THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

February 12, 2021

Glenn Krinsky, Esq.
Jones Day
555 South Flower Street
Fiftieth Floor
Los Angeles, CA 90071

Dear Mr. Krinsky:

This letter responds to the December 2, 2020, critical comment you filed on behalf of several unnamed organ transplant hospitals (Tab A). The critical comment raises concerns about the kidney allocation policy approved by the Organ Procurement and Transplantation Network (OPTN) Board of Directors (OPTN Board) on December 3, 2019 (the "Fixed Circle Policy"). You asked the Secretary of Health and Human Services (the Secretary) to take immediate action to stop implementation of the Fixed Circle Policy. As a result, the current kidney allocation policy which utilizes donation service areas (DSAs) and OPTN regions as units of distribution ("DSA-Based Policy"), would remain in effect. We also considered a supplement to your critical comment, submitted on January 10, 2021 (Tab B).

By letter dated December 14, 2020, the Health Resources and Services Administration (HRSA) directed that the OPTN Board hold in abeyance further implementation of the Fixed Circle Policy until February 13, 2021 (Tab C), while the Secretary considered the critical comment.[1]

On December 21, 2020, HRSA sought the views of the OPTN on the issues raised in your critical comment, as well as those presented in another critical comment filed by eight organ procurement organizations (OPOs) requesting a delay in implementation of the Fixed Circle Policy and a letter from four transplant centers in support of the Fixed Circle Policy (Tab D). On January 4, 2021, the OPTN (after consultation with the SRTR) submitted a 39-page response (Tab E).

HRSA continues its longstanding practice of relying on the expertise of the OPTN and its members to consider and address the requirements of the OPTN final rule as organ allocation policies are developed and revised. The Secretary is obliged to consider critical comments in light of the National Organ Transplant Act of 1984, as amended, (NOTA) and the OPTN final rule and may: "(1) Reject the comments; (2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or (3) Take such other action as the Secretary determines appropriate." 42 C.F.R. § 121.4(d); 42 U.S.C. § 274(c). We carefully

[1] The directive also authorized the OPTN to delay, pending completion of the Department's review, other policies scheduled for implementation on December 15, 2020, including the pancreas allocation policy, to avoid undue complications in the system.

reviewed your critical comment, your supplement, other correspondence concerning the Fixed Circle Policy, and the OPTN's response in light of the requirements of NOTA and the OPTN final rule. Our response is also informed by our prior reviews of the use of DSAs and regions in organ allocation and our oversight of the OPTN's organ allocation process.

Impact of COVID-19:

Your critical comment raises several concerns about the timing of the implementation of the Fixed Circle Policy during the COVID-19 pandemic, including concerns about transplant hospital resources that will be required for implementation of the new policy rather than providing support for COVID-19 cases, concerns that the OPTN has not adequately considered the impact of the pandemic, challenges with evaluating the effect of the policy due to impacts of the pandemic, and logistical challenges, such as reduced availability of flights, during the pandemic.

While we agree that COVID-19 has caused challenges for the U.S. healthcare delivery system, we disagree that this justifies a delay in implementing the Fixed Circle Policy. The U.S. transplant system has demonstrated resiliency in quickly adapting to the challenges and minimizing the impact of the pandemic on deceased donor organ procurement and transplantation, including kidney transplantation. In fact, the number of deceased organ transplants rose significantly in 2020 (17,583) compared with 2019 (16,534), despite the pandemic.[2] Specifically, the data show increased numbers of heart and liver transplants performed nationwide in 2020 despite the implementation of new OPTN heart and liver allocation policies in January 2020 and February 2020, respectively, which also removed DSAs as units of distribution.

| **Number of Deceased Donor Transplants Per Year** | | | | |
|---|---|---|---|---|
| | 2020 | 2019 | 2018 | 2017 |
| Heart | 3,658 | 3,552 | 3,408 | 3,242 |
| Liver | 8,415 | 8,372 | 7,849 | 7,715 |

On January 27, 2021, the University of Kansas Health System announced that, despite the pandemic, the transplant teams set a record during 2020 for their most procedures in a calendar year, including a record number of kidney transplants (203).[3] In fact, all six kidney transplant programs within transplant hospitals named as plaintiffs in *Adventist Health System v. HHS*, No. 20-cv-101 (S.D. Iowa), the pending lawsuit challenging the Fixed Circle Policy, performed more deceased donor transplants in 2020 than in 2019.

[2] OPTN data (January 25, 2021). While living donor transplants declined in 2020, such transplants are not impacted by the Fixed Circle Policy (which allocates deceased donor organs).
[3] LinkedIn post available at https://www.linkedin.com/posts/the-university-of-kansas-hospital_despite-the-pandemic-organ-and-heart-failure-activity-6758126273911914497-Lu23/ (last accessed January 29, 2021). University of Kansas also transplanted a record 43 hearts in 2020 even though the heart allocation policy changed from a DSA- and region-based allocation to a circle-based policy, effective January 9, 2020.

| Number of Deceased Donor Kidney Transplants Per Year | | | | | |
|---|---|---|---|---|---|
| | 2020 | 2019 | 2018 | 2017 | Increase 2020 over 2019 |
| Adventist Health | 156 | 123 | 128 | 142 | 27% |
| Medical University of South Carolina | 281 | 234 | 197 | 229 | 20% |
| University of Alabama | 278 | 203 | 170 | 185 | 37% |
| University of Iowa | 74 | 63 | 61 | 67 | 17% |
| University of Kansas | 175 | 122 | 87 | 87 | 43% |
| University of Kentucky | 94 | 87 | 68 | 71 | 8% |

We also do not agree that any potential changes in operational relationships resulting from a change in kidney allocation policy require delaying implementation of the Fixed Circle Policy. All OPOs in the United States have already developed relationships and processes to facilitate the allocation of livers, hearts, lungs, intestines, and vascularized composite allografts using fixed circles (rather than DSAs and regions) under new OPTN policies implemented since 2017. Thus, transplant hospitals that perform kidney transplants are likely benefiting from relationships that have already been forged. In addition, kidney transplant programs have experience working with OPOs outside of their DSAs even under the current DSA-Based Policy. Nearly 25 percent of kidneys under the DSA-Based Policy are allocated to hospitals in different OPOs. Transcript of Open Session of December 3, 2019, Meeting of the OPTN Board at 325.

We have also considered the logistical challenges you raised in your critical comment in general terms and specific to the pandemic, and concluded that they similarly do not justify a delay in the Fixed Circle Policy. The 250 nautical mile (NM) circle used in the Fixed Circle Policy was responsive to prior public comments concerning efficiency and transportation with respect to the prior proposed 500 NM circle. The OPTN Board adopted a 250 NM circle, based on the Kidney Committee's assessment that this distance would mitigate "the potential impact on patient outcomes, ischemic time, and organ loss," as well as "logistical concerns" raised in public comments.4 Indeed, the OPTN Kidney Committee determined that a 250 NM circle was the reasonable distance that organs could be driven rather than flown, and we believe this distance is still reasonable even during the pandemic. The Fixed Circle Policy further addresses distance through the use of proximity points, which prevent a kidney being transported further away when there is a candidate of similar priority closer to the donor hospital. Moreover, as with any organ allocation policy, if a hospital is unable to accept a kidney offer (due to the impact of COVID-19 at the hospital or for any other reason), the organ will be offered to other kidney transplant candidates on the waiting list until the kidney is accepted.

As detailed in Tab E, the OPTN has engaged in significant efforts prior to and throughout the pandemic to provide information, education, and other preparations to the transplant community, including transplant hospitals, with respect to the Fixed Circle Policy and the impact of the pandemic. Accordingly, the record does not support the argument that OPTN member hospitals

[4] https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf

had only 2 months to prepare for the new policy.[5] We are satisfied that the OPTN is proactively monitoring the impact of COVID-19 on transplantation, is regularly sharing data with HRSA, and has responded with appropriate policy changes when it determines that such changes were warranted.

Finally, we are satisfied that the OPTN's performance monitoring plan developed for the Fixed Circle Policy meets the requirements of the OPTN final rule, notwithstanding the challenges of isolating the effects of the policy raised in the critical comment. The OPTN has committed to a robust plan for post-implementation monitoring, including reviews of transplant recipient demographics such as race and socioeconomic factors, and HHS will exercise oversight going forward, including potential extensions of time for enhanced monitoring. Regardless, temporary difficulties in post-implementation monitoring do not justify the retention of an allocation policy that HHS has determined to be not compliant with the OPTN final rule.

After consideration of these arguments, we have determined that the pandemic and related issues raised in the critical comment do not warrant a further delay to or change in the Fixed Circle Policy given its projected benefits, including more equitable access to kidney offers for similarly situated kidney transplant candidates throughout the country.

SRTR Methodology and Models:

The critical comment raises concerns about the methodology and modeling used by the OPTN in developing the Fixed Circle Policy and avers that the new policy will harm patients. One of the primary goals of the Fixed Circle Policy is to ensure that kidney transplant candidates have more equitable access to kidney offers, regardless of the location of their transplant hospitals, by replacing the inequitable units currently being used (DSAs and regions)[6] with a more consistent and rational unit of distribution. We are unpersuaded that the Fixed Circle Policy will result in fewer kidney transplants, increased wastage, or increased discard of viable kidneys. The OPTN considered the modeling and predictions provided by the experts at the SRTR in light of the collective expertise of the members of the OPTN Kidney and Pancreas Committees and the OPTN Board, and concluded that the Fixed Circle Policy "makes significant steps towards achieving more equity in access to transplant by providing a consistent unit of distribution, 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." Tab E at 14. Nothing in the critical comment leads us to doubt the OPTN and SRTR's predictions about the outcomes of the change to the Fixed

[5] All OPTN member hospitals have been on notice since December 2019, when the Fixed Circle Policy was approved, that the policy was on track for implementation. The OPTN repeatedly referenced late 2020 for policy implementation over the course of many months and formally announced an implementation date of December 15, 2020, on October 20, 2020. All kidney transplant programs have been provided with extensive resources to assist in preparing for the policy change. *See* Tab E at 22-26, Att. 1.

[6] 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.

Circle Policy, particularly in light of the expertise and experience of the OPTN and SRTR to predict the outcomes of possible changes to organ allocation policies.

In particular, the OPTN response provides a detailed description of the modeling and methodology used and highlights that ". . . KPSAM [the model used] can make useful predictions about the direction of large-scale changes in many outcomes of interest to the policy development community, despite limitations in modeling behavior changes." *Id*. Of note, behavior changes can extend to myriad practices, including which organ offers are accepted and which personnel procure organs. The OPTN has explained that the model was "refined to better calibrate the simulation to expected behavior changes in response to the new policy," Tab E at 1. Given the reasonableness of OPTN's representations and in light of our ongoing oversight over the OPTN and the SRTR, we do not agree or find support for your assertion that the models were manipulated to produce desired results. As explained by the SRTR and the OPTN, changes were made to the model to eliminate an overestimate of the number of kidneys predicted to be discarded under the new policy. The 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. Transcript of Open Session of December 3, 2019, Meeting of the OPTN Board at 325. Under the Fixed Circle Policy, however, and informed by behavioral changes following other policy changes, including changes in individual transplant centers' organ acceptance criteria, the OPTN expects that higher quality kidneys will be offered and accepted outside of the DSA much more regularly. With respect to kidney-pancreas transplants, in light of the common practice of OPOs, we would expect that kidneys offered but not accepted for combined kidney-transplant procedures would be used in stand-alone kidney transplants rather than discarded. Therefore, we are comfortable with the models developed by the SRTR and utilized by the OPTN to predict the impact of the Fixed Circle Policy.

Consideration of Socioeconomic Factors:

We take seriously the allegation that the Fixed Circle Policy will increase harm to individuals with low socioeconomic status. However, we find persuasive the OPTN's response with respect to this issue given the projected impact of the Fixed Circle Policy on vulnerable populations. As noted above, one of the primary goals of the Fixed Circle Policy is "to grant kidney candidates more equitable access to transplantation, regardless of whether those candidates are of low or high socioeconomic status." Tab E at 27. The OPTN and SRTR endeavored to ensure that the Fixed Circle Policy would not have unintended negative effects on socioeconomically disadvantaged candidates. The SRTR extensively modeled the impact of the Fixed Circle Policy on different socioeconomic communities. In its updated analysis report, the SRTR provided a detailed overview of the predicted effect of ten different proposed kidney allocation policies, including the Fixed Circle Policy, on numerous demographic groups (including projections for transplant counts and percentages by race, ethnicity, insurance status (public or private insurance), and median household income. SRTR Analysis Report: Update, "Data Request from the OPTN Kidney Transplantation Committee: Provide KPSAM simulation data on effect of removing DSA and region from kidney/pancreas/kidney-pancreas organ allocation policy (June 21, 2019) at 29, 32, 48, 51, 55, 62, 65, 81, 84, 94, 104, 107, 123, 126, and 136. The Fixed Circle Policy is predicted to result in greater equity of transplant across populations, including

indicators of socioeconomic status, as compared with the DSA-Based Policy. Per SRTR projections, the Fixed Circle Policy is expected to result in an increased transplant rate for candidates enrolled in Medicaid, African American candidates, and Latino candidates.[7] Moreover, the record reflects that the OPTN thoroughly considered the socioeconomic impact of the policy and the SRTR's projections (e.g., in the OPTN's solicitation of public comments on kidney allocation, at meetings of the Kidney Committee, and at the December 2019 OPTN Board meeting). Further, the OPTN exercised reasonable judgment in not utilizing the metrics mentioned in your critical comment. The OPTN and SRTR have explained the limitations of such community-based metrics, opting instead to use the more granular and specific metrics that reflect the demographics of actual transplant candidates. Finally, because allocation policies only apply to individuals on the OPTN waiting list, such policies cannot address any inequities regarding the initial inclusion of specific patients on the OPTN waiting list.

Procedural Considerations:

Beyond these issues, the critical comment argues that the Fixed Circle Policy should have been referred to the Secretary's Advisory Committee on Organ Transplantation (ACOT) and published in the Federal Register. Consistent with HHS's longstanding practice, we reaffirm our position that 42 C.F.R. § 121.4(b)(2) does not apply to the Fixed Circle Policy. The same legal claim was rejected in a unanimous opinion by the United States Court of Appeals for the Eleventh Circuit. *Callahan v. HHS*, 939 F.3d 1251 (11th Cir. 2019). Putting aside the fact that such referral and publication is not legally required, we do not believe that taking these steps now would further the equitable allocation of organs. In 2010, the ACOT raised concerns about the inequities presented by DSAs in organ allocation and noted disparities created by a DSA-Based Policy.

In addition, members of the public were able to offer their public comments more than once as part of the OPTN process. The OPTN's public comment solicitation, open August-October 2019, proposed a policy utilizing a 500 NM circle, but also provided extensive data about several alternative policy proposals modeled by the SRTR, including the Fixed Circle Policy. The public comment document specifically solicited comments about the appropriate size of the circle utilized and the Fixed Circle Policy (which uses a 250 NM circle) was favored after consideration of public comments and concerns raised about a larger (500 NM) circle. This followed a prior (January-March 2019) solicitation of public comments on a concept paper that included five proposed kidney allocation policies. Members of the public were also able to share their views through other avenues, including at numerous OPTN meetings.

HHS has also exercised close oversight throughout the development of the Fixed Circle Policy, such as by attending all meetings of the OPTN Board and OPTN Committees, reviewing all written materials circulated with respect to the development of the Fixed Circle Policy, and reviewing all public comments submitted to the OPTN. HHS further exercised its authority under 42 C.F.R. 121.4(d) to seek the comments of the OPTN to assist in evaluating the assertions raised in your critical comment. We do not believe, however, that it is appropriate or necessary

[7] SRTR Analysis Report: Update (June 21, 2019). The Kidney Committee further concluded that "broader distribution is not disadvantaging non-metropolitan candidates compared to metropolitan candidates; it is equalizing their access." https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf at 29.

to refer the Fixed Circle Policy to ACOT or to publish the policy in the Federal Register for comment. No OPTN policy has ever undergone such procedures.

Both the Kidney Committee and the Pancreas Committee separately discussed whether to adopt transition procedures, and concluded that none were needed.[8] The OPTN Board received and adopted these conclusions, as described in Tab E.[9] As the OPTN final rule requires only that transition procedures be considered, we accept that the OPTN has complied with the requirement.

The critical comment and the supplement to the critical comment also raise allegations of bias by UNOS or OPTN employees or volunteers, referencing documents that are under seal in pending litigation concerning policymaking with respect to the OPTN's liver allocation policy. Your submissions do not cite any specific documents or make clear how you believe those documents may be relevant to the Fixed Circle Policy. In any event, the referenced materials that remain under seal were reviewed within the Department in connection with *Callahan v. HHS* and do not change HHS's conclusions with respect to the Fixed Circle Policy. We recognize that individuals may have strong policy preferences and perspectives with which others may vehemently disagree; HHS bases its independent determinations on whether the policy adopted by the OPTN Board, the rationale provided, and the supporting evidence are consistent with applicable law.

Elimination of DSAs:

We maintain HRSA's July 2018 conclusion that DSAs and OPTN regions cannot be justified as units of distribution in organ allocation policies. We find the arguments presented in the critical comment with respect to this conclusion unpersuasive given the nature of these sometimes non-contiguous administrative units, as described in HRSA's July 2018 letter (*e.g.*, varying in geographic size and population). As HRSA explained in that letter, organ allocation policies may "not be based on a candidate's place or residence or place of listing, except to the extent *required*" by certain other considerations, such as "sound medical judgment," "the best use of donated organs," and avoiding the wastage of organs. *See* 42 C.F.R. § 121.8(a)(1)-(5), (8) (emphasis added). Nothing in the regulation requires the use of DSAs and regions as unit of allocation, and all available evidence demonstrates that their use is inconsistent with that regulation. Both HRSA and the OPTN have repeatedly recognized that use of DSAs and regions in allocation has caused significant inequity in terms of access to organs, based entirely on a candidates' place of residence or listing. HRSA has noted that the problems associated with DSAs were not limited to liver allocation. Such problems have been widely recognized for many years with respect to the allocation of *all* organs, including the ACOT's recognition of persistent "geographic disparities in patient access to transplantation" in 2010. Moreover, the July 2018 letter did not mandate that the OPTN pursue any particular policy and made clear that geographic constraints may be appropriate if they can be justified in light of the regulatory

[8] https://optn.transplant.hrsa.gov/media/3772/20200422-kidney-meeting-summary.pdf; https://optn.transplant.hrsa.gov/media/3771/20200416_pancreas_meeting-summary.pdf

[9] OPTN Memo: June 2020 – Consideration of Transition Procedures for Recent OPTN Allocation Policies. Distributed to the OPTN Board of Directors in June 2020. Available upon request to the OPTN.

requirements. Thus, the OPTN was free to adopt an allocation policy that utilized geographic constraints tailored to kidneys, consistent with the requirements of the OPTN final rule.[10] The sole prohibition included in the July 2018 letter concerned the use of DSAs and OPTN regions (as then-constituted) as units of distribution based upon HRSA's independent recognition, consistent with prior findings of the OPTN and the ACOT, that the deficiencies associated with using these administrative units in organ allocation are not specific to any organ type.

HRSA conducted an independent review of the legality of DSAs, as reflected in the July 2018 letter, which references findings and correspondence by non-OPTN sources, and reaffirms its position here concerning the legal and policy problems with allocation policies that use DSAs as units of distribution in organ allocation policy, and, specifically, with respect to the kidney policy.[11]

Conclusion:

As HRSA explained in its July 2018 letter, it is not always possible for the OPTN, which represents the diversity of transplant stakeholders, to achieve consensus as it develops organ allocation policies. Given that the demand for donated organs tragically exceeds the supply, it is understandable that there are inevitable disagreements by some in the transplant community. Even so, the OPTN is charged with developing equitable allocation policies that apply nationwide to best serve patients awaiting the precious resource of donated organs. The experts in the OPTN concluded that the Fixed Circle Policy best achieves equitable allocation of organs among patients based upon expert modeling predicting that the policy will produce better outcomes for kidney transplant candidates as a whole. Upon review of all of the materials presented in this matter, based upon our oversight of the OPTN's policy development process, and in light of the statutory and regulatory requirements that apply to organ allocation, I am persuaded that the Fixed Circle Policy should go into effect without further delay.[12] On this basis, I am resolving your critical comment.

[10] HRSA's July 2018 letter clarified that its findings were made only with respect to OPTN regions as then constituted and that "[u]sing other regional units as part of organ allocation policies is not foreclosed under the OPTN final rule as long as the regulatory requirements are satisfied."

[11] HRSA has no concerns about the use of DSAs for other purposes, such as organ procurement or organizational matters.

[12] As counsel in *Adventist v. HHS*, you are aware that the Government has agreed that the Fixed Circle Policy should not go into effect until 30 days after the date of this letter, to permit sufficient time for briefing and decision in that matter. Per that schedule, the Court will be afforded thirty days, beginning today, to be briefed by the parties on any renewed motion for injunctive relief and to rule on such motion. Thus, the Fixed Circle Policy will not be implemented prior to the expiration of that timeframe.

We greatly appreciate the concerns expressed in your critical comment and are mindful of the patients impacted by every OPTN organ allocation policy.

Sincerely,

Norris W. Cochran IV -S

Digitally signed by Norris W. Cochran IV -S
Date: 2021.02.12 17:11:23 -05'00'

Norris Cochran
Acting Secretary

Enclosures:
Tab A: Critical Comment (December 2, 2020)
Tab B: Supplement to the December 2, 2020, critical comment (January 10, 2021)
Tab C: HRSA letter to the OPTN (December 14, 2020)
Tab D: HRSA letter to the OPTN (December 21, 2020)
Tab E: OPTN response to HRSA (January 4, 2021)

JONES DAY

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December 1, 2020

VIA E-MAIL AND COURIER

The Honorable Alex M. Azar II
Secretary of the U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Email: secretary@hhs.gov

**Re: OPTN Kidney Distribution and Allocation Policy**

Dear Secretary Azar:

This firm represents hospitals across the country with multi-specialty transplant centers that perform thousands of kidney transplants each year (collectively, the "Hospitals"). On behalf of their patients and physicians, these Hospitals object to the flawed new kidney allocation policy and to the OPTN's decision to plunge ahead with its implementation in the midst of a massive strain on the nation's health care system resulting from the unprecedented escalation in COVID-19 cases.[1] We ask that you give this letter your immediate attention in light of the proposed policy implementation date of December 15, 2020 and the pressing need for hospitals to devote human and financial resources to the pandemic.

This letter serves as a "critical comment" under 42 C.F.R. § 121.4(d) regarding the manner in which the Organ Procurement Transplantation Network ("OPTN") is carrying out its duties. The Hospitals respectfully request that you take immediate action to stop implementation of the new kidney allocation policy (the "Fixed Circle Policy"). The Hospitals request that you direct the OPTN to provide the Fixed Circle Policy for your review at least 60 days prior to implementation and further that you refer this "significant" policy to the Advisory Committee on Organ Transplantation and publish the policy in the Federal Register for comment. *Id.* § 121.4(b)(2).

[1] *See, e.g.*, Reed Abelson, *Covid Overload Pushes Hospitals to the Brink*, N.Y. Times (Nov. 28, 2020).

## BACKGROUND

Kidney disease is the ninth-leading cause of death in the United States, and the cost to care for those affected accounts for more than one in five dollars spent by Medicare.[2] The primary form of treatment for kidney failure is dialysis, which is expensive and burdensome for both patients and the health care system, but there is a better option—organ transplants. Unfortunately, there are almost 100,000 Americans currently on the waiting list for kidneys, and there are not enough organ donors to help. This shortage of organs has led to debate over the best way to distribute these life-saving gifts to patients in need.

Historically, organs have been distributed in part based on donation service areas ("DSAs") and larger geographic areas known as Regions. In recent years, a subset of individuals within the transplant community, many of whom stand to benefit financially from a change in allocation policy that eliminates DSAs, successfully captured control of the entity that operates the OPTN, the United Network for Organ Sharing ("UNOS"). In a lawsuit that challenged the removal of DSAs in liver allocation, the court recognized that plaintiffs had "proffered evidence of bad faith, undisclosed ex parte communications, and improper predetermination by Defendant UNOS."[3] Further, the process to change the liver policy "was managed [by UNOS] in a rushed time frame and manner that bred ill will and the sense of railroading to a 'predetermined' policy end line."[4] As a result of this improper behavior and influence within UNOS, the OPTN has largely shirked its statutory and regulatory responsibility to ensure that the organ transplantation system is operated with scientific consensus in a manner that prevents organ waste, is attuned to socioeconomic disparities, and ensures safe and fair transitions when there is a change in allocation policy.

In February 2020, when testifying before the Senate Appropriations Subcommittee, you yourself expressed concerns and frustrations with UNOS. In fact, you testified that HHS had requested UNOS to reconsider its decision to implement the liver allocation policy. However, you further testified that you were powerless to require any changes to the policy. You claimed that by statute you were "walled off" from changing the OPTN's decisions.[5] As explained in this letter, that is simply not true. In fact, at a minimum, you have clear authority to: (1) request the OPTN to provide proposed policies to you at least sixty days before their proposed

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[2] *Advancing American Kidney Health*, U.S. DEP'T OF HEALTH & HUMAN SERVS. 3-4 (July 10, 2019), available at https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.

[3] *Callahan v. U.S. Dep't of Health & Human Servs.*, 434 F. Supp. 3d 1319, 1364 (N.D. Ga. 2020).

[4] *Id.* at 1366.

[5] *See* Letter from Roy Blunt, U.S. Senator, to Alex Azar, Secretary, U.S. Dep't of Health & Human Servs. (Mar. 16, 2020), available at https://www.blunt.senate.gov/imo/media/doc/Letter%20to%20Azar%20-%20March%202020_Signed.pdf.

implementation and (2) direct the OPTN to revise its policies or practices consistent with your response to any critical comment, such as this one. 42 C.F.R. § 121.4(b)(2), (d)(2).

Because of the bad faith exhibited by UNOS, your oversight of these matters and exercise of your regulatory authority is critical. In the liver litigation, the district court concluded that it could not impute UNOS's bad faith onto HHS, "absent a showing that HHS was involved in, or at the very least, aware of the bad faith."[6] Yet today, HHS is very much aware of UNOS's bad faith and has full access to documents that remain under seal in the liver litigation.[7] HHS cannot now claim that it is unaware of the biased forces at work within UNOS that have led to the Fixed Circle Policy and to the effort to radically change kidney allocation in the middle of a public health crisis.

Moreover, HHS's instruction, as expressed through the Health Resources and Services Administration ("HRSA"), led in part to the development of this ill-conceived policy. In the summer of 2018, HRSA asked UNOS to justify the use of DSAs, and rather than defend the long-standing system, UNOS's biased leadership argued that such a system could not legally be defended. On July 31, 2018, HRSA notified the OPTN that the use of DSAs and OPTN Regions "has not been and cannot be justified under the OPTN final rule." HRSA then "direct[ed] further OPTN action consistent with HRSA's oversight role," specifically to remove DSAs and Regions from all organ allocation policies, including kidney.[8] The next week, the OPTN Kidney-Pancreas Workgroup started its meeting with "a reminder of our task: to remove DSA and regions from kidney allocation policy."[9] Given that you issued this directive in 2018, you cannot now shy away from the legal responsibility you have to make sure the OPTN acts in a lawful manner.

The Fixed Circle Policy and the process that led to it are both deeply flawed, but the most troubling aspect of the process is that UNOS is now set to implement a drastic policy change in

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[6] *Callahan*, 434 F. Supp. 3d at 1356 (Doc. 261 at 60).

[7] The district court has granted an order unsealing the documents (*Callahan v. U.S. Dep't of Health & Human Servs.*, No. 1:19-cv-1783-AT, 2020 WL 6336129 (N.D. Ga. Sept. 29, 2020) (Doc. 298), but the documents remain sealed pending UNOS's appeal of that order. *Callahan v. United Network for Organ Sharing*, No. 20-13932 (11th Cir. appeal filed Oct. 20, 2020).

