)) (per curiam);[5] *see Providence Journal Co. v. Fed. Bureau of Investigation*, 595 F.2d 889, 890 (1st Cir. 1979) ("Where, as

[4] The status quo to which the Court refers throughout this Order is the continuing operation of the liver allocation policy that had been in effect immediately prior to May 14, 2019, which is the implementation date of the April 2019 liver allocation policy at issue in this case.

[5] In *Bonner v. City of Prichard*, 661 F.2d 1206 (11th Cir. 1981) (en banc), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981. *Id.* at 1209. *Ruiz* was issued on June 26, 1981. 650 F.2d at 555.

here, the denial of a stay will utterly destroy the status quo, irreparably harming appellants, but the granting of a stay will cause relatively slight harm to appellee, appellants need not show an absolute probability of success in order to be entitled to a stay."). With these guiding standards in mind, the Court turns to the instant motion.[6] *See Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844–45 (D.C. Cir. 1977) ("Prior recourse to the initial decisionmaker would hardly be required as a general matter if it could properly grant interim relief only on a prediction that it has rendered an erroneous decision. What is fairly contemplated is that tribunals may properly stay their own orders when they have ruled on an admittedly difficult legal question and when the equities of the case suggest that the status quo should be maintained.").

To begin, the Court grounded its May 13, 2019 Order primarily upon the substantial deference which is generally accorded to an agency's interpretation of its own regulations as espoused in prevailing Supreme Court precedent. *See Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945) and *Auer v. Robbins*, 519 U.S. 452 (1997). However, in the same breath, the Court highlighted the fact

[6] While HHS posits that "Plaintiffs' request is properly framed as seeking a mandatory injunction" since "the [April 2019 liver] Policy went into effect this morning [May 14, 2019]," (Doc. 80 at 4 n. 1) the Court finds this position to be somewhat disingenuous. This is because although the status quo has arguably been altered through implementation of the April 2019 liver allocation policy in a hyper technical sense, from a practical standpoint, this policy has been in effect for less than 48 hours. Thus, the Court does not see how putting a halt to any further forward movement with respect to implementation of the April 2019 Policy at this early stage would entail any great prejudice to HHS or UNOS especially under the circumstances here, where Defendants were on notice of the Court's view that maintaining the status quo would better serve the public interest. As such, the Court is not convinced that it need apply the stricter standard generally required when analyzing requests for mandatory injunctive relief (as opposed to the more common request for prohibitory injunctive relief).

that this standard could well be upended by the Supreme Court in the very near future in light of an imminent decision by the Court in *Kisor v. Wilkie*, No. 18-15, 139 S. Ct. 657 (2018) (Supreme Court's Order granting certiorari, argued March 27, 2019). Nevertheless, due to the intractability of both Defendants' HHS and UNOS, the Court was thrust into the untenable position of applying existing law concerning the bedrock issue of deference in view of the distinct possibility that the legal landscape would undergo a seismic shift in this discrete legal area in the very near future.

The Court, in its previous Order, stated up front that it "harbors serious reservations concerning Defendants' position with respect to the level of deference [that should be accorded] to HHS' interpretation of its own procedural review regulation—specifically 42 C.F.R. Section 121.4(b)(2), which concerns Organ Procurement and Transplantation Network Policies, including Secretarial review and appeals." (Doc. 74 at 7).[7] Nevertheless, following an in-depth review of the National Organ and Transplant Act, 42 U.S.C. Section 273 *et seq.*, the regulatory language contained in 42 C.F.R. Section 121.4(b)(2), in conjunction with a dissection of 63 Federal Register 16296-16338 (final rule governing operation of OPTN) as well as 64 Federal Register 56650-56661 (setting forth "improvement to the final rule governing operation of the [OPTN], published in 1998" based upon the "advice of a panel convened by the National Academy of

[7] The Court further elaborated on Defendants' position vis-à-vis the level of deference required, as well as the tenuous pieces of evidence relied upon by Defendants in support of this position in its prior Order and will not do so again here.

Science's Institute of Medicine"), the Court ultimately was "left with the distinct possibility that the 42 C.F.R. Section 121.4(b)(2) is susceptible to two interpretations, one of which, supports, at least minimally, HHS' view as to when the formal procedures contemplated in Section (b)(2) are required to be utilized." (Doc. 74 at 9). That realization, coupled with only a partial record before it and the deference that the Court viewed as required under existing precedent, necessitated according HHS' interpretation (*i.e.*, that the more robust procedures called for in Section (b)(2) are required only in the event OPTN recommends to the Secretary that a policy be "enforceable") with substantial deference." *Id*. at 10. In light of the instant motion, the Court shall revisit this finding through the lens of the standard applicable here.

While the Court has previously set forth Defendants' position concerning the interpretation of 42 C.F.R. Section 121.4(b)(2), the Court did not previously identify Plaintiffs position, which is relevant to the inquiry here. Not surprisingly, Plaintiffs advocate that the "scope of [Section 121.4(b)(2)] must not be limited to enforceable policies. Rather, the paragraph addresses several categories of proposed policies and sets forth different procedures for each." (Doc. 49 at 8). As is relevant here, Plaintiffs interpret the regulation to require that "the Secretary 'will' follow certain procedural requirements for 'significant' policies and 'will determine' the lawfulness of 'the' proposed policies." *Id*. at 8-9. Specifically, as concerns the April 2019 liver allocation policy, Section(b)(2), in Plaintiffs' view, requires that with respect to "significant proposed policies" the

Secretary must refer such policies to the Advisory Committee on Organ Transplantation ("ACOT") and publish them in the Federal Register for public comment. (Doc. 2-1 at 16); *see* 42 C.F.R. § 121.4 (b)(2). Indeed, according to Plaintiffs, "Defendants' reading would result in the entirety of Section 121.4(b)(2) having no consequence if the required procedures could simply be avoided by the OPTN deciding never to recommend a policy be enforceable." (Doc. 49 at 10).

