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

RANDALL CALLAHAN, KATRYNA GRISSON, CANDICE SEAMAN, MICHAEL WINGATE, EMORY UNIVERSITY D/B/A EMORY UNIVERSITY HOSPITAL, HENRY FORD HEALTH SYSTEM, INDIANA UNIVERSITY HEALTH, OREGON HEALTH & SCIENCE UNIVERSITY, PIEDMONT HEALTHCARE, THE RECTOR AND VISITORS OF THE UNIVERSITY OF VIRGINIA on behalf of its Medical Center, THE REGENTS OF THE UNIVERSITY OF MICHIGAN on behalf of its academic medical center, Michigan Medicine, SAINT LUKE'S HOSPITAL OF KANSAS CITY, UNIVERSITY OF IOWA, UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, a body politic and corporate and an independent instrumentality of the State of Kansas, UNIVERSITY OF KENTUCKY, VANDERBILT UNIVERSITY MEDICAL CENTER, VIRGINIA COMMONWEALTH UNIVERSITY HEALTH SYSTEM AUTHORITY, THE WASHINGTON UNIVERSITY, and BARNES-JEWISH HOSPITAL, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES through ALEX M. AZAR II in his official capacity as Secretary of the United States Department of Health and Human Services, and UNITED NETWORK FOR ORGAN SHARING, Defendants.	:	CIVIL ACTION NO. 1:19-CV-1783-AT

MEMORANDUM OPINION

I. Introduction

The Plaintiffs in this case, including an array of major hospitals and transplant centers in the South and Midwest as well as individual transplant patients, seek to enjoin the nationwide implementation of Defendants' new policy for allocating donated livers. The Parties' disagreement on how to fairly and properly allocate donated liver organs consistent with over-arching federal legal requirements, touches on a complex welter of data, differing perspectives and conditions that vary throughout the nation. The institutions and patients also stand to be seriously impacted by the policy decision, one way or another.

The issues at stake have causes, ramifications, and potential legislative remedies that extend beyond the contours of this case. The Court is mindful that this is just one clash in an ongoing struggle to shape national organ transplant policy and that all parties involved view the issues as involving life and death consequences.

The Court's role in this case is not to determine which policy is best, but whether the policymakers in question acted at very least within legal requirements – that their adoption of the new liver allocation policy was not arbitrary or capricious or in violation of Plaintiffs' procedural due process rights. The Court holds today that Defendants met this basic threshold legal standard. The Court also recognizes, however, the profound issues and institutional disruption created by Defendants' handling of this policy change.

II. Background

A. Procedural Background

Plaintiffs are four transplant candidates (the "Patient Plaintiffs")[1] and fourteen transplant centers that treat end-stage liver disease patients (the "Transplant Center Plaintiffs"). Plaintiffs filed the instant action on April 22, 2019 against Defendants, the United States Department of Health and Human Services ("HHS") and United Network for Organ Sharing ("UNOS") (collectively, the "Defendants") alleging three Counts.[2] The first Count asserted that the Acuity Circles policy should be set aside on the grounds that it was adopted in violation of the procedural aspects of the regulation governing allocation policy. After expedited briefing and a hearing, the Court denied a preliminary injunction on the first count.[3] However, the Court the following day enjoined Defendants' implementation of the Acuity Circles policy, pending appeal, given the gravity and uncertainty of the legal issues, including the outcome of a then-pending Supreme Court case. (Docs. 74, 82.) The Eleventh Circuit affirmed the Court's decision on Count One on grounds other than those articulated by this Court.

[1] "Since the time Plaintiffs filed the Complaint, two of the four Patient Plaintiffs have successfully received liver transplants and are doing well post-operatively. Michael Wingate and Katryna Grisson have been transplanted, while Randall Callahan and Candice Seaman remain on the waitlist." (Pls.' Renewed Br. at 44 n. 13)

[2] As the technical verbiage surrounding the issues, policies, and organizations are thick with acronyms, the Court has included as an appendix to this Order a modified version of the glossary of terms that the Plaintiffs filed early in the case (Doc. 28) in response to the Court's directive for such.

[3] Due to the extremely restricted time for hearing and review, this Court's initial analysis of the case for preliminary injunction purposes focused on the significant threshold procedural review requirements posed by Plaintiffs' first claim that was grounded on the procedural review requirements imposed by the Final Rule, 42 C.F.R § 121.4(b).

Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II, 939 F.3d 1251, 1257 (11th Cir. 2019). The Appeals Court remanded the matter to this Court for consideration of the remaining two counts: specifically, that in adopting the Acuity Circles policy, Defendants violated "the Administrative Procedure Act ("APA") (5 U.S.C. § 706(1), (2)) as well as the Due Process Clause of the Fifth Amendment." *See* Complaint ("Compl") (Doc. 1).

The Eleventh Circuit provided specific guidance to this Court as to additional fact finding and analysis to be conducted, particularly as to UNOS's status and actions in this administrative review process. The Circuit directed this Court to analyze whether UNOS has in effect functioned in the realm of organ allocation policy making and administration as a federal agency, state actor, or merely a private contractor.

B. Issues at Play

As the Eleventh Circuit recounted in review of this case, "[i]n the United States, organ transplants are a public-private affair." *Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II*, 939 F.3d 1251, 1254 (11th Cir. 2019). "The National Organ Transplant Act of 1984 ("NOTA") requires HHS to appoint and oversee the Organ Procurement and Transplant Network (OPTN)—a private nonprofit responsible for . . . maintain[ing] a list of transplant candidates, implement[ing] a system for allocating donated organs, and ensur[ing] the organs' equitable distribution." *Id.* (citing 42 U.S.C. §§ 27, 274(b)).

Defendant UNOS serves as the current OPTN.[4] In 1999, HHS issued a "Final Rule," codified at 42 C.F.R. §§ 121.1–.13, which governs, among other things, the procedural aspects surrounding the OPTN's issuance of policies, section 121.4, and the substantive criteria the OPTN should consider when determining policies, section 121.8. The Final Rule also provides a procedure for interested parties to submit "critical comments" about the OPTN's performance to the Secretary of HHS, who may either act on them, reject them, or take some other action in response to them. 42 C.F.R. § 121.4(d). The Secretary of HHS exercises these oversight roles through the Health Resources and Services Administration (HRSA), an agency within HHS. The Court will not distinguish between HHS and HRSA for the purpose of this Order.

This dispute centers on the policy governing liver allocation — the Acuity Circles policy, now set to take effect on January 17, 2020 absent the Court's granting of Plaintiffs' motion for a preliminary injunction. (Doc. 210). UNOS, after extended review, adopted a new policy in December 2017 to replace its 2013 liver allocation policy (which the parties have referred to as the "Current Policy" and which the Court, to avoid confusion, will refer to as the "2013 Current Policy"). Both the 2013 Current Policy and the December 4, 2017 policy ("2017 Revised Policy") utilize smaller geographic groupings known as Donor Service Areas ("DSAs") and larger OPTN Regions as allocation mechanisms. Unlike the

[4] For the purpose of this Order, references to "UNOS" do not distinguish between Defendant UNOS's capacity as a nonprofit and its role as the OPTN contractor.

2013 Current Policy, the 2017 Revised Policy also takes into account 150 nautical mile circles for allocating livers to severely ill patients. The 2017 Policy was premised on a strategy of evolving, data-based transition to a new, more geographically expansive liver organ placement strategy that would meet the various objections of the Final Rule.

Three days before the 2017 Revised Policy's adoption, Motty Shulman, the New York Greater Hospital Association's counsel (now representing Intervenors in the instant case) sent a letter to Acting Secretary of HHS on behalf of a liver transplant patient, asking HHS to immediately direct the OPTN to set aside the OPTN's "arbitrary geographic limitations" in its proposed (but not yet adopted) allocation policy. Mr. Shulman later submitted a May 30, 2018 critical comment on under the Final Rule on behalf of his clients (the "May 2018 Critical Comment"). The May 2018 Critical Comment triggered a storm of activity in the organ transplant community. HRSA Administrator Sigounas, on behalf of HHS, wrote UNOS a letter requiring UNOS to respond to the May 2018 Critical Comment. UNOS responded to the comment, but clearly not to Shulmand and his clients' satisfaction. Shulman's law firm, Boies Schiller Flexner, on July 16, 2017, filed a lawsuit, *Cruz et al v. U.S. Dept. of Health and Human Services et al.*, No. 1:18-cv-6371-AT (S.D.N.Y. July 16 2017) in federal court in New York, challenging the HHS/OPTN liver allocation policies, on behalf of his clients. HHS immediately, in effect, sought then to resolve or dispose of the litigation.

On July 31, 2018, HHS issued a letter determining that "OPTN has not justified and cannot justify the use of DSAs and Regions" in allocation policy and directing OPTN to adopt a new policy by December 2018 (the "July 2018 Letter"). Though UNOS had already adopted the 2017 Revised Liver Policy, it had not yet gone into effect. Accordingly, this determination effectively left the 2013 Current Liver Policy in place pending adoption of a new policy. In light of HHS's July 31 directive, on August 9, 2018 the *Cruz* Plaintiffs moved to stay proceedings in the *Cruz* case pending the OPTN's adoption of a new liver allocation policy, with a status report to be filed by December 21, 2018. The motion and stay were granted by Judge Torres.[5]

Much as HHS has tried to mark the line of scrimmage at the moment Plaintiffs submitted their critical comment, it would be myopic to ignore the history that led to this moment, from the point Intervenors (Shulman's clients) first challenged UNOS's liver allocation policy, through the adoption of the 2017 Revised Liver Policy, and to the present date. Grasping this context is critical to understanding how the Acuity Circles policy unfolded and what got the Parties here. To aid in providing this context, the Court provides the following timeline. After the timeline, the Court will summarize in very broad terms the differences in the policies.

[5] This stay remains in effect.

C. Timeline of Events

Date	Event	Record Citation
12/1/2017	Intervenor's counsel sends letter to Acting Secretary of HHS Hargan on behalf of Tamiany de La Rosa (age 25, in New York) requesting that the OPTN be directed to revise liver allocation policy to "be based on medical criteria instead of arbitrary geographic limitations such as the Organ Procurement Organization's (OPO) region or the OPO's donor service area (DSA)."	HHS_00007216
12/4/2017	2017 Revised Liver Policy adopted, to be implemented 12/2018. The Policy Notice's Problem Statement identifies the problem to be addressed as follows: "Regional and donation service area (DSA) boundaries determine current liver distribution. . . This leads to a situation where a medically urgent candidate, who may be in close proximity of the donor, but outside of the defined region, has limited access to the donor organ." To attempt to remedy this concern, the 2017 Revised Policy superimposes a 150 nautical mile (nm) circle over the donor hospital to potentially reach candidates outside the donor's DSA and Region, among other strategies for protecting candidates. As such, the policy does not entirely eliminate DSAs and Regions, but attempts to reduce their importance to allocation. UNOS establishes an Ad Hoc Geography Committee to examine the issue further.	HHS_00007007 HHS_00006881
3/1/2018	HRSA Administrator Sigounas responds to Ms. de La Rosa's letter. While not indicating that HHS would take any action in response, he acknowledges that "[t]he development of the current liver allocation and distribution policy began in 2012 when the OPTN Board determined that geographic disparities in	HHS_00007225

	liver allocation were unacceptably high."	
5/30/2018	Intervenor's counsel Motty Shulman sends a critical comment to HHS Secretary Azar requesting that the 2017 Revised Liver Policy be set aside on the grounds that it does not comply with the Final Rule: "The new policy approved by the OPTN Board in December 2017, does not solve this problem. As set forth below, the new policy implements an allocation hierarchy that still includes region and DSA criteria."	HHS_00007228
5/31/2018	The morning after the Shulman critical comment was submitted, UNOS General Counsel Jason Livingston sends HRSA an analysis of the December 2017 Policy, which begins by stating that "Regions and DSAs are arbitrary and capricious," but then states that the 2017 Revised Policy "expands distribution beyond the arbitrary regional boundaries." Explains that the 150 nm circle was not arbitrarily chosen but instead statistically modeled, and that the "use of the DSA is minimized significantly in the new policy."	HHS_00002070
6/8/2018	HRSA Administrator Sigounas writes to Shulman indicating he has asked OPTN to respond to issues raised by *Cruz* Plaintiffs. The same day, Sigounas writes to Dr. Becker, current President of the OPTN, questioning whether the use of DSAs and OPTN regions in liver allocation was consistent with the NOTA and Final Rule.	HHS_00004945 HHS_00007239
6/13/2018	Liver and Intestinal Organ Transplantation Committee meets. The committee considers two options for recommendations to Executive Committee: (1) Insist that the 2017 Revised Policy is compliant with the final rule "because it allocates to most urgent candidates [sic] to a larger area," or (2) admit that the 2017 Revised Policy, while "a	HHS_00004946, 4960

	thoughtfully determined compromise . . . is not compliant with the final rule." The committee opts to defend the policy, admitting that DSAs and Regions play a limited role, but insisting that the incorporation of 150 nautical mile circles as units of allocation for the most urgent candidates creates a combination that is "supported by the final rule."	HHS_0004961
6/22/2018	Emergency Board of Directors' Executive Committee meeting. The Executive Committee determines to direct the Liver Committee to review data and propose a replacement for DSAs/Regions in time for December meeting. Several members support this strategy on the grounds that it puts the "best foot forward for any potential lawsuit if the legal risk materializes."	HHS_00014110
6/25/2018	OPTN President Dr. Becker responds to the HRSA letter, defending the 2017 Revised Policy on the grounds similar to those outlined by the liver committee, but admitting that DSAs and Regions are "imperfect substitute[s] for proximity between the donor and candidates." The response outlines a course of action for developing "Final Rule - compliant replacements for DSA and region in liver allocation policy," including a special comment period in October or November 2018 and adoption of a replacement for DSAs and Regions at the December 2018 meeting.	HHS_00006877
6/26/2018	Second letter from Shulman, responding to OPTN letter. Shulman demands immediate action, contending that "the OPTN Letter also makes clear that, left to its own devices, the OPTN is incapable of bringing the Liver Allocation Policy into compliance with NOTA and the final rule."	HHS_00001852
6/29/2018	Letter from Plaintiff Piedmont Healthcare in opposition to 5/30 and 6/26 Shulman letters.	HHS_00010314

7/2/2018	Shulman responds to Piedmont letter.	HHS_00001974
7/6/2018	Letter from Plaintiffs Vanderbilt University Medical Center, et al., in opposition to Shulman letters.	HHS_00001983
7/16/2018	Shulman files the *Cruz* lawsuit in the Southern District of New York.	HHS_00010321
7/31/2018	HRSA Administrator Signounas responds to Shulman critical comment and UNOS response letter. HRSA determines that "the OPTN has not justified and cannot justify the use of" DSAs and Regions. HRSA requires OPTN to adopt a new policy by December 2018 that does not allocate by regions; letter determines 2017 Revised Liver Policy cannot be justified under the Final Rule.	HHS_00004991
8/10/2018	*Cruz* court grants *Cruz* Plaintiffs' motion to stay all proceedings pending UNOS's adoption of a new policy.	
9/24/2018	The Scientific Registry of Transplant Recipients (SRTR), a contractor that provides statistical and analytic support to OPTN, publishes analysis report on circle-based allocation policies.	HHS_00009574
10/6/2018	UNOS publishes a policy proposal for both the Broader 2 Circle Policy (B2C) and Acuity Circles policy (AC) on the OPTN website and opens three weeks of public comment October 8 through November 1.	HHS_00008952
11/1/2018 11:10 p.m	UNOS policy analyst, circulates a spreadsheet with 1,200 public comments, which Plaintiffs have fairly characterized as "virtually unreadable."	HHS_00001544, HHS_00001146
11/2/2018 8:30 a.m.	Liver and Intestine Committee meeting votes on policy, less than 24 hours after close of public comment period. Seventeen comments from major institutions submitted through the public comment email were not provided to committee members. Liver and Intestine Committee recommends that the OPTN Board support committee's	 HHS_00001542 HHS_00008952

	recommendation for the Broader 2 Circle policy (B2C) as opposed to Acuity Circles policy (AC).	
11/30/2018 at 6:27 p.m.	UNOS staff distributes to all OPTN Board members, including Board members associated with Plaintiffs, an amendments booklet for the Sunday–Tuesday, December 2-4 OPTN Board meeting, which includes an amendment to adopt Acuity Circles instead of B2C.	HHS_00002338
12/3/2018	OPTN/UNOS Board meeting. HRSA representatives attending the meeting reiterate to the Board HHS's position that DSAs and Regions do not meet the requirements of the Final Rule. Mr. Shepherd (Exec. Director of UNOS/OPTN) speaks on the pressure to vote: "we have a very clear letter from the Secretary that insists that the OPTN adopt a new policy that does not include DSA by this meeting . . . a decision not to move forward on one of the — at least one of the liver options today would carry tremendous organizational risk and potentially harm our ability to make these decisions in the future." Amendment offered and approved by OPTN Board, adopting Acuity Circle Policy. April 2019 implementation date projected.	HHS_00009374 HHS_00009502
12/19/2018	HRSA Administrator Sigounas writes letter to Sue Dunn, President of the OPTN, approving new Acuity Circles policy and communicating that HRSA expects OPTN to move forward expeditiously with implementation.	HHS_00002213
2/13/2019	*Callahan* Plaintiffs write critical comment letter to Secretary of HHS Azar opposing the Acuity Circles policy. ("February 2019 Critical Comment").	HHS_0000001
3/14/2019	Administrator Sigounas refers *Callahan* critical comment to OPTN.	HHS_0000024

3/15/2019	SRTR issues response to *Callahan* plaintiffs.	HHS_0000042
3/26/2019	UNOS issues response to *Callahan* plaintiffs.	HHS_0000026
4/22/2019	Plaintiffs file this lawsuit along with a motion for a temporary restraining order.	
4/23/2019	HRSA Administrator Sigounas writes to *Callahan* Plaintiffs stating no action will be taken by HHS in response to Plaintiffs' critical comment regarding the Acuity Circles policy, leaving the policy in place for implementation.	HHS_00000021

D. The Allocation Policies

As the Eleventh Circuit noted, "[u]nder the [2013] 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." *Callahan,* 939 F.3d at 1255 n.2.