[8] Letter from George Sigounas, HRSA Administrator, to Sue Dunn, OPTN President (July 31, 2018), available at https://optn.transplant.hrsa.gov/media/2583/hrsa_to_optn_organ_allocation_20180731.pdf. The Hospitals maintain that HRSA's direction and the OPTN's action were based on an erroneous conclusion of law (that DSAs and Regions can never be justified), and as such, the action must be set aside as invalid. *See Transitional Hosps. Corp. of La., Inc. v. Shalala*, 222 F.3d 1019, 1029 (D.C. Cir. 2000).

[9] Minutes, OPTN/UNOS Kidney-Pancreas Workgroup, (Aug. 7, 2018), available at https://optn.transplant.hrsa.gov/media/3348/20190807_kp-workgroup-meeting.pdf.

the midst of a global pandemic without any consideration as to how the COVID-19 crisis will affect the implementation or impact of the policy. The policy was developed in 2019 and was adopted by the OPTN Board of Directors in December 2019. From the time the COVID-19 crisis hit until October 20, 2020, when the implementation date was announced, there was apparently no effort to study the effects of the pandemic and consider whether the policy change was appropriate.

Under these circumstances, it is your obligation to suspend the implementation of the Fixed Circle Policy and request that the OPTN present the policy to you at least sixty days before implementation. Further, given the significant nature of the policy, not to mention the questionable motives of UNOS leadership as explained in this letter, you must submit the policy to the Advisory Committee on Organ Transplantation ("Advisory Committee") and publish it in the Federal Register for public comment.

## IT IS UNLAWFUL AND DANGEROUS TO CHANGE KIDNEY ALLOCATION POLICY DURING THE COVID-19 PANDEMIC

Fundamentally changing organ allocation policy during the middle of a global pandemic that has dramatically affected health care in the United States is arbitrary, capricious, and an abuse of discretion. Hospitals must continue to focus on caring for patients rather than being forced to overhaul their operations and explain complex and life-altering policy changes to their patients and staff. In addition, if the new policy were to be implemented later this month as scheduled, it would be virtually impossible to assess its effects as required by law because of the confounding variables presented by the pandemic's impact on organ transplantation. You have the authority to postpone the policy by at least sixty days, simply by asking the OPTN Board to provide you with the policy before it is implemented. It is unlawful for you to fail to exercise such authority under the current circumstances.

### A. The Policy Change Requires Resources and Attention that Are Necessary to Respond to the Public Health Emergency

Changing an organ allocation policy has significant effects for both hospitals and patients. The OPTN has recognized that the new policy will require hospitals "to develop relationships" with new organ procurement organizations ("OPOs"), "with whom they have not worked previously."[10] In addition, "transplant hospitals may need to adjust their operations to

[10] Scott Castro, *Eliminate the Use of DSA and Region from Kidney Allocation Policy* 44, available at https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf (last visited Nov. 30, 2020) [hereinafter "Policy Proposal"].

account for the practices of their new OPO partners."[11] Further, the changes "may also impact overall transplantation program costs" and "programs may need to hire more transplant surgeons to travel further to recover kidneys from donors."[12] Finally, and perhaps most importantly, transplant programs must educate their patients on the impact of the new policy and how it affects the patients' likelihood of receiving organ offers.

Thus, a policy change of this magnitude is a significant burden on transplant programs and is difficult at any time, but it is an abuse of discretion to require hospitals to devote resources to an unnecessary policy change in the middle of a public health crisis. The COVID-19 pandemic is demanding the full attention of hospitals while at the same time crippling their finances, and the recent surge in cases is only making things more challenging. It is imperative that hospitals focus on responding to the pandemic and performing life-saving organ transplants in the middle of these unprecedented times rather than forging new relationships with OPOs and needing to adjust long-standing operations in response to an entirely new process.

Moreover, the change in policy could dramatically affect a patient's waiting time and likelihood of receiving an organ, requiring that transplant physicians and personnel carefully explain the meaning of the new policy to patients, especially because the OPTN has failed to set forth any transition policy. The Final Rule requires that when the OPTN revises organ allocation policies, "it shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies." 42 C.F.R. § 121.8(d)(1). Notably, in the liver litigation, the district court opined that "[t]he implementation of transition measures to mitigate disruption and patient harm as the new [allocation] policy is implemented should be an essential priority."[13] Yet the OPTN has not published any statements or analysis regarding the consideration of such transition procedures for either kidney or liver—procedures that are even more essential in light of the pandemic.[14]

Not only has the OPTN failed to consider the impact of COVID-19 on both hospitals and patients, the OPTN did not even announce the date for implementation until October 20, 2020—

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[11] *Id.* at 45.

[12] *Id.*

[13] *Callahan*, 434 F. Supp. 3d at 1373 (Doc. 261 at 99-100).

[14] The Kidney Committee briefly discussed transition procedures, but there is no reference to the impact of COVID-19 or analysis explaining why the Committee concluded that transition procedures were not necessary. *See* Meeting Summary, OPTN Kidney Transplantation Committee (Apr. 22, 2020), available at https://optn.transplant.hrsa.gov/media/3772/20200422-kidney-meeting-summary.pdf.

giving transplant centers less than two months to prepare and discuss with their patients.[15] Transplant patients are especially apprehensive about COVID-19,[16] meaning that transplant centers need even more time than usual to carefully explain the impact the new policy will have. Compressing patient notifications into a short period of time while hospital resources are already strained impairs the hospitals' ability to serve its patients. The current allocation policy has been in effect for six years, and there is no reason why the policy must be changed right now when hospital physicians, administrators, and other staff rightfully have their attention focused on the once-in-a-generation challenges of the pandemic.

### B. The Effect of a Policy Change Cannot Be Evaluated During a Pandemic as Required by Law

The implementing regulations of the National Organ Transplant Act (known as the "Final Rule") require that each change in allocation policy include metrics to measure how well the policy achieves its performance goals and the amount of projected improvement. 42 C.F.R. § 121.8(c)(1), (2). In addition, the regulation states that "the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of OPOs and the OPTN contractor." *Id.* § 121.8(c)(3). Implementing a policy change during the middle of a pandemic makes it impossible for the OPTN and HHS to comply with this regulation.

HRSA's data contractor, the Scientific Registry of Transplant Recipients ("SRTR"), has reported that "COVID-19 has had a large impact on the transplant system."[17] Indeed, research has shown that "COVID-19 has affected virtually all aspects of kidney transplantation, including

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[15] *Dec. 15 Implementation Date Set for Changes to Kidney, Pancreas Allocation*, UNITED NETWORK FOR ORGAN SHARING (Dec. 12, 2020), available at https://unos.org/news/dec-15-implementation-date-set-for-changes-to-kidney-pancreas-allocation. Previously, UNOS had stated the policy would change in "late 2020," but no date had been provided. Moreover, until the announcement on October 20, it was not clear to those within the transplant community that UNOS intended to move forward with the change in policy during the pandemic.

[16] Philipp A. Reuken, et al., *Between Fear & Courage: Attitudes, Beliefs, and Behavior of Liver Transplantation Recipients and Waiting List Candidates During the COVID-19 Pandemic* (May 27, 2020), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16118.

[17] *COVID-19 Changes: Upcoming Adjustments to Transplant Program and OPO Evaluation Metrics*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS (Aug. 6, 2020), https://www.srtr.org/news-media/news/news-items/news/#covid19psrosrchanges.

the donor supply and both candidates and recipients."[18] Moreover, the effects of COVID-19 have not been uniform throughout the country. "Preliminary data suggest that the pandemic has had a differential effect on different areas of the country at different times, making it a challenge to deal with statistically until more data becomes available."[19] Simply put, different geographic regions have experienced the pandemic differently, resulting in significant geographic variation in the number of transplant procedures and the data usually assessed for policy changes. These geographical differences are especially important when considering a change to policy such as that contemplated for kidney—where the stated policy goal is "to increase geographic equity in access to transplantation."[20] Because COVID-19's impact on transplantation varies across the country, it will be impossible to say whether geographic variances seen in transplant after the implementation of a new policy are attributable to COVID-19 or to the change in policy.

This is exactly what happened when the OPTN evaluated a change to liver allocation policy that took effect just six weeks before the declaration of the national emergency. In October 2020, the OPTN examined data from six months after implementation, and the SRTR opined that the "true impact of [the] policy change is very challenging to determine" because of COVID-19.[21] For example, the six-month report showed that there were 143 fewer liver transplants performed after the new policy was implemented compared to the same time period the year before. Yet the report notes that this information "should be interpreted with caution as the COVID emergency that followed shortly after policy implementation impacted transplant practices across the U.S."[22] An SRTR representative explained that "it's hard to sort out effects of [the change in policy] and COVID-19 as they overlap in periods."[23] A similar warning was issued in July when the OPTN reviewed the three-month data: "The impact of [the] COVID-19 pandemic will continue to be a confounding factor in analyzing this policy change in the coming

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[18] Brian J. Boyarsky, *Early National & Center-Level Changes to Kidney Transplantation in the United States During the COVID-19 Epidemic* 3132 (June 28, 2020), available at https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.16167.

[19] SCI. REGISTRY OF TRANSPLANT RECIPIENTS, *supra*, note 17.

[20] Scott Castro, *Elimination of DSA & Region from Kidney Allocation Policy* 2, available at https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (last visited Dec. 1, 2020) [hereinafter "Briefing Paper"].

[21] Samantha M. Noreen, et al., *Out-of-the-Gate Monitoring of Liver & Intestine Acuity Circle Allocation* 11 (Oct. 18, 2020), available at https://optn.transplant.hrsa.gov/media/4121/liver_allocation_6monthmonitoringreport_2020oct18.pdf.

[22] *Id.* at 25.

[23] Meeting Summary, OPTN Liver & Intestinal Organ Transplantation Committee 3 (Oct. 22, 2020), available at https://optn.transplant.hrsa.gov/media/4177/20201022_liver_meeting_summary.pdf

months."[24] In fact, for some analyses, SRTR completely excludes data impacted by COVID-19 because of the confounding effect. "Under normal circumstances, the liver allocation system would likely take several months to reach an equilibrium. The emergence of COVID-19 likely confounds many of the analyses included in the evaluation. For this reason, the adjusted analyses include data only up to March 12, 2020, the day before the declaration of a national emergency for COVID-19."[25]

For the proposed change in kidney policy, the OPTN has stated that it will formally evaluate the Fixed Circle Policy's effects 3 months, 6 months, 1 year, and 2 years post-implementation.[26] During a recent webinar, in response to a question as to whether the policy change could cause adverse effects, the OPTN expressly stated that "unforeseen effects could happen," and that is "part of the reason we always, when we make changes like this, we insist on monitoring afterwards so that if the unforeseen changes are major and have a negative effect that we can then immediately intervene on them and address them."[27] As part of this monitoring, the OPTN has explained that it would review metrics such as new kidney waitlist registrations, waitlist mortality, variance in deceased donor transplant rate across DSA, and post-transplant outcomes.[28] Yet the SRTR has concluded that these exact metrics are *not* reliable after March 13, 2020 and has removed them from its reporting on transplant center performance.[29] Moreover, one recent study found that the impact of COVID-19 on these metrics varies widely across the country. Specifically, waitlist mortality "was 2.2-fold higher than expected in the 5 states with highest COVID-19 burden," even though it was consistent with normal expectations nationwide.[30] In addition, states with higher COVID-19 incidence experienced greater drops in

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[24] Meeting Summary, OPTN Liver & Intestinal Organ Transplantation Committee (July 2, 2020), available at https://optn.transplant.hrsa.gov/media/3911/20200702_liver_meeting_summary.pdf.

[25] *Liver Allocation: SRTR Evaluation of Acuity Circles*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS, https://www.srtr.org/reports-tools/acuity-circles-evaluation (last visited Nov. 30, 2020).

[26] Policy Proposal, *supra*, note 10, at 45.

[27] *Transplant Patient Webinar Recording Now Available*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, at 49:40 (Nov. 23, 2020), available at https://optn.transplant.hrsa.gov/news/transplant-patient-webinar-recording-now-available/.

[28] Policy Proposal, *supra*, note 10, at 46-47sa.

[29] SRTR has removed "patient and donor data from the performance metrics following the declaration of a national emergency on March 13, 2020. For transplant programs, this means that . . . waitlist survival, transplant rate, and outcomes will not be assessed after that date." *COVID-19 Changes: Upcoming Adjustments to Transplant Program & OPO Evaluation Metrics*, AM. SOC. OF TRANSPLANTATION (Aug. 7, 2020), https://www.myast.org/covid-19-changes-upcoming-adjustments-transplant-program-and-opo-evaluation-metrics.

[30] Boyarsky, *supra*, note 18, at 3136.

new waitlist registrations and the number of transplants.[31] In short, the data the OPTN plans to track to monitor the effects of the Fixed Circle Policy has been affected by the pandemic in ways that are significant, but variable and impossible to predict. It would be arbitrary and capricious to implement a new policy and purport to rely on assessment metrics to track the success or failures of that policy when such metrics are unreliable in the midst of this crisis.

### C. HHS Must Act to Evaluate the Policy and Implementation Timeline in Light of the Public Health Emergency

Under the Final Rule, you have the authority to direct the OPTN to provide ***any*** policy to you at least sixty days before implementation. 42 C.F.R. § 121.4(b)(2); *see Callahan v. U.S. Dep't of Health & Hum. Servs.*, 939 F.3d 1251 (11th Cir. 2019) ("[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 . . . ."). Further, you have a legal obligation to refer "significant proposed policies to the Advisory Committee on Organ Transplantation" and "publish them in the Federal Register for public comment." 42 C.F.R. § 121.4(b)(2).[32] A policy that completely overhauls the way in which life-saving kidneys are distributed across the country is undoubtedly "significant."

Your careful oversight and review of the Fixed Circle Policy is especially important because the policy was developed, modeled, and adopted before the pandemic. Despite the fact that the OPTN has made other policy and operational changes as a result of COVID-19,[33] there has been no assessment of the effects of COVID-19 on the Fixed Circle Policy. Indeed, based on the public discourse to date, *the OPTN has entirely failed to consider the impact of COVID-19 on kidney allocation policy*.

As one example, it is clear that the OPTN has not adequately considered how the significant change in commercial flight schedules—and especially the decrease in direct

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[31] *See id.* at 3135.

[32] Under the most natural reading of the regulation, you must refer to the Advisory Committee and publish in the Federal Register any significant proposed policy, or at least any significant proposed policy of which you have constructive receipt. While the Hospitals disagree with HHS's regulatory interpretation and reserve the right to challenge it, this letter assumes you are in agreement with HHS's legal position that you do not necessarily have an automatic legal obligation to refer this significant policy to the Advisory Committee and Federal Register. Even if that were so, however, it is arbitrary and capricious for you to fail to ask the OPTN for the kidney allocation policy sixty days before implementation for the reasons set forth in this letter.

[33] *See, e.g.*, *COVID-19 operational actions to remain in effect through Dec. 31*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK https://optn.transplant.hrsa.gov/news/covid-19-operational-actions-to-remain-in-effect-through-dec-31 (describing the actions taken to help "address and document COVID-19 issues affecting organ donation and transplantation").

flights—will impact the effects of the policy. Based on data modeling, the OPTN concluded that the Fixed Circle Policy would decrease transplant rates in non-metropolitan areas but only slightly.[34] However, that prediction does not consider the significant decrease in direct flights and limited commercial transportation available because of COVID-19, especially in non-metropolitan areas. Unlike donated hearts or lungs, which typically fly via charter jet, donated kidneys are beholden to commercial air travel. One study examining the effect of COVID-19 on organ transplantation found that there were 65.1% fewer flights between selected cities in April 2020 compared to April 2019.[35] The decreased flight availability affected certain cities more than others—some routes lost 100% of direct flights. Further, there was an increase in wait time between flights from a median of 1.5 hours in 2019 to 4.9 hours in 2020, affecting how quickly a donated organ could arrive at the recipient hospital. There was also an increase in flight cancellations, which was especially concerning because a donated kidney set to travel on a designated flight may instead end up sitting at the airport for hours and "could significantly increase [cold ischemic time] while worsening recipient posttransplant outcomes."[36] In making the decision to plow ahead with implementation of the Fixed Circle Policy in December 2020, there was no consideration given to the effect of this substantial change in commercial air transportation, a change that is likely to last far longer than the pandemic.

HHS's role in overseeing the OPTN, and especially in reviewing allocation policies, is even more critical in light of evidence that arose during litigation surrounding a similar change to liver allocation policy. Specifically, it was demonstrated that there was "colorable evidence of animosity and even some measure of regional bias" by OPTN and UNOS leadership.[37] "[M]ajor players within the transplant community had an agenda" and "enjoyed particularly close access to the ear of UNOS's executives" in 2018 and 2019.[38] This agenda has been driven in part by the

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[34] Briefing Paper, *supra*, note 20, at 29.

[35] Alexandra T. Strauss, et al., *Impact of the COVID-19 Pandemic on Commercial Airlines in the United States and Implications for the Kidney Transplant Community* 3128 (Aug. 19, 2020), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16284.

[36] *Id.* at 3129; *see also* Gregory Wallace & Pete Muntean, *Delta cancels more than 500 flights this week amid crew shortages*, CNN Business (Nov. 27, 2020), https://www.cnn.com/2020/11/27/business/delta-cancels-more-than-500-flights-this-week-amid-crew-shortages/index.html. The lack of flights and broader geographic distribution of organs also impairs the transplant system's ability to properly perform HLA typing necessary for transplantation.

[37] *Callahan*, 434 F. Supp. 3d at 1363. Specific examples of this animosity and bias were presented to a federal district court as part of the liver litigation but remain under seal. As noted above, the district court concluded in that case that there was insufficient evidence that HHS was aware of the bad faith displayed by UNOS. Even if that were true, as a result of the liver litigation, HHS is now on notice of UNOS's biases and must act with additional care before allowing a significant policy change to move forward.

[38] *Id.*

fact that its supporters stand to financially benefit if such policies take effect and move organs from poorer, rural regions into wealthier, metropolitan areas. Given these facts, it is essential that HHS take the time to evaluate changes to kidney allocation policy and ensure that any new policy is truly the best allocation policy for the country, not just for the biased few currently in charge at UNOS.[39]

The Fixed Circle Policy was developed, analyzed, and adopted in a pre-coronavirus climate that is vastly different from the current environment. There is no immediate need for kidney allocation to be changed during the middle of a global health crisis. You have the authority and the responsibility to direct the OPTN to submit the policy to you sixty days before implementation so that HHS may consider the impact of the pandemic on the policy change and seek counsel from the Advisory Committee and public comment.

## THE FIXED CIRCLE POLICY WILL HARM PATIENTS

Even setting aside COVID-19, there are numerous other issues with the Fixed Circle Policy that make it unlawful for you to fail to stop its implementation. The President's Executive Order on Advancing American Kidney Health requires you to "streamline and expedite the process of kidney matching and delivery to reduce the discard rate."[40] Indeed, as part of compliance with this Executive Order, you have set a goal to double the number of kidneys available for transplant by 2030 and to increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate.[41] Regrettably, the Fixed Circle Policy works against these goals by *decreasing* utilization of available organs and *increasing* the discard rate. In addition, the OPTN has not adequately assessed the policy's impact on socially vulnerable communities and has failed to consider transition policies to assist patients who are currently waitlisted. Because of the legal and public policy problems created by all of these failures, the law requires you to halt implementation of the policy.

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[39] The OPTN public comment process of the Fixed Circle Policy was seriously flawed, which further calls into question the OPTN's decision to move forward with the policy implementation during the pandemic. The request for public comment focused only on a policy proposal that would share organs across a 500 nautical mile circle in contrast to the final 250 nautical mile circle policy. The public lacked adequate notice that the 250 nautical mile policy was under consideration, and very few comments substantively addressed this version of the policy.

[40] Exec. Order No. 13879, 84 Fed. Reg. 33817, 33818 (2019), https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health.

[41] U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra*, note 2, at 3.

### A. The Fixed Circle Policy Reduces the Number of Kidney Transplants

Under the Final Rule, allocation policies must, among other things, "seek to achieve the best use of donated organs" and "be designed to avoid wasting organs."[42] The Fixed Circle Policy acts against these requirements by causing significantly more organs to go to waste. At best, there will be 250 *fewer* kidney transplants performed annually under the Fixed Circle Policy.[43] In addition, according to SRTR's analysis, the waitlist mortality count and graft failure rates will both *increase* under the new policy.[44] If the policy results in fewer transplants, increased waitlist mortality, and increased failed transplants, more patients will surely die.

But instead of facing the reality that the policy endorsed by its biased leaders will cause patient harm, UNOS has turned to the variation in transplant rates across DSAs as a justification for the kidney allocation change.[45] The OPTN asserts that these variable rates are indicative of inequities in organ allocation, which are attributable to certain DSAs unfairly having better access to organs than other DSAs. Yet if this were true, and variation in transplant rate was simply reflective of allocation policy, then transplant centers within the same DSA—with current access to an identical pool of organs—would have similar transplant rates. But that is far from the reality. For example, the transplant rate at New York University is 39.5 while the transplant rate at Mount Sinai—in the same DSA with access to the same organs—is 5.9.[46] Does that mean the allocation within the DSA is flawed and the national policy needs to be changed? No.

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[42] 42 C.F.R. § 121.8(a)(2), (5).

[43] The OPTN has claimed this loss of kidneys will be compensated in part with an increase in kidney-pancreas transplants, but that assumption fails to take into account that pancreata have a lower tolerated ischemic time, which affects acceptable travel distance for those dual organ transplants. Further, to the extent there could be an increase in kidney-pancreas transplants, this would disadvantage the Black community in a way that was not contemplated by the OPTN. Kidney-pancreas transplants are primarily used for diabetes patients, but insurance companies only routinely cover such transplants for Type 1 diabetes, which predominantly affects white individuals. Insurance companies do not uniformly cover kidney-pancreas transplants for Type 2 diabetes, which predominantly affects Black individuals. The SRTR modeling of the policy's effects did not consider these variations in insurance coverages.

[44] SALLY GUSTAFSON ET AL., SCI. REGISTRY OF TRANSPLANT RECIPIENTS, ANALYSIS REPORT: UPDATE 10 (June 21, 2019), https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf.

[45] OPTN/UNOS Public Comment Proposal, Eliminate the Use of DSA and Region from Kidney Allocation Policy at 6, 19-21, https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf.

[46] SCI. REGISTRY OF TRANSPLANT RECIPIENTS, MOUNT SINAI MEDICAL CENTER PROGRAM-SPECIFIC REPORT 6 (July 8, 2019), www.srtr.org/PDFs/072019_release/pdfPSR/NYMSTX1KI201905PNEW.pdf (rate for adult deceased donor transplant); SCI. REGISTRY OF TRANSPLANT RECIPIENTS, NEW YORK UNIVERSITY MEDICAL CENTER PROGRAM-SPECIFIC REPORT 6 (July 8, 2019), https://www.srtr.org/PDFs/072019_release/pdfPSR/NYUCTX1KI201905PNEW.pdf.

Transplant rates vary across DSAs because those rates vary across transplant centers within the DSAs. Transplant rates are affected by, among other things, each transplant center's waitlist population and waitlist management, organ acceptance practices, and the availability of living donor transplants, in addition to local OPO performance.[47] Importantly, the transplant rate is directly affected by the number of candidates on the waitlist, *including inactive candidates*.[48] Inactive candidates are not eligible to receive an organ offer, but they currently comprise approximately 40% of overall waitlisted kidney candidates.[49] Some geographic regions and transplant centers list large numbers of inactive status patients, which significantly decreases the DSA's transplant rate without reflecting any type of geographic inequity in allocation. Notably, UNOS does not even attempt to consider the reasons for why the variation in transplant rates across DSAs exists—it simply takes as a given that such variation is problematic and is the result of a flawed allocation policy. But in light of the inherent variation in transplant rates across transplant centers within the same DSA, for reasons unrelated to organ allocation, variation in transplant rate is not defensible as the driving force behind allocation policy change.

UNOS has invented a problem by inaccurately claiming that variation in transplant rates can and should be resolved by allocation policy. In fact, by adopting the Fixed Circle Policy, the OPTN will cost patient lives without yielding any benefit to the kidney transplant community.[50]

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[47] As CMS expressed recently, "[i]t is clear that our historical approach to measuring OPO performance has resulted in a wide range of performances. This variability is unacceptable to patients and CMS." Centers for Medicare & Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule*, https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf (Nov. 20, 2020). When poor-performing OPOs are required to improve performance under the new outcome measures issued by CMS, their local transplant centers may have improved transplant rates, even without any change to allocation policy.

[48] The SRTR defines transplant rate as the number of candidates who received a transplant (numerator) divided by the person-years observed at the program (denominator, which reflects how many candidates were on the waiting list and for how long). *See* SCI. REGISTRY OF TRANSPLANT RECIPIENTS, USER GUIDE 1 (July 8, 2019), https://www.srtr.org/document/pdf?fileName=\072019_release\pdfPSR\GAEMTX1KI201905PNEW.pdf. "Candidates who are inactive on the waiting list are included in the calculations for this table." *Technical Methods for the Program-Specific Reports*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS, https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#tableb4 (last visited Dec. 1, 2020).

[49] *National Data Reports, Organs by Status,* ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/# (based on data as of Dec. 1, 2020, showing 54,746 active waitlisted candidates and 39,040 inactive waitlisted candidates).

[50] The decrease in transplant volume especially threatens small transplant programs, which serve a smaller patient population, have shorter waitlists, and will receive fewer organ offers when sharing organs with large transplant programs within the fixed circle. These small programs risk closure because of the decline in transplant volume, which would result in their communities no longer having access to transplantation. The Final Rule requires that allocation policies "promote patient access to transplantation," 42 C.F.R. § 121.8(a)(5), not reduce

### B. Questionable Data Modeling and UNOS's Motives Call Into Question the Effects of the Fixed Circle Policy

The Fixed Circle Policy is predicated upon SRTR analysis that was altered in a manner inconsistent with sound scientific principles and likely influenced by biased personnel, leading the Hospitals to conclude that the proposed policy will result in dramatically lower transplant rates than the modeling predicts.

In September 2018, the SRTR analyzed the allocation policy changes and concluded that there would be *at least 1,000 fewer kidney transplants* performed nationally each year, possibly 2,000 fewer transplants.[51] Understandably, this first analysis "was negatively received due to the notable decreases in the number of transplants [and] . . . *In response*, SRTR began investigating" different modeling approaches.[52] In other words, there was no identified concern with the SRTR's modeling approach until the data did not turn out how UNOS leadership wished and was poorly received by the community. Only then did UNOS ask SRTR to consider new ways to approach the model. Such actions do not reflect sound scientific principles and fair-minded thinking.

In response to the concerns about the significant reduction in the predicted number of transplants, SRTR proposed to change the "acceptance model" portion of data model, which as the name implies is intended to reflect the likelihood that a transplant center will accept a certain simulated organ offer. Two options were presented as possible changes: Model 1 and Model 2. When predicting whether a transplant center would accept a simulated organ offer, Model 1 considered the distance the organ must travel from the donor hospital to the candidate transplant center. In Model 2, the analysis did not take into account how far the organ must travel to the recipient transplant center. The Workgroup voted 57% to 43% to use Model 2.[53] Thus, *the model relied on by the OPTN does not consider how far the organ must travel to the recipient transplant center in predicting whether a transplant center will accept or decline the organ offer*. Notably, in the UNOS-drafted meeting summary, there is no record of the Workgroup's discussion regarding the decision to exclude the distance the organ traveled or how such a

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access by causing transplant centers to close. Moreover, these risks are even more acute because of the strain caused by COVID-19. But the OPTN has not considered the threat to patient access resulting from such closures.

