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

ADVENTIST HEALTH SYSTEM/SUNBELT, INC. d/b/a ADVENTHEALTH ORLANDO; BOARD OF TRUSTEES OF THE UNIVERSITY OF ALABAMA for and on behalf of THE UNIVERSITY OF ALABAMA HOSPITAL; MEDICAL UNIVERSITY HOSPITAL AUTHORITY; UNIVERSITY OF IOWA; UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, a body politic and corporate and an independent instrumentality of the State of Kansas; UNIVERSITY OF KENTUCKY; and ALEXANDER BERRIOS, JR., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; NORRIS W. COCHRAN, IV,[1] in his official capacity as Acting Secretary of the United States Department of Health and Human Services; HEALTH RESOURCES AND SERVICES ADMINISTRATION; THOMAS J. ENGELS, in his official capacity as Administrator of the Health, Resources and Services Administration; and UNITED NETWORK FOR ORGAN SHARING, Defendants.	)	Case No. 3:20-cv-00101-SMR-SBJ ORDER DENYING PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

[1] Plaintiffs commenced this action naming Alexander M. Azar, II, then-Secretary of the United States Department of Health and Human Services. [ECF No. 1]. On January 20, 2021, Mr. Azar stepped down from his position and Norris W. Cochran, IV, was elevated to serve as the Acting Secretary. Pursuant to Rule 25(d) of the Federal Rules of Civil Procedure, Acting Secretary Cochran is automatically substituted for Mr. Azar as a defendant.

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This lawsuit is brought under the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*, and challenges a nationwide policy governing the allocation of transplant kidneys. Plaintiffs move for a temporary restraining order and preliminary injunction to stay the policy's anticipated March 14, 2021 implementation. Because the balance of factors necessary to obtain preliminary relief weigh decisively against granting an injunction, Plaintiffs' Renewed Motion for Temporary Restraining Order and Preliminary Injunction, [ECF Nos. 3; 54], is DENIED.

I. BACKGROUND[2]

A. Statutory and Regulatory Framework

"In the United States, organ transplants are a public-private affair." *Callahan v. U.S. Dep't of Health and Human Servs.*, 939 F.3d 1251, 1254 (11th Cir. 2019) (*Callahan II*). Congress established a national organ transplant infrastructure in 1984 by enacting the National Organ Transplant Act of 1984, Pub. L. 98-507, 98 Stat. 2339 (Oct. 19, 1984) (codified as amended at 42 U.S.C. § 273 *et seq.*) (the "Transplant Act" or "Act"). The Act directed the Secretary ("Secretary") of Health and Human Services ("HHS") to establish and operate the Organ Procurement and Transplant Network ("OPTN" or the "Network"), an entity with "expertise in

[2] For purposes of this Order the factual background is derived from the exhibits submitted in support of Plaintiffs' motion, as well as those filed in opposition. *See generally* [ECF Nos. 4-2 (Carrell Aff.); 31-1 (Walsh Decl.); 32-1 (Carter Decl.); 59-3 (Carrell Aff.); 67-5 (Drezner Decl.); 68-1 (Carter Decl.)]. Due to the unorthodox manner in which Plaintiffs filed their supporting documents, the Court will reference the specific exhibit number in addition to citing the electronic docket entry.

organ procurement and transplantation" that is tasked with maintaining a national list waitlist of individuals in need of organs and assisting in their "nationwide distribution . . . equitably among transplant patients." 42 U.S.C. § 274(a), (b)(1)(A)–(B), (b)(2)(D).

The OPTN is a membership organization that was established to be "operated by the transplant community . . . with oversight by HHS." Final Rule for the Organ Procurement and Transplantation Network, 63 Fed. Reg. 16,296, 16,297–98 (proposed Apr. 2, 1998) (codified at 42 C.F.R. pt. 121). It is governed by a Board of Directors that is made up of representatives from transplant centers, physicians, organ candidates, donors, and recipients, along with organ procurement organizations ("OPOs"), voluntary health associations, and members of the general public. 42 U.S.C. § 274(b)(1)(B); 42 C.F.R. § 121.3(a)(1). Members include OPOs, transplant hospitals, and other institutions or individuals with an interest in organ donation. 42 C.F.R. § 121.3(b)(1). Various committees formed by the OPTN serve to address distinct areas of transplantation, often organized by organ type. *See id.* § 121.3(a)(4). United Network for Organ Sharing ("UNOS") is the private nonprofit entity that has been designated to serve as the Network for the last thirty-five years. *Callahan II*, 939 F.3d at 1255.[3] Federal oversight of the Network's nationwide organ transplant policies is conducted by the Health Resources and Services Administration ("HRSA"), an agency within HHS. *See* 42 U.S.C. § 274c.

HHS's implementing regulation—the "Final Rule" (42 C.F.R. Part 121)—provides the framework under which OPTN develops policies in fulfillment of its statutory mission. Generally, OPTN policy changes under consideration may be adopted only after solicitation and consideration of public comments by members and other interested parties. *Id.* § 121.4(b)(1). Any interested

[3] The OPTN Board consists of the same individuals who are elected to serve on UNOS's Board. [ECF No. 4-4 at 214] (Pls.' Ex. 31 at 18, OPTN Bylaws § 2.8).

party may submit to the Secretary a "critical comment" in response to OPTN policies or practices. 42 C.F.R. § 121.4(d). After soliciting the OPTN's response to the issues raised in a critical comment and considering whether the policy or practice is consistent with the Transplant Act, the Secretary may (1) reject the comment; (2) direct the OPTN to revise the policy or practice; or (3) take any other appropriate action. *Id.* Under limited circumstances that will become relevant later in this Order, the Secretary is required to refer certain "significant proposed policies" to the Advisory Committee on Organ Transplantation ("ACOT" or the "Advisory Committee"), publish them in the Federal Register for public comment, and determine their consistency with the Transplant Act. *See id.* § 121.4(b)(2); *Callahan II*, 939 F.3d at 1258.

Recognizing that "[h]uman organs that are given to save lives are a public resource and a public trust," 63 Fed. Reg. at 16,300, HHS developed the Final Rule "to ensure that donated organs are equitably allocated among all patients, with priority to those most in need in accordance with sound medical judgment," *id.* at 16,298. The Final Rule charges the OPTN with developing, among other things, "[p]olicies for the equitable allocation of cadaveric organs in accordance with § 121.8." 42 C.F.R. § 121.4(a)(1). Section 121.8, in turn, provides substantive regulations mandating that organ allocation policies:

> (1) Shall be based on sound medical judgment;
>
> (2) Shall seek to achieve the best use of donated organs;
>
> (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);
>
> (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
>
> (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

> (6) Shall be reviewed periodically and revised as appropriate;
>
> (7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and
>
> (8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5) of this section.

Id. § 121.8(a). This substantive regulation then requires that the organ allocation policies be developed "in accordance with the policy development process described in § 121.4." *Id.* To ensure organ allocation policies are scientifically sound, the Transplant Act created the Scientific Registry of Transplant Recipients ("SRTR") to provide statistical and analytic support services to HHS and the OPTN. *See* 42 U.S.C. § 274a.

B. The Dispute Over Organ Allocation Policy

1. Overview

Historically, donated organs have been distributed to candidates based on a system involving two different geographic criteria: "Donation Service Areas," or "DSAs" (fifty-eight smaller areas within and among states) and "Regions" (eleven groupings of DSAs within a collection of states). [ECF No. 57-1 at 331–33] (Pls.' Ex. 23); [ECF No. 56-1 at 320] (Pls.' Ex. 10 at 1 nn.2–3). Neither are correlated with population, transportation logistics, or medical need, and thus are not designed to optimize equitable organ distribution. *See* [ECF No. 57-1 at 331–33] (Pls.' Ex. 23). Each DSA is operated by one OPO, which is certified by HHS to obtain donor organs within their area and necessarily develops relationships and protocols with the medical facilities operating within their area of coverage. *See* [ECF No. 57-1 at 331] (Pls.' Ex. 23).

Regions are simply "the collection of DSAs in which there were historical relationships between the OPOs and transplant hospitals." *Id.*

Under current policy employing DSAs, donated organs are offered first to candidates listed at hospitals within the same DSA as the donor hospital. Organ offers not accepted by candidates within the same DSA are then made to candidates within the same Region as the donor hospital. Those not accepted by patients within the same DSA or Region are then offered to candidates listed at hospitals anywhere else in the United States. Thus, organ allocation under a DSA–Region regime necessarily tends to favor local distribution of donated organs. *See* 63 Fed. Reg. at 16,311 (describing "the 'local first' feature" as "the most controversial aspect of current allocation policies"); *cf. id.* at 16,314 (observing "differing opinions over the issue of broader [organ] sharing" and the views of commentators that "local preference draws upon, and reinforces, close bonds among local organ procurement organizations and local hospitals and physicians").

The use of DSAs and Regions has been the subject of a longstanding debate on geography-based organ allocation policy. *See* 63 Fed. Reg. at 16,311 (describing how the "local first" feature "creates inequities in access for organs among patients of equal medical urgency" because it "makes where [patients] live or list a more important factor than objective measures of medical status in obtaining an organ"). Indeed:

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

Callahan II, 939 F.3d at 1255. Even when HHS first drafted the Final Rule in 1998 the agency recognized that "[r]eliance on boundaries that make sense for administrative convenience may lead to inequities in organ allocation criteria." 63 Fed. Reg. at 16,313. Since 2010, ACOT has recommended the Secretary "take steps to ensure the OPTN develops evidence-based allocation policies which are not determined by arbitrary administrative boundaries such as OPO service areas, OPTN regions[,] and state boundaries." [ECF No. 68-2 at 2] (UNOS Ex. 14) ("ACOT believes that the current status does not comply with the intent of the [OPTN] Final Rule . . . . The OPTN must seek to minimize inequities due to arbitrary geographic barriers to distribution."). And even as recently as 2017 the OPTN Board has expressed skepticism that the use of DSAs as a distribution metric was consistent with the equity-based policy embraced by the Final Rule. *See* [ECF No. 68-3 at 2] (UNOS Ex. 15). Predictably, the dispute boils down to money: "some hospitals and their patients reap the benefits of . . . highly productive OPO[s] and they are concerned that they may receive fewer organs under a national system." 63 Fed. Reg. at 16,314.