The 2017 Revised Policy, which was adopted by UNOS but never went into effect, modified the 2013 Current Policy. The Revised Policy also first matches and offers livers to Status 1A or 1B within the Region, but additionally now superimposes a statistically modeled circle of 150 nautical miles over the procuring hospital, potentially giving an opportunity for severely ill patients

within the circle but in a different region access to the liver. Next, within that same Region/circle overlay, the policy offers the liver to patients with a MELD/PELD score of 32 (inclusive of a three-point proximity increase for patients within the circle or the same DSA), or who have an "approved HAT [hepatic artery thrombosis] exception." If there are no matching candidates, then the liver is offered to candidates within the DSA with a MELD or PELD score of at least 15. (HHS_00007014).

"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." *Callahan*, 939 F.3d at 1256 n.5.

The Plaintiff institutions, located in Regions with significant rural swaths of poverty as well as higher under-insurance rates, are predicted by the statistical

modeling generated in connection with the Acuity Circles policy to lose their relative position of access to transplant organs. (*See, e.g.*, Compl. ¶ 78; HHS_00009623, 26, 28, 30, 31; HHS_00009860). Areas such as New York State, with greater urban populations, present high organ transplant population demands and higher medical insurance coverage rates, are projected to gain greater liver organ access. (HHS_00009860, 63). The impact on transplant access of issues such as physicians' greater use of "exception" points that may boost patients' transplant rankings (i.e., the measure of the criticality of patients' liver disease status) in regions such as New York that enjoy broader medical coverage (via insurance and state Medicaid expansion, individual wealth etc.) remain in debate between the opposing medical factions here. It is no surprise then, when allocation policies touch on so many societal fault lines, that disputes like the instant case are so deeply contentious.

III. Legal Standards

A. Standard for a preliminary injunction

Under the Administrative Procedure Act, the Court "may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings" "[o]n such conditions as may be required and to the extent necessary to prevent irreparable injury." 5 U.S.C. § 705. The "test to be applied as to whether a stay should be entered is the same as that which applies to requests

for preliminary injunctions." *Corning Sav. & Loan Ass'n v. Fed. Home Loan Bank Bd.*, 562 F. Supp. 279, 280 (E.D. Ark. 1983).

"To support a preliminary injunction, a district court need not find that the evidence positively guarantees a final verdict in plaintiff's favor." *Levi Strauss & Co. v. Sunrise Int'l Trading Inc.*, 51 F.3d 982, 985 (11th Cir. 1995). Instead, it must determine whether the evidence establishes: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury if the injunction were not granted; (3) that the threatened injury to the plaintiff outweighs the harm an injunction may cause the defendant; and (4) that granting the injunction would not be adverse to the public interest. *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998). At the preliminary injunction stage, a district court may rely on affidavits and hearsay materials which would not be admissible evidence for a permanent injunction, if the evidence is "appropriate given the character and objectives of the injunctive proceeding." *Levi Strauss & Co.*, 51 F.3d at 985 (quoting *Asseo v. Pan American Grain Co.*, 805 F.2d 23, 26 (1st Cir. 1986)); *McDonald's Corp.*, 145 F.3d at 1306. "A request for equitable relief invokes the district court's inherent equitable powers to order preliminary relief . . . in order to assure the availability of permanent relief." *Levi Strauss & Co.*, 51 F.3d at 987; *Federal Trade Commission v. United States Oil and Gas Corp.*, 748 F.2d 1431, 1433–34 (11th Cir. 1984) (stating that a district court may exercise its full range of equitable powers, including a preliminary

asset freeze, to ensure that permanent equitable relief will be possible). However, a preliminary injunction "is an extraordinary and drastic remedy not to be granted unless the movant clearly established the 'burden of persuasion' as to the four prerequisites." *McDonald's Corp.*, 147 F.3d at 1306 (internal citations omitted). Significantly, in this Circuit, "a finding of substantial likelihood of success on the merits [is required] before injunctive relief may be provided . . . [and this circuit has] held on occasion that when a plaintiff fails to establish a substantial likelihood of success on the merits, a court does not need to even consider the remaining three prerequisites of a preliminary injunction." *Pittman v. Cole*, 267 F.3d 1269, 1292 (11th Cir. 2001); *Bloedorn v. Grube*, 631 F.3d 1218, 1229 (11th Cir. 2011) ("If Bloedorn is unable to show a substantial likelihood of success on the merits, we need not consider the other requirements.").

B. Standard for review of agency action

The applicable standard under the APA is whether the agency's action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *Defenders of Wildlife v. U.S. Dept. of Navy*, 733 F.3d 1106, 1114-1115 (11th Cir. 2013). An agency action may be found arbitrary and capricious:

> where the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Miccosukee Tribe of Indians of Florida v. United States, 566 F.3d 1257, 1264 (11th Cir. 2009) (quoting *Alabama–Tombigbee Rivers Coal. v. Kempthorne*, 477 F.3d 1250, 1254 (11th Cir. 2007)).

"The arbitrary and capricious standard is 'exceedingly deferential.'" *Defenders of Wildlife*, 733 F.3d at 1115 (citing *Fund for Animals, Inc. v. Rice*, 85 F.3d 535, 541 (11th Cir. 1996)).

> To determine whether an agency decision was arbitrary and capricious, the reviewing court 'must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.' ***This inquiry must be 'searching and careful,' but 'the ultimate standard of review is a narrow one.'*** Along the standard of review continuum, the arbitrary and capricious standard gives an appellate court the least latitude in finding grounds for reversal; '[a]dministrative decisions should be set aside in this context ... only for substantial procedural or substantive reasons as mandated by statute, ... not simply because the court is unhappy with the result reached.' The agency must use its best judgment in balancing the substantive issues. The reviewing court is not authorized to substitute its judgment for that of the agency concerning the wisdom or prudence of the proposed action.

Fund for Animals, 85 F.3d at 541–42 (quoting *North Buckhead Civic Ass'n v. Skinner*, 903 F.2d 1533, 1538–40 (11th Cir. 1990) (footnotes and citations omitted)) (emphasis added).

In determining whether the agency acted arbitrarily and capriciously, the Court must ask whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action." *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Engineers*, 781 F.3d 1271, 1288 (11th Cir.

2015) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The Court is not authorized to substitute its judgment for the agency's as long as the agency's conclusions are rational. *Defenders of Wildlife*, 733 F.3d at 1115 (citing *Miccosukee Tribe of Indians*, 566 F.3d at 1264); *Sierra Club v. Van Antwerp*, 526 F.3d 1353, 1360 (11th Cir. 2008); *Pres. Endangered Areas of Cobb's History, Inc. ("PEACH") v. U.S. Army Corps of Eng'rs*, 87 F.3d 1242, 1246 (11th Cir. 1996) ("The court's role is to ensure that the agency came to a rational conclusion, 'not to conduct its own investigation and substitute its own judgment for the administrative agency's decision.'")). While the Court should "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned . . . [it] may not supply a reasoned basis for the agency's action that the agency itself has not given." *Black Warrior Riverkeeper,* 781 F.3d at 1288 (internal citations omitted).

The Court has limited discretion to reverse an agency's decision when it "is making predictions, within its area of special expertise, at the frontiers of science . . . as opposed to simple findings of fact, a reviewing court must generally be at its most deferential." *Defenders of Wildlife v. Bureau of Ocean Energy Mgmt.*, 684 F.3d 1242, 1248-49 (11th Cir. 2012) (quoting *Miccosukee Tribe of Indians*, 566 F.3d at 1264 (quoting *Balt. Gas & Elec. Co. v. Natural Res. Def. Council*, 462 U.S. 87, 103 (1983))).

C. Standard for procedural Due Process claim

The Due Process Clause of the Fifth Amendment provides "that certain substantive rights—life, liberty, and property—cannot be deprived except pursuant to constitutionally adequate procedures." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 541 (1985). "In short, once it is determined that the Due Process Clause applies, 'the question remains what process is due.'" *Id.* (quoting *Morrissey v. Brewer*, 408 U.S. 471, 481 (1972). "An essential principle of due process is that a deprivation of life, liberty, or property 'be preceded by notice and opportunity for hearing appropriate to the nature of the case.'" *Id.* at 542 (quoting *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 313 (1950)). The authority of courts to set agency aside action which does not comply with the constitution is recognized in the APA. 5 U.S.C. § 706(2)(B) (a court may set aside agency action "which is contrary to constitutional right, power, privilege, or immunity.").

IV. Discussion

The Court of Appeals identified several "unavoidably fact-sensitive" questions for the Court to address on remand. *Callahan*, 939 F.3d at 1266. In furtherance of this directive, the Court has endeavored through several orders to ensure that Defendants have compiled a complete administrative record for review of the final agency action. However, in some ways, this has presented a "cart before the horse" problem. When presented with a claim to set aside agency

action, "the court shall review the whole record or those parts of it cited by a party." 5 U.S.C. § 706(2). "Ordinarily, this inquiry 'is limited to evaluating the agency's contemporaneous explanation [for its action] in light of the existing administrative record.'" *Mayor & City Council of Baltimore v. Trump,* No. CV ELH-18-3636, 2019 WL 6970631, at *6 (D. Md. Dec. 19, 2019) (quoting *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019)).

Herein lies the problem. As the Court of Appeals recognized, Plaintiffs' claims present several "threshold issues":

> "Plaintiffs' arbitrary-and-capricious claim . . . 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."

Callahan, 939 F.3d at 1265 (quoting *Dong v. Smithsonian Inst.*, 125 F.3d 877, 881 (D.C. Cir. 1997)).[6] The Parties dispute not only what act constituted the agency action under review, but indeed who constitutes the agency. This has created a somewhat moving target for the boundaries of the record.

For example, despite being the party initially responsible for formulating the policy in question, Defendant UNOS has steadfastly denied that it is an administrative agency. This raises questions about to what extent the usual

[6] *See also id.* ("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.') (quoting *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614 (1991)).

deference and limitations on the record even apply to UNOS. *See Dep't of Commerce*, 139 S. Ct. at 2573 (2019) ("[I]n reviewing agency action, a court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record. That principle reflects the recognition that further judicial inquiry into executive motivation represents a substantial intrusion into the workings of another branch of Government and should normally be avoided.") (citations and internal quotations omitted).

To further complicate matters, Plaintiffs have brought constitutional due process claims alongside their APA claims. As one district court recently noted, "[t]he case law regarding the propriety of allowing extra-record discovery for constitutional claims asserted alongside APA claims is unsettled." *Mayor of Baltimore*, No. CV ELH-18-3636, 2019 WL 6970631, at *6 (allowing discovery). In recognition of the above complexities, and in light of the Court of Appeals' directive to engage in fact finding on remand, the Court has allowed limited, supervised discovery against Defendant UNOS. Where Plaintiffs have uncovered materials in discovery which they contend bear on the formulation and adoption of the Acuity Circles policy, they have sought inclusion of these materials in the record. Defendant HHS has, for the most part, opposed these requests on the grounds that it, not UNOS, is the decisionmaker whose decision is under review. But time and again, HHS has deferred to UNOS, as the OPTN, and has admitted in this case that HHS has not made any formal findings of its own (though

arguably such were not necessary). (Transcript of Dec. 17, 2019 hearing at 54:16–23, Doc. 238).

The Court has, to some extent, pretermitted resolving this question up until now. For example, in its Order of December 6, 2019, the Court wrote:

> When the (b)(1) policymaking structure is viewed as a collaborative decision-making process, it is clear that materials and information which influenced UNOS's policymaking in its role as OPTN also at least indirectly influenced HHS's determination as to whether to modify UNOS's adoption of the Acuity Circles policy via its review of Plaintiffs' critical comment. It bears stating that the HHS–OPTN relationship provided under the Final Rule for a (b)(1) policy appears to be a unique arrangement. In short, how can a reviewing Court determine whether the OPTN assessed the appropriate considerations under Section 121.8 of the Final Rule, and whether HHS similarly did so in turn, if it cannot review the materials and information that the OPTN actually considered as part of the administrative record?

(Doc. 206 at 9). To purportedly answer the Court's inquiry of how it is supposed to determine whether the OPTN (and HHS in turn) assessed the appropriate considerations if it does not have before it all that the OPTN considered, Defendant HHS responded, "[t]his Court may determine whether HHS 'assessed the appropriate considerations' under the Final Rule by reviewing those documents that HHS actually considered directly or indirectly—that is, the proper administrative record." (Doc. 219 at 7). But this exactly begs the question.

Putting it all together, to review the merits of Plaintiffs' APA claims, the Court must do so on a complete record. To ascertain the proper scope of the record, the Court must reach the threshold questions posed by the Court of

Appeals. The Court will essentially follow this roadmap for the remainder of this Order, turning first to the APA claim, and second to the due process claim.

A. Threshold issues for APA review

1. Who is the agency?

While no party disputes that HHS (through its HRSA) constitutes an agency, the parties disagree as to whether UNOS, in its role as the OPTN, constitutes an agency. Under the APA, "agency" means "each authority of the Government of the United States, whether or not it is within or subject to review by another agency." 5 U.S.C. § 701. As recognized by the Court of Appeals, the cornerstone for whether an entity constitutes an agency subject to review is whether it exercises "substantial independent [government] authority." *Callahan*, 939 F.3d at 1265 (quoting *Dong v. Smithsonian Inst.*, 125 F.3d 877, 881 (D.C. Cir. 1997).). However, "cases have made it clear that any general definition can be of only limited utility to a court confronted with one of the myriad organizational arrangements for getting the business of the government done . . . The unavoidable fact is that each new arrangement must be examined anew and in its own context." *Washington Research Project, Inc. v. Dep't of Health, Ed. & Welfare*, 504 F.2d 238, 245–46 (D.C. Cir. 1974) (citations omitted).

In *Dong*, the D.C. Circuit held that the Smithsonian Institution was not an "agency" for the purpose of the Privacy Act, which incorporates the APA's definition of agency. *Dong*, 125 F.3d at 878. The Smithsonian Institution was established by a federal charter. 20 U.S.C. § 41. The D.C Circuit noted that the

federal government plays a role in appointing the Institute's governing body: "nine of the seventeen members of its governing Board of Regents are appointed by joint resolution of Congress, and six of the remaining eight are members of Congress. (The other two are the Vice President and the Chief Justice of the United States). *Id.* at 879 (citing 20 U.S.C. §§ 42, 43) (internal citations omitted). The plaintiff in *Dong*, an employee, outlined an "impressive array of links between the Smithsonian and the federal government" in support of her argument that the Smithsonian was an agency:

> To list the main ones: the Smithsonian operates under a federal charter granted by Congress in 1846; most of its employees—some 70% according to plaintiff, Brief for Appellee at 16 n.3—are considered federal civil service employees; its Regents, as mentioned, are federal officials or are selected by federal officials; it receives extensive federal funding and must submit a detailed annual statement of its expenditures to Congress, 20 U.S.C. § 49; its use of public monies is subject to the audit and reporting requirements of the General Accounting Office; "[a]ll moneys recovered by or accruing to [the Smithsonian are] paid into the Treasury of the United States, to the credit of the Smithsonian bequest, and separately accounted for," 20 U.S.C. § 53; it enjoys federal immunity from taxes and libel actions; it receives representation (as in this case) from the Department of Justice; and it publishes rules and notices in the Code of Federal Regulations and the Federal Register.