[51] SALLY GUSTAFSON ET AL., SCI. REGISTRY OF TRANSPLANT RECIPIENTS, ANALYSIS REPORT 6 (Sept. 24, 2018), https://optn.transplant.hrsa.gov/media/2768/kp_analysisreport_20181207.pdf.

[52] Minutes, OPTN/UNOS Kidney Transplantation Committee, (Mar. 25, 2019), available at https://optn.transplant.hrsa.gov/media/2935/20190325_kidney_meeting_minutes.pdf (emphasis added).

[53] Minutes, OPTN/UNOS Kidney-Pancreas Workgroup (Mar. 22, 2019), available at https://optn.transplant.hrsa.gov/media/3030/20190322_kp_workgroup_min.pdf. The Workgroup minutes do not list the number of voting members at the meeting or the vote counts.

decision was consistent with organ acceptance behavior in practice. There is also no discussion of whether it was possible for SRTR to run both models. However, the meeting minutes do reflect that in selecting Model 2 over Model 1, UNOS and the Workgroup were aware that Model 1 was "[m]ore likely to predict a decrease in transplant" while Model 2 was "[l]ess likely to predict a decrease in transplant."[54] The presence of such information (and no other explanation for selecting Model 2) suggests the new model was chosen intentionally to eliminate the predicted decrease in the number of transplants seen in the earlier modeling, not because Model 2 was more predictive of likely organ acceptance behavior.

This suspicious change in modeling is especially concerning in the context of the gross biases within UNOS leadership in favor of policies like the Fixed Circle Policy, as explained above. These biased persons are the same individuals who instructed SRTR to revise its data modeling and then advised the Workgroup on the selection of the model they knew in advance would improve the appearance of the data. It seems the goal was simply to push through the change in policy without considering what was best for patients.

In practice, the factor ignored in the revised modeling—the distance the organ must travel to reach the transplant center (as an approximation of time)—is absolutely a factor that surgeons take into consideration when determining whether or not to accept an organ. If the transplant surgeon knows he or she can personally procure an organ that would require minimal ischemic time to return to the transplant center, the surgeon is more likely to accept such an organ as compared to the same organ a farther distance away that would be procured by a different surgical team and require many hours of travel before reaching the transplant center. Moreover, surgeons in cities that lack a major airport may not be able to accept organs they would otherwise deem appropriate for their patients if those organs require long flights or layovers to reach the transplant center. Travel considerations are even more significant during COVID-19, as explained above.

In short, distance and travel time between the donor organ and potential recipient are key factors in whether an organ offer is accepted, but the SRTR model and thus the OPTN entirely failed to consider these factors when opting to implement the Fixed Circle Policy. As a result of the critical flaw in the analysis, the model underestimates the reduction in kidney transplants that will truly occur if this policy is allowed to take effect. Given this obvious flaw and intentional manipulation of the data model, your failure to request the policy proposal sixty days prior to implementation is an arbitrary abdication of your responsibility to oversee the actions of the OPTN.

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[54] Minutes, OPTN/UNOS Kidney Transplantation Committee, (Mar. 25, 2019), available at https://optn.transplant.hrsa.gov/media/2935/20190325_kidney_meeting_minutes.pdf.

### C. The Fixed Circle Policy Fails to Reduce Disparities in Transplantation for Low Socioeconomic Status Patients

Under the Final Rule, allocation policies must be reformed based on an assessment of their cumulative effect on socioeconomic inequities and shall promote patient access to transplantation. 42 C.F.R. § 121.4(a)(3)(iv); *id.* § 121.8(a)(5). The Fixed Circle Policy does neither. The OPTN gives no consideration to the significant inequities in waitlist access, and although it purports to be concerned about the impact of the policy change on low socioeconomic status candidates, its analysis regarding underserved communities is deficient. The SRTR did not model the impact of the policy based on cumulative community risk scores, which is a metric specifically designed to assess the impact of socioeconomic factors in kidney transplantation,[55] nor did it consider Centers for Disease Control social vulnerability index.[56] The OPTN has offered no explanation for why it did not use these metrics, which is especially questionable because the SRTR did model cumulative community risk scores for the change in liver allocation policy.[57]

The only modeling regarding socioeconomic effects are those regarding insurance status, median household income in the zip code, and urbanicity. The OPTN claims that transplant access has increased for low socioeconomic candidates because the data model reflects an increase in Medicaid recipients, but this data is unduly influenced by geography in light of inconsistent Medicaid expansion.[58] For example, an increase in Medicaid recipients could simply mean an increase in transplant recipients from Illinois, Virginia, or other states that adopted Medicaid expansion as organs are shifted away from non-expansion states like Alabama or Tennessee. Notably, the SRTR data for transplant rates based on household income shows decreases for candidates in zip codes with median incomes of $35k to $70k.[59] Thus, at best, the data from SRTR is inconclusive with respect to the effect of the proposed policy on candidates of

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[55] Jesse D. Schold et al., *The Association of Community Health Indicators With Outcomes for Kidney Transplant Recipients in the United States*, 147 ARCHIVES OF SURGERY 520 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880685/.

[56] Agency for Toxic Substances and Disease Registry, *CDC Social Vulnerability Index*, https://www.atsdr.cdc.gov/placeandhealth/svi/index.html (last reviewed Sept. 15, 2020).

[57] Given the questionable change to the data model described above and UNOS's biased leadership, HHS must question whether community risk modeling was not performed or not published because UNOS knew it would demonstrate that the policy change would harm vulnerable communities.

[58] *See Medicaid Coverage in Your State*, https://www.healthinsurance.org/medicaid/ (last visited Nov. 27, 2020).

[59] GUSTAFSON, *supra* note 44, at 55.

lower socioeconomic status, in contrast to the legal requirement that the OPTN reform allocation policy in a manner that *reduces* socioeconomic disparities. *See* 42 C.F.R. § 121.4(a)(3).

**CONCLUSION**

The COVID-19 pandemic demands the full attention of health care leaders and providers. It is unconscionable that UNOS would press ahead with implementing a significant change in organ allocation during the middle of this public health crisis. And yet, just six weeks ago, UNOS announced it planned to implement the Fixed Circle Policy on December 15, 2020—leaving hospitals scrambling. In so doing, UNOS offered no statements regarding how it would monitor the effects of the policy change while the virus wreaks havoc on normal data metrics or how it would manage to fly organs to non-metropolitan areas in an era where direct flights are non-existent in some communities. In deciding to implement the Fixed Circle Policy, UNOS is acting as though COVID-19 does not exist. But UNOS cannot wish the virus away, and under these circumstances, you have an obligation to direct the OPTN to provide the new kidney allocation policy to you for review sixty days before implementation. Further, as a significant policy, the Final Rule provides that you must refer the policy to the Advisory Committee and publish it in the Federal Register for public comment. Only after following these procedures can you fulfill your regulatory responsibilities and be confident that a change in policy will not benefit UNOS leadership at patients' expense.

Respectfully,

Glenn L. Krinsky

Glenn L. Krinsky

JONES DAY

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January 10, 2021

VIA E-MAIL

The Honorable Alex M. Azar II
Secretary of the U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Email: secretary@hhs.gov

**Re: OPTN Kidney Distribution and Allocation Policy**

Dear Secretary Azar:

This letter serves as a supplement to my critical comment dated December 1, 2020 ("December Comment"), which I submitted on behalf of multiple hospitals across the country that perform kidney transplants (the "Hospitals"). The Hospitals urged you to suspend implementation of a new kidney allocation policy ("Fixed Circle Policy"), which was then set to take effect on December 15, 2020. The December Comment detailed, among other things, HHS's erroneous conclusion of law that led to the development of the Fixed Circle Policy, the significant problems with implementing the Fixed Circle Policy during the middle of the COVID-19 pandemic, and the ways in which the Fixed Circle Policy will harm patients by reducing the number of transplants nationwide and increasing the number of transplants that fail. On December 9, 2020 you received a similar critical comment from leaders of eight organ procurement organizations ("OPOs"), stating that implementation of the new policy during the COVID-19 pandemic would severely burden the OPOs and increase the number of organs that are wasted because of the heightened logistical challenges under the Fixed Circle Policy.

On December 14, 2020, the afternoon before the policy was set to take effect, the Health Resources Services Administration ("HRSA") directed the Organ Procurement and Transplantation Network ("OPTN") to hold in abeyance implementation of the Fixed Circle Policy until February 13, 2021, while HHS reviewed the December Comment. The Hospitals commend this decision to stay the Fixed Circle Policy on the eve of its implementation, giving the agency the opportunity to re-evaluate the policy in light of the commenters' concerns and the surging COVID-19 pandemic. Kidney allocation policy directly affects nearly 100,000 Americans waiting for a transplant, and a dramatic change in that policy requires sober analysis, especially when the government predicts such a change will cost American lives. To that end,

the Hospitals reiterate their request from the December Comment that you refer this significant proposed policy to the Advisory Committee on Organ Transplantation and publish it in the Federal Register for comment in accordance with 42 C.F.R. § 121.4(b)(2).[1]

After directing the stay, on December 21, 2020, HRSA requested that the OPTN provide its views on the issues raised by the critical comments. The OPTN responded to HRSA's request on January 4, 2021, and this response was made public through the OPTN website on January 8, 2021.[2] Recognizing that you may currently be reviewing the policy alongside of the OPTN's January 4th letter, I write now on behalf of the Hospitals to call your attention to several aspects of the OPTN's response and to urge you not to authorize implementation of the Fixed Circle Policy on February 13, 2021.[3]

### A. The Fixed Circle Policy Was Developed As A Result Of The OPTN's Erroneous Assumption That It Was Legally Required To Change The Kidney Allocation Policy

As the December Comment explained, the Fixed Circle Policy was developed in response to HRSA's July 2018 directive, which instructed the OPTN to eliminate the framework for organ distribution that had been in place since before the formation of the OPTN. Under that framework of more than 30 years' standing, organs were distributed in part based on geographic boundaries known as donation service areas ("DSAs") as well as larger areas known as Regions, which collectively facilitate efficient organ placement. The July 2018 HRSA directive erroneously concluded that DSAs and Regions can *never* be part of a lawful organ allocation policy and ordered the OPTN to remove DSAs and Regions from kidney allocation. The Fixed

[1] The OPTN argues that the procedural requirements of section 121.4(b)(2) do not apply because "the OPTN does not recommend that this policy be enforceable." Response at 12. But in the next sentence, the OPTN states that these procedures are required for enforceable policies *and* policies "otherwise directed by the Secretary to be submitted for his review." *Id.* Thus, even under the OPTN's reading of the regulation, you may refer this policy to the Advisory Committee and publish it in the Federal Register.

[2] Letter from David Mulligan, OPTN President, to Thomas J. Engels, HRSA Administrator (Jan. 4, 2021), https://optn.transplant.hrsa.gov/media/4301/optn-response-to-critical-comment-received-about-revised-kidney-policy.pdf. As plaintiffs in litigation currently challenging the Fixed Circle Policy, the Hospitals received a copy of the OPTN's response from opposing counsel on January 7, 2021. The critical comments do not appear to be available on the OPTN website.

[3] The Hospitals maintain all the concerns identified in the December Comment, even if not specifically discussed in this supplement, and would be pleased to provide further information about those issues upon request.

Circle Policy is a direct result of this order. In fact, the policy proposal itself was titled and stated its purpose as "Eliminate the Use of DSA and Region in Kidney Allocation Policy."[4]

The OPTN's January 4th response reinforces this point by providing no reason for adopting the Fixed Circle Policy except to eliminate DSAs and Regions. *See* Response at 13. The OPTN reiterates its prior claims that "the use of DSAs is not defensible." *Id.* The basis of the OPTN's claim of illegality is that DSAs are of varying sizes and shapes and were not designed for organ allocation. *Id.* Even assuming this is true, that does not make DSAs inherently unlawful. Matters of public policy routinely rely on demarcations that were not designed for their various functions but carry geographic, political, or social significance. The boundaries of a school district, for example, may be drawn along the path of a river or a train track that was not built to determine school enrollment and that weaves through a populated area in an arbitrary fashion. But that does not mean the school district boundary is indefensible much less unlawful. And if a proposal to change the district lines were predicted to result in 250 students dropping out each year, no superintendent would endorse that policy.

Yet that is effectively what the OPTN proposes here. As explained below, the government's own data predicts that at least 250 *fewer* kidney transplants will be performed under the new policy, meaning 250 American lives sacrificed, simply to change the allocation line from the DSA border to an arbitrary 250 nautical mile border. The OPTN's myopic and legally misguided emphasis on eliminating any use of DSAs and Regions contrasts with its having ignored clear policy *mandates* in the Final Rule: avoid wasting organs and futile transplants, promote patient access to transplantation and the efficient management of organ placement, and reduce inequities from socioeconomic status. This was not a policymaking process undertaken to improve kidney allocation policy. The OPTN's response does not in any way whatsoever make a case to the contrary. All it argues is that randomly conceived 250 nautical mile circles are somehow less arbitrary and therefore a better policy choice than DSAs and Regions. But that's a premise that the OPTN and HHS—because of the bogus purported legal restraint enunciated in the July 2018 directive—never allowed the policymaking process to test.

### B. HHS Must Take Into Account UNOS's Biased Leadership In Its Review Of The Fixed Circle Policy

The contrived need to eliminate DSAs and Regions—and the resulting Fixed Circle Policy—was conceived of and advanced by a few well-connected OPOs, hospitals, and OPTN executives who stood to benefit from a change to allocation policy that they could not otherwise

[4] OPTN, Notice of OPTN Policy Changes, Eliminate the Use of DSA and Region from Kidney Allocation Policy, https://optn.transplant.hrsa.gov/media/3452/kidney-removal-of-dsa-policy-notice.pdf.

persuade the transplant community to support. In fact, even with this false legal premise, 158 transplant hospitals and OPOs voted *against* the change to kidney allocation policy, while only 119 voted in favor.[5] Nonetheless, the biased leadership of UNOS convinced the OPTN Board to adopt the Fixed Circle Policy at its December 2019 meeting.

Not surprisingly, the OPTN now defends the Fixed Circle Policy in the January 4th response and states that after a "thorough review of the issues," the policy should move forward. HHS has an obligation to consider this self-described "thorough" review and recommendation in the context of the demonstrated bias and bad faith that exists within the OPTN contractor, the United Network for Organ Sharing ("UNOS"). As the December Comment explained, a federal district court has found there was "colorable evidence of animosity and even some measure of regional bias" exhibited by OPTN and UNOS leadership in the process that led to the HHS July 2018 directive to eliminate the use of DSAs and Regions. December Comment at 10. Notably, despite HRSA's December 21st invitation that the OPTN provide its views on any "issues raised in the critical comment," the OPTN declined in its January 4th letter to respond to the critical comment's observations regarding bad faith and improper predeterminations related to allocation policies.

The federal district court has ordered that the documents evidencing this bad faith be unsealed and placed in the public domain, but the unsealing order is stayed pending UNOS's appeal. However, as parties to the litigation, both the UNOS/OPTN Board and HHS administrators should have been afforded full access to the documents that reflect the bad faith of those in power within UNOS. (And, of course, UNOS could withdraw its appeal at any time, allowing the records to become public and available to all those within the transplant community.) To the extent UNOS has failed to share these records with members of the OPTN Board or Executive Committee, the Board members' reliance on UNOS staff or other Board members for guidance on the Fixed Circle Policy or legality of DSAs is misplaced. HHS must evaluate the OPTN's January 4th response accordingly, recognizing that OPTN Board members likely have not seen the sealed documents demonstrating UNOS's bad faith and cannot assess the biases at play that were identified by the district court.

Moreover, individuals at HHS evaluating the Fixed Circle Policy must also fully understand the contents of the sealed records and scope of bias within UNOS before rendering a decision on the December Comment. The agency cannot properly evaluate the Fixed Circle Policy without knowing how to filter information that UNOS provides. Yet as of April 2020,

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[5] *See* OPTN, Eliminate the Use of DSA and Region in kidney allocation policy, https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-kidney-allocation-policy. The "Comments" section on this webpage includes vote tallies from each of the 11 OPTN regions, which have been aggregated to arrive at the number noted here.

HRSA Administrator Thomas Engels offered no indication that he was familiar with these records. In response to a question from Senator Roy Blunt asking whether Administrator Engels had been "briefed on [the] contents" of the evidence, Administrator Engels stated that the documents "are subject to a court order, and we await the court's determination on this matter."[6]

If you and Administrator Engels still have not viewed these materials, the Hospitals respectfully submit that you must do so before issuing a response to the December Comment. Alternatively, given the volume of documents and complexity of the issues, you may well wish to defer to your successor in rendering a decision on whether or not to move forward with the Fixed Circle Policy.

### C. The OPTN Does Not Dispute That HHS Modeling Predicts That The New Policy Will Harm Patients

The December Comment made very clear that the government data predicts the Fixed Circle Policy will result in fewer kidney transplants, greater waitlist mortality, and more failed transplants. *See* December Comment at 11-13. The OPTN response does not challenge this data. In fact, the OPTN stresses that the SRTR simulation model "can be very useful in estimating the relative direction of possible effects related to proposed policy changes," and further notes that simulations "predict the direction of changes within various subgroups." Response at 14 (emphasis omitted). But the response ignores the plain fact that for the Fixed Circle Policy, the "direction" predicted by the SRTR model is increased patient harm—fewer transplants and higher mortality. This is a policy headed in the wrong direction.

The OPTN then tries to sweep the loss of life under the rug by saying that when combining dual organ transplants (kidney and pancreas) with kidney-only transplants, the total number of transplants results in "almost no change from baseline." Response at 18. Notably, the OPTN fails to respond to the December Comment's warning that pancreata have a lower tolerated ischemic time, which affects acceptable travel distances for these dual organ transplants and will result in more organ wastage. December Comment at 12 n.43. But more importantly, even assuming the OPTN's optimal scenario, the OPTN fails to mention that "almost no change" means at least nine fewer transplants per year.[7] Apparently the OPTN thinks those nine lives are not worth saving.

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[6] *See* Letter from Roy Blunt, U.S. Senator, to Alex Azar, Secretary, U.S. Dep't of Health & Human Servs. (Mar. 16, 2020), available at https://www.blunt.senate.gov/download/letter-to-sec-azar-march-2020; Letter from Thomas J. Engels, HRSA Administrator, to Roy Blunt, U.S. Senator (Apr. 20, 2020), available upon request.

[7] The government's own data estimates a current baseline of 13,080 kidney-only transplants and 815 kidney-pancreas transplants (total of 13,895 kidney transplants). Under the Fixed Circle Policy, the data predicts 12,830 kidney-only transplants and 1,056 kidney-pancreas transplants (total of 13,886 kidney transplants). SALLY

**D. The OPTN Misrepresents Its Change In Data Modeling**

In the December Comment, the Hospitals described the suspicious change to the data modeling, which completely eliminated any assessment of the distance an organ must travel to the recipient transplant hospital in predicting whether the hospital accepts or declines that organ. December Comment at 14-15. In the old simulation model (which predicted at least 1,000 fewer transplants and caused an uproar within the transplant community), a hospital in South Carolina was considered more likely to accept an organ if the organ offered was from its own DSA, which in effect meant the organ was within the State of South Carolina. In the new simulation model (which predicts 250 fewer transplants), a hospital in South Carolina is considered equally as likely to accept an organ from South Carolina as it is to accept an organ from California. This makes no sense because an organ traveling from California would obviously require significantly greater cold ischemic time and be less viable to the surgeon in South Carolina than the in-state organ. A third option, which was proposed by the data contractor (SRTR) but rejected by UNOS was to take into consideration the distance between the donor organ and the transplant hospital, but not base that consideration on DSA.[8]

The OPTN response describes the change in the SRTR data model as a reasonable and necessary change to better tailor the data model to the new policy. Only reading the OPTN's response, one would conclude that the options were: (a) use the existing DSA-based data model, which did not align with the new policy or (b) use the new data model that was selected. But the OPTN completely ignores the third option, which rationally aligns with the Fixed Circle Policy (which itself allocates organs based on distance from the donor organ to the transplant hospital) better than the selected data model. As pointed out in the December Comment, in the UNOS-drafted meeting summary, there is little record of UNOS's discussion regarding the decision to exclude the distance the organ traveled or how such a decision was consistent with organ acceptance behavior in practice. December Comment at 14-15. And yet again, in its January 4th response, the OPTN offers no insight into this issue, which suggests UNOS completely failed to consider the important fact that the distance between a donor and transplant recipient matters

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GUSTAFSON ET AL., SCI. REGISTRY OF TRANSPLANT RECIPIENTS, ANALYSIS REPORT: UPDATE 8 (June 21, 2019), https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (scenario BL is the baseline and scenario 250.250.2.4 is the Fixed Circle Policy).

[8] *See* SCOTT CASTRO & ABBY FOX, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, BRIEFING PAPER: KIDNEY/PANCREAS WORKGROUP BOARD REPORT 9 (2019), https://optn.transplant.hrsa.gov/media/2990/kidney_pancreas_boardreport_201906.pdf (describing the two options proposed by the SRTR, with one model that "includes the distance the organ would have to travel," not based on DSA, and a second model that "does not include distance the organ would have to travel").

when predicting organ acceptance. In light of this missing element from the data model, the actual organs wasted are likely to be much higher than the model predicts.

### E. Implementing The Fixed Circle Policy During COVID-19 Would Create Havoc Within The System And Prohibit Proper Monitoring Of The New Policy

As explained in the December Comment, transplants hospitals and OPOs are severely strained by the unabated COVID-19 surge now overwhelming much of the nation's medical system, with the daily death toll continuing to climb. *See* December Comment at 4-5. Implementing this new policy, which requires the establishment of new relationships and a dramatic increase in distance the average donated kidney must travel, would risk patient lives and prohibit the OPTN from effectively monitoring the impact of the policy. Notably, the December Comment further explained the geographic discrepancies of the pandemic's impact, quoting the SRTR's observation "that the pandemic has had a differential effect on different areas of the country at different times." December Comment at 7-8. The December Comment also quoted a peer-reviewed article, in which researchers, including one from the SRTR, concluded that despite normal national numbers, "states with highest COVID-19 burden" were differently affected, and "[t]here was substantial geographic heterogeneity." *Id.*[9]

In response, the OPTN purportedly describes the impact of COVID-19 on the transplant system by providing aggregate national data on transplant rates in 2020, which the OPTN argues are largely similar to 2019 data, and then professes that the OPTN can adequately monitor data regarding the kidney policy change despite the pandemic's effects. But the OPTN fails to respond to the critical comment's concerns regarding how COVID-19 affected different parts of the country in different ways at different times. In reality, because of these ever-changing geographic impacts, the OPTN will *not* be able to assess the regional impacts of the Fixed Circle Policy on a real-time basis until the pandemic has stabilized across the country.

The OPTN contractor, UNOS, was keenly aware of these meaningful differences in a peer-reviewed article that was published in November 2020. There, the UNOS researchers made similar observations as the January 4th letter regarding the collective impact of COVID-19 in national aggregate data, but then concluded:

> Despite these national data observations, there continue to be regions of the country disproportionately affected by the pandemic. Because the pandemic has had different effects on different areas of

[9] The quoted article is Brian J. Boyarsky, et al., *Early National & Center-Level Changes to Kidney Transplantation in the United States During the COVID-19 Epidemic* 20 Am. J. Transplantation 3131 (June 28, 2020), available at https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.16167.

> the country at different times, *the ability to assess transplant center and OPO performance in statistically valid ways using the conventional OPTN metrics is likely not possible for the foreseeable future*, and has been recognized by the Scientific Registry of Transplant Recipients (SRTR). . . . This recognition will pose challenges for performance monitoring and data collection going forward . . . .[10]

UNOS and the SRTR have both acknowledged the challenges that the pandemic has brought upon the transplant community and the corresponding difficulty in monitoring data, but nonetheless, the OPTN inexplicably concludes it can adequately monitor a dramatic change in kidney allocation policy.

Lastly, in the same November article, UNOS recognized the "unanticipated challenges for organ placement due to the ability of transplant programs to accept organs because of hospital logistical limitations and limited commercial airline availability affecting transportation of kidneys," but the OPTN's January 4th response fails to address the pandemic's ongoing effects on commercial air travel or how the regional variation in the impact of these effects affects transplantation under the new policy.[11] This omission is especially glaring because the December Comment cited a peer-reviewed article by a researcher from the government data contractor (SRTR), which described "the significant effect of the pandemic on airlines that will potentially limit the availability of organs, increase [cold ischemic time], and increase the risk to organs during delivery."[12] These issues must be evaluated with scientific rigor before moving forward with a policy that increases the distance organs travel to their intended recipients, especially since even without the heightened challenges caused by the pandemic, that policy is predicted to result in more organs wasted.[13]

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[10] Rebecca R. Goff et al., *Navigating the COVID-19 Pandemic: Initial Impacts and Responses of the Organ Procurement and Transplantation Network in the United States*, AM. J. TRANSPLANTATION 1, 11 (Nov. 17, 2020) (emphasis added).

[11] *Id.* Alexandra T. Strauss, et al., *Impact of the COVID-19 Pandemic on Commercial Airlines in the United States and Implications for the Kidney Transplant Community*, 20 AM. J. TRANSPLANTATION 3123, 3128 (Aug. 19, 2020), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16284 (cited by December Comment at 10).

[12] *See* December Comment at 10 (citing Alexandra T. Strauss, et al., *Impact of the COVID-19 Pandemic on Commercial Airlines in the United States and Implications for the Kidney Transplant Community*, 20 AM. J. TRANSPLANTATION 3123, 3128 (Aug. 19, 2020)).

[13] It remains unclear why the OPTN finds it appropriate to hurry implementation of this unnecessary and misguided policy now when it continues to slow-walk essential measures to improve OPO performance. *See, e.g.*, Letter from Charles E. Grassley, Ron Wyden, Todd Young, and Benjamin L. Cardin, U.S. Senators, to Brian Shepard (Feb. 10, 2020), available at https://www.finance.senate.gov/download/grassley-wyden-young-cardin-to-

**CONCLUSION**

The OTPN's January 4th response does not alleviate the concerns expressed by the Hospitals and the OPOs in their critical comments. The new kidney policy is not only legally unnecessary—it is medically damaging. Even the OPTN does not dispute that its data predicts lives will be lost if the policy is permitted to take effect. And that would be under the best implementation circumstances. Yet implementing an overhaul to organ transplant operations in the middle of a once-in-a-generation global pandemic is a far from optimal, and the OPTN offers no explanation for why this dramatic policy change in kidney allocation must take effect now—especially when the pandemic may turn a corner in the foreseeable future with mass vaccination on the horizon.

The Hospitals would welcome any opportunity to meet with you or your successor to discuss more thoroughly the issues raised by the critical comments and responses.

Respectfully,

Glenn L. Krinsky

Glenn L. Krinsky

cc: Thomas J. Engels, HRSA
Robert Walsh, HRSA
Frank L. Holloman, HRSA
Michael Drezner, Department of Justice

unos_-information-request-on-organ-transplant-system (stating that the OPTN is tasked with monitoring OPOs and observing that UNOS "either missed" or "neglected to remediate" serious issues related to OPO performance).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Rockville, MD 20857

December 14, 2020

David C. Mulligan, M.D.
President, Organ Procurement and Transplantation Network
Professor and Chief, Section of Transplantation and Immunology/Director
Yale New Haven Hospital
20 York Street
New Haven, CT 06510

Brian Shepard, Executive Director
Organ Procurement and Transplantation Network
United Network for Organ Sharing
P.O. Box 2484
Richmond, VA 23218

Dear Dr. Mulligan and Mr. Shepard:

While the Department reviews the critical comment submitted on December 2, 2020, the Health Resources Administration (HRSA) directs that the Organ Procurement and Transplantation Network (OPTN) Board of Directors hold in abeyance further implementation of the new OPTN kidney allocation policy until February 13, 2021. HRSA also authorizes the OPTN to delay, pending completion of the Department's review, other policies scheduled for implementation on December 15, 2020, including the pancreas allocation policy, to avoid undue complications in the system.