The Court finds substantial merit in Plaintiffs' interpretation especially where, as here, there exists "serious and difficult questions of law in an area where the law is somewhat unclear." *Canterbury Liquors & Pantry v. Sullivan*, 999 F. Supp. 144, 150 (D. Mass. 1998) (recognizing that "with regard to the first prong of the *Hilton* test, the movant must only establish that the appeal raises serious and difficult questions of law in an area where the law is somewhat unclear").[8] In addition, Plaintiffs' interpretation finds some support in the Federal Register discussing the OPTN Final Rule (*i.e.*, 42 C.F.R. Section 121).

The OPTN Final Rule (the "Final Rule") was initially published in 93 Federal Register 16296-16638 in order to "govern[ ] the operation of [OPTN], which performs a variety of functions related to organ transplantation under contract with HHS." 93 Fed. Reg. 16296. The Final Rule was meant to "improve the effectiveness and equity of the Nation's transplantation system and to further

[8] To be clear, although the principles set forth in *Seminole Rock* and *Auer* are still presently good law, it is far from clear that these precedents will survive in the short term given that a decision from the Supreme Court in *Kisor* is imminent. Thus, from a practical standpoint, the law is "unclear" in this particular area but should be clarified, one way or another, in the weeks to come.

the purpose of [NOTA], as amended." *Id*. In this regard, the Final Rule sets forth specific policies concerning the structure of OPTN, listing requirements, organ procurement, identification of organ recipients, policies and secretarial review, allocation of organs, designated transplant program requirements, reviews, evaluation and enforcement, appeals of OPTN policies and procedures, record maintenance and reporting requirements and preemption. *Id*. at 16297. As concerns this case, which is focused, in part, on the procedural correctness of the adoption of the April 2019 liver allocation policy, the Final Rule set forth the following:

> ***The Secretary also recognizes the need for additional public participation in the development of some OPTN policies, such as fundamental revisions to organ allocation policies***, and has included in this rule provisions that (1) require the OPTN Board to provide opportunity for the OPTN membership and other interested parties to comment on all of its proposed policies, (2) enable the Secretary to seek comment from the public and to direct the OPTN to revise policies if necessary, and (3) provide timely access to information for patients, the public, and payers.
>
> ***
>
> Both the genesis and wording of the National Organ Transplant Act (NOTA), as amended, obligate the Secretary to utilize the transplantation community substantially in both developing and executing transplantation policy. ***Under the statutory framework established by the Congress, however, the Department has oversight obligations, arising from the NOTA, as well as other laws and executive orders. For example, 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.*** In this regard, however, most commenters stated, and the Secretary agrees, that Departmental oversight should not micro-manage the development of purely medical criteria or routine day to day decision-making of attending medical professionals or the OPTN contractor.
>
> The Department, in the preamble to the proposed rule (59 FR 46486), made clear its intention to ***provide the public with an opportunity to comment on organ allocation policies and proposed changes to them. While we believe that the comment process administered by the OPTN itself is invaluable in obtaining technical advice, 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.*** These principles are carried forward in the final rule.

63 Fed. Reg. 16301, 16309-310 (emphasis added).

Prior to the Final Rule's effective date, Congress interceded and delayed its implementation until October 21, 1999 based upon concerns voiced by the transplant community as well as the general public. *See* 112 Stat. 2681, 359-60, Pub. L. No. 105-277, § 213; *see* 64 Fed. Reg. 56650. In light of such concerns, Section 213 of Public Law 105-277 mandated an "independent review through the National Academy of Science's Institute of Medicine ['IOM']. It also suggested development of improved information on the effectiveness of the transplantation system, including center-specific information if possible. Finally, it suggested further discussions between HHS and representatives of the transplant community." 64 Fed. Reg. at 56650. In light of this mandate, "HHS [ ] met on 11

separate occasions with representatives of 11 transplant organizations" and conducted "an additional meeting" which took place on "September 15, 1999 . . . [in order to] discuss together issues that had been surfaced" and, on that basis "HHS [ ] further clarif[ied] these issues with [64 Fed. Reg. 56650]." *Id*. at 56651.

As is relevant here, the amended version of the Final Rule states, in part, that

> In response to comments asking which OPTN policies are to be submitted to the Secretary, the Department has modified the language of §121.4(b)(2) to provide that the Board of Directors is required to provide the Secretary with proposed policies that the OPTN recommends be enforceable under §121.10 (including allocation policies) ***and others as specified by the Secretary. As discussed above, the rule has been revised to adopt the IOM's recommendation that the Advisory Committee assist the Secretary in reviewing OPTN policies and practices as well as to indicate the purposes of the Secretary's review.***
>
> ***
>
> ***The Department intends to implement the recommendation of the IOM, as discussed above, to create an independent, multidisciplinary scientific advisory board [the Advisory Committee on Organ Transplantation] which will assist 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."*** Constitution of such an advisory committee and its consultation by the Secretary, as appropriate, in the words of the IOM, "would also enhance public confidence in the integrity and effectiveness of the system." The Department has added a new §121.12 to provide for the establishment of an Advisory Committee

> on Organ Transplantation. The Committee, to be established in accordance with the Federal Advisory Committee Act [5 U.S.C. App.], will be available to the Secretary to provide comments on proposed OPTN policies and other matters related to transplantation.

64 Fed. Reg. at 56656-57 (emphasis added).

The Court pauses for a moment to circle back to the pertinent regulatory language in Section(b)(2) which contemplates application of the more robust traditional notice and comment procedure under certain circumstances. Specifically, the OPTN Board of Directors shall

> 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). These policies will not be enforceable until approved by the Secretary. ***The Board of Directors shall also provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. 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 also may 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. 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.