Id. at 880 (citations omitted). However, the court ultimately found these links to be insufficient to establish the Smithsonian as an agency, focusing on the word "authority" in the statute. The court held that the Smithsonian lacked "substantial government authority" because it "does not make binding rules of general application or determine rights and duties through adjudication. It issues

no orders and performs no regulatory functions." *Id.* at 882. The court found that "Congress's delegation to the institution of limited police powers, including arrest powers, on its own grounds . . . [and] authoriz[ation to] the Smithsonian to promulgate regulations in support of its power to maintain safety and order on its premises," merely "enable the Smithsonian to protect its own collections and facilities, [and] fall far short of converting the Smithsonian into 'an authority of the Government of the United States.'" *Id.*

Several cases involving Defendant HHS's predecessor department, the Department of Health Education & Welfare ("HEW"), have dealt with more analogous situations here, involving contractors or paid consultants. For example, in *Washington Research Project*, HEW contracted with groups of consultants, known as IRGs, to review grant applications and submit the recommendations to the government to fund. 504 F.2d at 242. The D.C. Circuit, in determining whether IRGs constituted agencies, noted that "[e]mploying consultants to improve the quality of the work that is done cannot elevate the consultants to the status of the agency for which they work unless they become the functional equivalent of the agency, making its decisions for it." *Id.* at 247–48. The court held that the fact that the IRGs did the primary evaluative work subject to "perfunctory review" did not cross the line into making decisions for the agency: "just as the APA makes the fact that a government authority's decisions are subject to review irrelevant in determining whether that authority is

an agency, at least in this case the degree of scrutiny its decisions are given on review is equally beside the point." *Id.* at 248. Rather, "[t]he important consideration is whether it has any authority in law to make decisions." *Id.*; *accord Lombardo v. Handler*, 397 F. Supp. 792, 795 (D.D.C. 1975) ("Starting at that point, this Court notes that the [National Academy of Sciences] cannot be said to be making decisions for the E.P.A. with regard to the Clean Air Act. The E.P.A. has clearly felt free to make its own decisions irrespective of the Academy's advice."), *aff'd*, 546 F.2d 1043 (D.C. Cir. 1976).

The D.C. Circuit built on its analysis in *Washington Research Project* in another case involving Defendant HHS's predecessor, *Public Citizen Health Research Grp. v. Dep't of Health, Ed. & Welfare*, 668 F.2d 537, 539 (D.C. Cir. 1981). That case involved Professional Standard Review Organizations (PSRO). Somewhat in the vein of HHS's contractual relationship with UNOS, the Secretary there would enter "into an agreement with a "'qualified organization', which is designated as the PSRO for a particular locale" with "a funding preference to PSROs that are nonprofit, local, physician membership organizations." *Id.* (citing 42 U.S.C. § 1320c-1(a), (b)(1)(A) (repealed 1982)).[7] (Of

[7] Prior 42 U.S.C. § 1320c-1(b)(1) read:

> (b) For purposes of subsection (a), the term 'qualified organization' means---
> (1) when used in connection with any area---
> (A) an organization (i) which is a nonprofit professional association (or a component organization thereof), (ii) which is composed of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area, (iii) the membership of which includes a substantial proportion of all such physicians in such area, (iv) which is organized in a manner which makes

course, UNOS, by contrast, is contracted to fulfill OPTN's national policy responsibilities, rather than performing designated functions solely in a particular locale).

PSRO's primary responsibilities were "reviewing health care services rendered by or in institutions for which payment may be made under the Medicare and Medicaid programs" and determining "(1) whether the services are or were medically necessary; (2) whether the quality of services meets professionally recognized standards of health care; and (3) whether the services could have been more appropriately rendered in another less expensive manner. *Id.* (citing 42 U.S.C. § 1320c-4(a)(1)). At the time these statutory procedures were in full effect, the PSRO's responsibilities were implemented in the following manner. After admission of a patient on Medicare or Medicaid, "PSRO members review an admission during the first day of hospital stay to determine whether a

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> available professional competence to review health care services of the types and kinds with respect to which Professional Standards Review Organizations have review responsibilities under this part, (v) the membership of which is voluntary and open to all doctors of medicine or osteopathy licensed to engage in the practice of medicine or surgery in such area without requirement of membership in or payment of dues to any organized medical society or association, and (vi) which does not restrict the eligibility of any member for service as an officer of the Professional Standards Review Organization or eligibility for and assignment to duties of such Professional Standards Review Organization, or, subject to subsection (c) (i),
> (B) such other public, nonprofit private, or other agency or organization, which the Secretary determines in accordance with criteria prescribed by him in regulations, to be of professional competence and otherwise suitable.

Pub. L. 92-603, 86 Stat. 1329, 1430. Subsection (c)(1) prohibited the Secretary from entering into an agreement with an organization other than a (b)(1)(A) organization unless no such organization was available within the area.

patient needs to be hospitalized at all. Based on that review, members predict or 'assign' the appropriate length of the patient's stay." *Id.* at 540 (citing 42 U.S.C. § 1320c-4(a)(2) (repealed 1982)). In the event a patient remains hospitalized longer than the assigned stay, the PSROs "determine whether continued hospitalization is in fact needed." *Id.* (citing 42 U.S.C. § 1320c-5(d) (repealed 1982)). If further hospitalization is determined to be "medically unnecessary, the patient must thereafter either leave the hospital or make private payment."

Unlike the IRGs in *Washington Research Project*, no agency need approve these determinations; the determinations by PSRO "shall constitute the conclusive determination on those issues . . . for purposes of payment under this chapter." *Id.* at 540 (citing 42 U.S.C. s 1320c-7(c) (Supp. III 1979). However, the D.C. Circuit still found that PSROs were not agencies for three main reasons. First, the court looked primarily to the structure and purpose of the statute, which required the Secretary to contract with qualified organizations to serve as PSROs. The court thus concluded that the "purpose of the statute" was "that a PSRO shall be an organization independent of the government." *Id.* The court examined the structure of the PRSO in question:

> The Foundation is a corporation organized under the law of the District of Columbia, and not under federal law. It is controlled by a Board of Trustees all of whom are private individuals. Its physician members are paid for their time on an hourly fee basis. Its employees are not government employees. It carries out its work pursuant to a contract with HEW. It is free to contract, and indeed does contract, to perform various functions for state and city agencies and for insurance companies.

Id.

Next, the court appeared to take a functionalist approach, examining "the nature of the decisions which the Foundation makes." *Id.* The court found that the opinions rendered by the PRSOs do not make them "part of a government organization, any more than a single physician, consulted on similar questions and submitting a similar expert opinion, would become part of a government organization." *Id.* at 544. The court gave short shrift to the argument that PRSO decisions are conclusive: "[t]rue, the statute makes their favorable opinions conclusive; but a moment's reflection will demonstrate that any other arrangement would be impractical: if the Department undertook to review each of the hundreds of thousands of medical opinions submitted the result would be the creation of an unworkable bureaucratic monster." *Id.*

Lastly, the D.C. Circuit rejected the argument that "pervasive procedural requirements" imposed upon PSROs by the statute and by regulations rendered the PSROs agencies pursuant to *Forsham v. Harris*, 445 U.S. 169 (1980).[8] *Id.* at 544. The court held that "those controls are only those necessary to assure that the funds given to PSROs are expended properly, that the PSROs comply with the specifications of their contracts and follow uniform procedures." *Id.* While the

[8] *Forsham* involved the question of whether records held by federal grant recipients were "agency records" under FOIA. 445 U.S. at 182. As the Court interpreted the legislative history of FOIA to exclude grant recipients, the dispute in that case did not center on whether the grantees were agencies themselves, but rather whether supervision by an agency rendered the grantee's own records agency records. *Forsham*, then, is not on point for the question presented in this case.

Supreme Court summarily approved this statutory scheme in another case,[9] the PSROs were widely criticized and phased out by the Peer Review Improvement Act of 1982, included as part of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248.

The Court can find few examples of courts determining that an entity is an agency when that entity was not created by statute or regulation as part of the government. For example, *Grumman Aircraft Engineering Corp. v. Renegotiation Bd.*, 482 F.2d 710, 715 (D.C. Cir. 1973), *rev'd on other grounds*, 421 U.S. 168 (1975) involved the Renegotiation Act of 1951. That act established a Renegotiation Board (or National Board), which engaged in contract renegotiation with government contractors. Regional Boards "were established in 1952 by regulation . . . pursuant to statutory authorization . . ." and made up of "Regional Board members" which were "civil servants." 421 U.S. at 173 n.6. The Regional Boards in some cases made recommendations regarding excessive profits by contractors which were subject to automatic review by the National Board. However, in other cases, the Regional Boards made final decisions themselves. The D.C. Circuit held that Regional Boards were agencies based in part upon this authority. 482 F.2d at 716. The dispute in that case was not

[9] *Association of Am. Physicians and Surgeons v. Weinberger*, 395 F. Supp. 125 (D. Ill. 1975), *aff'd*, 423 U.S. 975. The court, in an opinion summarily affirmed by the Supreme Court, noted that "[u]nderlying the constitutionality of the legislation is the fact that the program is a voluntary one in which a physician may freely choose whether or not to participate." 395 F. Supp. at 140. Physicians could choose not to participate in the program and not receive payment from Medicare or Medicaid, but could continue practicing medicine. But as the Court notes above, Congress subsequently abolished this form of professional standards review.

whether the Regional Boards were part of the government, but whether their decisional authority was sufficiently final such that they would constitute an agency in their own right vis-à-vis the National Board.[10] The Supreme Court, in reversing on other grounds, ultimately did not reach the issue. 421 U.S. at 188.

The Court now turns to the OPTN, cognizant of its responsibility to "examine anew" the structure of the OPTN's authority under NOTA in light of the "myriad organizational arrangements for getting the business of the government done." *Washington Research Project*, 504 F.2d at 245–46. In determining whether UNOS, in its capacity as the OPTN, exercises "substantial government authority," the Court focuses on the following structural aspects of OPTN:

(a) The text and purpose of Section 372 of the National Organ Transplantation Act, 42 U.S.C. § 274, including the organizational structure of the OPTN, and the level of government control of operations. *See Public Citizen*, 668 F.2d at 543–44.

(b) Whether the OPTN "has any authority in law to make decisions," *Washington Research Project*, 504 F.2d at 248, and the nature of such decisions. *Pub. Citizen*, 668 F.2d at 543–44. Relatedly, whether the OPTN "make[s] binding rules of general application or determine[s] rights and duties through adjudication." *Dong*, 125 F.3d at 882.

[10] *See also Soucie v. David*, 448 F.2d 1067, 1070 n.2 (D.C. Cir. 1971) (Office of Science and Technology (OST), part of the Executive Office of the President).

a. Structure and Purpose of OPTN Legislation

This Part deals specifically with the structure and purpose of statutes which create and organize the OPTN. It does not deal with the statutory provisions that govern the authority and decision-making of the OPTN; those are dealt with in the following Part. Section 372 of NOTA, 42 U.S.C. § 274, authorizes the Secretary of HHS to "by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network." 42 U.S.C. § 274(a). The statute further provides that the OPTN shall "be a private nonprofit entity that has an expertise in organ procurement and transplantation," shall "have a board of directors that includes representatives of organ procurement organizations . . . transplant centers, voluntary health associations, and the general public," and "shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board." 42 U.S.C. § 274(b)(1).

Dicta in *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 392 (1995), suggests that statutory designations may be important for determining whether an entity is an agency subject to judicial review under the APA. (Pls.' Br. at 34 n.9, Doc. 216-1).[11] NOTA does not contain a disclaimer of agency status found in

[11] *Lebron* was not a case about agency status under the APA. The Supreme Court's main holding after review of the central features of Amtrak's authorizing legislation, including the board appointment process, was that Amtrak was "an agency or instrumentality of the United States for the purpose of individual rights guaranteed against the Government by the Constitution," even if its potential liability as a government agency might be different with respect to other statutory procedures or claims. *Lebron*, 513 U.S. at 393 ("[I]t is not for Congress to make the

other statutes, but Congress's requirement that the OPTN be a "private nonprofit entity" supports the conclusion that Congress did not intend for the OPTN to be a government agency. (*But see* Pls.' Renewed Br. at 34 n.9 (citing Mem. Op. for the General Counsel, Office of Management and Budget, Status of National Veterans Business Development Corporation, 28 Op. O.L.C. 70, 72 (2004)) (concluding that when a statute lacks the "express disclaimer" that was present in the Amtrak statute "[t]he silence raises the question" of whether the entity should be treated as a government agency)).

The above is buttressed by the legislative history of NOTA. The Senate Report for the Act stated that the OPTN would be "located in the private sector rather than in government." S. REP. No. 382, 98th Cong., 2d Sess. 4, reprinted in 1984 U.S. CODE CONG. & ADMIN. NEWS 3975, 3981. In a Senate Committee hearing for NOTA, Senator Nickles stated that the OPTN would not be "a new bureaucracy." (Def. UNOS's Resp., Ex. A, Senate Comm. Hr'g at 18, Doc. 229-1). Representative Walgreen, a cosponsor of the bill, stated that NOTA will "build on existing transplant organizations, retaining the expertise of medical professionals

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final determination of Amtrak's status as a Government entity for purposes of determining the constitutional rights of citizens affected by its actions. If Amtrak is, by its very nature, what the Constitution regards as the Government, congressional pronouncement that it is not such can no more relieve it of its First Amendment restrictions than a similar pronouncement could exempt the Federal Bureau of Investigation from the Fourth Amendment. The Constitution constrains governmental action 'by whatever instruments or in whatever modes that action may be taken.' And under whatever congressional label. As we said of the Reconstruction Finance Corporation in deciding whether debts owed it were owed the United States Government: 'That the Congress chose to call it a corporation does not alter its characteristics so as to make it something other than what it actually is....') (quoting *Ex parte Virginia*, 100 U.S. 339, 346–347 (1880) and *Cherry Cotton Mills, Inc. v. United States*, 327 U.S. 536, 539 (1946)).

and the many private, voluntary groups that have developed the services this far." (Def. UNOS Resp, Ex. B, 130 Cong. Rec. H11087–89, Doc. 229-2). The Court notes, though, Justice Scalia's view that "[w]hether the floor statements are spoken where no Senator hears, or written where no Senator reads, they represent at most the views of a single Senator." *Hamdan v. Rumsfeld*, 548 U.S. 557, 666 (2006) (Scalia, J., dissenting). So the Court does not leap to any firm conclusions based on these statements alone.

As discussed above, NOTA requires that the OPTN "be a private nonprofit entity that has an expertise in organ procurement and transplantation." 42 U.S.C. § 274(b)(1). Structurally, this appears to be similar to the Act in *Public Citizen*. 42 U.S.C. § 1320c-1(b)(1) (repealed 1982), *supra* ("[A]n organization (i) which is a nonprofit professional association (or a component organization thereof . . . which is organized in a manner which makes available professional competence to review health care services of the types and kinds with respect to which Professional Standards Review Organizations have review responsibilities under this part."). NOTA goes slightly further in organizing the OPTN than the act in *Public Citizen,* requiring it to "have a board of directors that includes representatives of organ procurement organizations . . . transplant centers, voluntary health associations, and the general public," and to "establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board." 42 U.S.C. §274(a)(1)(B). But

this is far less federal involvement than the appointment of the Smithsonian Institution's Board of Regents. *Dong*, 125 F.3d at 879 (citing 20 U.S.C. § 42, 43).[12]

The lower court in *Public Citizen* held that "detailed government control" of the PSROs rendered them agencies, a ruling rejected by the D.C. Circuit. The appeals court held that the government oversight was only as "necessary to assure that the funds given to PSROs are expended properly, that the PSROs comply with the specifications of their contracts and follow uniform procedures." *Public Citizen*, 668 F.2d 537, 544 (D.C. Cir. 1981). The regulatory oversight of the OPTN in the NOTA is comparatively light.[13] 42 U.S.C. § 274(b)(2) lays out a number of duties for the OPTN to comply with, but gives little instruction on how to carry out the duties. Section 274(b)(2)(L) requires the OPTN to "submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network."