Sincerely,

Thomas J. Engels
Administrator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

December 21, 2020

David Mulligan, M.D., President
President, Organ Procurement and Transplantation Network
Professor and Chief, Section of Transplantation and Immunology/Director
Yale New Haven Hospital
20 York Street
New Haven, CT 06510

Brian Shepard, Executive Director
Organ Procurement and Transplantation Network
United Network for Organ Sharing
P.O. Box 2484
Richmond, VA 23218

Dear Dr. Mulligan and Mr. Shepard:

On December 2, 2020, the U.S. Department of Health and Human Services (HHS) received an email and letter from Mr. Glenn L. Krinsky of the Jones Day law firm (see Attachment A). Mr. Krinsky wrote to HHS expressing concerns about the kidney allocation policy approved by the Organ Procurement and Transplantation Network (OPTN) in 2019.

On December 9, 2020, I received an email from eight organ procurement organizations (OPOs) seeking a delay in implementation of the kidney allocation policy (see Attachment B).

The Health Resources and Services Administration (HRSA) considers both of these communications to be critical comments under the National Organ Transplant Act of 1984, as amended (NOTA), and the final rule governing the operation of the OPTN (OPTN Final Rule) as described in 42 U.S.C. § 274(c), 42 C.F.R. § 121.4(d). Under the OPTN Final Rule, "[t]he Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices." HHS seeks the OPTN's views on the issues raised in these critical comments.

To assist HHS in considering these critical comments, I am seeking the views of the OPTN on the issues raised. Please provide the OPTN's views on whether the revised OPTN Kidney Allocation Policy, including its use of 250 mile fixed circles as units of allocation, is consistent with the requirements of NOTA and the OPTN final rule. Additionally, please provide (1) a rationale for and discussion of the adequacy of the methodology used to model the predicted impacts of the change to kidney allocation policy; (2) a description of the OPTN's consideration of a potential transition policy in relation to the change in kidney allocation policy; (3) an analysis of the adequacy of the OPTN's plan to evaluate the impact of the new kidney allocation policy in general and in light of disruptions to the transplantation system caused by the COVID-

19 pandemic; (4) an analysis of the adequacy of efforts to support transplant centers and organ procurement organizations to prepare for the implementation of the new policy in general and in light of disruptions to the transplantation system caused by the COVID-19 pandemic; (5) an overview of any efforts taken to educate OPTN members, the public, and patients about the revised OPTN Kidney Allocation Policy; and (6) a description of the OPTN's analyses regarding the impact of the new kidney allocation policy on transplant candidates of low socioeconomic status. We also welcome the OPTN's views on any other issues raised in the critical comments.

On December 11, 2020, I received a letter from four transplant centers urging support for the new kidney allocation policy (see Attachment C). Please also consider this letter in the context of the critical comments and your response.

This request does not mandate the OPTN reach any particular conclusions.

The Chronic Disease Research Group, the contractor that operates the Scientific Registry of Transplant Recipients (SRTR), is copied on this request. HRSA expects that the OPTN will coordinate with the SRTR as necessary to develop the OPTN response. HRSA specifically asks the SRTR to address the letter's concerns related to modeling and acceptance criteria.

By letter dated December 14, 2020, I directed the OPTN to hold in abeyance any further implementation of the new OPTN kidney policy until February 13, 2021. To expeditiously resolve these issues, please send your comments to me, with a copy to Cheryl Dammons, Associate Administrator of HRSA's Healthcare Systems Bureau, as soon as possible, but no later than January 4, 2021. Given that my role as the HRSA Administrator is one of oversight, I will review the OPTN's comments in light of NOTA's requirements and the OPTN final rule.

Sincerely,

Thomas J. Engels
Administrator

Enclosures
Attachment A: Critical Comment from Jones Day
Attachment B: Email from Eight OPOs Requesting Delay in Implementation
Attachment C: Email from Four Transplantation Centers Supporting Changes

cc: Jon Snyder, Project Director
Chronic Disease Research Group

JONES DAY

555 SOUTH FLOWER STREET • FIFTIETH FLOOR • LOS ANGELES, CALIFORNIA 90071.2300

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December 1, 2020

VIA E-MAIL AND COURIER

The Honorable Alex M. Azar II
Secretary of the U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Email: secretary@hhs.gov

**Re: OPTN Kidney Distribution and Allocation Policy**

Dear Secretary Azar:

This firm represents hospitals across the country with multi-specialty transplant centers that perform thousands of kidney transplants each year (collectively, the "Hospitals"). On behalf of their patients and physicians, these Hospitals object to the flawed new kidney allocation policy and to the OPTN's decision to plunge ahead with its implementation in the midst of a massive strain on the nation's health care system resulting from the unprecedented escalation in COVID-19 cases.[1] We ask that you give this letter your immediate attention in light of the proposed policy implementation date of December 15, 2020 and the pressing need for hospitals to devote human and financial resources to the pandemic.

This letter serves as a "critical comment" under 42 C.F.R. § 121.4(d) regarding the manner in which the Organ Procurement Transplantation Network ("OPTN") is carrying out its duties. The Hospitals respectfully request that you take immediate action to stop implementation of the new kidney allocation policy (the "Fixed Circle Policy"). The Hospitals request that you direct the OPTN to provide the Fixed Circle Policy for your review at least 60 days prior to implementation and further that you refer this "significant" policy to the Advisory Committee on Organ Transplantation and publish the policy in the Federal Register for comment. *Id.* § 121.4(b)(2).

[1] *See, e.g.*, Reed Abelson, *Covid Overload Pushes Hospitals to the Brink*, N.Y. Times (Nov. 28, 2020).

**BACKGROUND**

Kidney disease is the ninth-leading cause of death in the United States, and the cost to care for those affected accounts for more than one in five dollars spent by Medicare.[2] The primary form of treatment for kidney failure is dialysis, which is expensive and burdensome for both patients and the health care system, but there is a better option—organ transplants. Unfortunately, there are almost 100,000 Americans currently on the waiting list for kidneys, and there are not enough organ donors to help. This shortage of organs has led to debate over the best way to distribute these life-saving gifts to patients in need.

Historically, organs have been distributed in part based on donation service areas ("DSAs") and larger geographic areas known as Regions. In recent years, a subset of individuals within the transplant community, many of whom stand to benefit financially from a change in allocation policy that eliminates DSAs, successfully captured control of the entity that operates the OPTN, the United Network for Organ Sharing ("UNOS"). In a lawsuit that challenged the removal of DSAs in liver allocation, the court recognized that plaintiffs had "proffered evidence of bad faith, undisclosed ex parte communications, and improper predetermination by Defendant UNOS."[3] Further, the process to change the liver policy "was managed [by UNOS] in a rushed time frame and manner that bred ill will and the sense of railroading to a 'predetermined' policy end line."[4] As a result of this improper behavior and influence within UNOS, the OPTN has largely shirked its statutory and regulatory responsibility to ensure that the organ transplantation system is operated with scientific consensus in a manner that prevents organ waste, is attuned to socioeconomic disparities, and ensures safe and fair transitions when there is a change in allocation policy.

In February 2020, when testifying before the Senate Appropriations Subcommittee, you yourself expressed concerns and frustrations with UNOS. In fact, you testified that HHS had requested UNOS to reconsider its decision to implement the liver allocation policy. However, you further testified that you were powerless to require any changes to the policy. You claimed that by statute you were "walled off" from changing the OPTN's decisions.[5] As explained in this letter, that is simply not true. In fact, at a minimum, you have clear authority to: (1) request the OPTN to provide proposed policies to you at least sixty days before their proposed

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[2] *Advancing American Kidney Health*, U.S. DEP'T OF HEALTH & HUMAN SERVS. 3-4 (July 10, 2019), available at https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.

[3] *Callahan v. U.S. Dep't of Health & Human Servs.*, 434 F. Supp. 3d 1319, 1364 (N.D. Ga. 2020).

[4] *Id.* at 1366.

[5] *See* Letter from Roy Blunt, U.S. Senator, to Alex Azar, Secretary, U.S. Dep't of Health & Human Servs. (Mar. 16, 2020), available at https://www.blunt.senate.gov/imo/media/doc/Letter%20to%20Azar%20-%20March%202020_Signed.pdf.

implementation and (2) direct the OPTN to revise its policies or practices consistent with your response to any critical comment, such as this one. 42 C.F.R. § 121.4(b)(2), (d)(2).

Because of the bad faith exhibited by UNOS, your oversight of these matters and exercise of your regulatory authority is critical. In the liver litigation, the district court concluded that it could not impute UNOS's bad faith onto HHS, "absent a showing that HHS was involved in, or at the very least, aware of the bad faith."[6] Yet today, HHS is very much aware of UNOS's bad faith and has full access to documents that remain under seal in the liver litigation.[7] HHS cannot now claim that it is unaware of the biased forces at work within UNOS that have led to the Fixed Circle Policy and to the effort to radically change kidney allocation in the middle of a public health crisis.

Moreover, HHS's instruction, as expressed through the Health Resources and Services Administration ("HRSA"), led in part to the development of this ill-conceived policy. In the summer of 2018, HRSA asked UNOS to justify the use of DSAs, and rather than defend the long-standing system, UNOS's biased leadership argued that such a system could not legally be defended. On July 31, 2018, HRSA notified the OPTN that the use of DSAs and OPTN Regions "has not been and cannot be justified under the OPTN final rule." HRSA then "direct[ed] further OPTN action consistent with HRSA's oversight role," specifically to remove DSAs and Regions from all organ allocation policies, including kidney.[8] The next week, the OPTN Kidney-Pancreas Workgroup started its meeting with "a reminder of our task: to remove DSA and regions from kidney allocation policy."[9] Given that you issued this directive in 2018, you cannot now shy away from the legal responsibility you have to make sure the OPTN acts in a lawful manner.

The Fixed Circle Policy and the process that led to it are both deeply flawed, but the most troubling aspect of the process is that UNOS is now set to implement a drastic policy change in

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[6] *Callahan*, 434 F. Supp. 3d at 1356 (Doc. 261 at 60).

[7] The district court has granted an order unsealing the documents (*Callahan v. U.S. Dep't of Health & Human Servs.*, No. 1:19-cv-1783-AT, 2020 WL 6336129 (N.D. Ga. Sept. 29, 2020) (Doc. 298), but the documents remain sealed pending UNOS's appeal of that order. *Callahan v. United Network for Organ Sharing*, No. 20-13932 (11th Cir. appeal filed Oct. 20, 2020).

[8] Letter from George Sigounas, HRSA Administrator, to Sue Dunn, OPTN President (July 31, 2018), available at https://optn.transplant.hrsa.gov/media/2583/hrsa_to_optn_organ_allocation_20180731.pdf. The Hospitals maintain that HRSA's direction and the OPTN's action were based on an erroneous conclusion of law (that DSAs and Regions can never be justified), and as such, the action must be set aside as invalid. *See Transitional Hosps. Corp. of La., Inc. v. Shalala*, 222 F.3d 1019, 1029 (D.C. Cir. 2000).

[9] Minutes, OPTN/UNOS Kidney-Pancreas Workgroup, (Aug. 7, 2018), available at https://optn.transplant.hrsa.gov/media/3348/20190807_kp-workgroup-meeting.pdf.

the midst of a global pandemic without any consideration as to how the COVID-19 crisis will affect the implementation or impact of the policy. The policy was developed in 2019 and was adopted by the OPTN Board of Directors in December 2019. From the time the COVID-19 crisis hit until October 20, 2020, when the implementation date was announced, there was apparently no effort to study the effects of the pandemic and consider whether the policy change was appropriate.

Under these circumstances, it is your obligation to suspend the implementation of the Fixed Circle Policy and request that the OPTN present the policy to you at least sixty days before implementation. Further, given the significant nature of the policy, not to mention the questionable motives of UNOS leadership as explained in this letter, you must submit the policy to the Advisory Committee on Organ Transplantation ("Advisory Committee") and publish it in the Federal Register for public comment.

## IT IS UNLAWFUL AND DANGEROUS TO CHANGE KIDNEY ALLOCATION POLICY DURING THE COVID-19 PANDEMIC

Fundamentally changing organ allocation policy during the middle of a global pandemic that has dramatically affected health care in the United States is arbitrary, capricious, and an abuse of discretion. Hospitals must continue to focus on caring for patients rather than being forced to overhaul their operations and explain complex and life-altering policy changes to their patients and staff. In addition, if the new policy were to be implemented later this month as scheduled, it would be virtually impossible to assess its effects as required by law because of the confounding variables presented by the pandemic's impact on organ transplantation. You have the authority to postpone the policy by at least sixty days, simply by asking the OPTN Board to provide you with the policy before it is implemented. It is unlawful for you to fail to exercise such authority under the current circumstances.

### A. The Policy Change Requires Resources and Attention that Are Necessary to Respond to the Public Health Emergency

Changing an organ allocation policy has significant effects for both hospitals and patients. The OPTN has recognized that the new policy will require hospitals "to develop relationships" with new organ procurement organizations ("OPOs"), "with whom they have not worked previously."[10] In addition, "transplant hospitals may need to adjust their operations to

[10] Scott Castro, *Eliminate the Use of DSA and Region from Kidney Allocation Policy* 44, available at https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf (last visited Nov. 30, 2020) [hereinafter "Policy Proposal"].

account for the practices of their new OPO partners."[11] Further, the changes "may also impact overall transplantation program costs" and "programs may need to hire more transplant surgeons to travel further to recover kidneys from donors."[12] Finally, and perhaps most importantly, transplant programs must educate their patients on the impact of the new policy and how it affects the patients' likelihood of receiving organ offers.

Thus, a policy change of this magnitude is a significant burden on transplant programs and is difficult at any time, but it is an abuse of discretion to require hospitals to devote resources to an unnecessary policy change in the middle of a public health crisis. The COVID-19 pandemic is demanding the full attention of hospitals while at the same time crippling their finances, and the recent surge in cases is only making things more challenging. It is imperative that hospitals focus on responding to the pandemic and performing life-saving organ transplants in the middle of these unprecedented times rather than forging new relationships with OPOs and needing to adjust long-standing operations in response to an entirely new process.

Moreover, the change in policy could dramatically affect a patient's waiting time and likelihood of receiving an organ, requiring that transplant physicians and personnel carefully explain the meaning of the new policy to patients, especially because the OPTN has failed to set forth any transition policy. The Final Rule requires that when the OPTN revises organ allocation policies, "it shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies." 42 C.F.R. § 121.8(d)(1). Notably, in the liver litigation, the district court opined that "[t]he implementation of transition measures to mitigate disruption and patient harm as the new [allocation] policy is implemented should be an essential priority."[13] Yet the OPTN has not published any statements or analysis regarding the consideration of such transition procedures for either kidney or liver—procedures that are even more essential in light of the pandemic.[14]

Not only has the OPTN failed to consider the impact of COVID-19 on both hospitals and patients, the OPTN did not even announce the date for implementation until October 20, 2020—

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[11] *Id.* at 45.

[12] *Id.*

[13] *Callahan*, 434 F. Supp. 3d at 1373 (Doc. 261 at 99-100).

[14] The Kidney Committee briefly discussed transition procedures, but there is no reference to the impact of COVID-19 or analysis explaining why the Committee concluded that transition procedures were not necessary. *See* Meeting Summary, OPTN Kidney Transplantation Committee (Apr. 22, 2020), available at https://optn.transplant.hrsa.gov/media/3772/20200422-kidney-meeting-summary.pdf.

giving transplant centers less than two months to prepare and discuss with their patients.[15] Transplant patients are especially apprehensive about COVID-19,[16] meaning that transplant centers need even more time than usual to carefully explain the impact the new policy will have. Compressing patient notifications into a short period of time while hospital resources are already strained impairs the hospitals' ability to serve its patients. The current allocation policy has been in effect for six years, and there is no reason why the policy must be changed right now when hospital physicians, administrators, and other staff rightfully have their attention focused on the once-in-a-generation challenges of the pandemic.

### B. The Effect of a Policy Change Cannot Be Evaluated During a Pandemic as Required by Law

The implementing regulations of the National Organ Transplant Act (known as the "Final Rule") require that each change in allocation policy include metrics to measure how well the policy achieves its performance goals and the amount of projected improvement. 42 C.F.R. § 121.8(c)(1), (2). In addition, the regulation states that "the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of OPOs and the OPTN contractor." *Id.* § 121.8(c)(3). Implementing a policy change during the middle of a pandemic makes it impossible for the OPTN and HHS to comply with this regulation.

HRSA's data contractor, the Scientific Registry of Transplant Recipients ("SRTR"), has reported that "COVID-19 has had a large impact on the transplant system."[17] Indeed, research has shown that "COVID-19 has affected virtually all aspects of kidney transplantation, including

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[15] *Dec. 15 Implementation Date Set for Changes to Kidney, Pancreas Allocation*, UNITED NETWORK FOR ORGAN SHARING (Dec. 12, 2020), available at https://unos.org/news/dec-15-implementation-date-set-for-changes-to-kidney-pancreas-allocation. Previously, UNOS had stated the policy would change in "late 2020," but no date had been provided. Moreover, until the announcement on October 20, it was not clear to those within the transplant community that UNOS intended to move forward with the change in policy during the pandemic.

[16] Philipp A. Reuken, et al., *Between Fear & Courage: Attitudes, Beliefs, and Behavior of Liver Transplantation Recipients and Waiting List Candidates During the COVID-19 Pandemic* (May 27, 2020), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16118.

[17] *COVID-19 Changes: Upcoming Adjustments to Transplant Program and OPO Evaluation Metrics*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS (Aug. 6, 2020), https://www.srtr.org/news-media/news/news-items/news/#covid19psrosrchanges.

the donor supply and both candidates and recipients."[18] Moreover, the effects of COVID-19 have not been uniform throughout the country. "Preliminary data suggest that the pandemic has had a differential effect on different areas of the country at different times, making it a challenge to deal with statistically until more data becomes available."[19] Simply put, different geographic regions have experienced the pandemic differently, resulting in significant geographic variation in the number of transplant procedures and the data usually assessed for policy changes. These geographical differences are especially important when considering a change to policy such as that contemplated for kidney—where the stated policy goal is "to increase geographic equity in access to transplantation."[20] Because COVID-19's impact on transplantation varies across the country, it will be impossible to say whether geographic variances seen in transplant after the implementation of a new policy are attributable to COVID-19 or to the change in policy.

This is exactly what happened when the OPTN evaluated a change to liver allocation policy that took effect just six weeks before the declaration of the national emergency. In October 2020, the OPTN examined data from six months after implementation, and the SRTR opined that the "true impact of [the] policy change is very challenging to determine" because of COVID-19.[21] For example, the six-month report showed that there were 143 fewer liver transplants performed after the new policy was implemented compared to the same time period the year before. Yet the report notes that this information "should be interpreted with caution as the COVID emergency that followed shortly after policy implementation impacted transplant practices across the U.S."[22] An SRTR representative explained that "it's hard to sort out effects of [the change in policy] and COVID-19 as they overlap in periods."[23] A similar warning was issued in July when the OPTN reviewed the three-month data: "The impact of [the] COVID-19 pandemic will continue to be a confounding factor in analyzing this policy change in the coming

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[18] Brian J. Boyarsky, *Early National & Center-Level Changes to Kidney Transplantation in the United States During the COVID-19 Epidemic* 3132 (June 28, 2020), available at https://onlinelibrary.wiley.com/doi/full/10.1111/ajt.16167.

[19] SCI. REGISTRY OF TRANSPLANT RECIPIENTS, *supra*, note 17.

[20] Scott Castro, *Elimination of DSA & Region from Kidney Allocation Policy* 2, available at https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (last visited Dec. 1, 2020) [hereinafter "Briefing Paper"].

[21] Samantha M. Noreen, et al., *Out-of-the-Gate Monitoring of Liver & Intestine Acuity Circle Allocation* 11 (Oct. 18, 2020), available at https://optn.transplant.hrsa.gov/media/4121/liver_allocation_6monthmonitoringreport_2020oct18.pdf.

[22] *Id.* at 25.

[23] Meeting Summary, OPTN Liver & Intestinal Organ Transplantation Committee 3 (Oct. 22, 2020), available at https://optn.transplant.hrsa.gov/media/4177/20201022_liver_meeting_summary.pdf

months."[24] In fact, for some analyses, SRTR completely excludes data impacted by COVID-19 because of the confounding effect. "Under normal circumstances, the liver allocation system would likely take several months to reach an equilibrium. The emergence of COVID-19 likely confounds many of the analyses included in the evaluation. For this reason, the adjusted analyses include data only up to March 12, 2020, the day before the declaration of a national emergency for COVID-19."[25]

For the proposed change in kidney policy, the OPTN has stated that it will formally evaluate the Fixed Circle Policy's effects 3 months, 6 months, 1 year, and 2 years post-implementation.[26] During a recent webinar, in response to a question as to whether the policy change could cause adverse effects, the OPTN expressly stated that "unforeseen effects could happen," and that is "part of the reason we always, when we make changes like this, we insist on monitoring afterwards so that if the unforeseen changes are major and have a negative effect that we can then immediately intervene on them and address them."[27] As part of this monitoring, the OPTN has explained that it would review metrics such as new kidney waitlist registrations, waitlist mortality, variance in deceased donor transplant rate across DSA, and post-transplant outcomes.[28] Yet the SRTR has concluded that these exact metrics are *not* reliable after March 13, 2020 and has removed them from its reporting on transplant center performance.[29] Moreover, one recent study found that the impact of COVID-19 on these metrics varies widely across the country. Specifically, waitlist mortality "was 2.2-fold higher than expected in the 5 states with highest COVID-19 burden," even though it was consistent with normal expectations nationwide.[30] In addition, states with higher COVID-19 incidence experienced greater drops in

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[24] Meeting Summary, OPTN Liver & Intestinal Organ Transplantation Committee (July 2, 2020), available at https://optn.transplant.hrsa.gov/media/3911/20200702_liver_meeting_summary.pdf.

[25] *Liver Allocation: SRTR Evaluation of Acuity Circles*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS, https://www.srtr.org/reports-tools/acuity-circles-evaluation (last visited Nov. 30, 2020).

[26] Policy Proposal, *supra*, note 10, at 45.

[27] *Transplant Patient Webinar Recording Now Available*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, at 49:40 (Nov. 23, 2020), available at https://optn.transplant.hrsa.gov/news/transplant-patient-webinar-recording-now-available/.

[28] Policy Proposal, *supra*, note 10, at 46-47sa.

[29] SRTR has removed "patient and donor data from the performance metrics following the declaration of a national emergency on March 13, 2020. For transplant programs, this means that . . . waitlist survival, transplant rate, and outcomes will not be assessed after that date." *COVID-19 Changes: Upcoming Adjustments to Transplant Program & OPO Evaluation Metrics*, AM. SOC. OF TRANSPLANTATION (Aug. 7, 2020), https://www.myast.org/covid-19-changes-upcoming-adjustments-transplant-program-and-opo-evaluation-metrics.

[30] Boyarsky, *supra*, note 18, at 3136.

new waitlist registrations and the number of transplants.[31] In short, the data the OPTN plans to track to monitor the effects of the Fixed Circle Policy has been affected by the pandemic in ways that are significant, but variable and impossible to predict. It would be arbitrary and capricious to implement a new policy and purport to rely on assessment metrics to track the success or failures of that policy when such metrics are unreliable in the midst of this crisis.

### C. HHS Must Act to Evaluate the Policy and Implementation Timeline in Light of the Public Health Emergency

Under the Final Rule, you have the authority to direct the OPTN to provide ***any*** policy to you at least sixty days before implementation. 42 C.F.R. § 121.4(b)(2); *see Callahan v. U.S. Dep't of Health & Hum. Servs.*, 939 F.3d 1251 (11th Cir. 2019) ("[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 . . . ."). Further, you have a legal obligation to refer "significant proposed policies to the Advisory Committee on Organ Transplantation" and "publish them in the Federal Register for public comment." 42 C.F.R. § 121.4(b)(2).[32] A policy that completely overhauls the way in which life-saving kidneys are distributed across the country is undoubtedly "significant."

Your careful oversight and review of the Fixed Circle Policy is especially important because the policy was developed, modeled, and adopted before the pandemic. Despite the fact that the OPTN has made other policy and operational changes as a result of COVID-19,[33] there has been no assessment of the effects of COVID-19 on the Fixed Circle Policy. Indeed, based on the public discourse to date, *the OPTN has entirely failed to consider the impact of COVID-19 on kidney allocation policy*.

As one example, it is clear that the OPTN has not adequately considered how the significant change in commercial flight schedules—and especially the decrease in direct

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[31] *See id.* at 3135.

[32] Under the most natural reading of the regulation, you must refer to the Advisory Committee and publish in the Federal Register any significant proposed policy, or at least any significant proposed policy of which you have constructive receipt. While the Hospitals disagree with HHS's regulatory interpretation and reserve the right to challenge it, this letter assumes you are in agreement with HHS's legal position that you do not necessarily have an automatic legal obligation to refer this significant policy to the Advisory Committee and Federal Register. Even if that were so, however, it is arbitrary and capricious for you to fail to ask the OPTN for the kidney allocation policy sixty days before implementation for the reasons set forth in this letter.

[33] *See, e.g.*, *COVID-19 operational actions to remain in effect through Dec. 31*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK https://optn.transplant.hrsa.gov/news/covid-19-operational-actions-to-remain-in-effect-through-dec-31 (describing the actions taken to help "address and document COVID-19 issues affecting organ donation and transplantation").

flights—will impact the effects of the policy. Based on data modeling, the OPTN concluded that the Fixed Circle Policy would decrease transplant rates in non-metropolitan areas but only slightly.[34] However, that prediction does not consider the significant decrease in direct flights and limited commercial transportation available because of COVID-19, especially in non-metropolitan areas. Unlike donated hearts or lungs, which typically fly via charter jet, donated kidneys are beholden to commercial air travel. One study examining the effect of COVID-19 on organ transplantation found that there were 65.1% fewer flights between selected cities in April 2020 compared to April 2019.[35] The decreased flight availability affected certain cities more than others—some routes lost 100% of direct flights. Further, there was an increase in wait time between flights from a median of 1.5 hours in 2019 to 4.9 hours in 2020, affecting how quickly a donated organ could arrive at the recipient hospital. There was also an increase in flight cancellations, which was especially concerning because a donated kidney set to travel on a designated flight may instead end up sitting at the airport for hours and "could significantly increase [cold ischemic time] while worsening recipient posttransplant outcomes."[36] In making the decision to plow ahead with implementation of the Fixed Circle Policy in December 2020, there was no consideration given to the effect of this substantial change in commercial air transportation, a change that is likely to last far longer than the pandemic.

HHS's role in overseeing the OPTN, and especially in reviewing allocation policies, is even more critical in light of evidence that arose during litigation surrounding a similar change to liver allocation policy. Specifically, it was demonstrated that there was "colorable evidence of animosity and even some measure of regional bias" by OPTN and UNOS leadership.[37] "[M]ajor players within the transplant community had an agenda" and "enjoyed particularly close access to the ear of UNOS's executives" in 2018 and 2019.[38] This agenda has been driven in part by the

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[34] Briefing Paper, *supra*, note 20, at 29.

[35] Alexandra T. Strauss, et al., *Impact of the COVID-19 Pandemic on Commercial Airlines in the United States and Implications for the Kidney Transplant Community* 3128 (Aug. 19, 2020), available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.16284.

[36] *Id.* at 3129; *see also* Gregory Wallace & Pete Muntean, *Delta cancels more than 500 flights this week amid crew shortages*, CNN Business (Nov. 27, 2020), https://www.cnn.com/2020/11/27/business/delta-cancels-more-than-500-flights-this-week-amid-crew-shortages/index.html. The lack of flights and broader geographic distribution of organs also impairs the transplant system's ability to properly perform HLA typing necessary for transplantation.