42 C.F.R. § 121.4(b)(2) (emphasis added). When this regulatory section is juxtaposed against the pertinent excerpts from both the 1998 and 1999 Federal Register, there is a strong case to be made that the Secretary contemplated more

robust level of public involvement (including commentary) in the promulgation of organ allocation polices and that ACOT be intimately involved in the review of such policies in order to make certain 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." 64 Fed. Reg. 56657.

Given the above, there is a substantial basis to believe that the more robust notice and comment procedures as well as input from ACOT may have been required here—despite Defendants' interpretation to the contrary. Further, in light of the uncertain near-term viability of substantial deference to an agency's interpretation of its own promulgated regulations, the Court, upon further reflection, concludes that Plaintiffs have presented "a substantial case on the merits" as concerns this legal theory (*i.e.*, that the required regulatory procedures as set forth in 42 C.F.R. Section 121.4(b)(2) were not properly followed) based upon the "serious legal question" that is involved here (*i.e.*, the uncertain short-term applicability of the doctrine of *Seminole Rock* and *Auer* deference based upon the Supreme Court's upcoming decision in *Kisor*). *Ruiz*, 650 F.2d at 565.[9]

The Court has consistently recognized in these proceedings, the major medical, human health, institutional, and financial ramifications of both the

[9] Defendants argue that Plaintiffs "cannot show a likelihood of success based on the unknown application of a Supreme Court decision which does not exist." (Doc. 80 at 5, Opposition to Plaintiffs' Motion for Injunction Pending Appeal). However, the Plaintiffs do not rely on a phantom trend in the law or case where certiorari was never granted, as in the cases referenced by Defendants. *Id.* They seek a limited status quo injunction pending the Court of Appeals' review of this Court's ruling on a complex and difficult issue, with public significance, that may be impacted in short order by the Supreme Court's decision in *Kisor v. Wilkie*, No. 18-15, 139 S. Ct. 657 (2018) with respect to the administrative deference doctrine.

Defendants' new liver allocation policy and their rapid schedule for review and implementation of that policy. The individual Plaintiffs suffer from serious liver disease and are on the liver transplant waitlist. The Plaintiff medical institutions seek to protect the health and lives of their patients with serious liver disease as well as the efficacy and stability of transplant centers requiring enormous financial and professional investment. They have presented credible evidence that the new allocation policy will adversely impact the health of their patients, heighten the risk (and numbers) of deaths and liver wastage, increase institutional and liver transportation costs, and leave a higher percentage of their patients without transplants.[10] Defendants dispute some of this evidence, in particular as to heightened risk of death, and view the net risks differently. However, for the purpose of the assessment of irreparable injury, the Court finds that at this early juncture of the proceedings, Plaintiffs' evidence is sufficient to establish irreparable injury absent the grant of an injunction. *Blum v. Caldwell*, 446 U.S. 1311, 1316 (1980) (recognizing irreparable injury warranting equitable relief where plaintiffs' health status and risk of death impacted by the state defendants' application of particular rules for determining Medicaid eligibility); *Odebrecht Const., Inc. v. Secretary, Florida Dept. of Transp.*, 715 F.3d 1268,

[10] *See, e.g.*, Complaint allegation referencing statistical data collected by OPTN and other entities and supporting exhibits relating to projected increases in travel costs and medical risks, increased overall costs, decreased liver transplants, and their patients' likelihood of received a liver and survival. (Doc. 1 at ¶¶146-183, Complaint); (Doc. 2-5 at ¶19, Exhibit 5 to Motion for TRO). The Court notes that contrary to Defendants' apparent argument, Plaintiffs need not prove the immediate projected date of the death of their patients in order to credibly show that their patients' medical status is at risk, deteriorating, and depends on the availability of a timely liver transplant.

1289 (11th Cir. 2013) (finding irreparable harm in public contract bidding context and private company's entitlement to injunctive relief because no monetary recourse would be available against the government and its officials based on Eleventh Amendment immunity and cases to the same effect, cited therein); *Tex. Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 242 (D.D.C. 2014) (finding irreparable harm and granting injunction to maintain status quo in computation rule based on imminent financial harm to two hospitals resulting from modification of Medicaid cost rules promulgated in violation of the Administrative Procedure Act, where hospital cost expenditures would not be later recoverable from the government).

But the potential harm at issue at this juncture, looms even larger – and it is a harm that the Court endeavored to avoid by its request that the Government voluntarily agree to a continuation of the temporary two week hold on the effective date of the new transplant policy, pending the Supreme Court's issuance of its decision in *Kisor* in the current term. Instead, the Government has insisted on forging ahead despite the obvious likelihood of enormous disruption in operation of the medical and liver transplant system and the plaintiff transplant centers, especially if the Court determines in a matter of weeks post-*Kisor*[11] that it must enjoin implementation of the challenged policy and review procedures. This unfortunate brinksmanship places the Plaintiff medical institutions and

[11] The Court clearly will continue proceedings in this case, including conducting a hearing upon a party's further request for a preliminary injunction or conducting a trial on the merits.

their transplant patients – as well as the liver transplant system at large – unnecessarily at great risk. It disserves the public interest.

Given the gravity of the medical issues and risk of disruption in the transplant system and the concrete likelihood of harm to the plaintiffs and the public at large if the status quo is not maintained, the Court finds that the public interest is best served by the grant of injunctive relief pending appellate review of Plaintiffs' interlocutory appeal.