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[12] In practice, HHS provides oversight of UNOS's internal governance beyond what is required by NOTA. 42 CFR § 121.3(a)(1) allows the OPTN to establish a board of "whatever size the OPTN determines appropriate," but requires that approximately 50% of the board be transplant surgeons or physicians and at least 25% be candidates, recipients, donors, or family members. Additionally, the OPTN Bylaws provide that "U.S. Department of Health and Human Services (HHS) Project Officer for the OPTN Contract and the Director of the Division of Transplantation" be ex-officio, non-voting members of the Board. (OPTN Bylaws § 2.1, Eff. Jan 13, 2020, *available at* https://optn.transplant.hrsa.gov/media/3493/optn_bylaws.pdf). In its 2018 bid protest to the GAO, "UNOS argued that [HHS] does not have the authority under NOTA to direct the OPTN to have a board of directors that is separate from the entity that is awarded a contract to operate the OPTN because the OPTN and OPTN contractor are the same entity." (Pls.'s Renewed Mot. Ex. 8, UNOS_00000007.) The GAO concluded "that the protestor's argument that NOTA requires the OPTN and OPTN contractor to be the same entity has no support in the statute or the regulations." (*Id.*)

[13] The Court looks only to the NOTA in this section. The Court will examine the regulatory oversight mechanisms in the Final Rule in more detail in the following section.

Finally, Section 274(c) requires the Secretary to set up procedures for "receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network" and "the consideration by the Secretary of such critical comments." This is the basic oversight mechanism for the OPTN, but the plain meaning of the text seems to imply a primarily (though not solely) reactive, rather than proactive, approach to HHS' supervision of the OPTN. In any case, under the APA, an entity can be an "agency" "whether or not it is within or subject to review by another agency." 5 U.S.C. § 701(b)(1).

Other sections of the Act fail to show pervasive government control. Section 274b provides that the Secretary can set the form for an application for an OPTN contract.[14] Presumably, by contract, the Secretary can also require further oversight.[15] Section 274c requires the Public Health Service to "administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act," as well as "provide technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 274 of this title, and other entities in the health care system involved in organ donations, procurement, and transplants," among other responsibilities.

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[14] *But cf. Manhattan Cmty. Access Corp. v. Halleck*, 139 S. Ct. 1921, 1931 (2019) (holding that the fact that the government contracts with a private entity "does not convert the private entity into a state actor.").

[15] UNOS has, however, contended in a bid protest, that HHS may not add regulatory oversight beyond that intended by Congress by contract. (UNOS_0002889, 94).

The Court cannot say that the text and purpose of the NOTA, standing alone, render the OPTN an agency. However, this does not end the inquiry. The Court must next look to the discretion and decision-making powers that the OPTN is vested with to determine whether it exercises "substantial government authority."

b. Authority and Nature of Decisionmaking

As explained above, the OPTN as originally created by NOTA did not carry any structural hallmarks of government authority. However, this conclusion does not mean that the OPTN is not an agency. Congress or the Executive can later delegate authority where there was none before. The Court now turns to the authority exercised by the OPTN. The Court will first look to whether Congress has delegated substantial government authority to the OPTN. The Court will next consider whether the OPTN in fact exercises substantial government authority.

NOTA provided the OPTN with authority to "establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria." 42 U.S.C. § 274(b)(2)(B). UNOS's exercise of this authority is the center of the dispute in this case. However, at the time the Act was passed, Congress did not provide the OPTN with any mechanism to enforce its policies, and membership was entirely voluntary. The only major teeth were the Act's prohibition on purchasing organs,

which had the incidental effect of preventing a private market alternative to the OPTN. 42 U.S.C.A. § 274e.[16]

The most significant grant of authority to the OPTN is found not in a regulation, but in a statute, Section 1138 of the Social Security Act, 42 U.S.C. § 1320b-8. This section was added as part of the Omnibus Budget Reconciliation Act of 1986, passed only two years after NOTA. That provision states that the Secretary of HHS

> shall provide that a hospital or critical access hospital meeting the requirements of subchapter XVIII [Medicare] or XIX [Medicaid] **may participate in the program established under such subchapter only if** . . . in the case of a hospital in which organ transplants are performed, **the hospital is a member of, and abides by the rules and requirements of, the Organ Procurement and Transplantation Network** established pursuant to section 274 of this title.

42 U.S.C. § 1320b-8(a)(1)(B) (emphasis added). Notably, the Secretary has authority to waive certain requirements of that section, but not the requirement that the hospital be a member of the OPTN and abide by its rules and requirements. *Id.* § 1320b-8(a)(2).

The consequence of not being able to "participate in the program" for a hospital that performs organ transplants means exclusion from billing Medicare or Medicaid entirely, the hospital "death penalty." *Cf. Physician Hosps. of Am. v. Sebelius*, 770 F. Supp. 2d 828, 832 (E.D. Tex. 2011), *rev'd*, 691 F.3d 649 (5th Cir. 2012). Taking this statute at face value, this would seem to be the sort of

[16] The statute does not preclude directed donations or, in limited circumstances, paired donations.

"substantial government authority" of which the above cases speak. Unlike the Smithsonian, the OPTN's policies apply to all transplant hospitals nationwide, constituting "binding rules of general application." *Dong*, 125 F.3d at 882. Unlike the IRGs in *Washington Research Project*, the OPTN's policies do not need "rubber stamping" to be effective. 504 F.2d at 248. And unlike the decisions of the PSROs in *Public Citizen*, the OPTN does not merely make determinations about individual patients, but entire hospitals and Organ Procurement Organizations. 668 F.2d at 544. Under the plain language of the NOTA/Section 1138 regime, the OPTN essentially regulates by notice and comment. The Court can scarcely think of a more quintessential administrative role.

Keenly aware of the breadth of this authority, HHS stepped in. In its December 18, 1989 Notice to Medicare and Medicaid Programs entitled "Organ Procurement and Transplantation Network Rules and Membership Actions," HHS purported to interpret the meaning of "rules and requirements" to curtail this power:

> In order to be a rule or requirement of the OPTN, and therefore mandatory or binding on hospitals and OPOs participating in Medicare or Medicaid, the Secretary must have given formal approval to the rule or requirement. Approved rules and requirements will be issued in accordance with the Administrative Procedure Act (5 U.S.C. 501 et seq.). If an OPTN rule or requirement would constitute a "rule" within the meaning of the APA and is not exempt from the publication requirement, it will be published in the Federal Register. No hospital will be considered out of compliance with section 1138(a)(1)(B) of the Act or the regulations at 42 CFR 482.12(c)(5)(ii), and no OPO will be considered to be out of compliance with section 1138(b)(1)(D) of the Act or regulations at 42

> CFR 485.305 unless the Secretary has given the OPTN formal notice approving the decision to exclude the entity from the OPTN and has also notified the entity in writing.

54 Fed. Reg. 51802-01 (1989). HHS doubled down on this interpretation in the Final Rule. In the background section for the rule, HHS states that "authority for establishing conditions of participation in Medicare and Medicaid resides with the Secretary and cannot be exercised by another party without either oversight authority or delegation. Thus, review and oversight authority of OPTN policies by the Secretary of HHS is made even more necessary by section 1138." 64 Fed. Reg. 56650-01 (1999); s*ee also* 42 C.F.R. § 482.72 ("The term 'rules and requirements of the OPTN' means those rules and requirements approved by the Secretary pursuant to § 121.4 of this title."). Consequently, HHS has created a distinction between "rules and requirements" (that don't have consequences) and "*rules and requirements*" (that *do* have consequences).

As a result of this distinction, the Final Rule divided OPTN policies into two categories, with two separate paths for enactment: "Path number one—§ 121.4(b)(1)—provides for the usual, baseline OPTN-administered notice-and-comment review." *Callahan*, 939 F.3d at 1259. However, in 'path number two,' Defendant Secretary publishes the proposed policies in the Federal Register for public comment and independently "determine[s] whether the proposed policies

are consistent with" NOTA and the Final Rule. The Court has referred to these policy 'paths' as '(b)(1) policies' and '(b)(2) policies.'[17]

As best the Court can tell, the OPTN has followed along with these changes willingly. Appendix L to the OPTN bylaws provides that noncompliance with policies "covered by section 1138" can be punished only with approval from the Secretary of HHS. OPTN Bylaws App'x § L.13.F, eff. Jan. 13, 2020, *available at* https://optn.transplant.hrsa.gov/media/3493/optn_bylaws.pdf. Furthermore, despite the fact that Congress provided that the OPTN has authority to "establish membership criteria," 42 U.S.C. § 274(b)(2)(B), under the bylaws, "[t]ermination of membership requires Secretarial approval." (*Id.* § L.13.E).

While the interpretation of "rules and requirements" was not itself at issue in Plaintiffs' prior appeal, the Eleventh Circuit appeared to take this interpretation as a given:

> 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.

Callahan, 939 F.3d 1251, 1255 n.1.

[17] As the Court of Appeals held, OPTN policies need not undergo the (b)(2) process. The court does not retread on the mandate of the Court of Appeals.

The Court harbors concerns that Defendants' appellate presentation may have given an incomplete picture regarding factual and legal issues surrounding whether compliance is truly voluntary. For one, Congress expressly provided that the rules and regulations hospitals must follow were those "of" the OPTN, not of HHS. *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984) ("Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

The Court understands HHS's concern that "authority for establishing conditions of participation in Medicare and Medicaid resides with the Secretary and cannot be exercised by another party without either oversight authority or delegation." 64 Fed. Reg. 56650-01. However, the Supreme Court has "never suggested that an agency can cure an unlawful delegation of legislative power by adopting in its discretion a limiting construction of the statute." *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 472–73 (2001). While this is not a nondelegation case of a missing intelligible principal, the Supreme Court's logic in *Whitman* is instructive:

> The idea that an agency can cure an unconstitutionally standardless delegation of power by declining to exercise some of that power seems to us internally contradictory. The very choice of which portion of the power to exercise—that is to say, the prescription of the standard that Congress had omitted—would itself be an exercise of the forbidden legislative authority. Whether the statute delegates

> legislative power is a question for the courts, and an agency's voluntary self-denial has no bearing upon the answer.

Id. It is Congress, not HHS, that decides who has authority to write Medicare and Medicaid eligibility rules.

Even assuming Congress left HHS a "gap to fill" with respect to "rules and requirements," the OPTN's failure to make *any* allocation policies enforceable under Section 1138 may raise an inference that Defendant HHS's interpretation is inconsistent with Congress's intent in enacting Section 1138, particularly given the actual mandatory nature of the requirement that all transplant hospitals participate as members in the OPTN system and the express language of Section 1138 of the Social Security Act. *Compare* 42 U.S.C. § 1320b-8(a)(1)(B) (stating that HHS Secretary "shall provide" that a transplant hospital may only participate in Medicare/Medicaid if "the hospital is a member of, and abides by the rules and requirements of, the [OPTN]"), *with Callahan*, 939 F.3d at 1255 n.1 ("The OPTN has never asked the Secretary to make one of its organ-allocation policies enforceable."). HHS's interpretation effectively renders Congress's grant of authority to the OPTN a dead letter. That HHS may decide one day to publish an OPTN policy under the (b)(2) process does not breathe life into this statutory provision, because the Secretary *already has authority to regulate Medicare and Medicaid eligibility*. 42 U.S.C. § 1302(a). And the fact that NOTA provides a mechanism for Secretarial review of critical comments, 42 U.S.C. § 247(c), does not change this analysis, as under the APA, "agency" means "each authority of the

Government of the United States, **whether or not it is within or subject to review by another agency**." 5 U.S.C. § 701(b)(1) (emphasis added).

In spite of all of this, HHS's interpretation has one thing going for it — time. Justice Gorsuch has noted, "the 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." *Kisor v. Wilkie*, 139 S. Ct. at 2426 (Gorsuch, J., concurring in the judgment). The interpretation is also entitled to some weight based on Congress's having not changed it. Legislative efforts in 1993 appear to have sought to clarify HHS and the OPTN's respective handling of allocation policies and procedures. A proposed 1993 House Bill "direct[ed] the Secretary of HHS to issue a proposed rule establishing OPTN policies and procedures within 90 days of the date of enactment, and a final rule establishing such policies and procedures within one year after the date of enactment." Mintz, *Analyzing the OPTN Under the State Action Doctrine - Can UNOS's Organ Allocation Criteria Survive Strict Scrutiny?*, 28 Colum. J.L. & Soc. Probs. 339, 350 n. 60 (1995) (quoting H.R. Rep. No. 272 at 10, 103d Cong., 1st Sess. (1993)). "The Secretary's failure to issue such final rules would result in either the proposed rules becoming legally enforceable, or, in the absence of proposed rules, current OPTN policies becoming legally enforceable rules." *Id.* "Because both the Senate and the House passed dissimilar bills a conference committee was named to reconcile the differences. The conference committee

could not reach agreement before the 103d Congress adjourned." *Id.* (citing 140 Cong. Rec. S3933 (daily ed. Mar. 25, 1994); 140 Cong. Rec. H2247 (daily ed. Apr. 13, 1994)). While the meaning of Congress's apparent grant of authority to the OPTN raises a close question, ultimately the vintage of the interpretation is what convinces the Court to follow Defendants' reading.

Having considered the OPTN's authority in theory, the Court next examines the OPTN's power in practice. Defendants have consistently maintained that the OPTN lacks any real power, and that the OPTN is a voluntary organization with "excellent" compliance. The Court pauses for a moment to reflect on this "voluntariness." It seems at least a bit peculiar that three lawsuits were filed in as many years challenging "voluntary" policies. *Callahan v. U.S. Dep't of Health and Human Servs.*, No. 1:19-cv-01783-AT (N.D. Ga. filed Apr. 22, 2019); *Cruz v. U.S. Dep't of Health and Human Servs.*, No. 1:2018cv06371 (S.D.N.Y. filed July 13, 2018); *Holman v. Secretary of HHS*, No. 17 Civ. 09041 (S.D.N.Y. filed Nov. 19, 2017). Even if the OPTN's (b)(1) allocation policies are not legally enforceable, HHS has admitted, "patients have, as a practical matter, no choice but to use the system governed by the OPTN." 63 Fed. Reg. 16,296, 16,309 (Apr. 2, 1998).

Aside from its policymaking role, the OPTN also exercises some investigatory and adjudicatory powers. HHS has delegated some oversight authority to the OPTN by regulation. For example, the Final Rule, 42 C.F.R. §

121.10(b)(1)(iii), requires the OPTN to develop plans and procedures to conduct "ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies." It further requires the OPTN Board of Directors to "advise the Secretary of the results of any review and evaluations . . . which, in the opinion of the Board, indicate noncompliance with these rules or OPTN policies, or indicate a risk to the health of patients or to the public safety." *Id.* § 121.10(c)(1). The OPTN can recommend penalties, and the Secretary may act on these recommendations, or decline to, or take other action. *Id.* § 121.10(c)(2). As one court noted, "UNOS has been delegated responsibilities, now codified in federal regulations, to monitor transplant hospitals for compliance with federal requirements and to report to the Secretary of HHS noncompliance with those requirements or indications of risk to the health of patients or to the public safety. Those are contractual responsibilities as well. In short, the system provides for some reliance upon the private contracting agency for enforcing federal requirements and standards." *United States v. United Network for Organ Sharing*, No. 02 C 2295, 2002 WL 1726536, at *1 (N.D. Ill. May 17, 2002).

And while Defendants characterize voluntary compliance as "excellent," it has hardly been perfect. UNOS's Letter of October 23, 2019 indicated a litany of member hospitals that had not complied with UNOS policies. (Doc. 155 at 4–5). At oral argument, Counsel for UNOS identified several consequences of not

abiding by UNOS policies. Members could be placed on "probation" or become "a member not in good standing." (Transcript of at 69:18–25). UNOS contended that, while this would not result in removal from Medicare or Medicaid, it is "professionally embarrassing." This is an understatement. Professional consequences may have real world effects.[18]

If a transplant hospital is put on probation, or not in good standing, it must provide notice to all individual patients, which will likely result in the loss of said patients. OPTN Bylaws App'x L.12.D, Table L.-1, L-2, eff. Jan. 13, 2020, *available at* https://optn.transplant.hrsa.gov/media/3493/optn_bylaws.pdf.[19] Furthermore, a member's failure to come into compliance with OPTN Obligations while designated as a Member Not in Good Standing may result in the Board of Directors recommending that the Secretary take action against the member. (*Id.* at L.13.D). And the Secretary may theoretically punish a hospital if it "[e]ngages in behavior that poses a risk to patient health or public safety."[20]

All of this assumes a hospital is already a member of the OPTN. But NOTA also gives the OPTN the authority to develop membership criteria, 42. U.S.C. §

[18] The Court notes in passing that HHS has acknowledged in the past "Effectively all transplant centers are accredited by the JCAHO [Joint Commission on Accreditation of Healthcare Organizations], which already requires hospitals to participate in the Network." 53 Fed. Reg. 6526-01 (1988). Loss of accreditation may result in loss of access to Medicare and Medicaid through CMS, among other consequences at the state and local level.