2. The "Liver Litigation" and the July 31, 2018 Directive

The genesis of the present litigation surrounding the kidney allocation policy actually lies in earlier changes made to *liver* allocation policy. *See generally Callahan v. U.S. Dep't of Health and Human Servs.*, 434 F. Supp. 3d 1319, 1361 (N.D. Ga. 2020) (*Callahan III*). In December 2017, OPTN approved and published for public comment a new liver allocation policy that continued to rely on DSAs but reduced their importance in the distribution scheme. *See* [ECF No. 56-1 at 297–99] (Pls. Ex. 9). In response, a group of patients awaiting liver transplants in New York filed a critical comment with the Secretary of HHS, criticizing the continued use of DSAs in liver-allocation determinations and contending that current practice employing them as units of allocation violated the law by impermissibly imposing arbitrary geographic restraints. *Id.*

at 296–97; *see also* 42 C.F.R. § 121.8(a)(8) (prohibiting organ allocation policies from being "based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5)"). In a June 8, 2018 letter, HHS solicited the OPTN's response and asked for the Network's views on the continued use of DSAs and Regions in liver allocation. [ECF No. 32-4 at 3–4] (UNOS Ex. 3).

The OPTN responded in a letter on June 25, 2018. [ECF No. 32-5 at 3] (UNOS Ex. 4). The letter defended the revised liver policy as being based on sound medical judgment that prioritized medically urgent candidates and employed DSAs as one of several units of geographical allocation, distinguishing its 2017 review of the lung allocation policy that had previously relied exclusively on DSAs to the detriment of other interests embodied in the Final Rule. *Id.* Yet, the OPTN recognized that "DSAs are not a good proxy for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs . . . are not rationally determined in a manner that can be consistently applied equally for all candidates." [ECF No. 32-5 at 3] (UNOS Ex. 4). The OPTN stated its goal for future policy development was to "identify a single framework that once implemented over time will provide consistency across all organ types" and work towards "eliminat[ing] DSA or OPTN Regional boundaries as a component of distribution and utilize a different tool for incorporating proximity restrictions" that would be more consistent with the Final Rule's prohibition against basing allocation policy on a transplant candidate's location. *Id.* at 6.

On July 31, 2018, HRSA issued a letter disowning the legality of Regions and DSAs in liver allocation policies, announcing that although "geographic constraints may be appropriate if they can be justified" in light of satisfying other regulatory organ allocation priorities, "DSAs and Regions have not and cannot be justified" under the requirements of the Final Rule. [ECF No. 56-1

at 322] (Pls. Ex. 10) (the "July 31, 2018 Directive" or the "Directive"). Disclaiming "any particular policy outcome or allocation scheme," the agency directed the OPTN Board to "adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions and that is compliant with the OPTN [F]inal [R]ule." *Id.* But HRSA did not limit its finding to liver allocation policies—it went further, concluding that "the use of DSAs and Regions *in all other (non-liver) organ allocation policies* has not been and cannot be justified" under the Final Rule, either, because "the problems associated with DSAs and Regions are not limited to liver allocation." *Id.* at 324 (emphasis added). HRSA observed that its findings were consistent with those of the OPTN, noting that the Network had already "committed to eliminating the use of DSAs and Regions from all OPTN allocation policies" in future policymaking. *Id.* at 324. Exercising its oversight role, the agency further directed the OPTN Board to submit a detailed report outlining the "the OPTN's plans to eliminate DSAs and Regions from other (non-liver) organ-specific allocation policies" to ensure its proposed policies satisfied the equitable requirements of the Final Rule. *See id.* at 324.

A group of transplant hospitals, several of which are also Plaintiffs in this suit, opposed the revision to the liver allocation policy eliminating DSAs and Regions in a critical comment to the Secretary on February 13, 2019. *See Callahan III*, 434 F. Supp. 3d at 1334. When the Secretary declined to take action, they challenged the procedural development and substance of the proposed policy in federal court (the "Liver Litigation"). *Id.* The hospitals sought a temporary restraining order enjoining the implementation of the modified liver allocation policy, which the district court denied. *Callahan v. U.S. Dep't of Health and Human Servs.*, No. 1:19-cv-1783-AT, 2019 WL 3539815, at *2, *4 (N.D. Ga. May 14, 2019) (*Callahan I*). The United States Court of Appeals for the Eleventh Circuit affirmed, concluding the hospitals had "failed to demonstrate a substantial likelihood of success on the merits of their contention that HHS neglected to follow legally

required procedures during the new liver-allocation policy's development." *Callahan II*, 939 F.3d at 1257. On remand, the district court rejected the substantive claims made by the hospitals and concluded the modified liver allocation policy was not arbitrary and capricious. *Callahan III*, 434 F. Supp. 3d at 1359–71.[4]

3. Development of the Kidney "Fixed Circle Policy"

Meanwhile, revisions to other organ allocation policies were also underway. Following the July 31, 2018 Directive, the OPTN Kidney Committee published a paper proposing organ allocation policies based on varying "concentric-circle" models. [ECF No. 32-6 at 4, 8–30] (UNOS Ex. 5). After considering detailed statistical data modeling from the SRTR, [ECF Nos. 61-1; 61-2; 61-3; 61-4] (Pls.' Ex. 12); *see also* [ECF No. 57-1 at 23–203] (Pls.' Ex. 16), the Kidney Committee published the first version of its proposed "Fixed Circle Policy" for public comment in August 2019, [ECF No. 57-1 at 232–326] (Pls.' Ex. 21). This first version proposed replacing DSAs "in favor of a single fixed distance circle encompassing 500 nautical miles (NM) with the donor hospital at its center" and eliminating the use of Regions as a unit of distribution altogether. [ECF No. 57-1 at 235–36] (Pls. Ex. 21). Under the revised policy, donated kidneys would first be offered to a patient within the fixed circle of the donor hospital on a points-based system, giving priority to the sickest and longest-waiting-patients; if not accepted by those candidates, the organ would then be offered to eligible candidates outside the fixed circle, in order of medical need, cold ischemic time, and other logistical and transportation considerations. *See id.* at 236, 245–50, 270–71.

[4] After obtaining additional discovery, the district court granted the plaintiff-hospitals' request to unseal certain documents reflecting internal communications within the agency. That decision is currently pending on appeal. *See Callahan v. U.S. Dep't of Health and Human Servs.*, 1:19-cv-1783-AT, 2020 WL 6336129 (N.D. Ga. Sept. 29, 2020) (*Callahan IV*), *appeal docketed*, No. 20-13932 (11th Cir. Oct. 20, 2020).

Each of the hospital-Plaintiffs in this action submitted comments in response to OPTN's proposed policy change for kidney allocation during the public comment period on October 2, 2019. [ECF No. 4-7 at 37–48] (Pls.' Ex. 47); *see also* [ECF No. 32-7 at 20, 24, 41, 48–51] (UNOS Ex. 6). After considering the comments on its initial proposal, *see* [ECF No. 32-14 at 3–6] (UNOS Ex. 13), the Kidney Committee submitted a briefing paper to the OPTN Board in November 2019, recommending a revised kidney allocation policy employing a radius of 250 NM instead of 500, [ECF No. 57-1 at 329–30, 337–38, 341–54, 355–69] (Pls. Ex. 23). On November 27, 2019, several of the Plaintiffs again submitted comments opposing this modified proposal before the OPTN Board. *See* [ECF No. 4-7 at 50–53] (Pls. Ex. 48). The OPTN Board approved the policy proposal for kidney allocation on December 3, 2019, by a vote of thirty-four in favor, five against, and one abstention. [ECF No. 31-2 at 329] (HHS Ex. 1); *see also* [ECF No. 4-7 at 2–4] (Pls. Ex. 46).

C. Plaintiffs' Legal Challenge

Plaintiffs submitted a critical comment under § 121.4(d) to the Secretary of HHS nearly one year later on December 1, 2020. [ECF No. 56-1 at 25–41] (Pls. Ex. 4). In their letter, Plaintiffs requested that HHS (1) suspend the implementation of the Fixed Circle Policy; (2) instruct UNOS to present HHS with the policy at least sixty days before implementation; (3) submit the policy to the Advisory Committee for review; (4) publish the policy to the Federal Register; and (5) implement any change in the kidney allocation policy only after careful evaluation by neutral parties. *See id.* Without waiting for a response from the Secretary, this lawsuit and request for emergency injunctive relief followed on December 9, 2020. [ECF Nos. 1; 3]. With the Fixed Circle Policy originally slated to take effect on December 15, 2020, Plaintiffs sought a temporary

restraining order enjoining Defendants from implementing the revised policy and making any changes to the current kidney allocation policy pending complete judicial review.

Plaintiffs raise three claims under the APA. In Count I, they allege that HRSA's July 31, 2018 Directive that OPTN eliminate the use of DSAs in all organ allocation policies was arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A). Count II alleges HHS unlawfully withheld agency action and acted contrary to the procedural review requirements of the Final Rule in 42 C.F.R. § 121.4(b)(2) by failing to refer the Fixed Circle Policy to the Advisory Committee as a "significant proposed policy," in violation of 5 U.S.C. § 706(1). Finally, Count III alleges OPTN's adoption (and HHS's ratification) of the Fixed Circle Policy was arbitrary, capricious, and unlawful, in violation of 5 U.S.C. § 706(2)(A).