In assessing the public interest, the Court has also considered the factor of whether an injunction requiring maintenance of HHS's long established liver allocation policy prior to May 14th, on a time limited basis, "will substantially injure other parties interested in the proceeding." *Hilton*, 481 U.S. at 776; *Garcia-Mir*, 881 F..2d at 1453. Based on the current record and findings already articulated, the Court concludes that a protective injunctive order that effectively maintains the pre May 14, 2019 status quo and minimizes major disruption in the liver transplant medical field pending further order of the Court of Appeals does not substantially injure other interested parties in this proceeding. Indeed, further rollout of the new April 2019 liver transplant policy would only complicate the challenges posed by addressing any future relief orders in this case that may affect interested parties in these proceedings. Hitting the pause button to permit considered appellate review of a critical legal issue – with life, death, and major institutional and patient care consequences – simply does not

substantially injure the interests of Defendants or other interested parties, regardless of their administrative interest in proceeding right now.

Based upon the Court's finding that Plaintiffs have presented a substantial case on the merits, especially given the difficult questions of law at issue, have established, at least at this preliminary stage, irreparable injury and in light of the fact that the public interest weighs in favor of maintaining the transplant policy status quo pre May 14, 2019, the Court similarly concludes that in balancing the equities, the scales tilt convincingly in Plaintiffs' favor at this juncture. Indeed, "[a]n order maintaining the status quo is appropriate when a serious legal question is presented, when little if any harm will befall other interested persons or the public and when denial of the order would inflict irreparable injury on the movant. There is substantial equity, and need for judicial protection, whether or not movant has shown a mathematical probability of success." *Washington Metro. Area Transit Comm'n*, 559 F.2d at 844.

In light of the foregoing analysis, Plaintiffs' motion seeking injunctive relief [Doc. 76] pending their appeal of this Court's prior Order is hereby **GRANTED**. As such, Defendants' are **DIRECTED to immediately cease and desist** from any further efforts and/or conduct aimed at continued implementation of the April 2019 liver allocation policy until further Order from the Court or otherwise until such time as the Court of Appeals has passed upon the issues raised herein.[12]

[12] The Court finds that a bond is not required here.

IT IS SO ORDERED this 15th day of May, 2019.

AMY TOTENBERG
UNITED STATES DISTRICT JUDGE

EXHIBIT Q

Liver distribution policy, NLRB implementation deferred until May 14

UNOS News Bureau

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

Important update: *Policy and system changes are in place, effective May 14, 2019.*

At the direction of the Health Resources and Services Administration (HRSA), implementation of both the liver and intestinal organ distribution policy based on acuity circles and the National Liver Review Board (NLRB) will be deferred until May 14, 2019.

This decision is related to a federal lawsuit filed by several plaintiffs challenging the liver distribution policy approved by the OPTN Board of Directors in December 2018. The deferral will allow the court additional time to consider the issues raised in the lawsuit.

The conversion of exception scores to the new NLRB criteria will also be deferred until May 14. This means that candidates with an existing exception score will retain their score until that date unless it expires or is due for extension. The existing regional review boards will continue to consider requests for new or extended exception scores until the new implementation date.

We will keep you informed of additional developments.

Published on: Tuesday, April 23, 2019

Organ Procurement & Transplantation Network

EXHIBIT R

New national liver transplant system takes effect

UNOS News Bureau

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

The OPTN launched a new liver distribution system on May 14 as part of an effort to update and improve the organ sharing system responsible for saving tens of thousands of lives each year. This new policy will save more lives annually, with fewer patients dying while waiting for a liver transplant. It also is expected to increase the number of pediatric liver transplants, making this a national policy that will work more efficiently and fairly for patients across the entire country.

Adopted by the OPTN Board of Directors (https://optn.transplant.hrsa.gov/news/optnunos-board-approves-updated-liver-distribution-system/) in December 2018, the liver distribution policy re-calibrates how geography is considered when matching donated livers with transplant recipients based on experience gained with the previous, decades-old system that heavily relied on geographic boundaries of 58 donor service areas (DSAs) and 11 transplant regions. The new system emphasizes the medical urgency of liver transplant candidates and the distance between the donor hospital and transplant hospitals. The transplant community, including a committee comprising transplant

experts, organ recipients, and donor families from around the country and the OPTN Board of Directors—with extensive input from the public—came together to develop and approve this new liver policy.

Livers from all deceased donors will first be offered to the most urgent liver transplant candidates (Status 1A and 1B) listed at transplant hospitals within a radius of 500 nautical miles of the donor hospital. Livers from adult donors would next be offered to candidates at hospitals within distances of 150, 250 and 500 nautical miles of the donor hospital. These offers are grouped by medical urgency. Candidates at hospitals within 150 nautical miles are prioritized unless there are other candidates at considerably higher medical urgency farther away.

Statistical modeling of the new system projects that it will decrease waiting list deaths due to increased prioritization of highly urgent liver candidates. The new policy is also projected to increase pediatric transplants by increasing priority for pediatric candidates relative to adults when the donor is younger than age 18.

Also on May 14, the OPTN implemented a National Liver Review Board (NLRB) to replace the regional review process previously used to consider exception scores for liver candidates whose calculated MELD or PELD score does not reflect their medical urgency. The new process promotes equity by creating greater consistency in the review and application of exception scores for candidates nationwide. This article (/news/national-liver-review-board-is-implemented/) describes the NLRB.

Information about how the new system was developed is available in the liver distribution (https://optn.transplant.hrsa.gov/governance/policy-initiatives/liver/) section of the OPTN website. Transplant professionals, as well as transplant candidates and their families, can learn more details about the policy implementation in an implementation toolkit (https://optn.transplant.hrsa.gov/resources/by-organ/liver-intestine/).