[37] *Callahan*, 434 F. Supp. 3d at 1363. Specific examples of this animosity and bias were presented to a federal district court as part of the liver litigation but remain under seal. As noted above, the district court concluded in that case that there was insufficient evidence that HHS was aware of the bad faith displayed by UNOS. Even if that were true, as a result of the liver litigation, HHS is now on notice of UNOS's biases and must act with additional care before allowing a significant policy change to move forward.

[38] *Id.*

fact that its supporters stand to financially benefit if such policies take effect and move organs from poorer, rural regions into wealthier, metropolitan areas. Given these facts, it is essential that HHS take the time to evaluate changes to kidney allocation policy and ensure that any new policy is truly the best allocation policy for the country, not just for the biased few currently in charge at UNOS.[39]

The Fixed Circle Policy was developed, analyzed, and adopted in a pre-coronavirus climate that is vastly different from the current environment. There is no immediate need for kidney allocation to be changed during the middle of a global health crisis. You have the authority and the responsibility to direct the OPTN to submit the policy to you sixty days before implementation so that HHS may consider the impact of the pandemic on the policy change and seek counsel from the Advisory Committee and public comment.

## THE FIXED CIRCLE POLICY WILL HARM PATIENTS

Even setting aside COVID-19, there are numerous other issues with the Fixed Circle Policy that make it unlawful for you to fail to stop its implementation. The President's Executive Order on Advancing American Kidney Health requires you to "streamline and expedite the process of kidney matching and delivery to reduce the discard rate."[40] Indeed, as part of compliance with this Executive Order, you have set a goal to double the number of kidneys available for transplant by 2030 and to increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate.[41] Regrettably, the Fixed Circle Policy works against these goals by *decreasing* utilization of available organs and *increasing* the discard rate. In addition, the OPTN has not adequately assessed the policy's impact on socially vulnerable communities and has failed to consider transition policies to assist patients who are currently waitlisted. Because of the legal and public policy problems created by all of these failures, the law requires you to halt implementation of the policy.

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[39] The OPTN public comment process of the Fixed Circle Policy was seriously flawed, which further calls into question the OPTN's decision to move forward with the policy implementation during the pandemic. The request for public comment focused only on a policy proposal that would share organs across a 500 nautical mile circle in contrast to the final 250 nautical mile circle policy. The public lacked adequate notice that the 250 nautical mile policy was under consideration, and very few comments substantively addressed this version of the policy.

[40] Exec. Order No. 13879, 84 Fed. Reg. 33817, 33818 (2019), https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health.

[41] U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra*, note 2, at 3.

### A. The Fixed Circle Policy Reduces the Number of Kidney Transplants

Under the Final Rule, allocation policies must, among other things, "seek to achieve the best use of donated organs" and "be designed to avoid wasting organs."[42] The Fixed Circle Policy acts against these requirements by causing significantly more organs to go to waste. At best, there will be 250 *fewer* kidney transplants performed annually under the Fixed Circle Policy.[43] In addition, according to SRTR's analysis, the waitlist mortality count and graft failure rates will both *increase* under the new policy.[44] If the policy results in fewer transplants, increased waitlist mortality, and increased failed transplants, more patients will surely die.

But instead of facing the reality that the policy endorsed by its biased leaders will cause patient harm, UNOS has turned to the variation in transplant rates across DSAs as a justification for the kidney allocation change.[45] The OPTN asserts that these variable rates are indicative of inequities in organ allocation, which are attributable to certain DSAs unfairly having better access to organs than other DSAs. Yet if this were true, and variation in transplant rate was simply reflective of allocation policy, then transplant centers within the same DSA—with current access to an identical pool of organs—would have similar transplant rates. But that is far from the reality. For example, the transplant rate at New York University is 39.5 while the transplant rate at Mount Sinai—in the same DSA with access to the same organs—is 5.9.[46] Does that mean the allocation within the DSA is flawed and the national policy needs to be changed? No.

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[42] 42 C.F.R. § 121.8(a)(2), (5).

[43] The OPTN has claimed this loss of kidneys will be compensated in part with an increase in kidney-pancreas transplants, but that assumption fails to take into account that pancreata have a lower tolerated ischemic time, which affects acceptable travel distance for those dual organ transplants. Further, to the extent there could be an increase in kidney-pancreas transplants, this would disadvantage the Black community in a way that was not contemplated by the OPTN. Kidney-pancreas transplants are primarily used for diabetes patients, but insurance companies only routinely cover such transplants for Type 1 diabetes, which predominantly affects white individuals. Insurance companies do not uniformly cover kidney-pancreas transplants for Type 2 diabetes, which predominantly affects Black individuals. The SRTR modeling of the policy's effects did not consider these variations in insurance coverages.

[44] SALLY GUSTAFSON ET AL., SCI. REGISTRY OF TRANSPLANT RECIPIENTS, ANALYSIS REPORT: UPDATE 10 (June 21, 2019), https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf.

[45] OPTN/UNOS Public Comment Proposal, Eliminate the Use of DSA and Region from Kidney Allocation Policy at 6, 19-21, https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf.

[46] SCI. REGISTRY OF TRANSPLANT RECIPIENTS, MOUNT SINAI MEDICAL CENTER PROGRAM-SPECIFIC REPORT 6 (July 8, 2019), www.srtr.org/PDFs/072019_release/pdfPSR/NYMSTX1KI201905PNEW.pdf (rate for adult deceased donor transplant); SCI. REGISTRY OF TRANSPLANT RECIPIENTS, NEW YORK UNIVERSITY MEDICAL CENTER PROGRAM-SPECIFIC REPORT 6 (July 8, 2019), https://www.srtr.org/PDFs/072019_release/pdfPSR/NYUCTX1KI201905PNEW.pdf.

Transplant rates vary across DSAs because those rates vary across transplant centers within the DSAs. Transplant rates are affected by, among other things, each transplant center's waitlist population and waitlist management, organ acceptance practices, and the availability of living donor transplants, in addition to local OPO performance.[47] Importantly, the transplant rate is directly affected by the number of candidates on the waitlist, *including inactive candidates*.[48] Inactive candidates are not eligible to receive an organ offer, but they currently comprise approximately 40% of overall waitlisted kidney candidates.[49] Some geographic regions and transplant centers list large numbers of inactive status patients, which significantly decreases the DSA's transplant rate without reflecting any type of geographic inequity in allocation. Notably, UNOS does not even attempt to consider the reasons for why the variation in transplant rates across DSAs exists—it simply takes as a given that such variation is problematic and is the result of a flawed allocation policy. But in light of the inherent variation in transplant rates across transplant centers within the same DSA, for reasons unrelated to organ allocation, variation in transplant rate is not defensible as the driving force behind allocation policy change.

UNOS has invented a problem by inaccurately claiming that variation in transplant rates can and should be resolved by allocation policy. In fact, by adopting the Fixed Circle Policy, the OPTN will cost patient lives without yielding any benefit to the kidney transplant community.[50]

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[47] As CMS expressed recently, "[i]t is clear that our historical approach to measuring OPO performance has resulted in a wide range of performances. This variability is unacceptable to patients and CMS." Centers for Medicare & Medicaid Services, *Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule*, https://www.cms.gov/files/document/112020-opo-final-rule-cms-3380-f.pdf (Nov. 20, 2020). When poor-performing OPOs are required to improve performance under the new outcome measures issued by CMS, their local transplant centers may have improved transplant rates, even without any change to allocation policy.

[48] The SRTR defines transplant rate as the number of candidates who received a transplant (numerator) divided by the person-years observed at the program (denominator, which reflects how many candidates were on the waiting list and for how long). *See* SCI. REGISTRY OF TRANSPLANT RECIPIENTS, USER GUIDE 1 (July 8, 2019), https://www.srtr.org/document/pdf?fileName=\072019_release\pdfPSR\GAEMTX1KI201905PNEW.pdf. "Candidates who are inactive on the waiting list are included in the calculations for this table." *Technical Methods for the Program-Specific Reports*, SCI. REGISTRY OF TRANSPLANT RECIPIENTS, https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports#tableb4 (last visited Dec. 1, 2020).

[49] *National Data Reports, Organs by Status,* ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/# (based on data as of Dec. 1, 2020, showing 54,746 active waitlisted candidates and 39,040 inactive waitlisted candidates).

[50] The decrease in transplant volume especially threatens small transplant programs, which serve a smaller patient population, have shorter waitlists, and will receive fewer organ offers when sharing organs with large transplant programs within the fixed circle. These small programs risk closure because of the decline in transplant volume, which would result in their communities no longer having access to transplantation. The Final Rule requires that allocation policies "promote patient access to transplantation," 42 C.F.R. § 121.8(a)(5), not reduce

### B. Questionable Data Modeling and UNOS's Motives Call Into Question the Effects of the Fixed Circle Policy

The Fixed Circle Policy is predicated upon SRTR analysis that was altered in a manner inconsistent with sound scientific principles and likely influenced by biased personnel, leading the Hospitals to conclude that the proposed policy will result in dramatically lower transplant rates than the modeling predicts.

In September 2018, the SRTR analyzed the allocation policy changes and concluded that there would be *at least 1,000 fewer kidney transplants* performed nationally each year, possibly 2,000 fewer transplants.[51] Understandably, this first analysis "was negatively received due to the notable decreases in the number of transplants [and] . . . *In response*, SRTR began investigating" different modeling approaches.[52] In other words, there was no identified concern with the SRTR's modeling approach until the data did not turn out how UNOS leadership wished and was poorly received by the community. Only then did UNOS ask SRTR to consider new ways to approach the model. Such actions do not reflect sound scientific principles and fair-minded thinking.

In response to the concerns about the significant reduction in the predicted number of transplants, SRTR proposed to change the "acceptance model" portion of data model, which as the name implies is intended to reflect the likelihood that a transplant center will accept a certain simulated organ offer. Two options were presented as possible changes: Model 1 and Model 2. When predicting whether a transplant center would accept a simulated organ offer, Model 1 considered the distance the organ must travel from the donor hospital to the candidate transplant center. In Model 2, the analysis did not take into account how far the organ must travel to the recipient transplant center. The Workgroup voted 57% to 43% to use Model 2.[53] Thus, *the model relied on by the OPTN does not consider how far the organ must travel to the recipient transplant center in predicting whether a transplant center will accept or decline the organ offer*. Notably, in the UNOS-drafted meeting summary, there is no record of the Workgroup's discussion regarding the decision to exclude the distance the organ traveled or how such a

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access by causing transplant centers to close. Moreover, these risks are even more acute because of the strain caused by COVID-19. But the OPTN has not considered the threat to patient access resulting from such closures.

[51] SALLY GUSTAFSON ET AL., SCI. REGISTRY OF TRANSPLANT RECIPIENTS, ANALYSIS REPORT 6 (Sept. 24, 2018), https://optn.transplant.hrsa.gov/media/2768/kp_analysisreport_20181207.pdf.

[52] Minutes, OPTN/UNOS Kidney Transplantation Committee, (Mar. 25, 2019), available at https://optn.transplant.hrsa.gov/media/2935/20190325_kidney_meeting_minutes.pdf (emphasis added).

[53] Minutes, OPTN/UNOS Kidney-Pancreas Workgroup (Mar. 22, 2019), available at https://optn.transplant.hrsa.gov/media/3030/20190322_kp_workgroup_min.pdf. The Workgroup minutes do not list the number of voting members at the meeting or the vote counts.

decision was consistent with organ acceptance behavior in practice. There is also no discussion of whether it was possible for SRTR to run both models. However, the meeting minutes do reflect that in selecting Model 2 over Model 1, UNOS and the Workgroup were aware that Model 1 was "[m]ore likely to predict a decrease in transplant" while Model 2 was "[l]ess likely to predict a decrease in transplant."[54] The presence of such information (and no other explanation for selecting Model 2) suggests the new model was chosen intentionally to eliminate the predicted decrease in the number of transplants seen in the earlier modeling, not because Model 2 was more predictive of likely organ acceptance behavior.

This suspicious change in modeling is especially concerning in the context of the gross biases within UNOS leadership in favor of policies like the Fixed Circle Policy, as explained above. These biased persons are the same individuals who instructed SRTR to revise its data modeling and then advised the Workgroup on the selection of the model they knew in advance would improve the appearance of the data. It seems the goal was simply to push through the change in policy without considering what was best for patients.

In practice, the factor ignored in the revised modeling—the distance the organ must travel to reach the transplant center (as an approximation of time)—is absolutely a factor that surgeons take into consideration when determining whether or not to accept an organ. If the transplant surgeon knows he or she can personally procure an organ that would require minimal ischemic time to return to the transplant center, the surgeon is more likely to accept such an organ as compared to the same organ a farther distance away that would be procured by a different surgical team and require many hours of travel before reaching the transplant center. Moreover, surgeons in cities that lack a major airport may not be able to accept organs they would otherwise deem appropriate for their patients if those organs require long flights or layovers to reach the transplant center. Travel considerations are even more significant during COVID-19, as explained above.

In short, distance and travel time between the donor organ and potential recipient are key factors in whether an organ offer is accepted, but the SRTR model and thus the OPTN entirely failed to consider these factors when opting to implement the Fixed Circle Policy. As a result of the critical flaw in the analysis, the model underestimates the reduction in kidney transplants that will truly occur if this policy is allowed to take effect. Given this obvious flaw and intentional manipulation of the data model, your failure to request the policy proposal sixty days prior to implementation is an arbitrary abdication of your responsibility to oversee the actions of the OPTN.

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[54] Minutes, OPTN/UNOS Kidney Transplantation Committee, (Mar. 25, 2019), available at https://optn.transplant.hrsa.gov/media/2935/20190325_kidney_meeting_minutes.pdf.

### C. The Fixed Circle Policy Fails to Reduce Disparities in Transplantation for Low Socioeconomic Status Patients

Under the Final Rule, allocation policies must be reformed based on an assessment of their cumulative effect on socioeconomic inequities and shall promote patient access to transplantation. 42 C.F.R. § 121.4(a)(3)(iv); *id.* § 121.8(a)(5). The Fixed Circle Policy does neither. The OPTN gives no consideration to the significant inequities in waitlist access, and although it purports to be concerned about the impact of the policy change on low socioeconomic status candidates, its analysis regarding underserved communities is deficient. The SRTR did not model the impact of the policy based on cumulative community risk scores, which is a metric specifically designed to assess the impact of socioeconomic factors in kidney transplantation,[55] nor did it consider Centers for Disease Control social vulnerability index.[56] The OPTN has offered no explanation for why it did not use these metrics, which is especially questionable because the SRTR did model cumulative community risk scores for the change in liver allocation policy.[57]

The only modeling regarding socioeconomic effects are those regarding insurance status, median household income in the zip code, and urbanicity. The OPTN claims that transplant access has increased for low socioeconomic candidates because the data model reflects an increase in Medicaid recipients, but this data is unduly influenced by geography in light of inconsistent Medicaid expansion.[58] For example, an increase in Medicaid recipients could simply mean an increase in transplant recipients from Illinois, Virginia, or other states that adopted Medicaid expansion as organs are shifted away from non-expansion states like Alabama or Tennessee. Notably, the SRTR data for transplant rates based on household income shows decreases for candidates in zip codes with median incomes of $35k to $70k.[59] Thus, at best, the data from SRTR is inconclusive with respect to the effect of the proposed policy on candidates of

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[55] Jesse D. Schold et al., *The Association of Community Health Indicators With Outcomes for Kidney Transplant Recipients in the United States*, 147 ARCHIVES OF SURGERY 520 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880685/.

[56] Agency for Toxic Substances and Disease Registry, *CDC Social Vulnerability Index*, https://www.atsdr.cdc.gov/placeandhealth/svi/index.html (last reviewed Sept. 15, 2020).

[57] Given the questionable change to the data model described above and UNOS's biased leadership, HHS must question whether community risk modeling was not performed or not published because UNOS knew it would demonstrate that the policy change would harm vulnerable communities.

[58] *See Medicaid Coverage in Your State*, https://www.healthinsurance.org/medicaid/ (last visited Nov. 27, 2020).

[59] GUSTAFSON, *supra* note 44, at 55.

lower socioeconomic status, in contrast to the legal requirement that the OPTN reform allocation policy in a manner that *reduces* socioeconomic disparities. *See* 42 C.F.R. § 121.4(a)(3).

**CONCLUSION**

The COVID-19 pandemic demands the full attention of health care leaders and providers. It is unconscionable that UNOS would press ahead with implementing a significant change in organ allocation during the middle of this public health crisis. And yet, just six weeks ago, UNOS announced it planned to implement the Fixed Circle Policy on December 15, 2020—leaving hospitals scrambling. In so doing, UNOS offered no statements regarding how it would monitor the effects of the policy change while the virus wreaks havoc on normal data metrics or how it would manage to fly organs to non-metropolitan areas in an era where direct flights are non-existent in some communities. In deciding to implement the Fixed Circle Policy, UNOS is acting as though COVID-19 does not exist. But UNOS cannot wish the virus away, and under these circumstances, you have an obligation to direct the OPTN to provide the new kidney allocation policy to you for review sixty days before implementation. Further, as a significant policy, the Final Rule provides that you must refer the policy to the Advisory Committee and publish it in the Federal Register for public comment. Only after following these procedures can you fulfill your regulatory responsibilities and be confident that a change in policy will not benefit UNOS leadership at patients' expense.

Respectfully,

Glenn L. Krinsky

Glenn L. Krinsky

December 9, 2020

Thomas Engels

Administrator

Health Resources and Services Administration

13N-192

5600 Fishers Lane

Rockville, MD 20857

Dear Administrator Engels:

As organ procurement organization (OPO) leaders representing multiple geographic locations in the Nation, we write urging you to suspend implementation of the new Organ Procurement and Transplantation Network (OPTN) kidney allocation policy scheduled for December 15, 2020. With our Nation necessarily focused on the massive demands of coping with the COVID-19 pandemic, we believe this is not the time to make a change to the kidney allocation system. We are all bracing for a surge in coronavirus cases that is expected to hit before Christmas, and it is essential OPOs be permitted to maintain processes they have already adopted so we can continue providing life-saving organs for transplant. If the new allocation policy is implemented, it will add further burden with a complex set of new circumstances.

This new policy was adopted in December 2019, just before the pandemic, with an expectation that it would be implemented sometime in 2020. When COVID-19 hit, OPOs focused on maintaining a high level of service delivery while struggling with never-before-seen challenges. When it became clear the public health emergency would not soon resolve, we would have expected the OPTN to delay any major policy changes except those necessary to address the pandemic. Given that the new kidney allocation policy is heavily dependent on movement of more kidney and donor blood specimens to candidates within a 250 nautical mile radius, and beyond that for highly sensitized candidates, we are greatly concerned that severely limited commercial flight schedules and charter aircraft will prolong kidney cold ischemic times and increase discard rates. This outcome is in opposition to the stated goals of the policy.

On October 20, 2020, the OPTN announced its intention to implement the new kidney allocation policy on December 15th. Given the pressures the COVID-19 pandemic is having on OPOs (as described above) and transplant centers, we ask you to reconsider the implementation of such a significant policy change. It seems much more prudent, with a vaccine on the horizon, to delay the policy change until conditions in the country begin to normalize.

For all the reasons stated above, we urge you to please take immediate action to suspend the implementation of this policy. We welcome the opportunity to speak with you or provide additional information.

Sincerely,

Ginny McBride

Executive Director

OurLegacy

Maitland, Florida

Diane Brockmeier

President and CEO

MidAmerica Transplant Services

St. Louis Missouri

Janice Whaley

President and CEO

Donor Network West

Oakland, California

Patti Niles

President and CEO

Southwest Transplant Alliance

Dallas, Texas

Matthew Wadsworth

Chief Executive Officer

Life Connection of Ohio

Toledo, Ohio

Chris Meeks

Executive Director

Legacy of Hope

Birmingham, Alabama

Kyle Herber

President and CEO

Live On Nebraska

Omaha, Nebraska

Kevin Stump

Chief Executive Officer

Mississippi Organ Recovery Agency

Flowood, Mississippi

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**From:** Bry, William, M.D. <BryW@sutterhealth.org <mailto:BryW@sutterhealth.org>>
**Sent:** Friday, December 11, 2020 12:06 PM
**To:** Engels, Thomas (HRSA) <TEngels@hrsa.gov <mailto:TEngels@hrsa.gov>>
**Cc:** Holloman, Frank (HRSA) <FHolloman@hrsa.gov <mailto:FHolloman@hrsa.gov>>; McLaughlin, Chris (HRSA) <CMcLaughlin@hrsa.gov <mailto:CMcLaughlin@hrsa.gov>>; Walsh, Robert (HRSA) <RWalsh@hrsa.gov <mailto:RWalsh@hrsa.gov>>
**Subject:** In support of changes to Transplant Donor Kidney allocation opposing Iowa lawsuit

Thomas Engels

Administrator

Health Resources and Services Administration

13N-192;

5600 Fishers Lane

Rockville, MD 20857

December 11, 2020

Dear Administrator Engels:

The constituent transplant centers of the Donor Network West Organ Procurement Organization in Northern California - UCSF, Stanford and California Pacific Medical Center - are writing in support of the changes in kidney allocation going into effect December 15, 2020 and wish to respond to the complaint filed in Iowa 12/9/20.

The Final Rule, enacted in 2000, states that:

**Organs shall be allocated based on sound medical judgment and to avoid futile transplantations. Specifically, the amended Final Rule provides that "organs should be distributed over as broad a geographic area as feasible" and considers the urgency of a recipient patient's need for an organ transplantation.**

This map from the Epidemiology Research Group in Organ Transplantation at John's Hopkins graphically illustrates the geographic challenges many patients have faced in receiving a kidney transplant. Note that patients in many different parts of the country have long wait times. It is not just a bi-coastal phenomenon as suggested in the

plaintiff's complaint. The new allocation policy will not be shifting kidneys to the "coasts" as they imply; they will still go to deserving candidates within a 250-mile radius of the donor hospital, thus staying in the same geographic region as the plaintiff's transplant centers.

Prior to the enactment of this new allocation system, patients were encouraged to list themselves at multiple institutions to improve their chances of receiving a transplant sooner. This represented a barrier for many patients who did not have the means to travel to other regions. While an ideal system would create one giant waiting list for the whole country regardless of where the organ originated, this is not practical because allocation needs to be within reasonable travel distances to ensure that the transplants are completed in a timely manner to promote successful outcomes. The new allocation policy addresses the dramatic differences in wait times by creating proximity circles of 250 nautical miles around donor hospitals for allocation of kidneys rather than arbitrary geographic boundaries. For example, a donor in southeast Utah (Region 5) would be available to a recipient just a few miles away in southwest Colorado (Region 8), improving chances of a shorter wait time for this patient.

UNOS has conducted an exhaustive process to bring this new allocation system to fruition over the past several years including innumerable committee meetings, regional meetings in all eleven UNOS territories, inviting feedback from both the stakeholders and the general public. In fact, this proposal was approved by vote in every region from which the plaintiffs originate. Representatives of the department of HHS have participated extensively in these discussions.

The Jones Day Law Firm bringing this complaint was unsuccessful in trying to stop a similar allocation policy enacted by UNOS for Liver transplantation over the past two years, wasting time, money and possibly lives with a frivolous lawsuit. This current complaint represents an overreach by the same individuals using the same arguments that the court has already rejected.

The first part of the complaint focuses on the timing of the policy during the Pandemic being inappropriate. Just as this pandemic era has proved to be a fertile time to address the inequities faced by race and gender in this country, addressing the geographic inequities in access to donor kidneys for many patients is appropriate. The changes in allocation will have no impact on the usage of ICU beds and in no way will affect the care of patients infected with Covid 19.

Our appeal is not self-serving like the lawsuit being brought forward by the plaintiffs. In fact, many donor kidneys within the borders of our OPO that previously have gone to patients on our local waiting lists will now be shared with patients awaiting kidney transplantation in Southern California.  While the new allocation rules do not benefit our

three transplant centers, it is for the best interest of the patients. The map below demonstrates that Los Angeles based transplant programs will now have access to 22% of our local donors due to the proximity of busy donor hospitals in Fresno and Modesto, while the 250 mile radius from the San Francisco Bay Area going south does not include any major donor hospitals in the Southern California corridor.

We ask HHS to vigorously defend the new kidney allocation system from lawsuits that seek to maintain the unfair status quo to the detriment of deserving patients across the country.

William I Bry, M.D. FACS

Region V Representative to UNOS Board of Directors

Surgical Director of Kidney Transplantation

California Pacific Medical Center

Chris E. Friese, M.D. FACS

Division Chief of Transplant Surgery

University of California San Francisco

Carlos O. Esquivel, Ph.D., M.D. FACS

Division Chief of Transplant Surgery

Stanford University

Robert W. Osorio, M.D. FACS

Division Chief of Transplant Surgery

California Pacific Medical Center

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**VIA ELECTRONIC MAIL**

January 4, 2021

Thomas J. Engels, Administrator
Health Resources and Services Administration
Department of Health and Human Services
Rockville, MD 20857

Dear Mr. Engels,

On December 21, 2020, you wrote on behalf of the United States Department of Health and Human Services (HHS), requesting the views of the Organ Procurement and Transplantation Network (OPTN) on various issues raised in two critical comments, submitted to HHS on December 2, 2020 and December 9, 2020, respectively. The critical comments concern the OPTN's plans to implement the kidney allocation policy adopted by the OPTN in December 2019 (Revised Kidney Policy).[1,2] The critical comments submitted to HHS relate both to the substance of the Revised Kidney Policy, including the methods the OPTN used to develop it, and to the potential impact on the Revised Kidney Policy's implementation and ability to be monitored due to the COVID-19 pandemic.

[1] In December 2019 the OPTN Board of Directors also adopted the Policy to Eliminate the Use of DSA and Region in Pancreas Allocation Policy (https://optn.transplant.hrsa.gov/media/3370/eliminate-the-use-of-dsas-and-regions-in-pancreas-allocation_112219.pdf. (Accessed on December 24, 2020)). While the critical comments focus almost exclusively on the Revised Kidney Policy, the pancreas policy must not be overlooked. It too removes DSA and Region as units of distribution from pancreas allocation. This policy is inextricably intertwined with the Revised Kidney Policy because of the close association between kidney and pancreas allocation for transplant, and likewise could not be implemented on December 15, 2020 as a result of the Secretary's direction that the OPTN not implement the Revised Kidney Policy. While the majority of the discussion in this response will focus on the Revised Kidney Policy, most of the work to develop it was performed by a combined Kidney-Pancreas Workgroup comprised of members of both the Kidney and Pancreas Transplantation Committees, resulting in the two related proposals.

[2] Further entwined with the Revised Kidney Policy are three additional modifications that were approved by the OPTN Board of Directors during its June 2020 meeting: 1) Addressing Medically Urgent Candidates (*see* Notice of OPTN Policy Changes, June 2020, https://optn.transplant.hrsa.gov/media/3840/2020-06_kid_med_urgency_policy_notice.pdf (Accessed on December 28, 2020)); 2) Distribution of Kidneys and Pancreata from Alaska (*see* Notice of OPTN Policy Changes, June 2020, https://optn.transplant.hrsa.gov/media/3833/alaska_policy-notice-june-2020.pdf (Accessed on December 28, 2020)); and 3) Modifications to Released Kidney and Pancreas Allocation (*see* Notice of OPTN Policy Changes, June 2020, https://optn.transplant.hrsa.gov/media/3835/opo_kp-reallocation_policy-notice-june-2020.pdf (Accessed on December 28, 2020)). The OPTN did not implement any of these proposals on December 15, 2020 as planned, due to the December 14, 2020 directive from HRSA.