Thirty minutes before the hearing on Plaintiffs' motion, HHS notified the Court that the Acting Secretary had stayed implementation of the Fixed Circle Policy in order to respond to Plaintiffs' critical comment. *See* [ECF No. 40]. Plaintiffs submitted a supplement to their critical comment on January 10, 2021. [ECF No. 67-2 at 19–27]. After soliciting the views of the OPTN, the Acting Secretary issued his response to Plaintiffs' critical comment on February 12, 2021, declining to take action. *See* [ECF Nos. 67-1 (HHS Ex. 1) ("Acting Secretary's Response"); 67-2 at 56–84 ("OPTN's Response")]. The revised kidney allocation policy is set to take effect on March 14, 2021.

Plaintiffs renewed their motion for preliminary injunction and temporary restraining order on February 20, 2021. [ECF No. 54].[5] They make three core arguments for enjoining the implementation of the Fixed Circle Policy: First, they argue the policy is based on the "erroneous

[5] The Court ordered expedited briefing and Defendants supplemented their oppositions on February 26, 2021. [ECF Nos. 67 (HHS); 68 (UNOS)]; *see also* [ECF No. 75] (Pls.' Reply Br., filed March 2, 2021). A hearing was held on March 5, 2021.

and contrived" legal premise that DSAs and Regions are unlawful. Second, they urge that the adoption and ratification of the policy suffers from substantive flaws and the Secretary's failure to meaningfully consider those issues renders it arbitrary and capricious. Finally, Plaintiffs contend the Secretary failed to comply with HHS review procedures for "significant proposed policies," rendering the policy's formation defective and contrary to law.

II. DISCUSSION

Under the APA, a reviewing 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" to the extent "necessary to prevent irreparable injury." 5 U.S.C. § 705. Preliminary injunctive relief is an extraordinary remedy, made more so by the emergency nature of a temporary restraining order. Plaintiffs bear the burden of demonstrating (1) the probability or likelihood of success on the merits, (2) the real threat of irreparable harm or injury absent immediate relief, (3) that the balance of equities resulting from the issuance of the injunction against the order's effect on third parties weighs in favor of Plaintiffs, and (4) that the public interest favors immediate injunctive relief. *See Dataphase Sys., Inc. v. C L Systems, Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc). Balancing these "*Dataphase* factors" is not a "rigid formula," *Bandag, Inc. v. Jack's Tire & Oil, Inc.*, 190 F.3d 924, 926 (8th Cir. 1999), but instead requires courts to "flexibly weigh the case's particular circumstances to determine 'whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined,'" *Calvin Klein Cosmetics Corp. v. Lenox Labs, Inc.*, 815 F.2d 500, 503 (8th Cir. 1987) (quoting *Dataphase*, 640 F.2d at 113)). The Court does so below.

A. Irreparable Harm

In order to demonstrate the circumstances are such that an emergency injunction is necessary, Plaintiffs must, first and foremost, show that "harm is certain and great and of such imminence that there is a clear and present need for equitable relief." *Novus Franchising, Inc. v. Dawson*, 725 F.3d 885, 895 (8th Cir. 2013) (quoting *Iowa Utils. Bd. v. Fed. Commc'ns Comm'n*, 109 F.3d 418, 425 (8th Cir. 1996)); *see Gelco Corp. v. Coniston Partners*, 811 F.2d 414, 418 (8th Cir. 1987) ("The threshold inquiry [for preliminary injunctive relief] is whether the movant has shown the threat of irreparable injury."). Though no single *Dataphase* factor is dispositive, *Baker Elec. Co-op., Inc. v. Chaske*, 28 F.3d 1466, 1572 (8th Cir. 1994), "failure to show irreparable harm is, by itself, a sufficient ground upon which to deny [injunctive relief]," *Gelco Corp.*, 811 F.2d at 418.

Two aspects of the irreparable harm analysis are in dispute here: (1) Plaintiffs' delay in seeking legal redress; and (2) the injury they claim to have suffered as a result of Defendants' decision to implement the Fixed Circle Policy.

1. Delay

If "a party requesting a preliminary injunction must generally show reasonable diligence," *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018), then the need to promptly object and pursue legal avenues for redress is all the more imperative when claiming to be in need of "emergency" relief. That did not occur here. The OPTN first officially publicized the Fixed Circle Policy in a press release immediately after approving it on December 3, 2019. [ECF No. 32-8 at 2–5] (UNOS Ex. 7). Throughout the winter months and into the spring of 2020, the OPTN discussed the policy's rollout and publicly stated that its implementation would occur by December 2020. *See generally* [ECF No. 31 at 11–12] (HHS Br.) (citing publicly-accessible communications and

notices). In another press release on June 9, 2020, the OPTN confirmed it would implement the new policy "in late 2020." [ECF No. 32-9 at 2–4] (UNOS Ex. 8). Several months later, on September 10, 2020, the OPTN again reiterated that the implementation date was "planned for mid-December of [2020]." [ECF No. 32-10 at 2–5] (UNOS Ex. 9). And on October 20, 2020, the OPTN officially announced the policy's December 15, 2020 implementation date and the two-week transition period preceding its taking effect. [ECF No. 32-11 at 2–4] (UNOS Ex. 10).

Plaintiffs waited to file suit for more than one year after the OPTN's December 3, 2019 official adoption of the Fixed Circle Policy. They were put on notice several times throughout the last year of its inevitable implementation in late 2020. Yet Plaintiffs waited until less than two weeks before its implementation date to even file a critical comment with the Secretary of HHS, and less than five days (of which only three were business days) to file suit in federal court for immediate injunctive relief.

At the hearing scheduled for Plaintiffs' first request for "emergency" injunctive relief, the Court noted the "tough hurdle" created by Plaintiffs' own delay in bringing suit and that it would expect that Plaintiffs "pay a great deal of attention to that particular issue" if they were to succeed in obtaining preliminary relief. [ECF No. 68-7 at 10–11] (UNOS Ex. 19). Plaintiffs have failed to meaningfully address the issue, instead casting blame on HHS for delaying the policy's implementation date in order to accommodate review their critical comment. Plaintiffs' purported assumption that the policy would not be implemented during the COVID-19 pandemic is belied by the OPTN's repeated public announcements that it would implement the policy in late 2020 and the transitional resources provided to transplant hospitals to enable the change during the pandemic. *See Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc.*, 182 F.3d 598, 603 (8th Cir. 1999) (holiday the plaintiff's "delay in objecting" to the allegedly harmful conduct of the

defendant "belie[d] any claim of irreparable injury pending trial"); *see generally* [ECF No. 67-2 at 57–65] (HHS Ex. 2). The delay is unexcused.

2. Injury

a. Patient standing

In claiming to suffer irreparable harm by the implementation of the Fixed Circle Policy, Plaintiffs advance not only their own interests in the policy change as transplant hospitals but those of patients on the kidney transplant waitlist who they claim will suffer under the new organ allocation policy. To successfully assert third-party standing and proceed on behalf of their patients, the hospital-Plaintiffs must demonstrate an "injury in fact," that the hospitals possess a "close relationship" with their patients, and that there is some "hindrance" to their patients' ability to protect his or her own interests. *Campbell v. Louisiana*, 523 U.S. 392, 397 (1998) (quoting *Powers v. Ohio*, 499 U.S. 400, 411 (1991)); *see also Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004).

The hospital-Plaintiffs generally claim the Fixed Circle Policy will result in fewer kidney transplants occurring nationwide generally and at their facilities specifically, diminishing their patients' access to life-saving organs and increasing the cost of those transplants that do occur. They assert that their physicians have third-party standing on behalf of patients with whom they have an ongoing medical relationship. *See Singleton v. Wulff*, 428 U.S. 106, 118 (1976); *see also Aid for Women v. Foulston*, 441 F.3d 1101, 1112–13 (10th Cir. 2006); *Compassion in Dying v. Washington*, 79 F.3d 790, 795 (9th Cir. 1996), *rev'd on other grounds*, 521 U.S. 702 (1997). The anticipated effect of the Fixed Circle Policy in diminishing the number of kidney transplants at the hospital-Plaintiffs' facilities, if true, would certainly constitute an injury in fact shared by the hospitals and their patients alike. And in theory, at least, the hospital-Plaintiffs' physicians could be considered to have a "close" relationship with these third-party patients under their care with

whom they show to have an ongoing relationship. However, the patients in this case are hypothetical; there is no evidence in the record of such ongoing medical relationships. *Cf. Compassion in Dying*, 79 F.3d at 795 (specifically detailing pseudonymous patients through which physicians asserted third-party standing). And this suit is not brought by transplant doctors, but by the hospitals themselves.

Moreover, Plaintiffs assert practical barriers exist to these unnamed and unsubstantiated patients bringing suit to challenge the Fixed Circle Policy for themselves but fail to explain why Mr. Berrios—a named plaintiff in this case who is represented to be on the kidney waitlist at the University of Kentucky—is able to assert his rights while others are not. Courts agree that "if a third party actually asserts [its] own rights, no hindrance exists, and third-party standing is improper." *Hodak v. City of St. Peters*, 535 F.3d 899, 905 (8th Cir. 2008) (citing cases). Here, Mr. Berrios purportedly asserts his interests as a patient on the kidney transplant waitlist and claims an interest in the revised allocation policy. *See generally* [ECF No. 1 ¶ 13] (Compl.). But at the same time, Plaintiffs make no effort to advance the interests of their nominal patient-plaintiff. *See Hughes v. City of Cedar Rapids*, 840 F.3d 987, 992 (8th Cir. 2016) (rejecting third-party standing where the plaintiff "fail[ed] to show a hinderance to [the third party's] ability to protect her own interests"). Indeed, Plaintiffs spend the majority of their briefing demonstrating the hospitals' own financial stake in the adoption of the Fixed Circle Policy. *See* [ECF Nos. 66 at 44–48 (Pls.' Br.); 75 at 12–13 (Pls.' Reply Br.)]. They relegate the injury of Mr. Berrios and their other unspecified patients to a footnote. [ECF Nos. 66 at 45 n.73; 75 at 8 n.7]. There are no class allegations involved in this suit, and the record does not support Mr. Berrios's ability to stand as a representative on behalf of other absent patients at the hospital-Plaintiffs' facilities.