Published on: Tuesday, May 14, 2019

Organ Procurement & Transplantation Network

EXHIBIT S

Work in progress to revert to DSA based system due to court order

UNOS News Bureau

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

The Health Resources and Services Administration (HRSA) has instructed UNOS, as the OPTN contractor, to revert to the liver distribution policy in place prior to May 14, 2019, utilizing boundaries based on donation service areas and regions, consistent with a federal court order. For further information, refer to a HRSA letter to UNOS (https://unos.org/wp-content/uploads/unos/signed_Sigounas.Letter-to-UNOS.5172019.pdf) and UNOS' reply to HRSA (https://unos.org/wp-content/uploads/unos/UNOS-Response-to-HRSA-May-17-2019-Directive.pdf) on May 17, 2019.

In all instances, organ procurement organizations and liver transplant programs should continue to follow the match run generated in UNet^{SM} for liver donors and potential recipients.

We understand that these events are unfolding rapidly. We will continue to keep you informed of new developments.

Published on: Monday, May 20, 2019

EXHIBIT T

System notice: OPTN liver allocation policy reverted to DSA and regions

UNOS News Bureau

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

UNOS wants to reassure the donation and transplant community that despite the legal proceedings underway, donated livers continue to be allocated to patients on the waiting list; there is no disruption to this important work. Learn more below.

Key audiences:

Liver transplant program directors, surgeons, physicians, administrators, clinical coordinators and data coordinators; compliance and quality managers; clinical support staff; OPO executive directors and procurement directors/managers

Implementation date:

May 23, 2019

At-a-glance

On May 23, 2019, OPTN Policy 9 (Allocation of Livers and Liver-Intestines) reverted to use of the donation service area (DSA) and regional distribution boundaries in effect prior to May 14, 2019. This action complies with a federal court order dated May 17, 2019.

In all instances, organ procurement organizations and liver transplant programs should continue to follow the match run generated in UNetSM for liver donors and potential recipients.

The National Liver Review Board (NLRB) remains in effect. Candidates' currently assigned exception scores did not change. As always, transplant programs may request individual exception scores for candidates by the procedure set forth in OPTN Policy 9.4 (MELD or PELD Score Exceptions).

Resources

The updated liver allocation policy is available in the Policies section (/governance/policies/) of the OPTN website.
Online help documentation covering UNet functionality is also available.

Questions?

If you have questions about data or information systems, contact UNOS Customer Service at 800-978-4334. For policy-related questions, send an e-mail to member.questions@unos.org or call 844-395-4428.

Published on: Thursday, May 23, 2019

EXHIBIT U

NLRB update - MMaT calculation now based on DSA of transplant hospital

UNOS News Bureau

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

Key updates and actions:

- **MMaT now calculated by DSA of liver transplant hospital**
- **Scores converted as of 10:15 p.m. EDT May 24**
- **Waiting time may be adjusted upon request if MELD exception score increased**
- **Median PELD at transplant (MPaT) is not affected**

Note: To see the most up-to-date information on the OPTN website, make sure you always refresh your browser or clear your cache. You can accomplish this by pressing Ctrl F5 on your keyboard.

Effective May 24, 2019, at 10:15 p.m. EDT, the median MELD at transplant (MMaT) scores for liver candidates with exception scores are now based on recent liver transplants performed at liver transplant hospitals within the donation service area (DSA) where the candidates are listed.

When the National Liver Review Board (NLRB) was implemented on May 14, 2019, at the same time as the acuity circles distribution model, the basis of the MMaT calculation was recent transplants at all liver transplant hospitals included in a 250 nautical mile radius of the hospital listing the exception candidate. With the reversion to a donation service area (DSA) and region-based liver allocation system effective May 23, some DSAs had different MMaT scores among liver programs within their area. This in turn could create disparities affecting candidates' transplant access within the local DSA of the donor.

The OPTN Executive Committee, by teleconference May 24, unanimously approved basing the MMaT calculation on DSA to address unintended consequences of the reversion to DSA-based liver allocation.

The conversion has been made within UNet^{SM} for all liver transplant candidates who had an exception score based on MMaT within a 250 nautical mile radius. Please refer to this table (https://optn.transplant.hrsa.gov/media/2971/mts_dsa_distribution_20190311.pdf) for the MMaT score for each liver transplant program based on DSA. If you wish to compare it to the MMaT based on 250 nautical mile circles, this table (https://optn.transplant.hrsa.gov/media/2844/mts_distribution.pdf) lists the previous scores.

Many individual candidates' MMaT will remain the same under the conversion as it was under the previous calculation. Other candidates will have their exception scores either increase or decrease.

You may apply to UNOS to have a candidate's waiting time adjusted only if the candidate experiences an increase in their MELD exception score as a result of this action. The waiting time adjustment will include time the candidate had at a lower exception score from the May 14 initiation of NLRB up until this action. To request a waiting time adjustment for a candidate, please submit a Waiting Time Modification form. These forms are located in UNet^{SM}; navigate to the WaitList^{SM}, then on the top menu select "Resources", then select "Forms/Tools."

Median PELD at Transplant (MPaT) is unaffected by this action. MPaT is the same for all transplant programs with PELD exception candidates and will remain at 35.

As always, transplant programs may request individual exception scores for candidates by the procedure set forth in OPTN Policy 9.4 (MELD or PELD Score Exceptions).