[19] The OPTN submitted a copy of the Bylaws effective as of May 14, 2019 (Doc. 236-2). Since then, it appears the OPTN has adopted revisions effective January 13, 2020, available at https://optn.transplant.hrsa.gov/media/3493/optn_bylaws.pdf

[20] Plaintiffs have submitted an email which contains a second-hand account of a transplant program being shut out from accessing DonorNet. (Mot. 37-38, Ex. B to Ex. 2) Defendant UNOS's hearsay objection is well taken, but if proven at trial, this would be powerful evidence of "substantial authority."

274(a)(2). As all of the Hospital parties to this case are OPTN members, no party has raised the issue that the OPTN's gatekeeping function is sufficiently checked by HHS. *See* 42 C.F.R. § 121.3(b)(4) (providing right of appeal to Secretary for rejection of membership).

The Supreme Court has held that policies which are not directly binding on regulated entities may nonetheless have "coercive effect." *Bennett v. Spear*, 520 U.S. 154, 169 (1997); *see also Dep't of Transp. v. Ass'n of Am. Railroads*, 575 U.S. 43, 59 (2015) ("Because obedience to the metrics and standards materially reduces the risk of liability, railroads face powerful incentives to obey. That is regulatory power.").

However, D.C. Circuit case law would seem to point away from a finding that the OPTN exercises "substantial government authority" in practice. For one, like the IRGs in *Washington Research Project*, the OPTN in practice can only make recommendations, it relies on HHS to make actual "decisions" about sanctions. 504 F.2d at 248. In this way, the OPTN's adjudicatory authority is less than the PSROs found not to be agencies in *Public Citizen*, whose decisions were constituted "conclusive determination[s]." 668 F.2d at 543.

In sum, Congress at least purported to give the OPTN policies real regulatory authority, HHS attempted to rein in this authority, and whether OPTN policies are truly voluntary is debatable. It's a close case, especially in the context of organ allocation policies that in practice are the product of the OPTN's

national policymaking, review, and implementation, even at the organ waitlist level. But in light of the structural evidence indicating Congress's intent in passing NOTA that the OPTN be a nonprofit entity separate from the government and HHS's longstanding interpretation of Section 1138 of the Social Security Act, the Court holds that the OPTN is not an agency for the purpose of the Administrative Procedure Act.

2. What is the final agency action?

The consequence of this Court having held that the OPTN is not an agency is that only actions by HHS are subject to judicial review under the APA. Defendant HHS asserts that the only final agency action before the Court is HHS's April 23, 2019 determination not to take further action in response to Plaintiffs' critical comment (HHS_00000021) ("April 2019 Letter"). However, the Court can identify at least two other possible candidates for review, consistent with Plaintiffs' contentions: (1) HHS's July 31, 2018 directive to UNOS to develop a liver allocation policy that eliminates the use of DSAs (HHS_00004991) ("July 2018 Letter") after consideration of the *Cruz* critical comment (and in effect, HHS's disapproval of the 2017 Revised Policy); and (2) HHS's December 19, 2018 letter to UNOS approving of the Acuity Circles policy (HHS_00002213) ("December 2018 Letter").

Under the APA, the Court may only review final agency action. *See* 5 U.S.C. § 706. "As a general matter, two conditions must be satisfied for agency action to

be 'final': First, the action must mark the "consummation" of the agency's decisionmaking process . . . it must not be of a merely tentative or interlocutory nature. *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (quoting *Chicago & Southern Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948). "And second, the action must be one by which "rights or obligations have been determined," or from which "legal consequences will flow." *Id.* at 178 (quoting *Port of Boston Marine Terminal Assn. v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970).

There does not seem to be any dispute that the April 2019 Letter declining to act in response to Plaintiffs' critical comment is final agency action. (Pls.'s Reply at 11 n.5, Doc. 234 at ECF Page 15). The letter represented HHS's decision to "[r]eject the comment[]", the consummation of the Secretarial review process under the Final Rule. 42 C.F.R. § 121.4(d)(1).

The July 2018 Letter likewise represented the consummation of another Secretarial review process — the review of Intervenors' critical comment. (HHS_000049991 ("This letter addresses a critical comment dated May 30, 2018.") (footnote omitted)). The July 2018 Letter expresses HHS's determination, through HRSA, "that the [Defendant UNOS, as the] OPTN has not justified and cannot justify the use of donation service areas (DSAs) and OPTN Regions in the current liver allocation policy and the revised liver allocation." (*Id.* (footnotes omitted)). This determination is not "merely tentative or interlocutory

[in] nature." *Bennett*, 520 U.S. at 178. HHS did not invite the OPTN to continue trying to justify DSAs and Regions in liver allocation. The Court cannot think of a more 'final' way to express HHS's disapproval of DSAs and Regions still in some measure used in the 2017 Revised Policy than by saying Defendant UNOS "has not justified and *cannot* justify" their use. The letter effectively set aside the 2017 Revised Liver Policy, and "directed" UNOS to "adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions." (*Id.* at HHS_00004993). The letter represented HHS's decision to "[d]irect the OPTN to revise the policies or practices consistent with the Secretary's response to the comments." 42 C.F.R. § 121.4(d)(1). Complying with the directive became Defendant UNOS's "obligation," as the OPTN. *Bennett*, 520 U.S. at 178. It would lead to a striking lack of parallelism if the Secretary of HHS's decisions to reject critical comments represented final agency action, but decisions to adopt them did not. Accordingly, the July 2018 letter also represents final agency action. Indeed, the Eleventh Circuit seemed to assume as much. *Callahan v. United States Dep't of Health & Human Servs. through Alex Azar II*, 939 F.3d 1251, 1266 (11th Cir. 2019) ("Was HHS's decision to direct the new policy's development based on sufficient evidence?").

Finally, Plaintiffs did not need to address the July 2018 Letter in their February 2019 Critical Comment in order to preserve an APA challenge to the July 2018 Letter, though the letter was referenced several times.

(HHS_00000001 at n.1, n.6). The purpose of the critical comment mechanism is to address the performance of the OPTN or "Secretarial policies regarding the OPTN." 42 C.F.R. § 121.4(d). HHS's determination with respect to an individual critical comment is not a "Secretarial policy" — to hold otherwise would create an endless ping-pong match whereby interested parties with differing views would be required to complain about the Secretary's resolution of each other's critical comment. Furthermore, Transplant Center Patients voiced their opposition to Intervenors' May 30 critical comment which resulted in the July 2018 Letter in their letters dated June 29, 2019 (HHS_00010315) and July 6, 2019 (HHS_00001983). Plaintiffs are clearly persons aggrieved by the July 2018 Letter. (*Cf.* Intervenor's Mem. in Support of Mot. to Intervene at 11–12 (Doc. 18-1) (citing *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1398 (9th Cir. 1995)).

The last additional candidate for final agency action is HHS's December 2018 Letter which approved the Acuity Circles policy (HHS_00002213).[21] The December 18 Letter contains glowing praise for the OPTN and other policymakers, beginning with an expression of "appreciation for the substantial time" the OPTN and Liver Committee spent on developing the policy and noting that it "continues its longstanding practice of relying on the expertise of the

[21] Defendant HHS argues in its surreply that Plaintiffs waived the argument that the December 2018 Letter constitutes final agency action by failing to raise it in their opening brief (Def. HHS's Surreply at 5), but any prejudice from raising the argument in a reply was cured by the Court's grant of leave to file a surreply.

OPTN and its members." (*Id.* at 1). The letter "appreciates the extensive analysis prepared by the SRTR" and "commends the Liver Committee's outreach efforts and its almost weekly deliberations." (*Id.* at 3).

More importantly, the December 2018 Letter states that HHS "is satisfied that the OPTN complied" with its expectations as set forth in the July 2018 Letter and "expects the OPTN to proceed expeditiously in implementing" the Acuity Circles policy. (*Id.* at 1, 4). Plaintiffs have characterized this laudatory letter as "ratification." (Pls.'s Reply at 7, Doc. 234 at ECF Page 11). At the very least, it constituted approval. It also determined the OPTN's compliance with the final rule and directed the OPTN to proceed with implementation. Furthermore, the letter arguably was sent to support and commend the OPTN decision and Board and to ward off any critical comment of a policy adopted by the OPTN only 16 days earlier. For comparison, it took the *Cruz* Plaintiffs almost six months to submit their critical comment in opposition to the 2017 Revised Policy adopted by the OPTN Board on December 4, 2017. For all of these reasons, the Court holds that the December 2018 Letter constitutes final agency action as well. However, even if the Court were to rule otherwise, it is not clear to the Court that much is added by regarding the December 2018 Letter as agency action, as the April 2019 Letter essentially serves the same function by refusing to set aside the Acuity Circles policy. Furthermore, the administrative record for the December 2018 Letter would be entirely encompassed within the record for April 29 Letter

in combination with the earlier July 2018 Letter. Therefore, it is not likely that the Court's holding regarding the December 2018 Letter is in itself dispositive of any of Plaintiffs' claims.

3. Plaintiffs' outstanding requests for supplementation of the record.

The final threshold APA question before the Court is what constitutes the boundaries of the administrative record. The Court has already set forth the standard of review for supplementation in its prior Order of December 6, 2019 (Doc. 206) which granted in part and denied in part Plaintiffs' Motion to Supplement the Administrative Record (Doc. 167) and Addendum Motion to Supplement the Administrative Record (Doc. 188).

Pursuant to the Court's Amended Order of December 3, 2019 (Doc. 204), the Court set a deadline of December 9, 2019 for Plaintiffs to file any further motions for supplementation of the administrative record. Plaintiffs timely filed their Second Addendum Motion (Doc. 212), to which Defendant HHS responded (Doc. 219) and Plaintiffs filed a reply (Doc. 224). The Second Addendum motion sought supplementation of the record with respect to a number of communications. However, since then, the number of documents Plaintiffs seek has ballooned, and Plaintiffs have now requested that the Court direct the record

be supplemented with nearly 100 more records, nearly two weeks before the date this Court endeavored to have released this decision.[22] (Docs. 250, 251).

The Court's holding that the OPTN is not an administrative agency limits the boundaries of the record somewhat, but not to the exclusion of documents considered by UNOS entirely. As the Court has held in its prior Order, in a (b)(1) policy, "UNOS, as the OPTN, was primarily responsible for receiving public comment on the proposed policy, and for determining whether the policy was consistent with NOTA and the Final Rule in light of such comments." (Doc. 206 at 8). This is in contrast to a (b)(2) policy, where HHS must "publish the rule in the Federal Register" and make "a decision under Final Rule § 121.4(b)(2) about the legality" of the proposed policy. (*Id.*)

In *Overton Park*, the Supreme Court held that where "administrative findings . . . were made at the same time as the decision," the Court must review the decision based solely on the agency's justifications given on the administrative record, absent bad faith. *Overton Park*, 401 U.S. at 420. However, the Court does not have formal findings by HHS. (Transcript of Dec. 17, 2019 hearing at 54:16–23, Doc. 238). Instead, the Court has a number of short letters written by Administrator Sigounas which largely defer to the OPTN.[23]

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[22] The Court notes, though, the highly condensed timeline of proceedings in this case that stretched over the Thanksgiving and Christmas holidays, and that UNOS produced many of these documents belatedly.

[23] *See* July 2018 Letter at 3 ("HRSA is not directing any particular policy outcome or allocation scheme. HRSA continues its longstanding practice of relying on the expertise of the OPTN and its members."); December 2018 Letter at 1 (HRSA continues its longstanding practice of relying

As the Court held in its prior Order:

> When the (b)(1) policymaking structure is viewed as a collaborative decision-making process, it is clear that materials and information which influenced UNOS's policymaking in its role as OPTN also at least indirectly influenced HHS's determination as to whether to modify UNOS's adoption of the Acuity Circles policy via its review of Plaintiffs' critical comment. It bears stating that the HHS–OPTN relationship provided under the Final Rule for a (b)(1) policy appears to be a unique arrangement.

In reiterating its opposition to further supplementation, Defendant HHS cites cases involving agencies which "rely" on the determinations of other agencies.[24]

If this were a (b)(2) policy, where HHS engaged in notice and comment rulemaking and actually made a formal determination about the policy's legality, the Court agrees that any reliance on OPTN expertise would not require supplementation of the record with materials considered by the OPTN. However, this is not a case of an agency making policy in "reliance" on other agencies or experts. In a (b)(1) policy, the OPTN makes the policy, provides notice of the policy, takes into account comments, and then implements the policy. By

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on the expertise of the OPTN . . . HRSA has carefully monitored the OPTN's deliberations and is satisfied that the OPTN complied with HRSA's expectations."); April 2019 Letter at 2 ("HRSA continues its longstanding practice [etc] . . . We 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. Based upon this review, I do not believe further HHS actions are warranted.").

[24] *See* Def. HHS's Resp. to Second Add. Mot to Supp at 8, Doc. 219. HHS cites the following cases: *Saratoga Dev. Corp. v. United States*, 21 F.3d 445, 457 (D.C. Cir. 1994) (holding that agency not required to supplement record with reports created by entities consulted by agency); *Am. Petroleum Tankers Parent, LLC v. United States*, 952 F. Supp. 2d 252, 272 (D.D.C. 2013) ("The Administrative Record is not 'insufficient' merely because it omits documents that were considered by a different agency that provided advice to the agency responsible for making the ultimate decision."); *City of Duluth v. Jewell*, 968 F. Supp. 2d 281, 290 (D.D.C. 2013 ("[R]eliance on the decision of a sister agency does not automatically require supplementation of the administrative record with the internal documents underlying the sister agency's decision.").

deferring to the OPTN defense of its own policy in HHS's review of Plaintiffs' Critical Comment (as well as issuing the December 2018 Letter approving the Acuity Circles policy), HHS "adopts [the OPTN's reasoning] as its own." *Washington Research Project, Inc. v. Dep't of Health, Ed. & Welfare*, 504 F.2d 238, 248 (D.C. Cir. 1974) (citing *American Mail Line, Ltd. v. Gulick*, 411 F.2d 696 (1969)). Accordingly, documents which were considered by the OPTN in formulating the Acuity Circles policy were "indirectly" considered by HHS and properly part of the record.

However, while HHS's adoption of UNOS's policymaking justifications may in some circumstances impute the "consideration" requirement to UNOS, the same cannot be said for "bad faith," absent a showing that HHS was involved in, or at the very least, aware of the bad faith, when it adopted UNOS's policymaking rationale.[25] As the Court notes below in the section addressing Plaintiffs' claim of bad faith, materials cited in Plaintiffs' supplemental brief show arguable evidence of bias, or at least, individuals' sporadic expressions of bad faith or agenda. However, Plaintiffs fail to tie any of this alleged misconduct to HHS, or to show that HHS was aware of it. Accordingly, these conversations are not properly part of the administrative record.

[25] *But cf. Associations Working for Aurora's Residential Env't v. Colorado Dep't of Transp.*, 153 F.3d 1122, 1128–29 (10th Cir. 1998) ("Accepting for the sake of argument that the Contractor's heightened expectation that it would receive the contract for future design work amounted to a conflict [and therefore bias], we nevertheless agree with the district court's conclusion that the degree of oversight exercised by defendants, particularly CDOT, is sufficient to cure any defect arising from that expectation.").

Further, much of what Plaintiffs offer anew are internal communications between UNOS employees and Executive Committee members, which would not be part of the record even if the Court were to have held that the OPTN was an agency. *Ad Hoc Metals Coalition v. Whitman*, 227 F.Supp.2d 134, 143 (D.D.C. 2002) ("Judicial review of agency action should be based on an agency's stated justifications, not the predecisional process that led up to the final, articulated decision."). While the Court has held that the deliberative process privilege was waived by UNOS *for the purpose of discovery*, the Court does not hold that these deliberative communications are properly part of the administrative record. While they are not part of the administrative record for the purpose of Plaintiffs' APA claim, they are still part of this Court's record, and the record on any appeal to the extent Plaintiffs' challenge this Court's ruling regarding bad faith, or whether the OPTN is an agency or state actor, or that Defendants denied Plaintiffs due process of law, as well as for the factors for injunctive relief.[26]

Accordingly, the Court **GRANTS** Plaintiffs' motion **IN PART**, as to UNOS_0011693, UNOS_0011694, UNOS_0012047, UNOS_0012220, UNOS_0013311, and UNOS_0013155, UNOS_13167.

[26] Plaintiffs seek supplementation of the record with several documents relating to UNOS's bid protest. These documents bear on UNOS's status as a state actor or agency, and are considered for that purpose. However, Plaintiffs do not attempt to justify their addition to the administrative record. These documents are accordingly not properly part of the administrative record.