Plaintiffs have not made a sufficient showing on third-party standing to assert the harm suffered by patients on the kidney transplant waitlist in support of their request for preliminary injunctive relief.

b. Hospital standing

That leaves the "administrative concerns" of the transplant hospital-Plaintiffs. *See* [ECF No. 66 at 38 n.73] (Pls.' Br.). Plaintiffs claim they are expected to perform 300 fewer kidney transplants per year under the Fixed Circle Policy. *See* [ECF No. 4-7 at 60] (Pls.' Ex. 49). They assert this reduction will also decrease revenue produced from those transplants that do occur "by increasing operations costs, including costs related to transporting organs farther distances, overhauling [their] system[s] and procedures, and developing effective working relationships with new entities." *See* [ECF No. 57-1 at 223] (Pls.' Ex. 19). The Court finds this harm is sufficient to establish their own injury in fact, and Defendants do not contend otherwise. *Cf. Granville House, Inc. v. Dep't of Health & Human Servs.*, 715 F.2d 1292, 1298 (8th Cir. 1983) (obstacles to mission can constitute injury in fact). But in context of the significant delay in mounting their legal challenge to the implementation of the Fixed Circle Policy, the Court concludes Plaintiffs have not shown such harm is "certain and great and of such imminence that there is a clear and present need for equitable relief." *Roudachevski v. All-Am. Care Ctrs., Inc.*, 648 F.3d 701, 706 (8th Cir. 2011) (citation omitted).

Plaintiffs fail to establish they will suffer irreparable harm if the injunction does not issue.

B. Likelihood of Success on the Merits

1. Legal standard

Of the four *Dataphase* factors, "the likelihood of success on the merits" is in many ways considered "[t]he most important" because "[a]n injunction cannot issue if there is no chance of

success on the merits." *Jet Midwest Int'l Co., Ltd. v. Jet Midwest Grp., LLC*, 953 F.3d 1041, 1044 (8th Cir. 2020) (citations omitted). Ordinarily, parties seeking preliminary relief need only show they have a "fair chance of prevailing," meaning something less than a fifty percent probability their suit will be successful on its merits. *D.M. ex rel. Bao Xiong v. Minn. State High Sch. League*, 917 F.3d 994, 999 (8th Cir. 2019) (citing *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 732 (8th Cir. 2008) (en banc)). But "a more rigorous standard" is required when preliminary relief "is sought to enjoin the implementation of a duly enacted [law]." *Id.* at 999–1000. This "heightened" scrutiny requires that parties seeking to strike down federal law show they are "likely to prevail" because "governmental policies implemented through legislation or regulations developed through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined lightly." *Rounds*, 530 F.3d at 732 & n.6 (endorsing *Able v. United States*, 44 F.3d 128, 131–32 (2d Cir. 1995)); *see Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Eng'rs*, 826 F.3d 1030, 1035 (8th Cir. 2016).

Because Plaintiffs seek "to stay government action taken in the public interest pursuant to a statutory or regulatory scheme," they must show they are "likely to prevail" on the merits. *First Premier Bank v. U.S. Consumer Fin. Prot. Bureau*, 819 F. Supp. 2d 906, 913 (D.S.D. 2011) (citing *Rounds*, 530 F.3d at 731–32, 732 n.4); *see also Aventure Commc'ns Tech., L.L.C. v. Iowa Util. Bd.*, 734 F. Supp. 2d 636, 655 (N.D. Iowa 2010) (applying the "substantial likelihood of success" standard where the challenged state administrative regulation was subject to formal "rule-making procedures" and "did not involve mere policy-making action of the executive branch"). Here, the Fixed Circle Policy is a product of express Congressional design, *see* 42 U.S.C. § 274(b)(2), and Defendants promulgated the revision through the administrative procedures written into the regulatory code, *see* 42 C.F.R. §§ 121.4(a)(1), (d), .8(a). *See also Able*, 44 F.3d at 131–32 (holding

heightened standard applied where agency action was "taken 'pursuant to a statutory or regulatory scheme'" (citation omitted)). The Fixed Circle Policy was the action of a federal regulatory body established by Congress, subject to "fulsome debate" within the transplant community making up the OPTN, and the product of a rigorous notice-and-comment procedure in revising the kidney allocation regime. 42 U.S.C. § 274(b)(1)(B)(i); 42 C.F.R. § 121.3(a)(1), (b)(1); *see, e.g.*, [ECF Nos. 31-2 (HHS Ex. 1); 32-7 (UNOS Ex. 6)]; *cf. Richland/Wilkin*, 826 F.3d at 1040–41 (applying "fair chance" standard where litigant sought to enjoin private party from construction project authorized "pursuant to expert agency recommendation," and delay it only "through the environmental review rather than until the court makes its final determination").[6]

Plaintiffs' claims are further subject to a stringent standard under the APA because judicial review of agency action is deferential to reasoned decisions that are based on a "rational connection between the facts and the choice made." *Simmons v. Smith*, 888 F.3d 994, 998 (8th Cir. 2018). It is especially true that courts must be at their "most deferential" when considering agency action "requir[ing] a high level of technical expertise," *Marsh v. Or. Nat'l Res. Council*, 490 U.S. 360, 377 (1989), or involving complex "scientific determination[s]," *Baltimore Gas & Elec. Co. v. Nat'l Res. Def. Council*, 462 U.S. 87, 103 (1983).

[6] Because the Court concludes the Secretary was not required to follow the procedure set forth in 42 C.F.R.§ 121.4(b)(2), *see infra* at 37–42, Plaintiffs have failed to rebut the presumption that the Fixed Circle Policy was developed through the "reasoned democratic processes" in order for the "fair chance" standard to apply. And although Plaintiffs continually reference UNOS's "bad faith" and other alleged misconduct, *cf. Callahan III*, 434 F. Supp. 3d at 1356, they have not advanced any facts, in this litigation, to substantiate their allegations that UNOS's actions tainted the development and adoption of the Fixed Circle Policy as it promulgated under the Final Rule.

2. Final agency action

In addition to disputing the standard of review in this case, the parties also quarrel over its scope.[7] The APA makes reviewable only "final agency action for which there is no other adequate remedy." 5 U.S.C. § 704. Agency action includes any "statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4); *see also id.* § 551(13) (defining "agency action" as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act"). The requirement that agency action be "final" denotes "some kind of terminal event," *cf. Smith v. Berryhill*, 139 S. Ct. 1765, 1774 (2019), that (1) "mark[s] the 'consummation' of the agency's decisionmaking process" and (2) is "one by which one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow,'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). There is a "'strong presumption' favoring judicial review of administrative action." *See Mach Mining, LLC v. E.E.O.C.*, 575 U.S. 480, 486 (2015) (citing *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986)). Courts generally take a "pragmatic" approach to finality under the APA. *E.g. U.S. Army Corps of Eng'rs v. Hawkes Co., Inc*, 136 S. Ct. 1807, 1815 (2016) (citation omitted). Plaintiffs advance two candidates for judicial review: the Acting Secretary's Response to Plaintiffs' December 2020 critical comment and the July 2018 Directive.

Though HHS stops short of admitting it is so, the agency affirms that the Acting Secretary's Response is a "plausible" final action reviewable under the APA. Indeed, the decision not to act

[7] The parties agree that the Court need not decide the issue of whether UNOS acts as a federal agency for purposes of the APA at this time because the Acting Secretary has responded to Plaintiffs' critical comment and declined to take action, ratifying the policy in his official capacity as a representative of HHS.

on Plaintiffs' critical comment tacitly assents to the OPTN's proposed policy, the effect of which is to stamp its changes and revisions with the agency's imprimatur. It is the final step provided by the Final Rule by which an interested stakeholder or member of the public may challenge a proposed organ allocation policy short of filing a lawsuit. *See* 42 C.F.R. § 121.4(d). And legal consequences certainly flow from the Secretary's declination to stop the implementation of a policy that dictates how donated organs are to be disbursed among transplant candidates: the policy carries significant consequences for kidney transplant patients and hospitals alike who "have, as practical matter, no choice but to use the system governed by the OPTN." 63 Fed. Reg. at 16,309. To conclude otherwise would serve to entirely shield the OPTN's decisions from scrutiny—a result that is anathema to the "basic presumption" of judicial review. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 140–42 (1967), *abrogated by Califano v. Sanders*, 430 U.S. 99 (1977); *cf. Morris v. Gressette*, 432 U.S. 491, 504 (1977). Defendants point to nothing in the Transplant Act or Final Rule that rebuts this presumption.