**After a thorough review of the issues raised by the critical comment, the OPTN Executive Committee concluded that moving forward with implementation of the Revised Kidney Policy is in the best interest of patients and should not be further delayed.**

The Revised Kidney Policy eliminates the use of donation service areas (DSAs) and OPTN regions as units of distribution for kidney allocation, and replaces them instead with a 250 nautical mile (NM) circle around the donor hospital. Points are assigned to a candidate based on how close the candidate's transplant hospital is to the donor hospital where the organ recovery occurs, and are included in the total kidney allocation score, along with other factors like time on dialysis and sensitization level determined by CPRA, to rank potential transplant recipients within classifications on a kidney match run. The goal of the policy is to ensure candidates awaiting a kidney transplant have more equitable access to kidney offers, regardless of where their transplant hospital is located by replacing the inequitable units currently being used (DSA and regions) with a more consistent and rational unit of distribution. The OPTN planned to implement the Revised Kidney Policy on December 15, 2020, but, due to your direction of December 14, 2020, will not do so until at least February 13, 2020.[3]

The OPTN appreciates the opportunity to provide its views to HRSA. After addressing the OPTN's extensive efforts in response to the COVID-19 pandemic (page 2), we will provide the OPTN's position that the Revised Kidney Policy is consistent with the requirements of NOTA and the OPTN final rule (page 9), as well as answers to the following questions asked:

1. Rationale for and discussion of the adequacy of the methodology used to model the predicted impacts of the change to kidney allocation policy (page 12);
2. Description of the OPTN's consideration of a potential transition policy in relation to the change in kidney allocation policy (page 16);
3. Analysis of the adequacy of the OPTN's plan to evaluate the impact of the new kidney allocation policy in general and in light of disruptions to the transplantation system caused by the COVID-19 pandemic (page 17);
4. Analysis of the adequacy of efforts to support transplant centers and organ procurement organizations to prepare for the implementation of the new policy in general and in light of disruptions to the transplantation system caused by the COVID-19 pandemic (page 20);
5. Overview of any efforts taken to educate OPTN members, the public, and patients about the revised OPTN Kidney Allocation Policy (page 22);
6. Description of the OPTN's analyses regarding the impact of the new kidney allocation policy on transplant candidates of low socioeconomic status (page 25).

The OPTN has coordinated with the Scientific Registry of Transplant Recipients (SRTR) on this response.

## The OPTN's Response to the COVID-19 Pandemic

The OPTN has launched a comprehensive approach to supporting the entire transplant community—including patients, transplant programs and Organ Procurement Organizations (OPOs)—during the COVID-19 crisis. The critical comments suggest that the OPTN has ignored

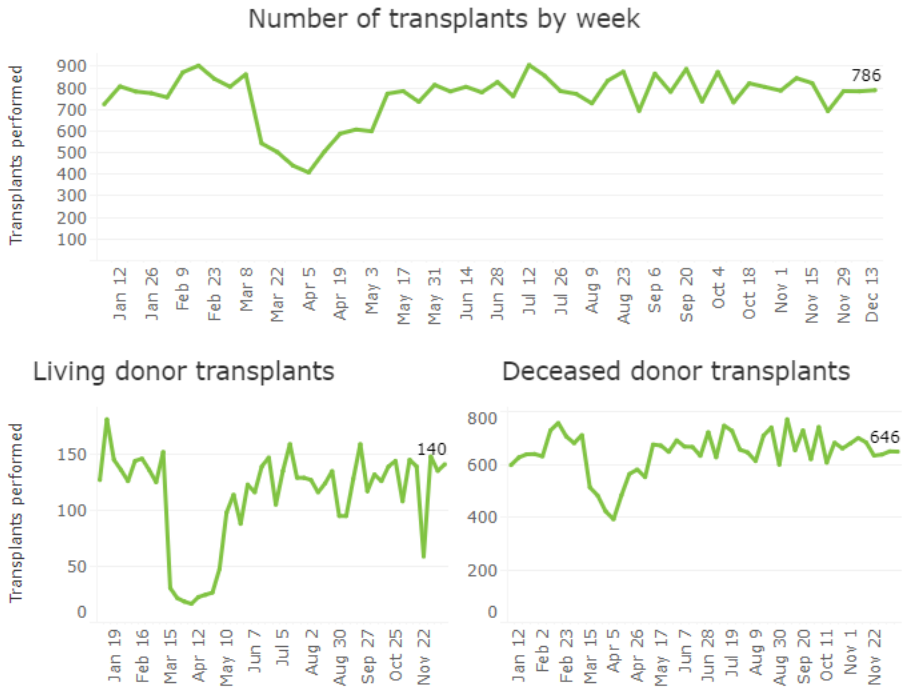
[3] Letter from HRSA Administrator Thomas J. Engels to the Dr. David Mulligan, President of the OPTN, and Brian Shepard, Executive Director of the OPTN, December 14, 2020.

the impact that COVID-19 has had on transplantation. This is simply not so. The OPTN has responded to the COVID-19 crisis since it began and continues to provide ongoing analysis, solicitation of community input, and myriad educational, data, policy, and other supports to assist the community in continuing to deliver donation and transplantation despite the challenges caused by the pandemic.

*General Impact of COVID-19*

The OPTN has been closely monitoring data since the pandemic began. In March of 2020, the organ donation and transplantation community experienced a drastic reduction in donor organ recovery and transplantation volumes. But that reduction was relatively short-lived, considering the tenacity of the pandemic. Figure 1 shows the number of transplants by week, from January 5 through December 22, 2020.

**Figure 1: Number of transplants by week 2020[4]**




While living donor transplants have remained at materially lower volumes when compared to 2019, the number of cumulative deceased donor organ transplants is actually higher by 1,246 transplants than it was at the same time a year earlier, as of December 15, 2020.[5]

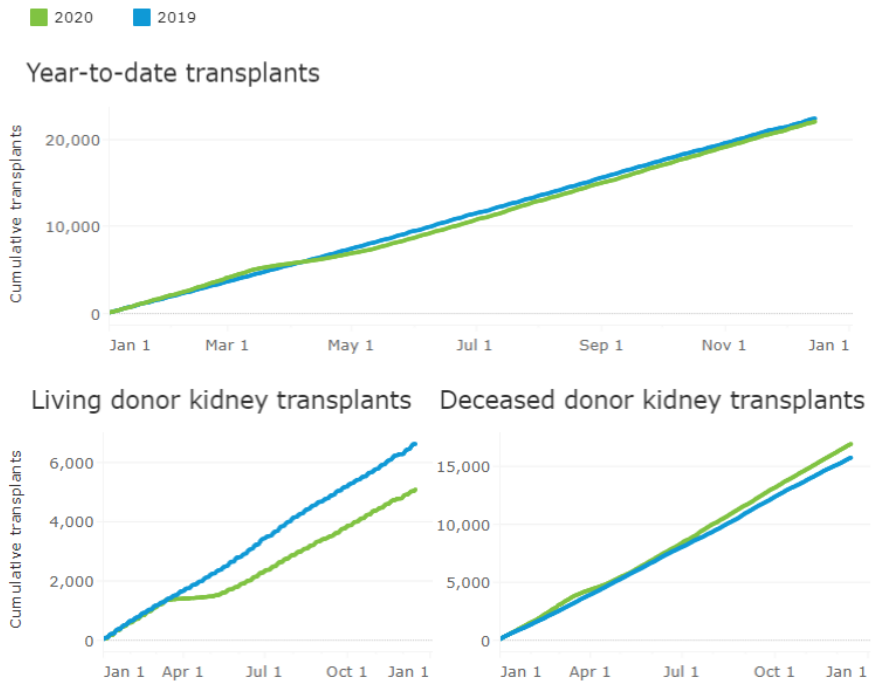
The trend of lower-than-normal living donor transplants and higher-than-expected deceased donor transplants is especially apparent with kidneys. Figure 2 shows that, while there have

[4] OPTN data, https://unos.org/covid/, accessed on December 22, 2020 at 3:34PM.
[5] *Id.*

been 351 fewer kidney transplants as of December 15, the number of deceased donor transplants has increased by 1,181 in 2020 over 2019.[6] The lower overall transplant volume has been driven almost exclusively by significant reduction in living donor kidney transplants. Consistent with national practices to reduce or eliminate "elective" surgeries, many transplant hospitals followed guidelines advising against bringing living donors and their intended recipients to the hospital during the pandemic periods of increased infectious risk to perform living donor organ recoveries.[7]

**Despite the pandemic, deceased donor kidney transplants are higher than the number of deceased donor kidney transplants in 2019 by 1,181: a nearly 8% *increase*.** *See* bottom right graphic in Figure 2:

**Figure 2: Year to Date Kidney Transplants, Overall and by Donor Type[8]**




[6] *Id.* Through December 15, overall kidney transplants are lower in 2020 compared to the same period in 2019 21,965 vs. 22,316: a difference of -351 (top graphic in Figure 2). However, this difference is fully driven by the decline in living donation this year (bottom left graphic in Figure 2), a decline which started at the onset of the COVID-19 pandemic in the US.

[7] American Society of Transplant Surgeons. ASTS COVID-19 Strike Force Guidance to Members on the Evolving Pandemic. March 24, 2020. https://asts.org/advocacy/covid-19-resources/asts-covid-19-strike-force/asts-covid-19-strike-force-initial-guidance#.X-pXVNhKiUl (Accessed on December 28, 2020).

[8] OPTN data, https://unos.org/covid/, accessed on December 22, 2020 at 3:34PM.

In terms of reviewing any COVID-19 impact on organ transportation, 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 from outside the donor's DSA.[9] Aside from the brief spike at the beginning of the pandemic, exhibited in Figure 3, the data show that organ offer acceptance practices of transplant programs for kidneys have largely returned to pre-pandemic norms.

**Figure 3: Median accepted offers by miles traveled[10]**

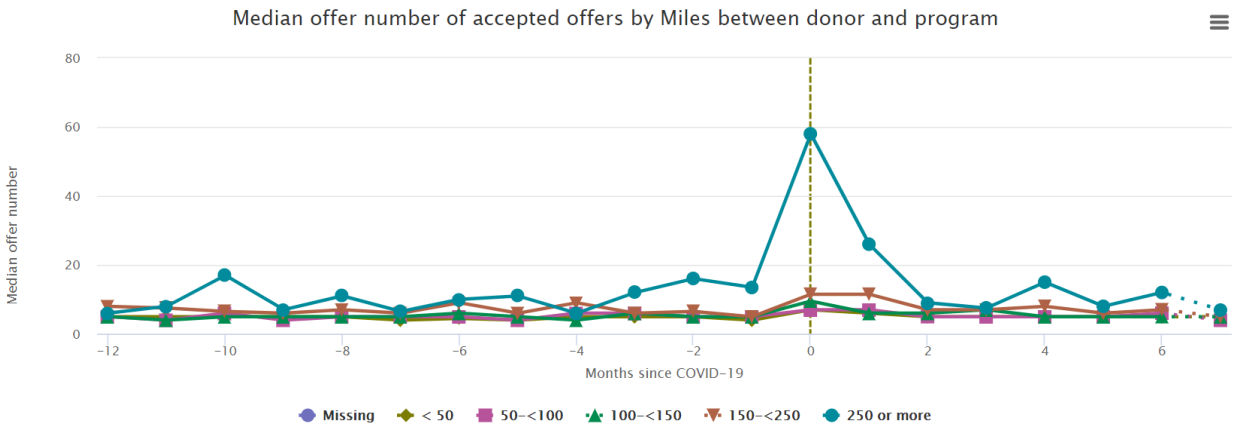
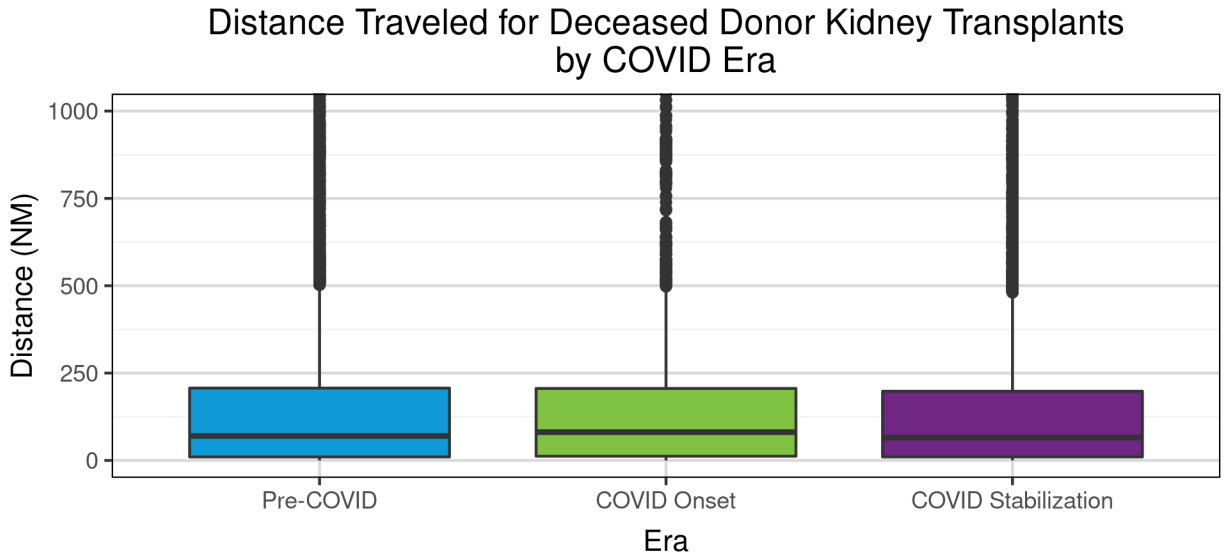



Figure 3 demonstrates the resiliency of the transplant network and shows that acceptance behavior reverted to pre-pandemic norms. The OPTN is confident that that the transplantation and donation community will similarly adapt to other changes to the system, such as the Revised Kidney Policy.

Figure 4 shows the distance traveled for deceased donor kidneys in different time periods between September 2019 and September 2020.

[9] *Id.* January-June 2019 compared to January-June 2020.
[10] SRTR: Effect of COVID-19 on the Transplant System. https://www.srtr.org/reports-tools/covid-19-evaluation/ (Accessed December 28, 2020).

**Figure 4: Distance traveled for deceased kidney donor transplants by COVID-19 Era[11]**




Pre-COVID: 9/1/2019-3/12/2020
COVID Onset: 3/13/2020-5/9/2020
COVID Stabilization: 5/10/2020-9/30/2020

While there was some variation in miles traveled during the pre-COVID and the COVID Onset and Stabilization eras, it was not significantly different. Even at a surge, the COVID-19 pandemic did not thwart transportation or offer acceptance practices.

*OPTN Policy and Committee Actions in Response to COVID-19*

The OPTN's frequent and ongoing review of the impact of COVID-19 on the donation and transplantation community led to a number of OPTN Executive Committee actions.[12] The OPTN Executive Committee approved a series of four emergency actions between March 17[13] and April 3, 2020[14], in order to protect patient safety and alleviate issues stemming from the COVID-19 crisis. The OPTN also implemented a number of COVID-related potential transplant recipient

[11] OPTN data, https://unos.org/covid/, as of December 18, 2020.
[12] "The Board of Directors shall elect an Executive Committee from the membership of the Board." 42 C.F.R. §121.3(a)(2). The OPTN Executive Committee "[c]ontinues the work of the Board of Directors without the necessity of convening the entire Board" and "[c]onsiders any issues that require expedited action between meetings of the Board of Directors." *See* OPTN Bylaws Article IV: Executive Committee. https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (Accessed on December 28, 2020).
[13] Notice of OPTN Policy Change: Updates to Candidate Data During 2020 COVID-19 Emergency. March 17, 2020. https://optn.transplant.hrsa.gov/media/3722/candidatedata2020covid19emergency.pdf (Accessed on December 28, 2020)
[14] Notice of Emergency Action: COVID-19 Emergency Policy Package. April 3, 2020. https://optn.transplant.hrsa.gov/media/3716/covid-19_emergency_policypackage_and_minibrief.pdf (Accessed on December 28, 2020).

refusal codes on March 25, 2020.[15] Those included candidate-related, donor-related, and OPO or transplant program COVID-related operational reasons for refusal. As the system-wide volume and refusal data show, OPOs and kidney transplant programs have adapted to the pandemic conditions, and the overall system has shown incredible resilience. For example, in early April 2020, 8% of all refusals of kidney offers were due to COVID-related operational issues; since the end of May 2020, COVID-related operational issues accounted for almost 0% of all refusals.[16]

The donation and transplantation community has been very supportive of the overall OPTN response to COVID-19. When the OPTN released the COVID-19 emergency actions for retrospective public comment, from August 4 to October 1, 2020, the community responded with strong support for the actions taken to date. [17] There were numerous comments of support; one example noted that the actions were "an excellent, timely, and balanced response to an unpredictable event."[18]

OPTN Committees have been a critical part of the OPTN's response to COVID-19. In an effort to encourage transplant programs to prioritize the best interests of their patients using their clinical judgement given the pandemic conditions, the Membership and Professional Standards Committee (MPSC) implemented several time-limited emergency changes to member monitoring. These include suspending functional inactivity reviews through December 31, 2020 and placing a temporary hold on reviews of patient notification of extended waiting list inactivity and transplant program inactivation through December 31, 2020.[19] Additionally, due to the extra demands that the COVID-19 crisis placed on resources at member institutions, virtual site surveys have been instituted in place of on-site visits, and the site survey schedule was adjusted to meet the needs of the members. [20] Reasonable requests to postpone surveys are considered, such as if the member is located in a current COVID hot-spot or is experiencing a high rate of inpatient COVID-19 patients, or if transplant resources are reallocated to fight the virus. These types of actions, as noted by members, have enabled the transplant community to focus on patient care and continue to recover donated organs and perform life-saving transplants despite the pandemic.

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[15]UNOS News: COVID-19 Refusal Codes for Transplant Hospitals Implemented March 25. March 25, 2020. https://unos.org/news/covid19/covid-19-refusal-codes-for-txc/ (Accessed on December 29, 2020).

[16] Cartwright, Laura, Amber Wilk, Sarah Taranto, Rick Franklin, John Beck, Brian Plucinski, Sarah Booker, and Alesha Henderson. "Summary of COVID-19 Emergency Policy and IT Changes." *OPTN Executive Committee Descriptive Data Request*, December 1, 2020.

[17] Comments on the OPTN Public Comment website regarding the COVID-19 Emergency Policies and Data Collection proposal. All comments can be viewed at https://optn.transplant.hrsa.gov/governance/public-comment/covid-19-emergency-policies-and-data-collection/. (Accessed on December 28, 2020).

[18] *Id.*

[19] OPTN: COVID-19-related OPTN Member Monitoring Changes. Last updated December 8, 2020. https://optn.transplant.hrsa.gov/media/3730/covid_evaluation_plan_supplement.pdf (Accessed on December 28, 2020).

[20] OPTN Executive Committee Meeting Summary, March 17, 2020. https://optn.transplant.hrsa.gov/media/3755/20200317_executive-committee_meeting-summary.pdf (Accessed on December 28, 2020).

The Policy Oversight Committee reviewed, evaluated and prioritized incoming ideas and suggestions from members regarding the impact of COVID-19 on OPTN policy.[21, 22] This process resulted in several proposals and subsequent policy actions to maximize patient safety by reducing potential COVID-19 exposure and to minimize reduced access when medical resources may not be available. Actions taken include allowing repeat use of needed laboratory values, modification of kidney wait time for candidates meeting criteria but unable to obtain updated lab values, and amnesty for follow-up data submission that would require recipients or living donors to have potential exposures for required follow up visits or tests. The actions demonstrate a keen awareness and willingness to act when necessary to prioritize patients and resources to mitigate pandemic impacts.

*Other Support Provided by the OPTN*

The OPTN has provided an unprecedented level of overall community support during the COVID-19 pandemic. General support and broad-based efforts include co-sponsorship of multiple town halls, led by the American Society of Transplantation. Several thousand attendees participated in these publicly available events which occurred on March 23, April 13, May 11, and December 3, 2020.[23] Registrants for the last town hall webinar submitted 190 suggestions and questions, many of which centered on patient care. While some asked that the general COVID-19 impact on transplant be covered, there were no specific questions or community concerns submitted regarding the pending implementation of the Revised Kidney Policy. Several COVID-19 educational offerings directed at supporting members were also developed and posted on UNOS Connect.[24]

The COVID Collaborative was an OPTN initiative to help members come together and share effective practices during the COVID-19 crisis.[25] Recognizing the importance of members' expertise, experience and collaboration during a crisis, the project and its moderated discussions aimed to help inform members' work in developing better solutions to support the transplant community. Discussion threads addressed a variety of topics including: patient testing, procurement team exposures, OPO strategies, living donation, decreased organ utilization, and telemedicine.[26]

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[21] OPTN Policy Oversight Committee Meeting Summary, March 26, 2020. https://optn.transplant.hrsa.gov/media/3747/20200326_poc_meeting-summary.pdf (Accessed on December 28, 2020).
[22] OPTN Policy Oversight Committee Meeting Summary, April 23, 2020. https://optn.transplant.hrsa.gov/media/3796/20200423_poc_meeting-summary.pdf (Accessed on December 28, 2020).
[23] UNOS Resources: Recorded COVID-19 Webinars. https://unos.org/covid-webinars/ (Accessed on December 28, 2020).
[24] UNOS News: COVID-19 Webinars Now Available on UNOS Connect. July 31, 2020. https://unos.org/news/covid-19-webinars-on-unos-connect/ (Accessed on December 28, 2020).
[25] UNOS News: Donation and Transplant Professionals: Share Your COVID-19 Practices in Real Time. May 6, 2020. https://unos.org/news/share-your-covid-19-practices-in-real-time/ (Accessed on December 29, 2020).
[26] OPTN News. Update on the OPTN COVID Collaborative. July 9, 2020. https://optn.transplant.hrsa.gov/news/update-on-the-optn-covid-collaborative/ (Accessed on December 28, 2020).

The OPTN website includes a number of resources for the community related to COVID-19.[27] This includes a dedicated location for the public--including all professionals, OPOs, transplant hospitals, and patients—to access up-to-date information and resources, as well as a link to the UNOS website page for additional COVID-19 and organ transplant information. Users can find recommendations, articles, OPTN policy actions, and multiple other resources. OPTN members and other stakeholders receive regular COVID-19 update emails every two weeks that provide a synopsis of recent events and highlight resources that may be helpful to the community.

Resources available to the public and members include several data tools. A COVID-19 data visualization tool is available on the UNOS website.[28] It shows high-level data on transplants, deceased donors recovered, patients added to the waitlist, and patients temporarily moved to inactive waitlist status. These data are updated daily. OPTN members and the public can create individualized data graphs by region, organ, age, ethnicity, and listing status for recoveries, transplants, and waiting list data. In another data-driven response to the COVID-19 pandemic, a temporary version of the Recovery and Usage Maps tool, or RUM, was developed for OPTN member use through the UNet$^{SM}$ data analytics portal.[29] This tool is updated weekly instead of quarterly with data since January 5, 2020. These data are intended to assist OPOs and transplant programs in evaluating how COVID-19 is potentially impacting their own practices.

At the onset of the pandemic, the OPTN created a member questionnaire on the front page of UNet$^{SM}$ solely for the purpose of identifying and responding to COVID-19-related impacts on donation and transplantation. Between March 16, 2020 and September 28, 2020, 32 unique OPOs and 88 unique transplant hospitals provided responses. The most commonly reported issue has been the inability to get timely COVID-19 testing most acutely experienced at the onset of the pandemic. Through May 18, 2020, a total of 13 OPOs reported delays in transportation of teams or organs due to lack of air/ground capacity.[30] Since then no further reports related to transportation have been received, and since the end of September, no members have used this avenue to report any other COVID-19 concerns to the OPTN.

The Member Questions service continues to provide support for members. Since March 1, 2020, the OPTN has fielded 1,090 questions from members, with 118 related to COVID-19. During this time approximately 17 questions were received related to implementation of the Revised Kidney Policy, but none of the questions asked about or suggested a delay in the implementation of the Revised Kidney Policy due to COVID-19.

The OPTN has robustly responded to the COVID-19 pandemic through monitoring, resources, policy changes, and member support while anchoring its response in patient safety and evidence-based actions. It has also provided many avenues for comments and questions from members. The OPTN considered the suggestions raised in the critical comments submitted to HHS in early December—reviewing them at meetings of both the OPTN Kidney Transplantation Committee and the OPTN Executive Committee on December 21, 2020—and concluded that an

[27] OPTN COVID-19. https://optn.transplant.hrsa.gov/covid-19/ (Accessed on December 28, 2020).
[28] UNOS. COVID-19 and solid organ transplant: Data. https://unos.org/covid/ (Accessed on December 28, 2020).
[29] UNOS News: COVID-19 Weekly RUM Report Now Available. April 28, 2020. https://unos.org/news/covid19/covid-rum-tool/ (Accessed on December 29, 2020).
[30] OPTN COVID-19 UNet Survey Report. May 18, 2020. Provided to HRSA on May 20, 2020. Available upon request.

additional measure of delaying the implementation of the Revised Kidney Policy is not needed.[31] As demonstrated by the record number of deceased donor kidney transplants that have been performed in 2020, despite the pandemic, the OPTN is confident that the community will adapt to the Revised Kidney Policy.

**Whether the revised OPTN Kidney Allocation Policy, including its use of 250 nautical mile fixed circles as units of allocation, is consistent with the requirements of NOTA and the OPTN final rule**

The Revised Kidney Policy is consistent with the requirements of NOTA and the OPTN final rule, both procedurally and substantively.

*Procedure*

The OPTN final rule requires the OPTN Board to develop, "with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN…."[32] The OPTN Board together with the Kidney Transplantation Committee (Kidney Committee) did just that: developed and approved the Revised Kidney Policy over the course of nearly 18 months (contrary to the statement from the author of the December 1 Critical Comment that the Committee developed the proposal "in 2019") and at least 30 Committee meetings.[33] The OPTN made all modeling results it relied upon readily available to any interested member of the public.[34, 35] From January through March 2019, the OPTN Kidney Committee and Pancreas Transplantation Committee (Pancreas Committee) sponsored a concept paper for public comment.[36] Representatives of the Kidney and Pancreas Committees presented it for awareness and feedback at all 11 OPTN regional meetings, which were attended by nearly 1,200 participants from the donation and transplantation community.[37] In June 2019, the Committees each hosted two webinars to provide the donation and transplantation community

[31] This issue was explicitly discussed by both the OPTN Kidney Transplantation Committee and the OPTN Executive Committee on December 21, 2020. Both Committees reviewed the critical comments, and neither Committee found reason to delay the implementation of the Revised Kidney Policy. Meeting summaries for both Committee deliberations will be posted on the OPTN website when available at https://optn.transplant.hrsa.gov/members/committees/.

[32] 42 C.F.R. §121.4(a)

[33] All Meeting Summaries of the OPTN Kidney Transplantation Committee from the relevant timeframe are available on the OPTN website at https://optn.transplant.hrsa.gov/members/committees/kidney-committee/.