B. Was the adoption or substance of the Acuity Circles policy arbitrary and capricious?

Having resolved the threshold APA questions, the Court now reaches the merits of the Plaintiffs' APA "arbitrary and capricious" claims. The Court will first address the Defendants' determination regarding the legality of the DSAs in the July 2018 Letter. The Court will next turn to Plaintiffs' procedural challenges regarding the adoption of the Acuity Circles policy, and lastly whether the Acuity Circles complies with the NOTA and Final Rule.

The Final Rule, Section 121.4, provides the procedural regulations for adopting allocation policies. In relevant part, it states:

> (a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including:
>
> > (1) Policies for the equitable allocation of cadaveric organs in accordance with § 121.8; . . .
> >
> > (3) Policies that reduce inequities resulting from socioeconomic status, including, but not limited to:
> >
> > . . .
> >
> > > (iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;
> >
> > . . .
>
> (b) The 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 . . . .

42 C.F.R. § 121.4. Another part of the Final Rule, Section 121.8, provides the substantive criteria for adoption of allocation policies:

> (a) Policy development. The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:
>
> (1) Shall be based on sound medical judgment;
>
> (2) Shall seek to achieve the best use of donated organs;
>
> (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);
>
> (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
>
> (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
>
> (6) Shall be reviewed periodically and revised as appropriate;
>
> (7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and
>
> (8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5) of this section.

42 C.F.R. § 121.8. The Parties agree that the Final Rule, against the backdrop of NOTA, is the standard by which all of the various liver allocation policies (the Current Policy, the 2017 Revised Policy, and the Acuity Circles policy) are to be judged. The Parties differ in their approach to how the criteria are to be weighed,

particularly the requirement in Section 121.8(a)(8) that liver allocation policies "[s]hall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5) of this section."

The Court will proceed chronologically through Plaintiffs' claims, beginning with Defendant HHS's decision in the July 2018 Letter that "the OPTN has not justified and cannot justify" the use of DSAs and Regions in the Current Policy or the 2017 Revised Policy. (HHS_00004991). The Court will next consider whether Defendant HHS acted arbitrarily and capriciously by setting "an unreasonable deadline of four months" for the OPTN to develop the policy (Compl. ¶ 9), and whether HHS should have set aside the Acuity Circles policy based upon its ultimate adoption process. Finally, the Court will consider Plaintiffs' claims that Defendant HHS should have set aside the Acuity Circles policy based upon its purported lack of compliance with NOTA and the Final Rule.

1. Defendants' determination regarding the legality of DSAs

As noted above, in the July 2018 Letter, Defendant HHS determined that "the OPTN has not justified and cannot justify" the use of DSAs and OPTN Regions in the Current Policy or the 2017 Revised Policy, and directed that Defendant UNOS adopt a new policy "by its December 2018 meeting." (HHS_00004991, 95).[27] Plaintiffs, in Count II of their Complaint, allege that

[27] HHS also found "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." (HHS_00004995).

"[t]he directive to develop and choose a new policy within this incredibly limited timeframe was arbitrary and capricious, and otherwise not in accordance with the law." (Compl. ¶ 206). The Eleventh Circuit has asked this Court to consider, on remand, whether "HHS's decision to direct the new policy's development [was] based on sufficient evidence." *Callahan*, 939 F.3d at 1266.

Plaintiffs, in their Renewed Motion for Preliminary Injunction, also take aim at the legal determination underlying the July 2018 Letter, that DSAs and Regions are "per se illegal." (Pls.' Renewed Mot. at 16, Doc. 216-1 at ECF Page 25). Defendants argue that Plaintiffs waived this latter argument by failing to raise it in their Complaint or February 2019 Critical Comment. (Def. HHS's Resp. at 25–27, Doc. 228 at ECF Page 32–34). The Court will first address the waiver argument.

a. Waiver

Plaintiffs clearly took aim at HHS's July 2018 Letter itself in their Complaint. (Compl. ¶ 206, Doc. 1 ("The [July 2018] directive to develop and choose a new policy within this incredibly limited timeframe was arbitrary and capricious, and otherwise not in accordance with the law.")). However, Defendant HHS contends that Plaintiffs waived their argument that HHS's "per se" legal determination about DSAs and Regions was erroneous based on a failure to raise it in their Complaint.

The purpose of a complaint is to the "provide the grounds of [the Plaintiff's] entitle[ment] to relief." *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotations omitted). Accordingly, a "complaint need not specify in detail the precise theory giving rise to recovery." *Brisk v. Shoreline Found., Inc.*, 654 F. App'x 415, 417 (11th Cir. 2016) (citing *Sams v. United Food & Commercial Workers Int'l Union*, AFL–CIO, CLC, 866 F.2d 1380, 1384 (11th Cir. 1989)). Defendant HHS's reliance on *Brown v. Snow*, 440 F.3d 1259, 1266 (11th Cir. 2006) is misplaced. That Title VII case involved a completely separate claim for retaliation which arose after the filing of the complaint. *Id.* Here, Plaintiffs identified the particular final agency action at issue in their claim for judicial review under the Administrative Procedure Act. Accordingly, Plaintiffs did not waive their right to challenge the July 2018 Letter under the Administrative Procedure Act by omitting it from their Complaint.

Furthermore, Plaintiffs did not waive the argument by failing to raise it before the agency. At the outset, Plaintiffs are correct that they did not need to lodge a critical comment specifically directed at HHS's July 2018 Letter. Under the Final Rule, the purpose of critical comments is for raising concerns with "the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN." 42 C.F.R. § 121.4(d). (Pls.' Reply at 3, Doc. 234). As the Court held above, HHS's determination with respect to an individual critical comment is not a "Secretarial policy."

Furthermore, as the Court noted above, Plaintiff hospitals voiced their opposition to Intervenors' May 30 critical comment which resulted in the July 2018 Letter. Plaintiff Piedmont Healthcare, in its letter to HHS dated June 29, 2019, rejected the contention that the 2017 Revised Policy was arbitrary and capricious, stating that "[t]he liver allocation policies comply with the spirit and language of" NOTA and that "it is highly unlikely a court would determine the liver allocation policies to be arbitrary and capricious given that the policies are the result of extensive consideration of a variety of factors, evidence and viewpoints." (HHS_00010315, 17). Plaintiff Vanderbilt University Medical Center, along with several other Transplant Center Plaintiffs in a letter dated July 6, 2019, argued that Intervenors' position that allocation policies "are illegal so long as they include reference to regional boundaries" "ignores fundamental elements of the laws governing organ allocation." (HHS_00001983). Both letters contended that existing OPTN policies were justified in light of the other factors in Section 121.8(a)(1), and that broader sharing would increase socioeconomic inequities. (HHS_00010316–18; HHS_00001984–85).

In HHS's July 2018 Letter, Administrator Sigounas stated that "HRSA has received correspondence from several parties opposing broader geographic sharing" and that "[n]one of these arguments or other information HRSA has considered alters our determination of the impressibility of using DSAs and Regions in liver allocation policy." (HHS_00004993). Plaintiffs voiced their

position before HHS, and HHS flatly rejected their position. To require Plaintiffs to restate their position in a critical complaint would have been futile. *Cf. Etelson v. Office of Pers. Mgmt.*, 684 F.2d 918, 925 (D.C. Cir. 1982). Accordingly, Plaintiffs did not waive their challenge to the July 2018 Letter on the grounds that it impermissibly concluded that DSAs and Regions were *per se* unlawful.

b. Was the July 2018 Letter based on an error of law?

Plaintiffs contend that the July 2018 Letter should be set aside on the grounds that it is based on the purportedly incorrect legal determination that any "form of geographic limitation" is impermissible under the Final Rule unless its "size and shape" is specifically "justified and required" by one of the factors described in 42 C.F.R. § 121.8(a)(1)-(5). (Pls.'s Renewed Br. at 15 (quoting HHS_00004993)). Plaintiffs' argument is based on the rule in *Chenery I* that "if the [agency] action is based upon a determination of law as . . . an order may not stand if the agency has misconceived the law." *Sec. & Exch. Comm'n v. Chenery Corp. (Chenery I)*, 318 U.S. 80, 94 (1943). This is so even if the agency action could be supported on policy grounds. The basis of this rule is that

> a judicial judgment cannot be made to do service for an administrative judgment. For purposes of affirming no less than reversing its orders, an appellate court cannot intrude upon the domain which Congress has exclusively entrusted to an administrative agency.

Chenery I, 318 U.S. at 88. Under the Final Rule, an allocation policy "[s]hall not be based on the candidate's place of residence or place of listing, except to the

extent required by paragraphs (a)(1)–(5) of this section." 42 C.F.R. § 121.8(a)(8) Paragraphs (a)(1)–(5) include, among other things, directives that allocation policies "be based on sound medical judgment," "seek to achieve the best use of donated organs," and "be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement."

Section 121.8(a)(8) begins with a general regulatory policy that allocation policies must not be "based on" where the candidate resides. However, any allocation policy that does not distribute every donor organ to the single patient most gravely in need nationwide will necessarily take into account geography. Accordingly, the Final Rule appears to give some flexibility to the OPTN to consider where the candidate resides, but only to the extent "required" by one of the other factors. For example, Section 121.8(a)(5) directs the OPTN to adopt policies that are "designed to avoid wasting organs," and therefore the OPTN could take into account whether transporting organs over long distances resulted in more wasted organs.

Despite the apparent strictness of the words "shall not" and "except to the extent required," Plaintiffs home in on the phrase "based on." (Pls.'s Renewed Br. at 15–16). Plaintiffs read much into this phrase, permitting a policy to incorporate a candidate's place of residence without demonstrating that it is necessitated by one of the other factors in Section 121.8 so long as it is not the

primary criterion for allocation. (Pls.'s Renewed Br. at 16 (citing *Oxford English Dictionary* (3d ed. 2011), defining "base" as "to place on (also upon) a foundation, fundamental principal, or underling basis.").

Plaintiffs' proposed reading of the Final Rule is implausible. The DSA are geographically areas, "some of which follow state lines but others of which do not" (Compl. ¶ 79) and Regions "are groupings of states." (Compl. ¶ 78). A policy which takes into account DSAs and Regions is "based on the candidate's place of residence or place of listing." However, that does not end the inquiry, as a policy which takes into account DSAs and Regions could potentially be permissible if it was "required" by one of the other factors. And these factors are relatively broad, including achieving "the best use of donated organs," and "to promote the efficient management of organ placement." 42 C.F.R. § 121.8(a)(1), (5). To effectuate these sorts of lofty criteria, the OPTN will have to bring its experience to bear. Perhaps having defined boundaries is the best way to "promote the efficient management of organ placement." These are precisely the types of policy judgments based upon expertise that Congress sought for the OPTN to make.

However, there's the rub. Plaintiffs contend that the July 2018 Letter, by making a "per se" determination about DSAs and Regions, took the OPTN's authorized policymaking off the table. Plaintiffs also contend that this per se determination is an abrupt about face, when HHS had not objected to policies containing DSAs and Regions in the past. The Court is certainly concerned by the

breadth of the language in the July 2018 Letter, particularly that "DSAs and Regions have not and cannot be justified" under any circumstances.[28] It certainly would have been a cleaner case had HHS cataloged the OPTN's rationales for using DSAs and Regions in the 2017 Revised Policy, stated why each one did not, as a policy matter, justify the retention of DSAs and Regions, and remanded the matter to the OPTN to try again. By taking DSAs and Regions off the table entirely, HHS appears at first glance to have adopted an interpretation of the Final Rule that eliminates the OPTN's discretion to justify DSAs and Regions in a modified form under the other Section 121.8 factors based on any future set of facts, collected data, analyses, or new policies.

However, the July 2018 Letter cannot be taken in a vacuum. HHS did in fact solicit the OPTN's justifications for continued use of DSAs and Regions in liver allocation in a June 8, 2018 letter. (HHS_00007240). In that letter, HHS noted that the "OPTN has identified the use of geography in OPTN organ allocation policies as an area of concern" since at least 2012 and noting that in response to a 2017 lawsuit, that the OPTN concluded that, at least with respect to lungs, "the current lung allocation policy contains an over-reliance on DSA as a unit of allocation." (HHS_00007241).

The OPTN Board President's June 25, 2018 response in defense of DSAs and Regions can best be described as lukewarm, although the December 2018

[28] The Court notes the recognized significant impact of transportation on transplant organ efficacy and wastage as well as the differences in data relating to each organ that may clearly pertain to geographical considerations.

Policy Notice addressed this question.[29] (HHS_00006879, HHS_00007007). As to DSAs, much of the June 25 letter is devoted to stating that DSAs are not the "primary distribution" units. One of the few statements that can arguably be seen as justifying DSAs is that they have "historically been relied upon" for "avoid[ing] organ wastage and to promote the efficient management of organ placement," but within the same sentence, the OPTN throws DSAs under the bus by "acknowledg[ing] the importance of moving to a framework that utilizes a more consistent and direct measure of distance." (HHS_00006880).

Regions fare little better. Like DSAs, Regions are justified based in part on the fact that 150 nautical mile circles are also superimposed under the 2017 Revised Policy. (*Id.*) At best, the OPTN notes that several Regions are larger than 150 nm circles, especially those that include Hawaii and Puerto Rico. But, the OPTN Board President's letter admits that, "like DSAs, OPTN Regions are an imperfect substitute for proximity between the donor and candidates." (*Id.*) (The Court notes, though, the new 150 nm circle approach had been statistically modeled by the SRTR).

The OPTN does, however, defend the use of adjustments to MELD/PELD scores based upon DSAs. (HHS_00006881). Proximity points within DSA are justified to "mitigate travel for small differences in medical urgency." (*Id.*)

[29] The Board President wrote on behalf of the organization. The evidence submitted indicates that the full OPTN Board of Directors did not vote to take the positions articulated. Instead critical members of the Executive Board and the OPTN Director appear to have concluded this approach was most strategic and appropriate under the circumstances.

However, the OPTN letter once more concedes that "the use of DSAs are not optimal units of geography to represent proximity between a donor and candidates." (*Id.*) Finally, the OPTN justifies using median MELD in DSAs for determining exception points as providing context among other patients in the DSA.

In the letter, the OPTN commits itself to adopting a replacement policy, and provides a timeline for a "deliberate, step-wise approach to further revising the liver allocation policy in a prompt but reasonable time-frame to eliminate reliance on DSA and OPTN Regions." (HHS_00006882).

Considering Section 121.8(a)(8) of the Final Rule's clear preference against basing allocation policies "on the candidate's place of residence or place of listing," it is not entirely irrational for HHS to have elected to set aside the 2017 Revised Policy in light of the OPTN's failure to offer a rigourous defense of the use of DSAs and Regions as a matter of policy and discretion. In its July 2018 Letter, HHS acknowledges that making policy means making tough calls, noting that there is an "imbalance between livers available for transplantation and those in need of liver transplants" and recognizing that "consensus for a new liver allocation may not be possible . . . [and] is not required under the OPTN final rule." (HHS_00004994). To the extent that HHS concluded that the OPTN failed to justify the 2017 Revised Policy, the Court finds the decision to set it aside was not arbitrary and capricious. And to the extent that HHS was concerned gridlock

was a barrier to adopting a Final Rule-complaint policy, HHS was justified in directing that the OPTN not take into account DSAs and Regions in developing a subsequent policy based on the OPTN's own self-imposed deadline and self-imposed commitment to eliminate DSAs and Regions.

For the same reasons, if a substantial evidence standard applies to HHS review of a critical comment, the decision was supported by substantial evidence in light of the OPTN's failure to offer a persuasive justification of DSAs and Regions. *See Bama Tomato Co. v. U.S. Dept. of Agric.*, 112 F.3d 1542, 1546 (11th Cir. 1997) ("Substantial evidence means 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'") (quoting *Consolidated Edison* Co. v. NLRB, 305 U.S. 197, 229 (1938)).

However, HHS went a bit further than merely setting aside the 2017 Revised Policy, boldly declaring that it "[has] determin[ed] that the OPTN has not justified and cannot justify the use of "DSAs and Regions," and that it "finds that the use of DSAs and Regions in all other (non-liver) allocation policies has not been and cannot be justified under the OPTN Final Rule." (HHS_00004991, 95) The Court, on the record before it, cannot say whether this conclusion was overbroad or not. However, having determined that HHS did not act arbitrarily and capriciously in setting aside the 2017 Revised Policy and directing the OPTN to write a new policy based upon its own self-imposed timeline, the Court is not compelled by *Chenery I* to remand to the agency based upon a legal conclusion

that was essentially dicta. As to those specific outcomes, because the Court is "sure" that on remand HHS would "reinstate its decision—if in other words the error in its decision was harmless—a reversal would be futile, and *Chenery* does not require futile gestures." *People of the State of Ill. v. I.C.C.*, 722 F.2d 1341, 1348 (7th Cir. 1983), *cited with approval in Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 756 (1986), *overruled on other grounds by Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833 (1992); 5 U.S.C.A. § 706 ("In making the foregoing determinations . . . due account shall be taken of the rule of prejudicial error.").