While the Acting Secretary's Response can be seen to mark the culmination of the policymaking process in developing or revising rules governing transplant kidney allocation, the July 2018 Directive at most marks its inception. The Directive was issued as the agency's response to a critical comment objecting to the use of DSAs in *liver* allocation policy, ordering the OPTN to "adopt a *liver* allocation policy that eliminates the use of DSAs and . . . Regions"; on the subject of *kidneys*, it noted the entity's long term goal of reducing reliance on geographic boundaries like DSAs and instructed the OPTN to submit a "detailed report" outlining its "*plans* to eliminate DSAs and Regions from other (non-liver) organ-specific allocation policies." [ECF No. 56-1 at 322, 324] (Pls.' Ex. 10) (emphasis added). The July 2018 Directive did not "[d]irect the OPTN to revise the policies or practices" concerning kidney allocation policy, only that the entity provide the steps

and timeline by which it would do so. *See* 42 C.F.R. § 121.4(d)(2). Unlike in the Liver Litigation, *cf. Callahan III*, 434 F. Supp. 3d at 1353, the July 2018 Directive was not "some kind of terminal event" for *kidney* allocation policy—the only policy at issue before this Court. *See Smith*, 139 S. Ct. at 1774.[8]

There are also "other adequate remed[ies]" by which to challenge agency's reasoning underlying the July 2018 Directive. *Bennett*, 520 U.S. at 161–62 (quoting 5 U.S.C. § 704). The July 2018 Directive has been—and continues to be—litigated in federal court concerning the Liver Litigation. *See Callahan III*, 434 F. Supp. 3d at 1353. Plaintiffs' grievance with HHS's conclusion that DSAs and Regions are not justified under the Final Rule may be effectively reviewed through a challenge to a specific proposed policy for a particular organ type, just as Plaintiffs have done here—challenging the Acting Secretary's Response to Plaintiffs' critical comment concerning transplant kidney allocation through the Fixed Circle Policy.

Plaintiffs lob three main challenges in their effort to block the implementation of the Fixed Circle Policy. The Court will consider each in turn.

3. Based on an "erroneous and contrived" legal premise

In their opening salvo, Plaintiffs contend the Fixed Circle Policy is arbitrary and capricious because it is built on the faulty legal premise that the use of DSAs in organ allocation policy was inconsistent with the Final Rule and per se unlawful. *See SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943) (holding agency action "may not stand if the agency has misconceived the law"); *Jelinek v. Bowen*, 870 F.2d 457, 458 (8th Cir. 1989) (permitting reversal if agency action "is based on an

[8] To the extent the Plaintiffs' challenge to the Fixed Circle Policy centers on the reviewability of the July 2018 Directive, the even greater delay in bringing this lawsuit to challenge that action specifically—two-and-a-half years since its issuance—negates any claim of irreparable harm by which a emergency injunctive relief could issue on that basis.

erroneous view of the law"). At issue here is not whether DSAs are not required, but rather whether they may be allowed as units of organ distribution under the Final Rule.[9] Because the OPTN did not consider DSAs and Regions as units of kidney distribution in its policy revisions as a result, Plaintiffs claim the Fixed Circle Policy must be set aside.

Plaintiffs point first to the original enactment of the Transplant Act and its subsequent amendments to argue that Congress has recognized DSAs as an appropriate unit of organ allocation. The Transplant Act originally charged the OPTN with "assist[ing] organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations," National Organ Transplant Act § 201, Pub. L. 98-507, 98 Stat. 2339, 2344 (Oct. 19, 1984) (codified at 42 U.S.C. § 274(b)(2)(C) (1984)), and directed that OPOs "ha[ve] a defined service area which is a geographical area of sufficient size which . . . will include at least fifty potential organ donors each year and which either includes an entire standard metropolitan statistical area . . . or does not include any part of such an area," *id.*, 98 Stat. at 2352–43 (codified at 42 U.S.C. § 273(b)(1)(E) (1984)). Plaintiffs argue this reflects an understanding that distribution based on an OPO's service area was a permissible unit of distribution. *See* H.R. Rep. No. 98-769 at 10 (1984) (recognizing "[l]ocal placement of organs saves time and therefore is a practice that [it] expects should continue").

But Congress amended the Act in 1988 and eliminated the language that limited its role in assisting OPOs in distributing only those organs that could not be placed within their service areas. Health Omnibus Programs Extension of 1988 § 403(a)(2), Pub. L. 100-607, 102 Stat. 3048, 3115 (Nov. 4, 1988) (amending now-42 U.S.C. § 274(b)(2)(D) by striking "which cannot be placed

[9] HHS does not seek *Chevron* or *Auer* deference to the agency's interpretation of the Transplant Act or the Final Rule. *See* [ECF No. 67 at 19] (HHS Br.) (stating *Auer* deference "is not at issue here").

within the service areas of the organizations"); *see also* S. Rep. No. 100-310 at 14 (1988) (removing "any statutory bias respecting the important question of criteria for the proper distribution of organs among patients" and disclaiming any intent to "establish[] a preference for, or against, distribution within the service area of the OPO"). Plaintiffs point to the fact Congress also altered language concerning the scope of OPOs' service areas. *See* Pub. L. 100-607 § 402(c)(1)(A), 102 Stat. at 3114 (amending 42 U.S.C. § 273(b)(1)(E) by replacing boundary that "the organization can reasonably expect to procure organs from not less than 50 donors each year"). But this language modified a numerical metric for determining OPO service boundaries, not criteria by which the OPTN was to make policy on donated organ distribution.

Indeed, Congress further amended the Act in 1990 to produce its current language in the relevant provisions, inserting into the OPTN's mission that the entity is to assist procurement organizations in the "nationwide" distribution of organs "equitably among transplant patients." Transplant Amendments of 1990 § 202(b)(1), Pub. L. 101-616, 104 Stat. 3279, 3284 (Nov. 16, 1990) (amending 42 U.S.C. § 274(b)(2)(D)); *see also* S. Rep. 101-530 at 14 (1990) (emphasizing "that the OPTN has a nationwide service area" and that "organs must be distributed equitably"). At the same time, Congress eliminated the strict geographic requirement of OPO service areas, instead emphasizing they service an area "that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs." Pub. L. 101-616 § 201(c)(1), 104 Stat. at 3283 (amending 42 U.S.C. § 273(b)(1)(E)).[10]

[10] *See also* 76 Fed. Reg. 78,216, 78218 (proposed Dec. 16, 2011) (amending 42 C.F.R. § 121.2) ("Prior to the enactment of [Transplant Act], deceased donor organs were allocated regionally, based on relationships between transplant programs and donor hospitals. Congress recognized the need to allocate this national resource on a national and equitable basis.").

Plaintiffs contend the history of the Transplant Act does not disapprove of the use of DSAs in allocating organs and reflects Congress's understanding that such use was permissible. They argue that the conclusion that DSAs may not be used is unsupported by the legal framework envisioned by Congress. The revisions to § 274, governing the mission of the OPTN, however, clearly reflect a trend giving priority to the equitable distribution of organs *nationally*, not based on any localized administrative limitation of OPOs. Plaintiffs' reliance on § 273, governing the qualities of OPOs and requiring them to possess a "defined service area," confuses OPO service criteria and their role facilitating organ distribution with the criteria guiding allocation policy itself. In other words, Plaintiffs conflate OPOs' geographic boundaries that provide administrative convenience with substantive government policy on the equitable distribution of organs.

Plaintiffs next turn their attention to the Final Rule. They argue that although § 121.8(a)(8) generally prohibits allocation policies from being "based on the candidate's place of residence or place of listing," that policy is not absolute and permits the consideration of geographic boundaries like DSAs "to the extent required by paragraphs (a)(1)–(5)" to achieve the equitable allocation of organs. But it is precisely because of the way DSAs prioritize geography over other considerations that the OPTN concluded, and HHS agreed, that DSAs are not optimized for equitable organ distribution purposes and cannot be justified under the Final Rule. [ECF Nos. 32-6 at 4, 8–30 (UNOS Ex. 5); 57-1 at 331 (Pls. Ex. 23)]; *see also* [ECF No. 67-1 at 8–9] (HHS Ex. 1). The Final Rule also requires that organ allocation policies "be based on sound medical judgement," 42 C.F.R. § 121.8(a)(1); "seek to achieve the best use of donated organs," *id.* § 121.8(a)(2); 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," among other things, *id.*§ 121.8(a)(5). Since 2010, the Advisory Committee has observed "geographic disparities in

patient access to transplantation" and specifically called for the elimination of DSAs and Regions in organ distribution. [ECF No. 68-2 at 2] (UNOS Ex. 14). And even earlier, HHS has recognized that "[r]eliance on boundaries that make sense for administrative convenience may lead to inequities in organ allocation criteria." 63 Fed. Reg. at 16,313 (reasoning the "differences in OPO size, geography, and population" support the position that "OPO areas should not be the primary vehicle for organ allocation").

After examining the relevant evidence, the OPTN reasonably found that DSAs "are not a good proxy for geographic distance between donors and transplant candidates" because "the disparate sizes, shapes and populations are not rationally determined in a manner that can be consistently applied equally." *See* [ECF No. 32-5 at 3] (UNOS Ex. 4). And because OPTN found those artificial boundaries have hindered, rather than aided, the equitable allocation of cadaveric organs, HHS rationally concluded organ allocation policies should no longer be based on those metrics. The OPTN letter addressing the 2018 comment critical of DSAs in liver allocation policy explained that moving away from relying on DSAs enabled "the most medically urgent patients [to be] prioritized regardless of whether they are located within or outside of the DSA." [ECF No. 32-5] (UNOS Ex. 4). As the Acting Secretary further explained in responding to Plaintiffs' critical comment concerning kidney allocation:

> Under the DSA-Based Policy, a kidney often travels a greater distance from the donor hospital because a transplant candidate listed within the same DSA receives priority over a geographically closer candidate (located in a different DSA) who has similar clinical characteristics and time on dialysis. For example, a donor kidney recovered in Minneapolis may be offered to a candidate listed at the Sanford Hospital in Bismarck, North Dakota (383 miles from the donor hospital) before a candidate listed at the Iowa Methodist Hospital in Des Moines (234 miles away) solely because the former hospital is in the same DSA as the donor hospital.

[ECF No. 67-1 at 5 n.6] (HHS Ex. 1). HHS's reliance on the OPTN's expertise certainly presents a "reasoned explanation" for its shift from its former policies employing DSAs and Regions. *See ANR Pipeline Co. v. FERC*, 71 F.3d 897, 901 (D.C. Cir. 1995); *cf. Callahan III*, 434 F. Supp. 3d at 1359–63. Plaintiffs have not established a preliminary showing that the Fixed Circle Policy's elimination of DSAs and Regions was premised on legal error requiring it to be set aside.