If you have questions about data or information systems, contact **UNOS Customer Service at 800-978-4334.** For policy-related questions, send an e-mail to member.questions@unos.org (mailto:member.questions@unos.org) or call **844-395-4428.**

Published on: Friday, May 24, 2019

EXHIBIT V

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

RANDALL CALLAHAN, *et al.*, Plaintiffs, v. 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, Defendants.	:	CIVIL ACTION NO. 1:19-CV-1783-AT

ORDER

This matter is before the Court on Plaintiffs' Motion to Adjust the Schedule Set Forth in the Court's Order (ECF No. 183). (Doc. 191.) The Court held a telephone conference in this matter on December 3, 2019. (Minute Entry, Doc. 197.) The Court discussed the outstanding motions filed by Plaintiff and sought input from the Parties about the current timeline for the renewal of Plaintiff's Motion for Preliminary Injunction and for the implementation of the April 2019 Policy by Defendants. At the Conference, Defendants indicated that they would be willing to push back the implementation date of the April 2019 Policy solely for the purpose of permitting the Court more time to evaluate Plaintiff's renewed motion. Having heard from all Parties about the conditions that would suffice for

a delay of implementation of the April 2019 Policy until January 15, 2020, and for cause shown, it is

ORDERED that the Court's November 25, 2019 Order (Doc. 183) is **AMENDED**, and the following deadlines apply to this case:

- December 5, 2019 – Plaintiffs must indicate with specificity whether they will seek to call a witness at the preliminary injunction hearing (citing appropriate authority) or expand the hearing on their Renewed Motion for Preliminary Injunction in some other fashion to include motions or matters beyond the issues currently before the Court (either as a result of the original Motion for Preliminary Injunction, the Eleventh Circuit's decision, the Court's ruling as to the administrative record, etc.)
- December 9, 2019 – Plaintiffs must file any remaining motions relating to discovery or for supplementation of the administrative record.
- December 10, 2019 – Plaintiffs shall file their Renewed Motion for Preliminary Injunction. Plaintiffs' brief may not exceed 50 pages.
- December 16, 2019 at 10:00 am – Defendants shall file their Responses to Plaintiffs' Renewed Motion for Preliminary Injunction. Intervenors may also file any response on this date, limited to 15 pages.
- December 17, 2019 – The Court anticipates hearing the Renewed Motion for Preliminary Injunction in the morning on this date. The Court intends that this will be the only hearing it holds on the Renewed Motion for Preliminary Injunction.

- December 18, 2019 at 4:00 pm – Plaintiffs' shall file their Reply in Support of the Renewed Motion. Plaintiffs' reply brief may not exceed 20 pages.
- January 15, 2020 – The Court anticipates issuing a decision on this date.

IT IS SO ORDERED this 3rd day of December, 2019.

Amy Totenberg
United States District Judge

EXHIBIT W

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

RANDALL CALLAHAN, *et al.*, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES *et al.*, Defendants.	)	CIVIL ACTION NO. 1:19-CV-1783-AT

JOINT STIPULATION AS TO THE COURT'S DECEMBER 3, 2019 AMENDED SCHEDULING ORDER (ECF NO. 204) AND THE PARTIES' AUGUST 16, 2019 JOINT STIPULATION (ECF NO. 143)

After the entry of the Court's December 3 amended scheduling Order (ECF No. 204), the parties conferred regarding Defendants' agreement with the Court, now reflected in that Order, "to continue a voluntary stay in connection with implementation of the Acuity Circles Policy through January 17, 2020 and to refrain from proceeding with implementation of the Acuity Circles Policy through that date." It is the parties' understanding that this agreement by Defendants with the Court supplements the parties' Joint Stipulation of August 16, 2019 (ECF No. 143) regarding maintenance of the status quo, which otherwise remains in full force and effect.

Dated: December 9, 2019

/s/ Peter C. Canfield

Peter C. Canfield
Ga. Bar No. 107748
Meredith C. Kincaid
Ga. Bar No. 148549
JONES DAY
1420 Peachtree Street, N.E., Suite 800
Atlanta, GA 30309
Telephone: 1.404.521.3939
Facsimile: 1.404.581.8330

John M. Majoras
Admitted pro hac vice
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001
Telephone: 1.202.879.3939
Facsimile: 1.202.626.1700

Will R. Taylor
Admitted pro hac vice
JONES DAY
717 Texas, Suite 3300
Houston, Texas 77002
Telephone: 1.832.239.3939
Facsimile: 1.832.239.3600

Glenn L. Krinsky
Admitted pro hac vice
JONES DAY
555 South Flower Street, 50th Floor
Los Angeles, CA 90071
Telephone: 1.213.243.2540
Facsimile: 1.213.243.2539

Courtney A. Carrell
Admitted pro hac vice
JONES DAY
2727 North Harwood Street
Dallas, Texas 75201
Telephone: 1.214.969.3705
Facsimile: 1.214.969.5100

Attorneys for Plaintiffs

JOSEPH A. HUNT
Assistant Attorney General

MICHELLE BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Michael L. Drezner
Michael Drezner
Trial Attorney
(VA Bar No. 83836)
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L. St., N.W.
Washington, D.C. 20005
Telephone: (202) 514-4505
Facsimile: (202) 616-8460
Michael.L.Drezner@usdoj.gov

Attorney for Defendant HHS

/s/ Linda T. Coberly
Linda T. Coberly,
Daniel D. Rubinstein
Thomas G. Weber
WINSTON & STRAWN LLP
35 W. Wacker Drive
Chicago, IL 60601
(312) 558-5600
lcoberly@winston.com

Sara Anderson Frey
GORDON REES SCULLY
MASUKHANI, LLP
1717 Arch Street
Suite 610
Philadelphia, PA 19103
(215) 717-4009
sfrey@grsm.com

Steven J. Flynn
GORDON REES SCULLY
MANSUKHANI, LLP

55 Ivan Allen Junior
Boulevard, NW
Suite 750
Atlanta, Georgia 30308
(404) 978-7316
sjflynn@grsm.com

Jay S. Blumenkopf
GORDON REES SCULLY
MASUKHANI, LLP
One Battery Park Plaza
28th Floor
New York, NY 10004
(212) 453-0798
jblumenkopf@grsm.com