There are considerable reasons that militate against reaching the issue of whether DSAs and Regions are *ever justifiable* in the abstract. First, it would be an inefficient use of judicial resources for this Court to address the legality of the 2017 Revised Liver policy, a policy that has not and will not go into effect, even if the Court were to set aside the July 2018 Letter. Second, the Court can consider from review of the record whether this legal determination impermissibly altered the entire compass of the review process that led to adoption of the Acuity Circles.[30] Accordingly, the Court will not remand to the agency solely on the grounds that its conclusion regarding the per se illegality of DSAs and Regions was arguably broader than necessary for HHS's ultimate decision.

[30] Additionally, Intervenors filed a lawsuit seeking a determination to the contrary more than nine months earlier than this action. While stayed, the case is still pending, *Cruz*, No. 18 Civ. 6371 (AT), ECF No. 27, and the Court might need as a matter of judicial efficiency to coordinate in some manner0 with the district court judge handling *Cruz*.

2. The Acuity Circles adoption process

a. Plaintiffs' claims regarding bad faith and predetermination

As the Supreme Court recently reiterated, "a court may not reject an agency's stated reasons for acting simply because the agency might also have had other unstated reasons." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2573, (2019) (citing *Jagers v. Federal Crop Ins. Corp.*, 758 F.3d 1179, 1185–1186 (10th Cir. 2014). Rather, agency "decisions are routinely informed by unstated considerations of politics, the legislative process, public relations, interest group relations, foreign relations, and national security concerns (among others)." *Id.*

There are, of course, limits. On the one hand, "[i]t is hardly improper for an agency head to come into office with policy preferences and ideas, discuss them with affected parties, sound out other agencies for support, and work with staff attorneys to substantiate the legal basis for a preferred policy." *Id.* at 2574. On the other hand, where predetermination leads to a "disconnect between the decision made and the explanation given," the Court is "not required to exhibit a naiveté from which ordinary citizens are free." *Id.* at 2575 (quoting *United States v. Stanchich*, 550 F.2d 1294, 1300 (2d Cir. 1977)) (internal quotations omitted). And where evidence discloses bad faith by the decisionmakers, the Court is not bound to accept the explanation given by the agency on the record, but may inquire into "the mental processes of administrative decisionmakers." *Id.* at 2573 (quoting *Overton Park*, 401 U.S. at 420).

Some of the materials cited in Plaintiffs' supplemental brief are certainly colorable evidence of animosity and even some measure of regional bias against transplant community professionals who advocated for continued use of DSAs or Regions. They show that some of these major players within the transplant community had an agenda and strongly held views in favor of new allocation policies (i.e., Acuity Circles) that aligned with their locations and institutional interests.[31] They also enjoyed particularly close access to the ear of UNOS's executives during the volatile events of 2018 and 2019.

However, Plaintiffs' proffered evidence of bad faith, undisclosed ex parte communications, and improper predetermination by Defendant UNOS is also notable for what it does not show, namely any connection to Defendant HHS's basis for its actions. As the Court has just held that the OPTN is not an agency itself, Plaintiffs must show that HHS's actions were not based on their stated rationale but instead infected by bad faith. Plaintiffs have failed to do so.[32]

One final note. As the Court held above, Defendant HHS properly based its decision to set aside the 2017 Revised Policy on the OPTN's failure to justify the policy in the June 25, 2018 letter. (HHS_00006879). On page 6 of their supplemental brief, Plaintiffs attempt to show that members of the Executive

[31] Of course, those transplant professionals with opposing views supportive of some use of DSAs or Regions that focused on different elements of the data and regulatory goals for allocation policies also had their own institutional interests that might be said to align with their locations.
[32] To the extent that HHS's decisions and policy course (or UNOS's) were triggered by litigation threats or risks, the Court cannot ipso facto determine that this assessment was arbitrary and capricious or reached in bad faith given the record in this case.

Committee who, on separate occasions expressed animosity toward Plaintiffs' position, watered down the justification for DSAs and Regions in OPTN's June 25, 2018 letter. At the time, all of the participants in the conversation were members of the Executive Board. The Court has reviewed the materials cited. (See Pls.'s Supp. Br. at 6 (citing UNOS_17652, 19009, 18655, 19158)). The materials do not show predetermination but an Executive Board balancing the prospect of discarding the 2017 Revised Policy that was the product of a great deal of work against the risk of the Intervenors' threatened lawsuit in New York, possible intrusive policy action by HHS, along with the strong views of Executive Board members who favored removal of the DSAs and Regions.

All that said, the Court recognizes that HHS, by ultimately categorically knocking out *any* OPTN consideration of the use of DSAs or Regions in its July 31, 2018 decision, in essence predetermined that OPTN could not consider any version of a DSA or Region in a new policy. And this would be so, whether or not a new proposed policy could be properly crafted to address the overarching requirements and goals of the Final Rule, underlying empirical organ specific transplant data, and other administrative empirical realities, whether in the realm of transportation, effective policy transition, etc. To this extent, the Plaintiffs are correct. But the record nevertheless does not demonstrate that HHS's decision to set aside the 2017 Revised Policy (or, for the reasons set forth

later in this Order, to refuse to set aside the Acuity Circles policy) was itself arbitrary and capricious.

b. Procedural irregularities

Plaintiffs next contend the Acuity Circles policy should have been set aside by HHS based on alleged procedural irregularities under the Final Rule. Agencies [and their contractors] must follow the rules they write: "an agency action may be set aside as arbitrary and capricious if the agency fails to 'comply with its own regulations.'" *Nat'l Envtl. Dev. Assoc.'s Clean Air Project v. E.P.A.*, 752 F.3d 999, 1009 (D.C. Cir. 2014) (citing *Environmentel, LLC v. FCC*, 661 F.3d 80, 85 (D.C. Cir. 2011)). However, the Court may not impose additional procedural rules upon an agency. "Absent constitutional constraints or extremely compelling circumstances the 'administrative agencies should be free to fashion their own rules of procedure and to pursue methods of inquiry capable of permitting them to discharge their multitudinous duties.'" *Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 543 (1978) (quoting *F.C.C. v. Schreiber*, 381 U.S. 279, 290 (1965)).

Before promulgating a policy, the Final Rule simply states that the OPTN Board shall "[p]rovide opportunity for the OPTN membership and other interested parties to comment on proposed policies[,]" and shall "take into account the comments received[.]" 42 C.F.R. § 121.4(b)(1).

The Court recounted the history of events in the timeline at the beginning of this Order but restates the relevant points here. On October 6, 2018, UNOS published a policy proposal for both Broader 2 Circle and Acuity Circles on the OPTN website and provided a three-week comment period of October 8 through November 1. HHS_00008952. Despite the contracted comment period, Defendant HHS notes that "UNOS received 1,242 comments from individuals and entities in 41 states, as well as Guam and Puerto Rico." (Def. HHS's Response at 16, Doc. 228 at ECF Page 23 (citing HHS_00009069–70)). These included more than 200 comments from patients. (HHS_00009069–70). According to Defendant UNOS, this was "among the highest volume the OPTN has ever received on a policy proposal." (Def. UNOS's Response at 11, Doc. 229 at 17).

The day the comments closed (November 1, 2018), a UNOS policy analyst circulated an Excel spreadsheet at 11:10 p.m. with most of the over 1,200 public comments Plaintiffs have fairly characterized as "virtually unreadable" because the information was compressed, the font tiny, and "multi-paged comments were pasted into a single, small cell." (HHS_00001544, HHS_00001146; Doc. 2-1) To review the Excel entries on a computer additionally required extensive time and effort on the part of any reviewer. The Liver and Intestine Committee met early the next morning, which Plaintiffs understandably contend provided an insufficient time for committee members' review of the comments provided. Furthermore, seventeen comments from major institutions submitted through

the public comment email were not provided to liver committee members. (HHS_00001542). UNOS has called this a "glitch." (Def. UNOS Resp. at 12). The Liver and Intestine Committee voted on November 2, 2018 to approve the Broader 2 Circles (B2C) Policy, though there also was considerable support for the Acuity Circles policy. (HHS_00001146).

The liver allocation policy was scheduled for Board review and action in the first days of December, with the Thanksgiving holiday break wedged in between the two meetings. On Friday, November 30, 2018, UNOS staff distributed to all OPTN Board members, including Board members associated with Plaintiffs, an amendments booklet for the Sunday-Tuesday, December 2-4 OPTN Board meeting. (HHS_00002338.) One of those amendments, Amendment 3, was to adopt the Acuity Circles model instead of the Broader 2 Circles model. (HHS_00002341, 54). At the OPTN/UNOS Board meeting on December 3, Amendment 3 adopting Acuity Circle Policy was approved. (*See* HHS_00002213).

Plaintiffs first argue that notice of the OPTN's intent to adopt the Acuity Circles policy was insufficient because the Liver and Intestine Committee had recommended Broader 2 Circles. However, UNOS sought and received comment on both policies. (HHS_00008952).[33] Further, Transplant Center Plaintiffs

[33] Considering that the Liver Committee candidly admitted "the majority of each group [of commenters] except for OPOs and histocompatibility labs strongly opposed B2C," (HHS_00008963) and that "patients as a group registered the largest support for acuity circles" (HHS_00008964), it is not shocking that the Board went with Acuity Circles over B2C. The

admit they received notice of the amendments prior to the meeting. (Doc. 232). While the Liver Committee recommended Broader 2 Circles, both possibilities were offered for comment, modeled, and properly before the Board. (HHS_00008952).

Plaintiffs next argue that UNOS failed to offer a "meaningful" opportunity for comment because "the abbreviated three-week timeframe for public comment did not allow sufficient time to make all interested patients aware of proposed changes that would affect their lives." (Renewed Br. at 21, Doc. 216-1 at ECF Page 30 (citing HHS_00002258)). However, this contention seems belied by the volume of comments received, including those received from patients. (HHS_00008963). In light of the fact that a substantial number of comments were actually received, the Court is reluctant to engage in line drawing about the proper length of a comment period, as this would necessarily mean imposing post hoc procedural rules not required by the statute or regulation. *Vermont Yankee*, 435 U.S. at 543.

The Court is troubled by the fact that seventeen comments from major transplant institutions submitted through the public comment email were not provided to Liver Committee members. (HHS_00001542.) This is in addition to the fact that the Liver Committee met the day after the comment period closed and was expected to digest a "virtually unreadable," 1,200-comment spreadsheet

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Liver Committee membership principally or exclusively draws on professionals in the liver/intestine field.

overnight. (HHS_00001544, HHS_00001146.) However, these defects, though serious and reflective of an administratively rushed review process driven by Defendants' self-imposed December 2018 deadline, do no alone ultimately undermine the Acuity Circles policy's adoption process. The OPTN Board, not the Liver Committee, is ultimately responsible for taking into account public comments, and there is no dispute that the OPTN Board did have access to the full range of comments provided in the comment period when it cast its vote in favor the Acuity Circles policy. That said, the comment and review process was managed in a rushed time frame and manner that bred ill will and the sense of railroading to a "predetermined" policy end line among those who favored alternatives.

3. The merits of the Acuity Circle policy

At last, the Court reaches the merits of the Acuity Circles policy. As the court noted above, an agency action may be found arbitrary and capricious:

> where the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Miccosukee Tribe, 566 F.3d at 1264 (quoting *Alabama–Tombigbee*, 477 F.3d at 1254). Stated simply, "a reviewing court may not set aside an agency rule that is rational, based on consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute." *State Farm*, 463 U.S. at 42.

The arbitrary and capricious standard is "exceedingly deferential." *Defenders of Wildlife*, 733 F.3d at 1115 (citing *Fund for Animals, Inc. v. Rice*, 85 F.3d 535, 541 (11th Cir. 1996)). Furthermore, the Court "has limited discretion to reverse an agency's decision when it 'is making predictions, within its area of special expertise, at the frontiers of science . . . as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.'" *Georgia Aquarium, Inc. v. Pritzker*, 135 F. Supp. 3d 1280, 1291 (N.D. Ga. 2015) (citing *Defenders of Wildlife*, 684 F.3d at 1248–49).

The "relevant factors" for the purpose of allocation policies are found in the Final Rule, 42 C.F.R. §§ 121.4 and 121.8, which the Court has reproduced in relevant part above. A discussion of the Acuity Circles policy is in the initial background Section of this Order.

a. The risk of wasting organs

Plaintiffs assert that the Acuity Circles policy does not comply with the Final Rule because Plaintiffs contend that it was not "designed to avoid wasting organs . . . and to promote the efficient management of organ placement." 42 C.F.R. § 121.8(a)(5). Plaintiffs' primary contention is that Defendants have failed to account for the logistical concerns associated with broader distribution. UNOS has admitted that "[t]he modeling report provided to the Liver Committee and the Board predicted the Acuity Circles policy will increase the percentage of livers flown from 53.8-54.9% to 71.4-74%." (HHS_00000038). This was a significant

leap. Plaintiffs assert that increased liver flights will lead both to increased wastage because pilots are not always available to fly on short notice, and to increased costs. The OPTN's Operations and Safety Committee conducted a survey of OPOs and transplant centers with respect to the likely increase in air travel. (HHS_00009060). A not insignificant minority of hospitals stated that they had at some point been unable to find pilots or planes for organ recovery or transport, and 59.2% of respondents stated that pilot duty hour restrictions have influenced recovery. (HHS_00009063). However, the majority of respondents reported that they had generally been able to find pilots and planes for recovery and organ transplant under the then existing allocation policy. (*Id.*)

Defendants point to UNOS's Executive Summary, dated December 13, 2018 in response. In the Executive Summary, UNOS notes that prior policy changes that resulted in more organs being flown "resulted in an increase in the number of livers transplanted and no increase in the number of discarded organs." (HHS_00008947). UNOS further notes that SRTR's models, did not predict any "substantial decrease in the number of organs transplanted" and the Board determined that it was therefore "logical to infer that there will be no negative impact on the number of organs discarded." (*Id.*).

In UNOS's response to Plaintiffs' February 2019 Critical Comment, UNOS also noted that the Acuity Circles model increases median travel time from 1.7 hours under the 2013 Current Policy to 1.9 hours, but stated that this was

clinically insignificant when accounting for a recommended 6 hour cold ischemic time (CIT), meaning the time between procuring the organ from the donor and re-starting blood supply upon transplanting the organ into the recipient. (HHS_00000038).

However, Plaintiffs criticize this finding as a post hoc rationalization, and contend that SRTR did not take into account pilot and plane shortages. While the Court disagrees with Plaintiffs' characterization of the justification as "post hoc,"[34] Plaintiffs' points here bear serious consideration. There is no question that the Defendants were aware of the fact that Acuity Circles would increase organ flights, and were aware of the concern that this would increase organ wastage, as well as logistical challenges and costs. Defendants did address the concerns, although it may be fair to say they were perhaps overly optimistic that things simply would "work out." However, between the findings of the Operations and Safety Committee, the SRTR data about increased travel time, and Defendant's historic experience with rolling out broader sharing policies, the Court cannot say that the decision is contrary to any evidence or rationales before the agency. Defendants understood that Acuity Circles would present difficulties related to air travel and potential liver wastage, but brought their medical

[34] The fact that the Executive Summary was prepared a week after the decision itself does not render the Executive Summary an improper post hoc justification, because the Executive Summary was generated prior to Plaintiffs' critical comment and was considered by HHS in response to the comment. It is therefore not akin to litigating positions adopted by counsel which are properly disregarded by the Court. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156 at 168 (1962).

experience to bear in determining that the potential benefits of broader sharing outweigh the difficulties and risks. The Court is unable to disturb this administrative judgment. *Georgia Aquarium*, 135 F. Supp. 3d at 1291.

b. Transition patient protections

Plaintiffs argue that the Acuity Circles violates the Final Rule based on UNOS's failure to consider transition patient protections. An agency action is arbitrary and capricious where the agency "entirely failed to consider an important aspect of the problem." *Miccosukee Tribe*, 566 F.3d at 1264. Under the Final Rule, "[w]hen the OPTN revises organ allocation policies under this section, **it shall consider** whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies." 42 C.F.R. § 121.8(d)(1) (emphasis added). In the July 2018 Letter, HHS provides that UNOS "may also implement transition patient protections," but does not require their adoption. (HHS_00004991). There does not appear to be any dispute that UNOS did not adopt a transition procedure under this section. However, the parties dispute whether transition procedures were considered by UNOS at all. The Liver Committee passingly referenced paragraph 121.8(d) in its briefing paper, justifying its selection of a 500 nautical mile circle as the initial unit of allocation:

> [t]he Committee wanted to make sure that candidates who would currently have access to livers within 500 nautical miles of the donor

> hospital would continue to [have access]. . . . The committee did consider the impact on currently waiting candidates and did not want to place them in a position to be treated less favorably than they already are.