4. Substantive development, adoption, and ratification of the Fixed Circle Policy

Agency action is substantively arbitrary and capricious if it fails to "engage in 'reasoned decisionmaking,'" *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (citation omitted), which occurs where the agency "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," *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). When engaging in policymaking on complex topics, "[t]he agency must explain the evidence which is available, and must offer a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

Plaintiffs' substantive attacks come in several shapes and sizes. They contend the Fixed Circle Policy, along with its March 14, 2021 implementation date, is arbitrary, capricious, and unlawful because it (a) will result in increased organ wastage and patient death; (b) fails to meaningfully consider the repercussions of the COVID-19 pandemic; and (c) repeatedly deferred to the OPTN while turning a blind eye to UNOS's alleged bias and misconduct.

a. Whether HHS failed to consider important aspects of kidney transplantation policy

First, Plaintiffs contend Defendants did not engage in reasoned decisionmaking in adopting and ratifying the Fixed Circle Policy, pointing to evidence they claim shows the policy will result

in increased organ wastage and more patient deaths. Although the Final Rule requires that the organ allocation policies "shall" be "based on sound medical judgment" and "designed to avoid wasting organs [and] to promote the efficient management of organ placement," 42 C.F.R. § 121.8(a)(1)(5), they claim the revised kidney allocation policy is neither. To survive judicial scrutiny, an agency must simply show that it "examin[ed] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts and the choice made." *Simmons*, 888 F.3d at 998 (citation omitted); *see State Farm*, 463 U.S. at 43.

Relying on the SRTR's data modeling and the OPTN's expertise, HHS included a lengthy discussion demonstrating that its decision not to block the implementation of the Fixed Circle Policy was based on sound medical judgment and the efficient use of organs. *See generally* [ECF No 67-1] (HHS Ex. 1) (Acting Secretary's Response). Statistical modeling was conducted and analyzed by SRTR. *See* [ECF Nos. 57-1 at 23–203 (Pls.' Ex. 16); 61-1; 61-2; 61-3; 61-4 (Pls.' Ex. 12)]. The Kidney Committee issued extensive and detailed concept papers to the transplant community and to the public. *See* [ECF No. 57-1 at 232–326] (Pls.' Ex. 21). Public comments were received and taken under consideration. *See* [ECF No. 32-7 at 20, 24, 41, 48–51] (UNOS Ex. 6). And the OPTN received thorough briefing papers explaining the scientific basis for the proposed policy revision. *See* [ECF No. 57-1 at 328–403] (Pls. Ex. 23). The disagreements advanced by Plaintiffs, *see* [ECF Nos. 60-1 at 6–7 (Pls.' Ex. 62) (Locke Aff.); 59-2 at 122–24 (Pls.' Ex. 73) (Reed Aff.); 57-1 at 223–24 (Pls.' Ex. 19) (Wandersleben Aff.)], were adequately addressed by SRTR's data modeling and OPTN's briefing papers, upon which the Acting Secretary relied, *see, e.g.*, [ECF No. 57-1 at 26, 51 (Pls.' Ex. 16), 347, 350–52, 356 (Pls.' Ex. 23)].

Based on the OPTN's expertise in the area of transplant organ allocation, HHS reasonably concluded the Fixed Circle Policy will not result in significantly fewer kidney transplants. [ECF

No. 67-1 at 5–6] (HHS Ex. 1) (Acting Secretary's Response); *see* [ECF No. 67-2 at 69–74] (HHS Ex. 2) (OPTN's Response). In its November 2019 briefing paper to the OPTN Board, the Kidney Committee acknowledged concern within the transplant community of a greater rate of kidney graft failure and discard due to logistical and transportation challenges in *rejecting* a policy proposal based on a policy employing "proximity points with a 500 NM circle." *See* [ECF No. 57-1 at 368–69]. (Pls.' Ex. 23). In fact, the Kidney Committee considered and ultimately recommended the 250 NM proposal specifically because it "still makes significant steps towards achieving more equity in access to transplant, while the proposed proximity points help to minimize the risk of poor utilization of donated organs, futile transplants by way of poor post-transplant outcomes, and logistical challenges associated with transporting organs further distances." *Id.* at 369.

The Kidney Committee also adopted the 250 NM Fixed Circle Policy because it provided demonstrably "greater equity in access to transplant" than the current system employing DSAs and Regions as units of allocation. [ECF No. 57-1 at 363–64] (Pls.' Ex. 23). At the same time, the committee observed modeling of the 250 NM policy proposal reflected "no projected change in waitlist mortality rate, no projected change in waitlist mortality count, and no projected increase in graft failure rate." *Id.* at 359. Although the SRTR's modeling projected that "kidney-alone" transplants might decrease under the revised kidney policy by 250 transplants per year, "kidney-pancreas" transplants are expected to increase by 241 transplants per year. [ECF No. 57-1 at 30] (Pls.' Ex. 16). That is, under the Fixed Circle Policy, data modeling predicted a net loss of only nine transplants involving kidneys per year;[11] the OTPN noted that, in light of this modeling,

[11] A baseline of approximately 13,895 total kidney transplants occur each year under the current policy employing DSAs. 13,886 kidney transplants are expected to occur under the Fixed Circle Policy. *See* [ECF No. 57-1 at 30].

"the total number of [kidney] transplants resulted in almost no change from baseline." [ECF No. 67-2 at 73] (HHS Ex. 2) (OPTN's Response).

Contrary to Plaintiffs' assertions, HHS also explained why the SRTR and the OPTN were reasonable in altering the data modeling framework to eliminate an overestimate of the number of kidneys predicted to be discarded under the revised policy. [ECF No. 67-1 at 6] (HHS Ex. 1) (Acting Secretary's Response). The first data model resulted in a "projected decline in transplant rate and count" that "was a major concern during public comment." [ECF No. 59-2 at 16] (Pls.' Ex. 65). The SRTR's second round of modeling, ultimately adopted by the OPTN, eliminated consideration of the distance between donor and recipient under the Fixed Circle Policy. *See id.* at 16–17; [ECF No. 57-1 at 4–5] (Pls.' Ex. 13). But both HHS and the OPTN explained why this metric was eliminated: "[t]he original model overestimated discard rates because it was based on the current practice in which over 75 percent of kidneys are allocated within the DSA, such that primarily poorer quality kidneys are offered outside the DSA, and thus more likely to be discarded." [ECF No. 67-1 at 6]; *see* [ECF No. 57-1 at 5] (explaining how the "'local' indicator" left over from DSA-based policy in the first model "likely contributed to lower transplant counts because fewer offers . . . were made 'locally' under broader sharing proposals"). Anticipated behavioral changes in transplant centers' organ acceptance criteria led OPTN, and thus HHS, to expect that "higher quality kidneys will be offered and accepted outside of the DSAs much more regularly," resulting in higher successful transplant rates. [ECF No. 67-1 at 6]; *see also* [ECF No. 67-2 at 73] (HHS Ex. 2) (OPTN's Response) (noting modeling changes were made "to better calibrate the simulation to expected behavior changes in response to the new policy"). Ultimately, it was the conclusion of these subject-matter experts that the second model was "less reliant on geography and therefore may better predict changes in behavior under a new allocation framework

less reliant on local offers." [ECF No. 59-2 at 17]; *see also* [ECF No. 67-2 at 72–73] ("Put differently, the change to the [second] model was intended to harmonize the modeling with the circle-based allocation system under consideration, reducing any bias in the data that flowed from the historical use of DSAs."). The Court cannot agree with Plaintiffs that the record shows even a fair chance that Defendants "manipulated" the data modeling "to produce desired results."

HHS also considered and explained how the Fixed Circle Policy was predicted to result in greater equity of transplants across socioeconomic factors, again contrary to Plaintiffs' assertions. *See* [ECF No. 67-1 at 6–7] (HHS Ex. 1) (Acting Secretary's Response). Indeed, SRTR simulations projected the rates of kidney transplants under the Fixed Circle Policy are expected to increase "among pediatric, female, African American, and Latino candidates," not decrease. [ECF No. 67-2 at 73] (HHS Ex. 2) (OPTN's Response) (citing [ECF No. 57-1 at 23–203] (Pls.' Ex. 16)). The same calculations predicted an increase in transplantation for candidates enrolled in Medicaid and those who have been on dialysis for more than five years. *See id.* And while recognizing small decreases in rural transplant rates, the Kidney Committee noted that SRTR's modeling demonstrated that "broader distribution is not disadvantaging non-metropolitan candidates compared to metropolitan candidates; it is equalizing their access." [ECF No. 57-1 at 263] (Pls.' Ex. 21).