[34] OPTN News: SRTR modeling results available for kidney and pancreas distribution proposal, December 8, 2018. https://optn.transplant.hrsa.gov/news/srtr-modeling-results-available-for-kidney-and-pancreas-distribution-proposal/ (Accessed on December 23, 2020)

[35] OPTN News: SRTR modeling results available for kidney and pancreas distribution, June 8, 2019. https://optn.transplant.hrsa.gov/news/srtr-modeling-results-available-for-kidney-and-pancreas-distribution/ (Accessed on December 23, 2020)

[36] Concept Paper: Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution. https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (Accessed on December 23, 2020)

[37] Presentation: Removal of DSA and Region from Kidney and Pancreas Distribution. Presented at January-March, 2021 OPTN Regional Meetings. https://unos.org/wp-content/uploads/unos/2019_Jan_KP-Proposal-Presentation-for-Reg-Mtgs_Updated.pptx (Accessed on December 23, 2020)

an opportunity to learn about the modeling results, hear an update on the Committee's progress, and solicit feedback before proposals were drafted for public comment.[38]

Both Committees submitted proposals to replace the use of DSA and Region with more equitable distribution units for public comment in the Summer of 2019 (August 2 – October 2) and again presented the proposals for awareness and feedback at all 11 OPTN regional meetings, this time attended by nearly 1,300 attendees.[39] In addition to the proposal presentations, further details on both proposals were provided at breakout sessions held at each of the 11 regional meetings, and the OPTN sponsored informational webinars.[40]

The Kidney and Pancreas Committees' deliberations during this time reflect their own experience and expertise as members of the OPTN and transplant community. The Committee also incorporated the input provided by members of the transplant community during multiple regional meeting cycles. Throughout the development of this proposal, the community has been engaged, involved, and their comments have been welcomed and considered.

Furthermore, both NOTA and the OPTN final rule require a formal comment process for proposed policy changes. NOTA requires that the OPTN "establish…medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria."[41] The OPTN final rule further stresses that the public comment process also requires that the OPTN actually "take into account the comments received in developing and adopting policies for implementation by the OPTN…"[42] While the proposal that the Kidney Committee distributed for public comment proposed a 500 NM circle in the drafted policy language, the Kidney Committee requested feedback on the "[w]hat factors should be used to select a circle size that distributes kidneys broadly and efficiently," and provided the community with ample information regarding various options for circle sizes, including multiple variations on the 500 NM circle and 250 NM circle.[43]

The Committee spent hours discussing the comments received during public comment over multiple meetings.[44] Indeed, the briefing paper details the various ways in which the Kidney

[38] OPTN News: Webinars discuss revisions to kidney and pancreas allocation policies, June 9, 2019. https://optn.transplant.hrsa.gov/news/webinars-discuss-revisions-to-kidney-and-pancreas-allocation-policies/ (Accessed on December 23, 2020)
[39] Presentation: Eliminate the Use of DSA and Region in Kidney Allocation Policy. August-October 2019 Regional Meetings. https://optn.transplant.hrsa.gov/media/3133/eliminatedsaregion_kidney.pdf (Accessed on December 23, 2020).
[40] OPTN News: Public Comment Open August 2 through October 2. August 2, 2019. https://optn.transplant.hrsa.gov/news/public-comment-open-august-2-through-october-2/ (Accessed on December 29, 2020).
[41] 42 U.S.C. §274(b)(2)(B)
[42] 42 C.F.R. §121.4(b)(1)
[43] OPTN Public Comment Proposal: Eliminate the Use of DSAs and Regions from Kidney Allocation Policy. August 2, 2019-October 2, 2019. https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf (Accessed on December 28, 2020).
[44] See Meeting Summaries of the OPTN Kidney Transplantation Committee from August 19, 2019, September 16, 2019, October 7, 2019, October 18, 2019, and October 21, 2019. Available at https://optn.transplant.hrsa.gov/members/committees/kidney-committee/

Committee was responsive to issues raised by commenters, as well as the rationale for not changing the proposal in reaction to certain comments.[45] Among other suggestions received in public comment and incorporated into the final proposal was the suggestion from multiple Regions and commenters that the distribution circle size be reduced from 500 NM to 250 NM.[46]

It is important to note that, like the federal notice and comment process, the OPTN's process does not require re-distributing a proposal for public comment any time the Committee makes a post-public comment change to the proposal. The OPTN evaluates whether the change is a result of logical outgrowth from the proposal originally distributed. If the public could have reasonably anticipated the ultimate change, and had a reasonable opportunity to comment, the OPTN does not distribute the updated proposal for another round of public comment before the OPTN Board considers it. This procedure ensures that the public's right to comment on proposals is preserved, while allowing the OPTN Board to "take into account the comments received," before "adopting policies for implementation by the OPTN."[47] As mentioned above, the public comment proposal made clear that the Committee was considering feedback on how to select a circle size, and that the Committee may ultimately select a different circle size.[48] The Committee distributed ample information on the 250 NM circle size that the Committee ultimately selected.[49] The Committee ultimately chose the 250 NM size in response to comments received during this process.[50]

Finally, the OPTN does not recommend that this policy be enforceable under §121.10 of the OPTN final rule. Therefore, the additional procedural requirements of 42 C.F.R. §121.4(b)(2) do not apply, contrary to the commenters' suggestion. Section 121.4(b)(2) sets forth additional procedures required for any OPTN policy that is: (1) proposed to be enforceable under Section 1138 of the Social Security Act, 42 U.S.C. § 320b-8, or (2) otherwise directed by the Secretary to be submitted for his review and the additional procedures under that provision. If a policy is enforceable, the Secretary may impose penalties on violators, including termination of the entire institution from the Medicaid and Medicare programs.[51] Significant enforceable policies require a formal approval by the Secretary, referral to the Secretary's Advisory Committee on Organ Transplantation ("ACOT"), and publication in the Federal Register for public comment.[52] None of the previous organ allocation policies adopted by the OPTN has ever been subject to these

[45] Briefing Paper: Elimination of DSA and Region from Kidney Allocation Policy, at page 14. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 23, 2020).
[46] Comments on the OPTN Public Comment website regarding the Proposal to Eliminate the Use of DSA and Region in Kidney Allocation Policy. All comments can be viewed at https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-kidney-allocation-policy/. (Accessed on December 28, 2020).
[47] 42 C.F.R. §121.4(b)(1)
[48] OPTN Public Comment Proposal: Eliminate the Use of DSAs and Regions from Kidney Allocation Policy. August 2, 2019-October 2, 2019. https://optn.transplant.hrsa.gov/media/3104/kidney_publiccomment_201908.pdf (Accessed on December 28, 2020).
[49] *Id.*
[50] Briefing Paper: Elimination of DSA and Region from Kidney Allocation Policy, at page 14. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 23, 2020).
[51] 42 C.F.R. §121.10(c)
[52] 42 C.F.R. §121.4(b)(2)

additional procedures. Indeed, the Eleventh Circuit has squarely rejected the commenters' interpretation of the final rule.[53]

*Substance*

The elements that the OPTN must consider and balance when developing equitable organ allocation policies include sound medical judgment, the best use of donated organs, avoiding unnecessary organ loss, avoiding futile transplants, promoting patient access to transplantation, and promoting the efficient management of organ placement.[54] The OPTN final rule further stipulates that organ allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by other elements of the final rule.[55] The best use of organs, avoiding unnecessary organ loss, and promoting the efficient management of organ placement may provide justification for constraining geographic distribution of organs to the extent required due to the impact on ischemic time, travel logistics, utilization and outcomes.

In light of the requirements of the OPTN final rule, it bears repeating that the OPTN still cannot justify the use of DSAs as a unit of distribution in allocation policy. The authors of the critical comment suggest that the OPTN did not "defend the long-standing system." This is true, and for good reason: the use of DSAs is not defensible. Lest there be any doubt, the use of regions, whose borders are similarly arbitrary, are no more justifiable than DSAs. DSAs and regions were never designed for the optimal distribution of organs, nor were they designed to satisfy the criteria set forth under the final rule. They are different sizes and shapes throughout the country and are a poor proxy for distance or time traveling as that impacts organ ischemic time. The only purported benefit of DSAs is the historic relationships that have developed as a result of their use over time. While the OPTN does not doubt the existence or effectiveness of these relationships, DSAs as distribution units nevertheless fail to satisfy all the requirements the OPTN must meet when it develops equitable allocation policies. And in time, new relationships will develop that should be just as effective. Indeed, the historic use of DSA for organ distribution has resulted in significant geographic disparities in candidate access to transplant as has been widely identified including by the Secretary's Advisory Council on Organ Transplantation (ACOT). As early as 2010 ACOT stated that "[t]he OPTN must seek to minimize inequities due to arbitrary geographic barriers to distribution" and recommended that the OPTN develop "evidence-based allocation policies which are not determined by arbitrary administrative boundaries such as OPO service areas, OPTN regions and state boundaries."[56]

After concluding DSAs are not a unit of distribution that could be justified under the constraints of the OPTN final rule, the OPTN considered other options. In particular, the Kidney Committee rejected the option of a national kidney allocation framework, or even a 500 NM circle, and instead ultimately proposed a 250 NM circle with proximity points.[57] This was based on the

[53] *Callahan v. United States Dep't of Health & Human Servs.*, 939 F.3d 1251 (11th Cir. 2019).
[54] 42 C.F.R. §121.8(a)
[55] 42 C.F.R. §121.8(a)(8)
[56] ACOT Recommendation #51 https://www.organdonor.gov/about-dot/acot/acotrecs51.html (Accessed on December 28, 2020).
[57] OPTN Briefing Paper: Elimination of DSA and Region from Kidney Allocation Policy, December 3, 2019. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 23, 2020).

OPTN members' sound medical judgment and collective specialized medical experience, consistent with the final rule requirements regarding avoiding unnecessary organ loss, and promoting the efficient management of organ placement, supported with directional simulation modeling of various circle sizes in two rounds of KPSAM modeling and feedback from the transplant community. The OPTN believes that the Revised Kidney Policy makes significant steps towards achieving more equity in access to transplant by providing a consistent unit of distribution, 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. These considerations are detailed in the briefing paper that was presented to the OPTN Board during its December 2019 meeting.[58]

1. **A rationale for and discussion of the adequacy of the methodology used to model the predicted impacts of the change to kidney allocation policy**

Like the OPTN, the Scientific Registry of Transplant Recipients (SRTR) was established by NOTA and is administered under a separate federal contract between HRSA and currently, the Hennepin Healthcare Research Institute (HHRI).[59] Among its other functions, the SRTR works collaboratively with the OPTN when the OPTN develops modifications to allocation policies.

*KPSAM Overview and Limitations*

The SRTR runs the Kidney-Pancreas Simulated Allocation Model (KPSAM) at the request of OPTN Kidney and Pancreas Transplantation Committees when they are considering changes to kidney or pancreas allocation policies. The purpose is to "simulate the allocation of kidneys and/or pancreata to candidates waiting for organ transplants and their outcomes" based on a historical, one-year cohort of waiting list candidates and transplant events to determine how organs would be allocated to potential transplant recipients (PTR) under new allocation rules.[60]

While limitations exist within the KPSAM acceptance model (as they exist in all forecasting and modeling tools), it is important to keep in mind that the KPSAM can be very useful in estimating the *relative direction* of possible effects related to proposed policy changes. Previous experience with the suite of simulation software used by the SRTR in support of OPTN policymaking, including the Liver Simulated Allocation Model (LSAM) and the Thoracic Simulated Allocation Model (TSAM) in addition to the KPSAM, suggests that the simulations often predict the direction of changes within various subgroups of patients. As documented during the development of the kidney allocation system (KAS) which was implemented in 2014, "...KPSAM can make useful predictions about the direction of large-scale changes in many outcomes of interest to the policy development community, despite limitations in modeling behavior changes."[61]

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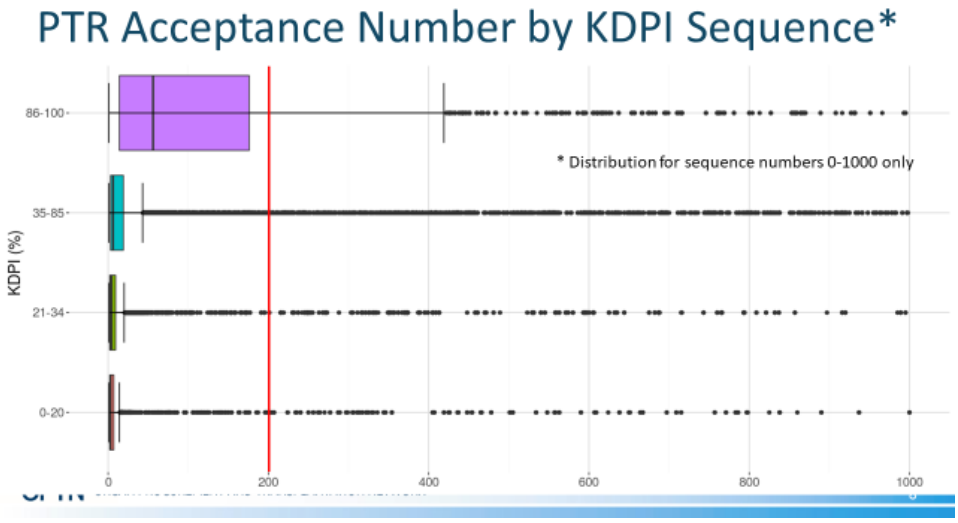
[58] *Id.*
[59] 42 U.S.C. §274(a). Scientific Registry.
[60] SRTR. Kidney-Pancreas Simulated Allocation Model – User's Guide. Version 2015, Last Updated April 20, 2015. https://www.srtr.org/media/1202/kpsam.pdf (Accessed on December 23, 2020).
[61] Gustafson, S., Israni, A. et. al. SRTR Abstract: Projection vs. reality: KPSAM and KAS. https://www.srtr.org/media/1176/projection-vs-reality_kpsam-and-kas.pdf (Accessed on December 24, 2020).

Importantly, the KPSAM's reliance on historic behavior, including historic offer acceptance patterns, may lead to differing numbers of total organs transplanted in the simulation if the allocation policy under study shifts allocation priority in ways not well characterized by historic patterns. For example, a policy that results in offers to higher priority candidates farther away from the donor may underestimate offer acceptance since historically organs originating from farther away were less likely to be accepted due to reasons related do donor quality (rather than simply distance). Therefore, the number of offers that the KPSAM must make in order to find an acceptance is likely to be higher than the number of offers that an OPO would have to make in order to find an acceptance in reality under the new policy. By design, KPSAM currently assigns an outcome of non-utilization, i.e., discard, for those organs that have been declined for the first 200 candidates on any match run. While this mechanism of determining kidney discard is important for computational efficiency of the simulation, it does not align perfectly with the acceptance of kidneys in actual practice as many kidneys are accepted and transplanted each year after 200 offers, particularly kidneys with a higher kidney donor profile index (KDPI) (Figure 5, below).

**Figure 5: PTR Acceptance Number by KDPI Sequence**




Therefore, if the policy under consideration results in longer match runs prior to acceptance as described above, the modeled transplant count may be lower than historically observed. A further limitation is the KPSAM can only use historic data for donor kidneys that were actually accepted. The model cannot incorporate data for kidneys that were declined, but would potentially be accepted under the Revised Kidney Policy. In other words, the KPSAM enters any *recovered* kidney through the acceptance model for possible acceptance and transplant, but observed acceptance data on which the model is trained can only include match runs with a previous acceptance because information on the timing of the discard event does not exist in the data. As a consequence, the KPSAM offer acceptance models cannot include any information on the process of kidney discard. Thus, the mechanism of discard in KPSAM inevitably does not align perfectly with the underlying observed data. Together, these issues emphasize limitations of relying exclusively on KPSAM to assess discard rates across different potential allocation policies.

The baseline run of KPSAM—i.e., the simulation of current policy with no changes—was not well calibrated to the actual number of transplants, potentially due to the difficulties with the acceptance models. Because simulations necessarily have limitations as described above, proposed policy changes are compared to a simulated baseline scenario rather than to actual historic data. Importantly, when the KPSAM simulated the baseline scenario, 1000 fewer transplants were predicted than were actually observed in reality. Since an ideal baseline scenario should accurately predict the same number of transplants as observed in reality, subsequent discussions about tuning parameters represent the calibration of the underlying simulation and not an attempt to alter the models to obtain more favorable results. In fact, any adjustment of the simulation was designed to achieve more accurate projections for analysis by the OPTN.

The Kidney-Pancreas Workgroup (Workgroup), consisting of members of both OPTN committees, was oriented to the fact that the KPSAM modeling is a tool to be used in combination with their collective experience. As noted above, the acceptance models are difficult to calibrate to proposed policies if acceptance patterns are expected to change due to allocation priority changes. This issue represents a limitation to relying on KPSAM in evaluating the number of predicted transplants in a new allocation schema, eventually leading to the Committee's decision to adopt SRTR-suggested changes to the KPSAM acceptance model to calibrate acceptance to the effects of changes in allocation by removing DSA as a determinant factor in modeled acceptance behavior described in more detail below.[62]

*First KPSAM Data Requests*

Following the initiation of the effort to change kidney and pancreas allocation in June of 2018, the Workgroup met frequently through the Fall of 2018 to submit a KPSAM request to the SRTR, culminating with a report presented on December 10, 2018.[63] The modeling results and the corresponding alternative allocation concepts were put forth as a concept paper for public comment in January 2019.[64] The concept paper detailed the fact that there were limitations to the KPSAM predicted results and emphasized that the KPSAM utilizes the current framework of DSA and OPTN Regions in allocation "...wherein there's a strong preference for local offers" based in part on local offers being of higher quality by current allocation design.[65] Furthermore, the concept paper transparently detailed the comments from the KPSAM report that "Acceptance behavior will likely change in response to changes in organ availability at a center, and transplant counts and rates may not decline in reality. Previous experience with the SAMs suggests that they under-predict the number of transplants that would occur in reality if a given

[62] OPTN Briefing Paper to the OPTN Board of Directors,: Elimination of DSA and Region from Kidney Allocation Policy, December 3, 2019. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 23, 2020).
[63] OPTN Kidney-Pancreas Workgroup Meeting Summary, December 10, 2018. https://optn.transplant.hrsa.gov/media/3021/20181210_kp_workgroup_minutes.pdf (Accessed on December 28, 2020)
[64] Concept Paper: Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution Concept Paper https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (Accessed on December 28, 2020)
[65] *Id.*

policy scenario were adopted, although they typically predict the direction of subgroup changes."[66]

This effect has previously been seen when comparing the post-implementation results of a policy change with the SAM predictions in prior kidney[67] and liver[68] allocation changes. The Workgroup, respective Committees, and SRTR were forthright and transparent about the limitations of KPSAM results based on the methodology used in this initial KPSAM request.

*Second KPSAM Data Request*

During the time the concept paper was out for public comment, the Workgroup continued to meet to discuss different allocation policy options, and the initial KPSAM results. In early March 2019, the Workgroup discussed the fact that the majority of the concern in public comment was focused on the predicted decrease in transplant rates and overall counts by the proposed allocation concepts.[69] Additionally, as noted previously, the Committee and SRTR staff openly discussed the limitations with the KPSAM and the fact that potential changes would be presented to the Workgroup in a future meeting.[70]

During a subsequent workgroup meeting on March 22, 2019, the Workgroup was presented with modifications to the KPSAM to address organ offer acceptance behavior under a broader distribution (no DSAs or OPTN Regions) allocation policy.[71] It was discussed that the previous KPSAM request utilized an offer acceptance model that a local offer (allocated from a donor to a candidate within the same DSA) would more likely be accepted based on local offers generally being of higher organ quality by allocation policy design, and that this attribute of the previous KPSAM modeling request may have contributed to the decrease in transplant counts seen in the previous modeling request.[72] It was noted that since DSAs would no longer be used as the first unit of distribution in the alternative allocation policies being considered (including kidneys of higher quality), this organ acceptance behavior tied to a local offer was expected to change.[73] During the March 22, 2019 meeting, the Workgroup voted to move forward with a change to the KPSAM acceptance model to reduce the impact of this integral discrepancy between observed past behavior and modeled anticipated future behavior.[74] Put differently, the change to the

[66] *Id.*
[67] Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. J Am Soc Nephrol. 2014;25(8)1842-8.
[68] Goel A, Kim WR, Pyke J, et al. Liver Simulated Allocation Modeling: Were the Predictions Accurate for Share 35? Transplantation. 2018;102(5):769-774.
[69] OPTN Kidney-Pancreas Workgroup Meeting Summary. March 5, 2019. https://optn.transplant.hrsa.gov/media/3030/20190322_kp_workgroup_min.pdf (Accessed on December 28, 2020)
[70] *Id.*
[71] OPTN Kidney-Pancreas Workgroup Meeting Summary. March 22, 2019. https://optn.transplant.hrsa.gov/media/3030/20190322_kp_workgroup_min.pdf (Accessed on December 23, 2020)
[72] *Id.*
[73] *Id.*
[74] *Id.*

KPSAM 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.

At a meeting three days later, the Kidney Committee openly discussed the fact that it was important for the community to understand that the change to the KPSAM was not being done to achieve desired results, and that it was being refined to better calibrate the simulation to expected behavior changes in response to the new policy.[75]

In sum, since the initiation of discussions on alternative allocation policies, and the use of KPSAM to support this development, the Workgroup and SRTR transparently discussed the limitations of KPSAM in its ability to model organ offer and acceptance behavior within a future broader distribution state. Following the results of the initial KPSAM request, the Committee openly identified a change to the KPSAM that would better represent the state of organ allocation within a predicted broader distribution scenario, and ultimately better support evidence-based policy development. Indeed, modeling based upon DSAs, if it remained unchanged, would not have provided a reliable framework for the Committee's decision. These deliberations were also detailed in a report provided to the OPTN Board of Directors in June 2019, while the Committees continued the development of the proposal.[76]

*Overview of KPSAM Results*

The full KPSAM report requested is available on the OPTN website.[77] Key takeaways from the report include:

- While there was a projected decrease in kidney and pancreas (non-KP transplants, but may include other organ combinations like liver-kidney) transplants, when examining the total number of kidney transplants (kidney and KP), the total number of transplants resulted in almost no change from baseline.
- Kidney transplant rates remained nearly constant under broader distribution:
    - Rates among pediatric, female, African American, and Latino candidates increased.
    - Rates among highly sensitized (80-99% cPRA) and prolonged dialysis time (5+ years) candidates increased.
- The larger the circle, the farther organs would travel. This may lead to increased cost and logistics issues for which there is only anecdotal evidence to examine, and was one of the reasons behind the Committee's ultimate decision to send a proposal with a 250 NM circle to the Board of Directors for approval rather than 500 NM.

[75] OPTN Kidney Transplantation Committee. Meeting Summary. March 25, 2019. https://optn.transplant.hrsa.gov/media/2935/20190325_kidney_meeting_minutes.pdf (Accessed on December 23, 2020)

[76] OPTN Kidney/Pancreas Workgroup Board Report, at page 9. June 2019. https://optn.transplant.hrsa.gov/media/2990/kidney_pancreas_boardreport_201906.pdf (Accessed on December 28, 2020).

[77] Gustafson, S., Wever, T., et. al. Analysis Report: Update: Data Request from the OPTN Kidney Transplantation Committee: Provide KPSAM simulation data on effect of removing DSA and region from kidney/pancreas/kidney-pancreas organ allocation policy. Version 1. June 21, 2019. https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (Accessed on December 24, 2020).

These results helped to shape the proposal the Kidney Committee ultimately put forth to the OPTN Board.

**2. A description of the OPTN's consideration of a potential transition policy in relation to the change in kidney allocation policy**

The OPTN final rule requires that when the OPTN revises organ allocation policies, it should "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."[78] The OPTN developed the Revised Kidney Policy as a transition between the current system using DSAs and regions in allocation and a planned next step, which will be a Continuous Distribution system, which will not have the same hard geographic boundaries as the current system.[79] The use of proximity points in the Revised Kidney Policy was designed to soften the geographic boundaries of allocation to help transition the transplant community for those future changes.[80]

Furthermore, the Committee believed moving to 250 NM would be a transitional step that would allow the Committee to evaluate implementation of a new framework of distributing kidneys and apply those findings to future broader distribution. The 250 NM framework still introduces an element from, and represents a step toward, Continuous Distribution.[81] The 250 NM variation retains much of the same equity gains and reduction of variance in access to transplant as was projected for the 500 NM variation while reducing the associated risks of longer travel times, including increased cold ischemic times, greater risk for organ loss, and greater possibility of graft failure.[82] The Committee did not identify any specific populations that would require a specific transition procedure when the OPTN implements the Revised Kidney Policy.[83] The Committees' recommendations regarding transition procedures were provided to the OPTN Board of Directors in June 2020. [84]

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[78] 42 C.F.R. §121.8(d).

[79] OPTN Policy Initiatives: Continuous Distribution. https://optn.transplant.hrsa.gov/governance/policy-initiatives/continuous-distribution/ (Accessed on December 28, 2020).

[80] "The proposal represents a removal of DSA and region from kidney allocation policy in alignment with the final rule as well as a transitional step from current policy towards the goal of implementing a framework of continuous distribution." OPTN Briefing Paper to the OPTN Board of Directors: Elimination of DSA and Region from Kidney Allocation Policy, December 3, 2019. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 28, 2020).

[81] OPTN Kidney Transplantation Committee Meeting Summary, October 21, 2019. https://optn.transplant.hrsa.gov/media/3344/20191021_kidney-in-person-meeting-summary.pdf (Accessed on December 28, 2020)

[82] OPTN Briefing Paper to the OPTN Board of Directors: Elimination of DSA and Region from Kidney Allocation Policy, December 3, 2019. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 28, 2020).

[83] OPTN Kidney Transplantation Committee Meeting Summary, April 20, 2020. https://optn.transplant.hrsa.gov/media/3772/20200422-kidney-meeting-summary.pdf (Accessed on December 28, 2020).

[84] OPTN Memo: June 2020 – Consideration of Transition Procedures for Recent OPTN Allocation Policies. Distributed to the OPTN Board of Directors in June 2020. Available upon request to the OPTN.

**3. An analysis of the adequacy of the OPTN's plan to evaluate the impact of the new kidney allocation policy in general and in light of disruptions to the transplantation system caused by the COVID-19 pandemic**

A key task of the OPTN is to monitor the impact of policy changes to determine if the policy met its goals and/or resulted in any positive or negative unanticipated changes.[85] A robust monitoring plan was provided to the OPTN Board of Directors as part of the policy proposal prior to approval.[86] The December 1 critical comment suggests that the OPTN is not permitted to implement this change during the COVID-19 pandemic because of the performance goals and monitoring requirements contained in § 121.8(c) of the OPTN final rule regarding performance indicators for allocation policies. However, the performance monitoring plan included with the Revised Kidney Policy meets all of the requirements contained in the OPTN final rule generally and despite the pandemic.

*Monitoring the Kidney Allocation Policy*

The Revised Kidney Policy seeks to achieve the performance goal stated in the OPTN final rule of "distributing organs over as broad a geographic area as feasible."[87] The plan for monitoring the removal of DSA and Region from kidney allocation includes waiting list, transplant, and donor utilization and allocation efficiency metrics stratified by patient demographics and across various geographic areas, as well as post-transplant outcomes as sufficient data accumulates.[88] Additionally, components assessing the changes pending implementation related to medical urgency, donors from Alaska, and released kidneys will be included. The policy will be formally evaluated by the OPTN at 3, 6, 12, and 24 months post-implementation. Additional data will be provided at the request of the Kidney Committee.

As discussed in detail below, the SRTR modeling results show projected improvement in the disparity in kidney transplant rate by DSA. Variation in access is one of the key metrics that will be evaluated following implementation.[89] The performance indicators will be "compared to an appropriate pre-policy cohort to assess performance before and after implementation"[90] of the Revised Kidney Policy.[91] By using the modeling to predict expected outcomes, and providing a plan for timely evaluation of the actual changes in those metrics, the OPTN addressed the requirements of the OPTN final rule. In fact, the monitoring plan is much more robust than the basic requirements laid out in the OPTN final rule.