Attorneys for Defendant UNOS

/s/ Evelyn N. Fruchter
Motty Shulman
Admitted pro hac vice
Evelyn N. Fruchter
Georgia Bar No. 261679
BOIES SCHILLER FLEXNER LLP
333 Main Street
Armonk, New York 10504
(914) 749-8200 (Telephone)
(914) 749-8300 (Fax)
mshulman@bsfllp.com
efruchter@bsfllp.com

Josh Belinfante
Georgia Bar No. 047399
Matthew T. Parrish
Georgia Bar No. 558262
ROBBINS ROSS ALLOY BELINFANTE
LITTLEFIELD LLC

500 14th Street, N.W.
Atlanta, Georgia 30318
Phone: (678) 701-9381
Facsimile: (404) 856-3250
jbelinfante@robbinsfirm.com
mparrish@robbinsfirm.com

Attorneys for Intervenor-Defendants Susan Jackson and Charles Bennett

CERTIFICATE OF SERVICE

This is to certify that on December 9, 2019, I have caused a copy of the foregoing to be electronically filed with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record.

/s/ Courtney A. Carrell
Courtney A. Carrell
Counsel for Plaintiffs

EXHIBIT X

Kidney and pancreas allocation proposals modified to advance 250 nautical mile distribution circle, fewer proximity points

UNOS News Bureau

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

The OPTN Kidney Transplantation and Pancreas Transplantation Committees, following consideration of extensive public comment (https://optn.transplant.hrsa.gov/governance/public-comment/), will advance updated allocation proposals to the OPTN Board of Directors for consideration at its December 3 meeting. The proposals eliminate donation service area (DSA) and region from policy and replace them with a system that allocates kidneys and pancreata based on distance between the hospital listing the transplant candidate and the donor hospital.

Statistical modeling (https://optn.transplant.hrsa.gov/news/srtr-modeling-results-available-for-kidney-and-pancreas-distribution/) suggests the proposed changes will reduce variation in the amount of time candidates wait for kidney transplants

in various areas of the country. The proposed policies should also increase transplant rates for key groups of candidates including ethnic minorities, children, and those who are difficult to match due to high immune sensitivity.

Under each proposal, after a kidney and/or pancreas is offered for any exceptionally well-matched donor-candidate combination nationwide, the next candidates to receive offers are those listed at hospitals within 250 nautical miles from the donor hospital. Offers not accepted for any of these candidates would then be made for those at hospitals beyond a 250 nautical mile radius.

This represents a change from proposals both committees circulated for public comment in August 2019. The committees studied various alternative circle sizes, including the 250 nautical mile radius, and simulation modeling suggested each option would improve upon current allocation based on key metrics. While the two committees initially recommended circles of 500 nautical miles, a substantial theme in public comment was that the wider proposed circle would pose major logistical challenges for organ acceptance and transportation.

“We appreciate the input of everyone who commented on the proposal,” said Vincent Casingal, M.D., chair of the Kidney Committee. “There was a range of views, but many were concerned about unwanted effects we might see with a 500 nautical mile approach. The 250 nautical mile radius is more consistent with established logistics while also replacing the current local and regional boundaries with a more consistent framework nationwide.”

Also under the proposals, transplant candidates would receive proximity points based on the distance between their transplant program and the donor hospital. Proximity points are intended to improve the efficiency of organ placement by adding priority for candidates closer to the donor hospital. Doing so can minimize organ preservation time and increase the likelihood of organ function.

As proposed, candidates within the initial 250 nautical mile radius would receive a maximum of two proximity points, while those outside the initial circle would receive a maximum of four proximity points. At each level, the points would be highest for those closest to the donor hospital and would decrease as the distance grows between the donor and transplant hospitals.

The proximity points in the revised proposals also decreased from those in the public comment proposals (as many as four for candidates in the initial circle and eight for those outside the circle). “With a smaller distribution circle, logistical challenges become less of a factor,” said Silke Niederhaus, M.D., chair of the Pancreas Committee.

The committees will present their updated proposals for action by the OPTN Board of Directors at its meeting December 3, 2019, in Dallas. Additional clarifying policy components will be circulated for additional public comment early in 2020 and implemented along with the policies as approved by the board. The additional components include classifying medical urgency for kidney candidates and providing for backup offers when a kidney or pancreas cannot be used for the first intended candidate.

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EXHIBIT Y

Modifications made to kidney and pancreas allocation proposals

UNOS News Bureau

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

The Organ Procurement and Transplantation Network's Kidney Transplantation and Pancreas Transplantation Committees have made key modifications to proposals to replace donation service area (DSA) and region as distribution units (https://optn.transplant.hrsa.gov/news/kidney-and-pancreas-allocation-proposals-modified-to-advance-250-nautical-mile-distribution-circle-fewer-proximity-points/) in kidney and pancreas allocation policy. These updates reflect major themes identified in public comment and additional committee discussion of potential effects of various policy options. These proposals will be presented to the OPTN Board of Directors at its meeting December 3, 2019.

The key actions as recommended by the committees after public comment include:

- Reduction of the circle size from a radius of 500 nautical miles to 250 nautical miles
- Import backup language removed from kidney and pancreas proposals for additional evaluation

- Medical urgency status removed from the kidney proposal for additional evaluation

Reduction in circle size

Key changes include reduction of the local allocation circle size to a 250 nautical mile radius, as well as reduction of proposed proximity points (a maximum of two points for candidates at transplant programs within the circle and a maximum of four points for candidates listed outside the circle).

Import backup and medical urgency

When they met in October, the committees concluded that additional study and discussion is needed before deciding on the import backup procedure for kidney and pancreas offers, as well as the criteria to determine medical urgency for kidney candidates. As a result, these elements will not be part of the proposals brought for action by the OPTN Board of Directors December 3. The committees will seek additional public comment on these elements, with the intent of including them in implementation alongside the final policies approved by the board.