In sum, these are exactly the type of substantive scientific analyses to which courts are to defer under the APA. *See Marsh*, 490 U.S. at 377. In rejecting Plaintiffs' critical comment, HHS reasonably relied on the predictive scientific expertise by SRTR and OPTN regarding the effect of the Fixed Circle Policy on kidney wastage, discard, and transplant rates. *See Alaska Airlines, Inc. v. TSA*, 588 F.3d 1116, 1120 (D.C. Cir. 2009) (granting "an extreme degree of deference" to agency actions "involv[ing] complex judgments about sampling methodology and data analysis that are

within the agency's technical expertise" (citation omitted)); *see generally* [ECF No. 67-1 at 5–6] (HHS Ex. 1) (Acting Secretary Response to Critical Comment). Plaintiffs do not demonstrate they are likely to succeed on their claim that the Fixed Circle Policy is arbitrary and capricious.

b. Whether Defendants erred in deferring to the OPTN's expertise

Along these lines, Plaintiffs argue it was arbitrary and capricious for HHS to defer to the OPTN's expertise in rejecting Plaintiffs' critical comment. Plaintiffs cite to an ongoing Congressional investigation into UNOS's oversight of OPOs as reason for HHS to reconsider its reliance on conclusions reached and recommendations made by the OPTN (read: UNOS). *See generally* [ECF Nos. 56-1 at 2–17; 59-1 at 2–3] (Pls.' Ex. 1, 2, 51). But Plaintiffs present no evidence, in this litigation, of malfeasance or bad faith. Although Plaintiffs point strenuously at the district court's preliminary findings in the Liver Litigation tending to show "arguable evidence of bias, or at least, individuals' sporadic expressions of bad faith or agenda," *Callahan III*, 434 F. Supp. 3d at 1356; *see also id.* at 1363–64, that court ultimately concluded those materials "did not reveal much," and certainly did not establish "bad faith, bias, or predetermination that could be traced to HHS's ultimate decision-making" such that it would justify further discovery into the matter, *Callahan IV*, 2020 WL 6336129, at *1. Plaintiffs' efforts to wholesale import their allegations of bad faith and predetermination against Defendants discussed in parallel litigation find no support in the record presently before this Court to convince it that immediate injunctive relief is necessary or appropriate.

Plaintiffs' complaints about the post-implementation effects of revised lung and liver allocation policies also do not make HHS's deference to the OPTN's expertise unreasonable to render the Fixed Circle Policy arbitrary and capricious. Plaintiffs argue that since revising other organ allocation policies there has been a "statistically significant increase in the discard rate" for

donated lungs and a nationwide decrease in liver "utilization rate." *See* [ECF Nos. 57-2 at 13 (Pls.' Ex. 24); 76 at 57 (Pls.' Ex. 77); 58-2 at 66 (Pls.' Ex. 50)]. But in doing so they fail to account for the differences between transplant organ types and the varying objectives and priorities in the policy governing their allocation. As counsel for UNOS pointed out at oral argument, discard rate is a less meaningful metric for evaluating lung allocation policy because transplant lungs are not commonly removed from a donor unless they will actually be used; lung policy *utilization rate* is therefore a better metric for those organs. *See* [ECF No. 58-2 at 31] (reporting an increase in "median distance between donor hospital and transplant program and a decrease in the number of local (within the same DSA) lung transplants" with a "minimal change in deceased donor utilization"). And liver allocation policy tends to prioritize medical urgency; thus, it is important to note that the revised liver policy has resulted in "[i]ncreased distance . . . from donor hospital to transplant program of recipient," "[n]o changes in liver waiting list transplant rates," and "[d]ecreased liver waiting list mortality rates." [ECF No. 57-2 at 13]. Plaintiffs also fail to mention that many of these results were expected under the new policies. *See* [ECF No. 57-2 at 13 ("While changes pre- to post-policy must be considered in light of this [COVID-19] national emergency, many of the results in this report align with the intended outcomes of the policy change that were supported by the SRTR modeling predictions prior to the implementation of this proposal."). The trade-off, the OPTN reasoned, was to achieve greater equity in transplant access for those organs consistent with the Final Rule.

By statute, the OPTN is the only entity with authority to develop national organ allocation policies and relies on the technical expertise of the SRTR. *See* 42 U.S.C. §§ 274(b)(2)(D), 274a. Plaintiffs have not made a sufficient showing that HHS's reliance on the OPTN's expertise renders the decision arbitrary and capricious.

c. Whether HHS failed to meaningfully consider the impact of the COVID-19 pandemic

Last, Plaintiffs urge that the Secretary failed to meaningfully consider their criticisms of implementing the Fixed Circle Policy in the midst of a global pandemic. *See PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (noting agency action can be arbitrary and capricious if the agency "'fail[s] to respond meaningfully' to objections raised by a party"). The decision to go ahead with implementing the Fixed Circle Policy on March 14, 2021, changing a fundamental aspect of kidney allocation as it has operated for thirty years during a global pandemic, they urge, renders the decision arbitrary and capricious. But it is clear Defendants did not idly sit on their hands and let the transplant community fend for itself. *See* [ECF No. 67-1 at 3–5] (HHS Ex. 1); *see also* [ECF No. 67-2 at 57–65] (HHS Ex. 2) (evaluating organ transplant data during the pandemic).

Though Plaintiffs argue COVID-19 has greatly disrupted the commercial airline industry, complicating kidney transportation logistics, they ignore the fact (which HHS points out) that the Fixed Circle Policy expressly adopted a distribution regime of 250 NM because it was expected to reduce reliance on commercial air travel and ease logistical concerns over broader distribution of kidneys. [ECF No. 57-1 at 352–53] (Pls. Ex. 23). And in fact, HHS observed that the overall rate of kidney transplants increased from 2019, as it did for other organs, despite the challenges posed to the medical community in 2020. [ECF No. 67-1 at 3] (HHS Ex. 1); *see also* [ECF No. 67-2 at 58–60] (HHS Ex. 2) (noting "there has been no material change in 2020 in the percent of kidneys transplanted into a recipient within the donor's DSA versus the percent of kidneys transplanted into a recipient form outside the donor's DSA").

Defendants meaningfully answered Plaintiffs' concerns about implementing the Fixed Circle Policy during the pandemic in responding to their critical comment. Further, OPTN has

invested many resources in organ transplantation monitoring and coordination among donors and candidates in response to the challenges posed by COVID-19. *See generally* [ECF No. 67-2 at 61–65] (HHS Ex. 2). Members of the transplant community received multiple communications confirming the implementation of the revised kidney allocation policy would proceed in December 2020. [ECF No. 67-2 at 77–81] (HHS Ex. 2). Although the effects of the pandemic are indeed formidable, Plaintiffs have not shown the decision to continue with the implementation of the Fixed Circle Policy was arbitrary and capricious on that basis.

5. Failure to follow established review procedures

Finally, the Court considers Plaintiffs' procedural claims. Plaintiffs contend the Fixed Circle Policy was a "significant policy" that the Final Rule required the Secretary to refer to the Advisory Committee, publish in the Federal Register, and consider consistent with the Transplant Act and accompanying regulations. *See* 42 C.F.R. § 121.4(b)(2). Because the Secretary did not do so, Plaintiffs argue they are likely to succeed on their claim that the Secretary "unlawfully withheld" required agency action and assert such a defect renders the revised policy "not in accordance with law" since it was enacted without observance of required procedures. *See* 5 U.S.C. § 706(1), (2)(A), (2)(D); *see also Voyageurs Region Nat. Park Ass'n v. Lujan*, 966 F.2d 424, 428 (8th Cir. 1992).

a. Whether the Final Rule requires OPTN to transmit all organ allocation policies to the Secretary for review

First, Plaintiffs argue the Final Rule requires the OPTN Board to transmit *all* organ allocation policies to the Secretary for review in accordance with § 121.4(b)(2)'s requirements for "significant proposed policies." In full, the regulation reads:

> (b) The [OPTN] Board of Directors shall:
>
> (1) Provide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take

> into account the comments received in developing and adopting policies for implementation by the OPTN; and
>
> (2) Provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies it recommends to be enforceable under § 121.10 (including allocation policies). These policies will not be enforceable until approved by the Secretary. The Board of Directors shall also provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. *The Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the Federal Register for public comment*. The Secretary also may seek the advice of the [Advisory Committee] . . . on other proposed policies, and publish them in the Federal Register for public comment. *The Secretary will determine whether the proposed policies are consistent with the [Transplant Act] and [the Final Rule], taking into account the views of the Advisory Committee and public comments*. Based on this review, the Secretary may provide comments to the OPTN. If the Secretary concludes that a proposed policy is inconsistent with the [Transplant Act] or [the Final Rule], the Secretary may direct the OPTN to revise the proposed policy consistent with the Secretary's direction. If the OPTN does not revise the proposed policy in a timely manner, or if the Secretary concludes that the proposed revision is inconsistent with the [Transplant Act] or [the Final Rule], the Secretary may take such other action as the Secretary determines appropriate, but only after additional consultation with the Advisory Committee on the proposed action.

42 C.F.R. § 121.4(b) (emphasis added). Plaintiffs' claim centers on the italicized text, referred to as the "significant proposed policies" sentence. In the Liver Litigation, the Eleventh Circuit held that § 121.4(b)(2)'s mandatory requirements of referral and publication for "significant proposed policies" is modified by the preceding sentences in that paragraph and "applies only to two specific types of proposed policies: those that OPTN's Board 'recommends be enforceable" and those pertaining to matters that the Secretary directs." *Callahan II*, 939 F.3d at 1260.

Here, Plaintiffs go further: they contend that a cohesive reading of § 121.4 and § 121.8, together, demands the conclusion that *any* allocation of organ policy proposal be submitted to the

Secretary as a "significant policy." Plaintiffs argue § 121.8(d)(1) presupposes that OPTN is required to transmit all proposed organ allocation policies to the Secretary because that section provides that it "shall" also transmit any transition procedures for patients already on the organ transplantation list. Under § 121.8(f), they claim, OPTN's transmission "shall include such supporting material . . . as the Secretary may require" to aid review of the revised allocation policies. Plaintiffs further point to § 121.8(e), a provision adopted shortly after establishing the Final Rule in 1999, requiring the Secretary to review OPTN's revisions to then-existing allocation policies under § 121.4 by a certain date, and argue that this emphasizes the Final Rule's intent to subject all organ allocation revisions to § 121.4 Secretarial review. Section 121.4(b)(2) is the only place providing guidelines for such review, they assert, and because it would be an absurd reading of the law to conclude organ allocation policies were anything but "significant proposed policies," the Secretary must refer the Fixed Circle Policy to the Advisory Committee and publish it in the Federal Register for public comment.