(HHS_00008975). Plaintiffs contend that this merely referenced the requirement, and does not constitute "consideration." Furthermore, Plaintiffs also point out that the Liver Committee made this contemplation in the context of the Broader 2 Circles policy, which was never adopted.

Defendants contend that Plaintiffs have waived the right to make this argument by failing to raise it in their February 2019 Critical Comment and Complaint. In some ways, the transition issue goes to the heart of Plaintiffs' dispute with broader sharing – that other regions were using inflated MELD scores and that eliminating DSAs and Regions would result in a potential flood of organs transferred outside of the region. However, in this case, Defendants are correct that Plaintiffs failed to preserve the absence of adequate consideration of transition plans for judicial review.

Neither the word "transition," nor a citation to 121.8(d) appear anywhere in Plaintiffs' February 2019 Critical Comment, nor their Complaint (Doc. 1), nor even their original Brief in Support of Motion for TRO (Doc. 2-1). Plaintiffs defend this omission by stating that "with regard to OPTN's failure to consider transition patient procedures, that failure has only become clear with the development of the record." (Pls.'s Reply Br. at 4). However, there is no reason that Plaintiffs could not have raised this issue before HHS in their critical

comment; the policy itself was public. Doing so would have given UNOS the opportunity to respond in their March 26,2019 letter (HHS_0000026) and potentially commit to adopting a transition policy that would have at least mitigated the immediate adverse impact of the change in policy on patients whose status on the waitlist would be negatively altered.

The Court is concerned about the absence of a transition policy – and indeed pursued questions about transition policy issues in the original preliminary injunction hearing. There is every reason that UNOS should still promptly adopt such a policy, even after implementing the Acuity Circles policy. But the absence of a transition policy is not fatal to the allocation policy.

c. Socioeconomic status

The Final Rule requires that the OPTN develop policies that "reduce inequities resulting from socioeconomic status," including the "[r]eform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities." 42 C.F.R. § 121.4(a)(3). However, this requirement is not among those factors listed in the Section 121.8(a) which are required to be taken into account in every allocation policy. Accordingly, UNOS has taken the position that "this requirement does not specify that all proposals specifically reduce inequities." (HHS_00000032).

Defendant UNOS contends that it relied on SRTR to model the impact of the Acuity Circles policy to "ensure that the policy would not have unintended

negative effects on socioeconomically disadvantaged candidates." (HHS_00000033). Defendants contend that the data show that "the Acuity Circles policy would decrease waitlist mortality rates across all types of communities, including those that generally display the lowest socioeconomic status." (HHS_00009872). This conclusion is based on the Cumulative Community Risk Scores ("CCRS"), which "evaluates communities based on a variety of health factors, including birth weights, number of poor health days, obesity rates, preventable hospital stays, illiteracy rates, and median household income, among others." (Pls.'s Renewed Mot. Ex. 1, Aff. Lynch ¶ 25, Doc. 215-2 at ECF Page 15). Plaintiffs point out that the SRTR data also show that Acuity Circles will decrease transplants per year for the highest-CCRS communities. (HHS_00009860). SRTR responded that because Acuity Circles is acuity-based, it prioritized sicker candidates and that "[i]f the candidates in some region have reduced priority under the Acuity Circles policy, that suggests that those candidates are currently benefitting from region - or DSA-based restrictions on the shipment of organs and that there are higher priority candidates nearby." (HHS_00000045). HHS, having reviewed SRTR's response, rejected Plaintiffs' critical comment. However, Plaintiffs' critical comment raised credible issues regarding the reliability of this specific SRTR analysis, considering the context of differential regional practices as to the application of exception points as well as other relevant data. Review of the Plaintiffs' critical comment and SRTR and

OPTN responses leads the Court to presume that consistent with the Final Rule, further analysis and potential modifications in the policy will be required in connection with this and other impacts requiring monitoring under the Rule, as the Acuity Circles policy is implemented in the months ahead.

Transplant organs are a limited good. Congress and HHS entrusted the OPTN to make tough decisions about allocation by providing factors for them to consider, but it is impossible that a given policy will always favor every factor. In adopting the Acuity Circles policy, the OPTN prioritized broader distribution over increasing transplants in areas with lower socio-economic status, envisaging that this would lead to sicker patients receiving more transplants nationwide. In fact, "[d]istributing organs over as broad a geographic area as feasible under paragraphs (a)(1)–(5) of [Section 121.8], and in order of decreasing medical urgency" is an explicit "allocation performance goal" by which HHS measures the OPTN's performance in its duties. This is exactly the type of determination "within [a policymaker's] area of special expertise, at the frontiers of science" where this Court "must generally be at its most deferential.'" *Georgia Aquarium*, 135 F. Supp. 3d at 1291.

d. SRTR data

Relatedly, Plaintiffs contend that Defendants ignored red flags with SRTR's data. Plaintiffs contend that "[b]ased on the DSA-level SRTR analysis in the administrative record, HHS_00009286-87, the SRTR predicts that 30 DSAs will

collectively lose a total of 519 liver transplants annually. But in those DSAs, the waitlist mortality prediction is only 7 more deaths per year. This absurd result should have caused Defendants to inquire about the coding underlying the model's output to assess its reliability." (Pls.'s Renewed Br. at 26–27, Doc. 216-1 at ECF Page 35–36). However, SRTR responded to these concerns in response to Plaintiffs' February 2019 Critical Comment. As Defendants point out, "[t]he SRTR's model predicted that the Acuity Circles policy would result in livers being shared more broadly, and, as a result, more patients with high levels of medical urgency would receive transplants." (Def. HHS's Resp. at 19, Doc. 228 at ECF Page 26 (citing HHS_00000036)). Essentially, by allocating livers to sicker patients, SRTR estimated that fewer patients would die *in the "short run."* (HHS_0000043 (emphasis provided)). Whatever the advantages or deficiencies of this strategy as a transplant policy, HHS, with the benefit of this response, declined to set aside the Acuity Circles policy. As the Court has held, neither UNOS nor HHS must analyze the SRTR's underlying data and algorithms to survive judicial review. SRTR is a "separate organization tasked with providing data support . . . . Were UNOS or HHS to review the code from scratch, it would defeat the purpose of SRTR." (Doc. 206 at 10).

e. "Candidates" vs. "Patients"

Plaintiffs contend that Defendants "entirely failed to consider an important aspect of the problem," by designing the Acuity Circles policy to promote access

to waitlisted candidates, rather than patients. *State Farm*, 463 U.S. at 43. Section 121.8(a)(5) states that "policies for the equitable allocation of cadaveric organs among potential recipients . . . shall be designed . . . to promote patient access to transplantation."

Defendant UNOS responds that the purpose of The National Organ Transplant Act is establishing a list to match organs to individuals on the list. (Def. UNOS Resp. at 20, Doc. 229 at 25 (citing 42 U.S.C. § 274(b)(2)(A)(i)–(ii)). Because under the Final Rule "[o]rgans may be offered only to potential recipients listed with the transplant programs," UNOS contends that promoting "patient access" means increasing the availability of donor organs to waitlisted transplant candidates. 42 C.F.R. § 121.7(b)(2).

This strikes the Court more as a policy judgment than one of regulatory interpretation. Defendants, in developing allocation policies properly and wisely under the Final Rule, could focus on lowering barriers to getting patients on the waitlist. *See, e.g.*, 42 C.F.R. § 121.4(a)(3)(i) (providing that the OPTN shall develop policies for "[e]nsuring that payment of the registration fee is not a barrier to listing for patients who are unable to pay the fee."). However, how Defendants prioritize the OPTN's policymaking responsibilities once again is a matter to which they are entitled to deference, whether or not the Court agrees with Defendants' prioritization.

For the foregoing reasons, the Court finds that Defendants did not act arbitrarily or capriciously in adopting the Acuity Circles policy and refusing to act on Plaintiffs' February 2019 Critical Comment.

C. Did the adoption of the Acuity Circles policy violate the Due Process Clause?

The final part of the Court's opinion deals with Plaintiffs' Due Process claims. While the Due Process Clause of the Fifth Amendment only constrains the Federal Government, "actions of private entities can sometimes be regarded as governmental action for constitutional purposes." *Lebron*, 513 U.S. at 378.

The Court has already exhaustively considered whether the OPTN is an agency for the purpose of the Administrative Procedure Act. However, the Supreme Court has made clear that the test for state action is broader (though perhaps "not . . . a model of consistency.") *Id.* (quoting *Edmonson v. Leesville Concrete Co.*, 500 U.S. 614, 632 (1991) (O'Connor, J., dissenting)). What is clear from the relevant case law is that an entity can be a state actor for the purpose of the Constitution's guarantees of individual rights but not for other purposes. *Id.* at 392.

Furthermore, even if an entity is not considered a governmental entity, the actions of a private entity can be considered "state action" under a handful of different "tests:"

> In particular, three tests are typically used to determine whether an entity will be considered a state actor: (1) whether the actor is engaged in a public function; (2) whether there is a sufficiently close

> nexus between the actor and the government; and (3) whether government authority aggravates or promotes the harm caused by the private action.

Mintz, *Analyzing the OPTN Under the State Action Doctrine - Can UNOS's Organ Allocation Criteria Survive Strict Scrutiny?*, 28 Colum. J.L. & Soc. Probs. 339, 358–59 (1995); *see also Nat'l Broad. Co. v. Commc'ns Workers of Am., AFL-CIO*, 860 F.2d 1022, 1026 (11th Cir. 1988).

Even if Plaintiffs can show state action, they must still show "a deprivation of a constitutionally-protected [life,] liberty or property interest" and "constitutionally-inadequate process." *Arrington v. Helms*, 438 F.3d 1336, 1347 (11th Cir. 2006) (citing *Grayden v. Rhodes*, 345 F.3d 1225, 1232 (11th Cir. 2003)). "An essential principle of due process is that a deprivation of life, liberty, or property 'be preceded by notice and opportunity for hearing appropriate to the nature of the case.'" *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985) (quoting *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 313 (1950)). "[E]ven in a rulemaking proceeding when an agency is making a 'quasi-judicial' determination by which a very small number of persons are 'exceptionally affected, in each case upon individual grounds,' in some circumstances additional procedures may be required in order to afford the aggrieved individuals due process." *Vermont Yankee*, 435 U.S. at 542 (quoting *United States v. Florida East Coast R. Co.*, 410 U.S., at 242–245, 93 S.Ct., at 819–821) (internal quotations omitted).

Plaintiffs contend that patients on a government-established waitlist for donor organs have a life interest in their expectation of receiving an organ. (Pls.'s Renewed Br. at 42, Doc. 216-1 at ECF Page 51).[35] Plaintiffs further contend that Defendants deprived them of this interest without adequate procedures by failing to notify the public that the OPTN Board was still considering adopting the Acuity Circles policy despite the Liver Committee's adoption of the B2C model, and by adopting the Acuity Circles policy under a "truncated timeline" with "abbreviated procedures." (*Id.* at 44).

Assuming without deciding for present purposes that the Acuity Circles policy is state action, Plaintiffs' due process claim poses a thought-provoking issue. Patient Plaintiffs do not contend that they have a property interest in livers not yet transplanted, nor could they. Plaintiffs do not appear to contend that they have a property interest in their position on the waitlist. *Cf., e.g*, *Kabando v. Prince William Cty. Office of Hous. & Human Dev.*, No. 1:15CV1040(JCC/JFA), 2015 WL 7283116, at *5 (E.D. Va. Nov. 17, 2015) (finding no "cognizable property right" to be called from housing voucher waitlist).[36]

Instead, as noted above, Plaintiffs frame their protected due process interest as a "life" interest in their "expectation of receiving an organ, such that a state action that substantially diminishes their chance of receiving a life-

[35] Plaintiffs did not address in their Renewed Brief Defendants' alleged violated the constitutional rights of Transplant Center Plaintiffs, but did previously.

[36] As Plaintiffs have not attempted to frame their claims as a property interest in a waitlist position, the Court takes no position on the correctness of this line of cases.

sustaining organ deprives them of a 'life' interest cognizable under the Due Process Clause."

The Tenth Circuit's decision in *Johnson by Johnson v. Thompson*, 971 F.2d 1487, 1490–91 (10th Cir. 1992) is instructive. That case involved a hospital which conducted a study on infants born with myelomeningocele (MM), a type of spina bifida. As part of the 5-year study, the

> MM team recommended 'vigorous treatment,' i.e., surgery and antibiotics, for thirty-six of the infants. One of these infants later died of unrelated causes; the rest survived. The team recommended 'supportive care,' i.e., no treatment other than making the infants as comfortable as possible, for the remaining thirty-three infants. The parents of five infants in the latter group rejected the recommendations, and three of these infants survived. Several other infants survived without treatment for several months and were subsequently treated. The remaining twenty-four infants receiving supportive care died.

Id. at 1941. Parents of infants who received supportive care filed a class action lawsuit alleging constitutional claims. The district court directed a verdict in favor of the hospital, and the Tenth Circuit affirmed. The Tenth Circuit noted that the "Due Process Clause does protect an interest in life," *id.* at 1495 (citing *Cruzan v. Director, Mo. Dep't of Health*, 497 U.S. 261, 271 (1990), but that it "does not follow, however, that the state necessarily has a constitutional duty to take affirmative steps to preserve life." *Id.* (citing *DeShaney v. Winnebago County Department of Social Services*, 489 U.S. 189 (1989)). Accordingly, the Tenth Circuit concluded the hospital did not violate the constitutional rights of

the infants by not providing treatment. Still, affirmative national transplant policies might place the instant case in a different posture.

Plaintiffs primarily rely on the Supreme Court's decision in *Cruzan*, 497 U.S. at 271. However, that case is distinguishable. *Cruzan* involved state interference in decisions to administer or withhold medical treatment to incapacitated persons. 497 U.S. at 271. The case does not support Plaintiffs argument that Patient Plaintiffs have a life interest in their opportunity to receive a donor liver.

The Court only addresses the very narrow question of whether a transplant candidate on the waiting list has a "life" interest in receiving a donor organ. The Court is not addressing whether Plaintiffs may be entitled to constitutional due process on some other theory, or whether other provisions of the constitution apply to the waitlist, assuming state action. *See Mintz*, 28 Colum. J.L. & Soc. Probs. at 384 (equal protection).

Even if Plaintiffs hold a protected interest in their waitlist expectation, they have not shown that Defendants deprived them of due process. As the Court found above, the Final Rule requires the OPTN "[p]rovide opportunity for the OPTN membership and other interested parties to comment on proposed policies[,]" and shall "take into account the comments received[.]" 42 C.F.R. § 121.4(b)(1). This aspect of the Final Rule provides "notice and opportunity for hearing appropriate to the nature of the case.'" *Mullane*, 339 U.S. 306 at 313.

Having held above that Defendants complied with that section of the Final Rule, the Court necessarily also holds that Patient Plaintiffs received adequate notice and an opportunity to be heard.[37] For these reasons, the Court need not reach the question of state action.

V. Conclusion

As the Court has found that Plaintiffs have not shown a substantial likelihood of success on the merits of their claims, the Court need not address the remaining factors for injunctive relief. Therefore, Plaintiffs' Motion for Preliminary Injunction (Doc. 216) is **DENIED**.[38]

But this is a difficult and wrenching case. As the Court has recognized from the outset, there are extraordinarily complex and compelling issues raised by the conflicts at the heart of organ transplant litigation. Unfortunately, the manner in which the liver transplant policy change was driven in this case made the capacity of the affected institutions to effectively and preemptively address these complexities and policy tensions together all the more difficult. Acrimony boiled over under these circumstances. Still, the OPTN process provides a route for further modifications of the policy adopted with the benefit of ongoing monitoring, data collection, and analysis. The implementation of transition measures to mitigate disruption and patient harm as the new Acuity Circles

[37] Patient Plaintiffs did not receive advance notice of the Acuity Circles amendment as Transplant Center Plaintiffs admittedly did (Doc. 232). However, UNOS sought and received comment, including from patients, on both policies. (HHS_00008952).

[38] Plaintiffs' Motion to Supplement the Record is **GRANTED** in part and **DENIED** in part.

policy is implemented should be an essential priority, at least from the Court's perspective, whether or not there is an appeal in this case. Other changes may be warranted too. But that is an observation, not an order.

Entered this 16th day of January, 2020.

Amy Totenberg
United States District Judge