A workgroup has been formed to address import backup, including members of the Kidney, Pancreas, OPO, Histocompatibility, and Operations and Safety Committees. They will meet weekly for the next month to determine a practical solution to the reallocation of kidneys and pancreata once DSA is removed from allocation. To address kidney candidate medical urgency, a subcommittee of the Kidney committee will also be meeting weekly over the next month to define medical urgency criteria for kidney transplant candidates and determine how this should be operationalized.

The workgroup and subcommittee intend to have criteria ready for supplemental proposals in the Spring 2020 public comment period. Each of the provisions to be presented in supplemental public comment proposals is intended to be incorporated into the kidney and pancreas policies set for approval at the Dec. 3 meeting. The deliberations about these supplemental proposals will include considerations of implementation timing and complexity, with the intent to deliver proposals that can be implemented simultaneously with the removal of DSA and region policies.

Find updates and additional kidney and pancreas resources here (https://optn.transplant.hrsa.gov/resources/by-organ/kidney-pancreas/).

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Organ Procurement & Transplantation Network

CONTACT

Organ Procurement and Transplantation Network (https://optn.transplant.hrsa.gov/)

United Network for Organ Sharing (http://www.unos.org/)

Post Office Box 2484 (http://www.unos.org/)

Richmond, Virginia 23218 (http://www.unos.org/)

EXHIBIT Z

OPTN board adopts new policy to improve kidney, pancreas distribution

Dec 5, 2019 | Kidney/pancreas, Liver/intestine, News, OPO, Policy changes, Transplant center

Dallas – The Board of Directors of the Organ Procurement and Transplantation Network, at its meeting Dec. 3, approved a new system for matching kidney and pancreas transplant candidates with organs from deceased organ donors. The new policy establishes new distribution areas based on the donor location and is projected to increase equity in transplant access for candidates regardless of where they live or list for a transplant.

"The local and regional boundaries we have used for decades often do not reflect the practical and clinical needs of transplant candidates based on how near or far they are to an organ donor," said Maryl Johnson, M.D., board president. "The new system is better at addressing distance as a factor in transplant matching. It's also in keeping with our mandate to make sure that objective medical factors, not geography, should be the key to matching donors and recipients."

New geographic area for offers; additional priority for candidates closer to donor location

Under the newly approved system, expected to be implemented in 2020, kidney and pancreas offers (except for rare, very well-matched donor and recipient combinations nationwide) will be offered first to candidates listed at transplant hospitals within 250 nautical miles of the donor hospital. Offers not accepted for any of these candidates will then be made for candidates beyond the 250 nautical mile distance.

Candidates also will receive proximity points based on the distance between their transplant program and the donor hospital. Proximity points are intended to improve the efficiency of organ placement by adding priority for candidates closer to the donor hospital. Candidates within the initial 250 nautical mile radius will receive a maximum of two proximity points, while those outside the initial circle will receive a maximum of four proximity points. The point assignment will be highest for those closest to the donor hospital and will decrease as the distance increases.

Differences from current system and predicted benefits

The new system will replace a three-tiered approach used since the beginning of national organ allocation policies in the mid-1980s. Currently, most kidney and pancreas offers go first to candidates listed at hospitals within the same donation service area (DSA) where the donor hospital is located. There are 58 DSAs reflecting the assigned service area of organ procurement organizations (OPOs). These DSAs are fixed, often irregular geographic boundaries, and were not set for the express purpose of optimizing organ allocation. In some instances, portions of the same DSA are not contiguous, meaning that some "local" donor matches may travel through service areas belonging to other OPOs.

Organ offers not accepted at the DSA level currently are made to candidates at hospitals within the same OPTN region as the donor hospital. Finally, offers not accepted at the DSA or regional level are made to candidates listed at transplant programs anywhere else in the United States.

“Under the current system, candidates listed at two different hospitals just a short distance apart from each other, and a short distance from a donor hospital, can appear much higher or lower on a match just because their hospitals are in different DSAs or regions,” Johnson said. “The new policy will remove those artificial distinctions for candidates who are much the same as each other in terms of distance and medical need.” In addition, statistical modeling indicates the policy will increase transplant access for key groups of transplant candidates, including children, women, ethnic minorities and those who are hard to match with many donor offers due to high immune sensitivity.

New procedure to improve liver placement

In other action, the OPTN board approved a policy change to allow more efficient placement of donated livers when a transplant program first accepts a donor offer and then rescinds it late in the recovery process. The update allows livers affected by such late refusals to be offered to transplant programs that opt to be contacted for such offers and that provide specific information in advance regarding the types of offers they would be willing to accept. Making subsequent liver offers first to transplant programs willing to consider them is expected to place the offers more quickly and increase the chance that the liver will be transplanted.

HOPE Act provisions extended

The board also approved a change to the expiration date of the OPTN policy variance supporting the federal HIV Organ Policy Equity Act (HOPE Act). Under the HOPE Act, research is underway to assess the effects of transplantation of organs from donors with HIV to candidates with HIV. The expiration date of the variance has been extended to January 1, 2022, to allow a more robust review of the results of the study.

Other actions

The board took additional actions as follows:

- Approved a slate of nominees for election to open positions on the board in July 2020
- Accepted clarifications to OPTN data submission and release policies
- Amended the process for selection of the Vice Chair of the OPTN Histocompatibility Committee
- Accepted updates to align units of distribution for a closed split liver variance
- Approved a policy clarifying the definition of pre-existing liver disease
- Approved updates to OPTN committee charters
- Terminated select allocation variances that are no longer applicable or no longer in use
- Approved changes to tables listing histocompatibility antigens and equivalents in OPTN policy
- Referred a list of project ideas to the OPTN Policy Oversight Committee to prioritize with the goal of increasing organ utilization through efficient donor/recipient matching