Several problems with this argument are immediately apparent. *First*, Plaintiffs misread § 121.8(d). That provision is expressly directed at "[t]ransition patient protections" and provides:

> When 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. The *transition procedures* shall be transmitted to the Secretary for review together with the revised allocation policies.

42 C.F.R. § 121.8(d)(1) (emphasis added). The regulation requires OPTN to consider such transition procedures and whether it is appropriate to adopt them when revising organ allocation policies; *if* it adopts transition procedures, *then* the regulation mandates that they be transmitted to the Secretary and that such transmission also include the proposed policy revisions. *See*

also 63 Fed. Reg. at 16,315 (explaining that upon a policy revision "the OPTN would determine whether a change disadvantaged some patients, and if so, consider developing a transition policy to eliminate that disadvantage"). Nothing in that section requires the transmission of any and all organ allocation policies. The same reasoning extends to § 121.8(f). And § 121.8(e), standing alone, does not support mandatory Secretarial review of anything but those policies in existence in 1999, when the regulation was promulgated. *See* 64 Fed. Reg. 56,650, 56,660 (Oct. 20, 1999) (implementing 42 C.F.R. § 121.8(e)); *accord* 63 Fed. Reg. at 16,309 (stating UNOS "would be required to submit to the Secretary for approval allocation policies [already] in effect. . . pursuant to the process described in the final rule" only "[f]or policies that the OPTN wants to be enforceable"; for all others, "OPTN members that disagree with those policies may appeal them to the Secretary").

Second, it cannot be ignored that § 121.4(b) itself governs what "[t]he [OPTN] Board of Directors shall" do. And what it directs OPTN to do is (1) "provide opportunity for the OPTN membership and other interested parties to comment on proposed policies" as a default rule, and (2) provide to the Secretary of HHS those proposed policies that (i) "it recommends to be enforceable under § 121.10 (including allocation policies)" or (ii) involve "such other matters as the Secretary directs." *Callahan II*, 939 F.3d at 1258. Plaintiffs' reference to § 121.8 does not undermine the conclusion that the "significant proposed policies" sentence relates to the previous two sentences directing OPTN to act under the "scope-of-subparts" canon of construction and provides "the most coherent" reading of § 121.4(b)(2). *See id.* at 1260–61. Meaningful Secretarial review of proposed organ allocation policies is not avoided by such a construction, as Plaintiffs claim, but accomplished through the critical comment process envisioned by § 121.4(d). *See id.* at 1264 ("[T]he Secretary can always 'direct' OPTN's Board of Directors to provide him with a

proposed policy 60 days in advance of its implementation, thereby bringing it within § 121.4(b)(2)'s ambit. Or, wholly separately, under § 121.4(d) the Secretary can review and suggest revision to any OPTN policy that has been the subject of a critical comment."). Plaintiffs' reading of the regulation would trigger the requirements of § 121.4(b)(2) any time the Secretary receives a "significant" proposed organ allocation policy through the submission of a critical comment, completely obviating the difference between the two review procedures. Had HHS, in promulgating the Final Rule, intended the "significant proposed policy" sentence to apply outside the context of the two express categories of policies preceding it, HHS could have directed that procedure specifically at the Secretary in its own subsection. Plaintiffs do not show they are likely to succeed on this claim.

b. Whether the circumstances present here require that the Fixed Circle Policy be treated as a "significant proposed policy" subject to § 121.4(b)(2)'s requirements

Next, Plaintiffs' procedural argument takes on a different tack. Plaintiffs contend § 121.4(b)(2) leaves no discretion once the Secretary *actually receives* a "significant proposed policy." Section 121.4(b)(2) would otherwise be a dead letter, they argue, because in its thirty-five-year history the OPTN has never "recommend[ed] to be enforceable" any proposed organ allocation policy. *See Callahan II*, 939 F.3d at 1254 n.1 (noting that "voluntary compliance [with the Final Rule] has been excellent"). Plaintiffs assert the Secretary—acting through HRSA employees present at OPTN meetings—had access to the Fixed Circle Policy and effectively contributed to its development here, leading to the conclusion that the Secretary was required to follow § 121.4(b)(2)'s procedure for "significant proposed policies."

This argument is simply a recycled iteration of the one rejected in *Callahan II*. Plaintiffs' reasoning depends on the premise that the "significant policy" sentence of § 121.4(b)(2) applies independently of the preceding two clauses. It does not, *see Callahan II*, 939 F.3d at 1260, and

because the Fixed Circle Policy was neither "recommend[ed] to be enforceable" by OPTN or "direct[ed]" by the Secretary, the requirement that he "refer" and "publish" the policy was not triggered, even if it is a "significant" one.

Independently, Plaintiffs contend § 121.4(b)(2)'s requirements were in fact fulfilled. The Secretary "direct[ed]" transmittal of the Fixed Circle Policy, they claim, when HRSA issued the July 2018 Directive. *See* [ECF No. 56-1 at 324] (Pls. Ex. 10). In essence, Plaintiffs argue that it was this letter that precipitated the Fixed Circle Policy, rendering it a significant proposed "polic[y] on such . . . matters as the Secretary directs" under § 121.4(b)(2).

The Directive makes clear, however, that it was issued as a Secretarial response to the 2018 critical comment under § 121.4(d). *Id.* at 320 n.1. And as described above, it did not specifically call for the transmission of a proposed policy, least of all by invoking § 121.4(b)(2). Rather, the Directive simply instructed the OPTN to submit a "detailed report" concerning its "*plans* to eliminate DSAs and Regions from all other (non-liver) organ-specific allocation policies." *Id.* at 324 (emphasis added). Nor did the letter direct referral specifically within 60 days of the proposed implementation date, as § 121.4(b)(2) would require if actually invoked.

In any event, Plaintiffs bear the burden to persuasively show that it is likely this degree of attenuation from the Fixed Circle Policy itself satisfies the "as the Secretary directs" sentence to trigger his obligations under § 121.4(b)(2). They do not.

6. Summary

In sum, Plaintiffs fail to meet their burden of showing a likelihood of success on the merits.

C. Balance of the Equities and the Public Interest

Finally, the Court considers the effects of enjoining the Fixed Circle Policy's implementation days before it is set to take effect, balancing the competing interests of

stakeholders in the transplant community, public officials, and the general public across the country invested in the equitable allocation of donated kidney. *See MPAY Inc. v. Erie Custom Comput. Applications, Inc.*, 970 F.3d 1010, 1020 (8th Cir. 2020) (weighing "'the threat of irreparable harm' shown by the movant against 'the injury that granting the injunction will inflict on other parties litigant'" (quoting *Dataphase*, 640 F.2d at 113)). "Given that [Plaintiffs'] interest is theoretically the public's, to some extent these factors are connected." *Glenwood Bridge, Inc. v. City of Minneapolis*, 940 F.2d 367, 372 (8th Cir. 1991); *cf. Nken v. Holder*, 556 U.S. 418, 435 (2009) (concluding the balance of equities and public interest "merge" when considering whether to stay lower court action and "the Government is the opposing party").

Plaintiffs urge that any harm suffered by delaying the implementation of the revised kidney allocation policy would be purely administrative, temporarily postponing changes to established policy until reaching a final judgment on the merits of their claims, while the harm in not granting the injunction would threaten the lives of patients who will no longer receive kidney transplants under the new policy. But the policy also purports to save the lives of those who are given a higher preference for kidney donation, and anticipates greater equity in the distribution of the organs to those with the greatest need. And given the priority on the equitable distribution of cadaveric organs that is embraced by both the Transplant Act and Final Rule, it is not clear that the interests of those patients under the current policy, which is governed by arbitrary geographical boundaries, outweigh those who stand to benefit from its revision.

Plaintiffs' delay in seeking *any* relief from the OPTN's policy proposal in the last year, let alone filing suit, weighs heavily against their interest in stopping the implementation of a policy expected and planned for by other transplant hospitals across the country. Contrary to Plaintiffs' assertions, confusion will be sown if the long-expected policy is enjoined at the last possible

minute, not if it is allowed. *See Benisek*, 138 S. Ct. at 1944–45 (holding the plaintiffs' "unnecessary" delay in asking for preliminary injunctive relief and public interest in the orderly administration of federal law weigh against granting the injunction). The OPTN has spent the last year issuing guidance and distributing resources to help transplant hospitals transition to the new kidney allocation policy. Particularly when it is expected to increase equity in kidney transplant access by achieving a broader distribution of donated organs to needier candidates regardless of their location or place of listing, allowing the Fixed Circle Policy to proceed as-planned maintains the status quo for every other interested party that has prepared for it.

In sum, neither the equities of Plaintiffs' request nor the public interest weigh in favor of issuing an emergency injunction.

III. CONCLUSION

This case demonstrates exactly why judicial review of agency action—particularly that based on scientific expertise, complex data modeling, and detailed statistical analysis—should be made in a slow, deliberate, and cautious manner. Plaintiffs raise genuine policy disagreements with the Fixed Circle Policy. But as presented in an expedited motion for emergency injunctive relief, they do not reach the high threshold required to block the enactment of a federal regulation. And even had they come closer to that bar, "[a]s a matter of equitable discretion, a[n] [emergency] injunction does not follow as a matter of course." *Benisek*, 138 S. Ct. at 1943–44 (citing *Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 32 (2008)). Here, again, does Plaintiffs' delay come to bear. The short time frame under which the Court is asked to rule on Plaintiffs' claims weigh strongly against enjoining the implementation of a presumptively valid policy and second-guessing the technical expertise of a scientific body.

For the reasons discussed above, the Plaintiffs' Motion for Preliminary Injunction and Temporary Restraining Order, [ECF Nos. 3; 54], is DENIED.

IT IS SO ORDERED.

Dated this 12th day of March, 2021.

STEPHANIE M. ROSE, JUDGE
UNITED STATES DISTRICT COURT