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

RANDALL CALLAHAN, *et al.*,	:	
Plaintiffs,	:	
v.	:	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES through ALEX M. AZAR II in his official capacity as Secretary of the United States Department of Health and Human Services,	:	CIVIL ACTION NO. 1:19-CV-1783-AT
Defendants.	:	

ORDER

Plaintiffs, Randall Callahan, Katryna Grisson, Candice Seaman and Michael Wingate (the "Patient Plaintiffs") along with Emory University, Henry Ford Health System, Indiana University Health, Oregon Health and Science University, Piedmont Healthcare, The Rector and Visitors of the University of Virginia, The Regents of the University of Michigan, Saint Luke's Hospital of Kansas City, University of Iowa, University of Kansas Hospital Authority, University of Kentucky, Vanderbilt University Medical Center, Virginia Commonwealth University Health System Authority, The Washington University, and Barnes-Jewish Hospital (the "Transplant Center Plaintiffs") (collectively, the "Plaintiffs") filed the instant action against Defendants, the United States

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

> ***The Secretary also recognizes the need for additional public participation in the development of some OPTN policies, such as fundamental revisions to organ allocation policies***, and has included in this rule provisions that (1) require the OPTN Board to provide opportunity for the OPTN membership and other interested parties to comment on all of its proposed policies, (2) enable the Secretary to seek comment from the public and to direct the OPTN to revise policies if necessary, and (3) provide timely access to information for patients, the public, and payers.
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> Both the genesis and wording of the National Organ Transplant Act (NOTA), as amended, obligate the Secretary to utilize the transplantation community substantially in both developing and executing transplantation policy. ***Under the statutory framework established by the Congress, however, the Department has oversight obligations, arising from the NOTA, as well as other laws and executive orders. For example, the Secretary has an affirmative obligation to make sure that policies and actions of the OPTN***

> ***do not violate the civil rights of candidates for organ transplants.*** In this regard, however, most commenters stated, and the Secretary agrees, that Departmental oversight should not micro-manage the development of purely medical criteria or routine day to day decision-making of attending medical professionals or the OPTN contractor.
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> The Department, in the preamble to the proposed rule (59 FR 46486), made clear its intention to ***provide the public with an opportunity to comment on organ allocation policies and proposed changes to them. While we believe that the comment process administered by the OPTN itself is invaluable in obtaining technical advice, it does not reach all of the affected public—including potential donors and interested persons who are not OPTN members and have no access to the OPTN—or otherwise provide the functions and protections accorded by the impartial review by the Secretary.*** These principles are carried forward in the final rule.

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

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

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

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

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

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

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

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

> Provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies it recommends to be enforceable under § 121.10 (including allocation policies). These policies will not be enforceable until approved by the Secretary. ***The Board of Directors shall also provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. The Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the Federal Register for public comment.*** The Secretary also may seek the advice of the Advisory Committee on Organ Transplantation established under § 121.12 on other proposed policies, and publish them in the Federal Register for public comment. The Secretary will determine whether the proposed policies are consistent with the National Organ Transplant Act and this part, taking into account the views of the Advisory Committee and public comments.

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

robust level of public involvement (including commentary) in the promulgation of organ allocation polices and that ACOT be intimately involved in the review of such policies in order to make certain that "the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible." 64 Fed. Reg. 56657.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

AMY TOTENBERG
UNITED STATES DISTRICT JUDGE