*Monitoring the Kidney Allocation Policy in light of COVID-19*

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[85] 42 C.F.R. §121.8(c)
[86] OPTN Briefing Paper: Elimination of DSA and Region from Kidney Allocation Policy, December 3, 2019, at 43. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 23, 2020).
[87] 42 C.F.R. § 121.8(b)(3).
[88] OPTN Briefing Paper: Elimination of DSA and Region from Kidney Allocation Policy, December 3, 2019, at 43. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 23, 2020).
[89] 42 C.F.R. § 121.8(c)(2)(ii)
[90] OPTN Briefing Paper: Elimination of DSA and Region from Kidney Allocation Policy, December 3, 2019, at 43. https://optn.transplant.hrsa.gov/media/3406/kidney_bp-update-121019.pdf (Accessed on December 23, 2020).
[91] 42 C.F.R. § 121.8(c)(2)(i)

Despite the allegations in the December 1 Critical Comment, the OPTN has made plans to account for the impacts of the policy change and the COVID-19 pandemic on transplantation. In addition to comparing metrics pre- versus post-policy implementation, data will be broken out by COVID-19 eras in order to determine if any observed changes persisted over the different stages of the pandemic. Currently, the COVID eras are defined as:

1. Pre-COVID: prior to March 13, 2020
2. COVID Onset: March 13-May 9, 2020
3. COVID Stabilization: May 10, 2020 – Present

These eras were determined based on trends in transplant data observed after the declaration of a national emergency on March 13, 2020.[92] Centers greatly reduced or stopped transplant activity early in the pandemic, but returned to stable levels after the community adjusted their operations in response. The OPTN may consider additional COVID eras to account for future case surges, mass vaccination (currently underway), or other developments as the pandemic evolves.

With the anticipated implementation of the Revised Kidney Policy in February 2021, the pre-policy cohorts for the 3, 6, and 12-month post-implementation monitoring analyses would all include data collected during the COVID-19 pandemic. The confounding effects of the pandemic will likely be attenuated as a result, since both the pre- and post-policy data will be impacted by COVID.[93]

The COVID-19 emergency policy package may also impact post-implementation monitoring.[94] One of the provisions relaxed data submission requirements for expected transplant recipient follow-up (TRF) forms completed by transplant hospitals. Hospitals are still required, however, to submit data on patient deaths and graft failures to the OPTN, but they do not need to complete follow-up forms for recipients who have not experienced these adverse events. It has not been decided whether that data will be submitted in the future. In order to address biases created by the data submission amnesty policy, the OPTN will supplement its data with death records from external sources and alter post-transplant survival analyses to assume patients are alive unless reported otherwise. Because transplant outcomes are reported to the OPTN at 6 and 12 months post-transplant, sufficient data to assess post-transplant outcomes under the Revised Kidney Policy will not accrue until nearly a year after implementation. The OPTN will reassess its analytical approach in response to any additional changes in data submission requirements.

The knowledge and experience of the transplant experts on the Kidney and Pancreas Committees will be essential to interpreting results collected during post-implementation monitoring. Many Committee members are clinicians or OPO staff, able to offer practical insight as to which changes would and would not have been impacted by the pandemic.

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[92] Trends informed by the UNOS COVID-19 Dashboard. https://unos.org/covid/ (Accessed on December 24, 2020).
[93] This is in contrast to the current liver acuity circles policy, which was implemented shortly before the COVID-19 pandemic began.
[94] Briefing to the OPTN Board of Directors: COVID-19 Emergency Policies and Data Collection. https://optn.transplant.hrsa.gov/media/4200/covid-19-emergency-policies-and-data-collection.pdf (Accessed on December 24, 2020)

*SRTR Modeling Under COVID-19*

The SRTR KPSAM uses a single year's worth of historic data to simulate the potential impact of the different policy changes being considered by the OPTN. Because the COVID-19 pandemic did not begin to impact donation and transplantation until mid-March 2020, sufficient data under the pandemic are not currently available to use in the KPSAM.

It is anticipated that even if the Committees were to request another KPSAM run using data collected during the COVID-19 pandemic, the results would likely align with prior runs. As partially evident by the deceased donor kidney transplant volume rebounding from the initial decrease in March and April 2020 to exceed 2019 volume (+1,181 deceased donor kidney transplants through December 15), the transplant community has adapted its operations in response to the pandemic and continued to provide patients life-saving transplants.[95] The impact COVID-19 has had and is still having on the transplant system has yet to be determined in full, as seen by continued slightly higher kidney waitlist mortality rates post- versus pre-COVID-19 pandemic.[96] The KPSAM is intended to estimate general trends, and an updated run using 2020 data would reflect changes in annual volume, not necessarily the impact of the pandemic during a portion of the year. And in any event, the KPSAM only models deceased donor transplants, which experienced far less of an impact from COVID-19 than living donor transplants.

Additionally, kidney transplants in 2020 compared to 2019 (through September) were similar in demographic distributions of Kidney Donor Profile Index (KDPI), Estimated Post-Transplant Survival (EPTS), recipient age, donor age, recipient race/ethnicity, DCD donation, and recipient primary source of payment.[97] Given that the types of transplants have not changed in response to the COVID-19 pandemic, the simulated changes should reflect what is already provided in the KPSAM data report.

Finally, if COVID-19 has caused a temporary change in transplant program and organ procurement organization practices, it may be unwise to use COVID-era data to model potential future allocation policies that would be implemented after resolution of the pandemic. Again, however, the professionals on OPTN committees will be well-positioned to evaluate this as it happens, reviewing the data at the time and taking into account any impact from COVID-19.

4. **An analysis of the adequacy of efforts to support transplant centers and organ procurement organizations to prepare for the implementation of the new policy in general and in light of disruptions to the transplantation system caused by the COVID-19 pandemic**

The OPTN has undertaken many efforts to ensure that the entire transplant community was engaged in both the development of the proposal, as well as educated on the impact of the proposal following adoption by the OPTN Board in December 2019. The specific implementation date of December 15, 2020 was announced in October (consistent with all other OPTN

[95] OPTN data, https://unos.org/covid/. Accessed on December 22, 2020 at 3:34PM.
[96] SRTR: Effect of COVID-19 on the Transplant System. https://www.srtr.org/reports-tools/covid-19-evaluation/ (Accessed on December 28, 2020).
[97] OPTN Data accessed on December 21, 2020.

implementations as the exact date of an implementation cannot be known until a few months before the date). However, prior to that time the OPTN consistently notified the transplant community that the policy would be implemented in "late 2020" and "December 2020." In January 2020, the Executive Update included information on the passage of the 2019 Kidney proposal, as well as plans to implement it by December 2020.[98] During the summer 2020 public comment cycle (Aug. 4 – Oct. 1), the Kidney Committee presented an update on the progress of implementing the 2019 Kidney policy including anticipated implementation in 2020 at each of the 11 regional meetings, and this time there were nearly 2,000 virtual participants.[99] The OPTN Update presented by OPTN leadership included an announcement that the kidney and pancreas policy changes were on schedule for the December 2020 implementation.[100]

Knowing all along that the OPTN would be implementing the policy before year's end, the OPTN undertook tremendous efforts to educate the community about the revised policy. These efforts are detailed in the response to Question 5: An overview of any efforts taken to educate OPTN members, the public, and patients about the Revised Kidney Policy.

In addition to the numerous communications, educational modules, and toolkits available to members (to be described in the next section), the OPTN provided interactive tools to help members prepare for the allocation changes. One of these is a dynamic map visualization tool.[101] This tool allows users to select any transplant center in the nation and see the donor hospitals and other transplant centers within a 250NM radius. Centers and OPOs can use the visualizations to plan for transportation scenarios and outreach activities. This tool was first made available to the public almost two years prior to the scheduled policy implementation, during the January – March, 2019 public comment period for the "Eliminate the Use of DSAs and Regions" concept paper.[102]

The second interactive tool was a "testing" version of the new allocation system in UNet, which was made available to members in late fall of 2020, *during* the pandemic. All OPOs were offered a two-week preview to conduct live simulated match runs for kidney and pancreas allocation. Out of 58 OPOs, 37 participated in the preview. The test site used for the preview contained blinded candidate data and allowed OPOs to initiate distance-based match runs

[98] Presentation: OPTN Update – Winter 2020 Regional Meetings, at slide 5. January-March 2020 Regional Meetings. https://optn.transplant.hrsa.gov/media/3632/2020_winter_optn_region_update.pdf (Accessed on December 23, 2020).
[99] Presentation: OPTN Kidney Transplantation Committee. August-October 2020 Regional Meetings. https://optn.transplant.hrsa.gov/media/3991/2020_aug_kidney_committee_update.pdf (Accessed on December 23, 2020).
[100] Presentation: Executive Update at slide 13. August-October 2020 Regional Meetings. https://optn.transplant.hrsa.gov/media/4061/2020_sept_executive_update.pdf (Accessed on December 23, 2020).
[101] Donor Hospitals and Transplant Programs within 250 Nautical Mile (NM) Distances of Selected Kidney Transplant Centers. https://public.tableau.com/profile/optn.kidney.committee#!/vizhome/KIDNEYALLOCATIONPROPOSALMAPS/FinalMap (Accessed on December 24, 2020).
[102] Concept Paper: Eliminate the Use of DSAs and Regions in Kidney and Pancreas Distribution. https://optn.transplant.hrsa.gov/media/2802/kidney_pancreas_publiccomment_20190122.pdf (Accessed on December 23, 2020).

including the new "released" kidney match run type. The OPO preview ran from November 2 to November 13, 2020, more than 30 days prior to the planned final implementation. A similar preview was offered to a subset of transplant centers to preview changes associated with medically urgent candidates and released matches. Participants from 11 different transplant centers participated in that preview. OPO and transplant users provided feedback that was generally positive and necessitated no changes in system setup or user interface.

Also, while not specific to the Revised Kidney Policy per se, UNOS and the OPTN have hosted, collaborated, or provided assistance on numerous webinars and provided information to the community about reacting to the COVID-19 pandemic in general.[103] These practices are adaptable to the new kidney allocation system. These include:

- OPTN Collaborative Educational Modules, available on the OPTN website[104] and hosted on the OPTN's educational platform:
  - Telemedicine, Transplant and COVID-19, May 7, 2020
  - COVID-19: Past, Present and Future OPO Operations, June 11, 2020
  - COVID19: Past, Present and Future Transplant Center Operations, July 24, 2020
- UNOS sponsored webinars:
  - New York vs. COVID19: We are Winning, April 17, 2020
- AST sponsored webinars[105]:
  - COVID 19: Organ Donation and Transplant Town Hall #1, March 23, 2020
  - COVID 19: Organ Donation and Transplant Town Hall #2, April 13, 2020
  - COVID 19: Organ Donation and Transplant Town Hall #3, May 11, 2020
  - COVID 19: Organ Donation and Transplant Town Hall #4, December 3, 2020

The OPTN Executive Committee has seriously considered whether the COVID-19 pandemic creates additional impacts to the implementation of the new policy beyond what. The authors of the critical comment worry that implementation of the Revised Kidney Policy will place undue burden on transplant hospitals to create relationships with OPOs outside of their DSA. Yet transplant hospitals have been on notice for more than a year that they would need to develop these relationships. And more importantly, relationships with OPOs outside the DSA are hardly a new phenomenon. Kidney and pancreas allocation policy are the only organ allocation policies to still use DSAs. Transplant hospitals have been working with OPOs outside of their DSA for every other organ type prior to and throughout the pandemic. And, they have had to do so for kidneys and pancreata as well, even under the existing allocation policies. Nearly a third of all kidney transplants are imported from donor hospitals outside the transplanting hospital's DSA under current kidney allocation.[106] Transplant hospitals must coordinate with OPOs beyond their DSA for many of their transplants already, pandemic or not. While the number of imported kidneys is expected to increase under the new policy (KPSAM modeling estimates roughly 60%

[103] UNOS Resources: Recorded COVID-19 Webinars. https://unos.org/covid-webinars/ (Accessed on December 24, 2020).
[104] OPTN. COVID-19: Webinars. https://optn.transplant.hrsa.gov/covid-19/ (Accessed on December 28, 2020).
[105] UNOS Resources: Recorded COVID-19 Webinars. https://unos.org/covid-webinars/ (Accessed on December 24, 2020).
[106] OPTN Executive Committee Presentation at Slide 22. Presented on December 21, 2020. Available upon request.

of transplants will utilize imported kidneys under the new policy[107]), the OPTN Executive Committee was in agreement that this does not present a heightened barrier for hospitals during the COVID-19 pandemic.[108]

**5. An overview of any efforts taken to educate OPTN members, the public, and patients about the revised OPTN Kidney Allocation Policy**

In an effort to educate members, the public and patients about the Revised Kidney Policy, the OPTN created and disseminated a wide range of content across multiple channels for more than two years. These include:

- Targeted emails (24 emails to kidney and OPO audiences) to inform members at all stages of policy development
- Web news items (18) to inform members, patients and the general public about the status of the initiative to remove DSA and region from kidney allocation
- Publication of analyses of SRTR modeling results in order to provide transparency and stimulate participation in public comment
- National discussion webinars to foster participation in policy development
- Patient education webinars to inform and also solicit input from candidates and their families
- Professional education webinars to allow for real-time questions and answers with staff and committee members
- Policy toolkits that provided summaries of changes and historical overviews of the policy development process, including links to public comment, board briefing papers and policy notices. Policy toolkits included additional resources such as downloadable visual aids, process animations, and links to the online professional education modules developed help members understand the changes.

These efforts to educate and inform about changes to kidney allocation began August 2, 2018, and continued at a regular cadence over the course of three public comment cycles leading up to the scheduled December 15 implementation. In addition to steady email communications to kidney and OPO professionals across the country, prominent calls to action were displayed on the OPTN website's home page to drive visitors to important policy updates as well as patient and professional education. A detailed account of the OPTN's efforts is attached as **Attachment 1**.

[107] Gustafson, S., Wever, T., et. al. Analysis Report: Update: Data Request from the OPTN Kidney Transplantation Committee: Provide KPSAM simulation data on effect of removing DSA and region from kidney/pancreas/kidney-pancreas organ allocation policy. Version 1. June 21, 2019. https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (Accessed on December 24, 2020).

[108] Deliberations of OPTN Executive Committee, December 21, 2020. The meeting summary will be posted on the OPTN website when available at https://optn.transplant.hrsa.gov/members/committees/board-of-directors-executive-committee/.

The OPTN also created six educational offerings to support members:

| Educational Offering | Made Available |
|---|---|
| Medically Urgent Status for Adult and Pediatric Candidates: Phase One | Nov. 3 (six weeks prior to planned implementation) |
| Medically Urgent Status for Adult and Pediatric Candidates: Phase Two | Nov. 17 (four weeks prior to planned implementation) |
| Modification to Released Kidney and Pancreas Allocation | Nov. 17 (four weeks prior to planned implementation) |
| Removing DSA and Region form Kidney and Pancreas Allocation | Nov. 17 (four weeks prior to planned implementation) |
| Notification Limits for Distance Based Allocation | Nov. 17 (four weeks prior to planned implementation) |
| Acceptance Criteria for Distance Based Allocation | Nov. 17 (four weeks prior to planned implementation) |

Additionally, the OPTN provided educational opportunities to patients. In addition to the patient webinar mentioned above[109], the Kidney and Pancreas Committees specifically sought the input of the OPTN Patient Affairs Committee when developing the policies.[110, 111]

**6. A description of the OPTN's analyses regarding the impact of the new kidney allocation policy on transplant candidates of low socioeconomic status**

The OPTN final rule provides a list of various categories of policies that the OPTN must develop. These policies include: policies for the equitable allocation of cadaveric organs; policies, consistent with CDC recommendations, for the testing of organ donors and transplant recipients to prevent the spread of infectious diseases; policies that reduce inequities resulting from socioeconomic status; and policies regarding the training and experience of transplant surgeons and physicians.[112] The requirement to develop policies to reduce inequities resulting from socioeconomic status is a separate requirement from that to develop policies for the equitable allocation of cadaveric organs. The Revised Kidney Policy was developed under the latter, which in turn requires the OPTN to factor in multiple considerations when developing equitable allocation policies.[113] Socioeconomic status is not explicitly one of the 121.8(a) factors. However, to the extent that socioeconomic status is an indicator of whether the OPTN is

[109] OPTN News: Transplant Patient Webinar Recording Now Available. November 23, 2020. https://optn.transplant.hrsa.gov/news/transplant-patient-webinar-recording-now-available/ (Accessed on December 28, 2020).
[110] Meeting Minutes: OPTN Patient Affairs Committee, February 25, 2019. https://optn.transplant.hrsa.gov/media/2898/20190225_pac_minutes.pdf (Accessed on December 24, 2020).
[111] Meeting Minutes: OPTN Patient Affairs Committee, August 20, 2019. https://optn.transplant.hrsa.gov/media/3226/20190820_pac_minutes.pdf (Accessed on December 24, 2020).
[112] 42 C.F.R. §121.4(a)
[113] 42 C.F.R. §121.8(a)

"promoting patient access to transplantation," seeking to "achieve the best use of donated organs," or "avoid futile transplants," then it can be a relevant consideration.[114]

The goal of the Revised Kidney Policy is to grant kidney candidates more equitable access to transplantation, regardless of whether those candidates are of low or high socioeconomic status. Nevertheless, in order to ensure that the policy would not have unintended negative effects on socioeconomically disadvantaged candidates, the OPTN did consider the impact the Revised Kidney Policy may have from a socioeconomic perspective. The OPTN relied upon inferential modeling results performed by the SRTR and presented in a 181-page report containing multiple metrics broken down by different demographics.[115]

In both of the KPSAM requests submitted, the Committees requested metrics including, but not limited to, counts/percentages of transplants, transplant and waiting list mortality rates, and post-transplant survival outcomes, stratified by the following SES-related subgroup populations:

- Candidate/recipient insurance status: Private, Medicaid, Medicare, Other
- Median income by recipient zip code at listing/transplant distribution: using the ACS zip code level publically available dataset[116]
- Urbanicity: based on RUCA codes; metropolitan, micropolitan, small town, rural

The results for the approved proposal showed that, for kidney, there was little change across the various categories of each subgroup population, particularly in light of other gains, including, but not limited to, increased pediatric and length dialysis time candidates, as well as decreased disparities in transplant rates across listing DSAs[117]:

- There was a decrease in transplant rates/counts/percentages for recipients using private pay but a concurrent increase in Medicaid-covered transplants. Given the corresponding predicted increase in transplants to patients on dialysis for longer periods, this trend is expected. There was little change related to waitlist and post-transplant mortality rates and graft failure rates across payment status types except for the 'Other' category, but given the small sample size in this subgroup, the estimate is less precise.
- There was little change in transplant rates for candidates residing in metropolitan areas, but candidates residing in micropolitan, small town, and rural areas were predicted to see a decrease in transplant rates, though that decrease diminished as the circle size decreased. Across all runs, there was little change in small town areas in the 250.250.2.4 ultimately Board-approved scenario from baseline, and there was no predicted change in transplant counts/percentages. The committee observed that while

[114] *Id.*
[115] Gustafson, S., Wever, T., et. al. Analysis Report: Update: Data Request from the OPTN Kidney Transplantation Committee: Provide KPSAM simulation data on effect of removing DSA and region from kidney/pancreas/kidney-pancreas organ allocation policy. Version 1. June 21, 2019. https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (Accessed on December 24, 2020).
[116] United States Census Bureau. American Community Survey. https://www.census.gov/programs-surveys/acs (Accessed on December 28, 2020).
[117] Gustafson, S., Wever, T., et. al. Analysis Report: Update: Data Request from the OPTN Kidney Transplantation Committee: Provide KPSAM simulation data on effect of removing DSA and region from kidney/pancreas/kidney-pancreas organ allocation policy. Version 1. June 21, 2019. https://optn.transplant.hrsa.gov/media/2985/ki2019_01_analysisreport.pdf (Accessed on December 24, 2020).

projected transplant counts remained relatively consistent across all variations for candidates in metropolitan areas (big cities), there were offsetting decreases in transplant rates for candidates in all other urbanicity subgroups, though the differences are negligible.

- There was little change related to waitlist and post-transplant mortality rates and graft failure rates across urbanicity category; the rate varied across the 10 KPSAM runs.

There was little variation in transplant rates/counts/percentages across modeled scenarios in relation to median household income of candidate's permanent zip codes. There was little change related to waitlist mortality and post-transplant mortality rates and graft failure rates across median household income categories; rates varied across the 10 KPSAM runs. UNOS staff provided draft metrics to determine viability of inclusion in the modeling prior to presenting options to the Workgroup, including the Cumulative Community Risk Score (CCRS) impact to mirror what was requested from the LSAM during the development of the currently implemented Acuity Circles liver allocation policy.

However, the SRTR expressed concerns with this metric for several reasons. First, the usefulness of population-based metrics is questionable in the context of evaluating an allocation system change because the metrics may not reflect the demographics of the listed candidates themselves. Given that allocation policies can only allocate organs to listed transplant candidates rather than the general population, this is an important distinction. Programs are under no obligation to list their candidates proportionally from their population's demographic and socio-economic case-mix. For example, the prevalence of adult obesity in a county may be 40%, yet a program's listing criteria may exclude anyone with a BMI above 30 or 35. In this case, it is the listing criteria limiting access for their population, not the allocation system. Looking at community or population-based metrics, instead of metrics of the candidates themselves, decreases the accuracy of an impact analysis on an allocation policy because the pool of listed transplant candidates is not necessarily reflective of the candidate's community population.

Second, SRTR and the Committee reviewed limitations in the performance of the CCRS metric, in particular relative to other SES indicators and waitlist mortality predictors. As noted by the authors introducing CCRS, "it is…important for interpretation of our study findings that ascribing broad area risks to each individual within that area is an ecological fallacy. Thus…it is inappropriate to directly assign risks to individuals within that community."[118] Other SES indicators are available with greater geographic resolution, such as zip code-level income, reducing the impact of this limitation.

Further, based upon its judgment and expertise, the OPTN believes that CCRS, is not a strong predictor of post-transplant mortality, compared with other predictors. The most significant predictors of post-transplant mortality are recipient age, recipient diagnosis, donor age, and

[118] Schold JD, Buccini LD, Kattan MW, et al. The Association of community health indicators with outcomes for kidney transplant recipients in the United States. Arch surg. 2012;147(6):520-526. doi:10.1001/archsurg.2011.2220.)..).

donor source, which all have a much greater association with post-transplant mortality than county-based CCRS.

Due to these concerns, and following deliberations by the Workgroup, the CCRS metric was ultimately not included in the formal KPSAM request.[119]

**Conclusion**

The OPTN adhered to its well-established, deliberative, transparent, and compliant policy development process—and exercised its judgment based on medical and scientific expertise—to adopt a revised kidney allocation policy that is more equitable for patients awaiting kidney transplantation. The OPTN involved the entire transplant community at every turn, incorporated feedback from the community throughout, and provided information and education on the new policy to all facets of the community. The OPTN also prepared the transplant community for an entire year in advance of the implementation through constant communication and education, both before the pandemic began, and throughout it.

The OPTN has been monitoring the effects of the pandemic closely and has assisted in mitigated COVID-19 impacts on transplant through a range of support and responses, guided by prioritizing patients. The Revised Kidney Policy is more equitable for patients and a marked improvement over the noncompliant DSA and region systems. Further delays to its implementation based on COVID-19 are not indicated by a thorough review of the data and would only harm those waiting for a kidney or pancreas transplant. The OPTN is proud of the community's ability to adapt and continue to deliver in this time of crisis, and it is equally confident in the community's ability to adapt to the Revised Kidney Policy.

Please do not hesitate to contact us if you have any questions or need additional information. We would welcome the opportunity to meet with you or your staff again to discuss this information, or other details concerning transplantation, at your convenience.

Sincerely,

David Mulligan, M.D.
OPTN President

[119] The December 1 critical comment suggested that the OPTN also should have considered the CDC social vulnerability index when evaluating the socioeconomic impact of the Revised Kidney Policy. Like the CCRS, the CDC social vulnerability index is calculated using population level data that may not be generalizable to patients on the waiting list due to hospital listing practices which may result in a pool of transplant candidates that are not reflective of the general population.

**ATTACHMENT 1**

**Communications to the Transplant Community about Revised Kidney Policy**

| Date (oldest to most recent) | Channel | Content | Details | Metrics* as of 12.20.2020 |
|---|---|---|---|---|
| 8/2/2018 | Member email | Subject line: OPTN/UNOS update regarding geographic distribution | Email from Sue Dunn concerning the 7.31.2018 HRSA letter, which was attached to email. The letter directs the OPTN to adopt amendments that remove the use of DSAs and regions in organ allocation policies. Recipients were all Transplant program directors, Transplant program administrators, OPO chief executive officers/executive directors, OPO procurement administrators/managers AND HLA laboratory directors. | |
| 8/17/2018 | Member email | Subject line: OPTN/UNOS update regarding geographic distribution | Another update from Dunn two weeks later, with link to UNOS' 8.13.2018 OPTN memorandum. The formal response communicates that work to eliminate DSA and region is underway. Recipients were all Transplant program directors, Transplant program administrators, OPO chief executive officers/executive directors, OPO procurement administrators/managers and HLA laboratory directors. | Sent to 2036 addresses |
| 10/31/2018 | Member email | Subject line: Kidney/pancreas distribution update, October 2018 | Sent on behalf of Kidney Chair Turgeon and Pancreas Chair Odorico. Recaps that HRSA has directed OPTN to develop policies to replace DSA and region with something that meets final rule. Outlines timeline and process for revising kidney and pancreas distribution. Sent to all Kidney and pancreas transplant program directors, Kidney and pancreas transplant program administrators, and OPO executive directors. | Sent to 988 addresses |
| 12/8/2018 | OPTN news item | SRTR modeling results available for kidney and pancreas distribution proposal | https://optn.transplant.hrsa.gov/news/srtr-modeling-results-available-for-kidney-and-pancreas-distribution-proposal/ | 3303 page views |

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| 12/9/2018 | Member email | Subject line: SRTR modeling results available for kidney and pancreas distribution proposal | Update on committee plans, links to KPSAM analysis and data tables. Notes that the committees are discussing the modeling results and developing a proposal for winter 2019 public comment period beginning in January. Sent to all Kidney and pancreas transplant program directors, Kidney and pancreas transplant program administrators, and OPO executive directors. | Sent to 930 addresses |
| 12/10/2018 | Member email | Subject line: OPTN/UNOS update regarding geographic distribution | From Dunn, recapping December board meeting, vote to support an acuity circles approach for all organs. Recipients were all Transplant program directors, Transplant program administrators, OPO chief executive officers/executive directors, OPO procurement administrators/managers AND HLA laboratory directors. | Sent to 2041 addresses |
| 1/22/2019 – 3/22/2019 | OPTN website | Public comment period for the concept paper "Eliminate the use of DSAs and regions from kidney and pancreas distribution" | https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsas-and-regions-from-kidney-and-pancreas-distribution/ | 3497 page views |
| 6/8/2019 | OPTN news item | SRTR modeling results available for kidney and pancreas distribution | https://optn.transplant.hrsa.gov/news/srtr-modeling-results-available-for-kidney-and-pancreas-distribution/ | |
| 6/9/2019 | OPTN webinar | Professional webinars discuss revisions to kidney and pancreas allocation policies | https://optn.transplant.hrsa.gov/news/webinars-discuss-revisions-to-kidney-and-pancreas-allocation-policies/ | 479 page views |
| 6/14/2019 | Member email | Subject line: SRTR modeling results available for kidney and | Links to reports, details about how to register to participate in discussion webinars scheduled for June 27 and June 28. Informs recipients that the committees will discuss the modeling results and | Sent to 979 addresses |

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| | | pancreas distribution | webinar input and publish proposals for the public comment period beginning Aug. 2. Sent to all Kidney and pancreas transplant program directors, Kidney and pancreas transplant program administrators, and OPO executive directors. | |
| 6/24/2019 | Member email | Subject line: Kidney and pancreas webinars to discuss SRTR modeling results | Reminder of discussion webinars, and that committees will incorporate input as they develop proposals to replace DSA/region. Sent to OPO executives and procurement directors, K/P transplant program administrators, program directors and program surgeons and physicians. | Sent to 2796 addresses |
| 7/4/2019 | OPTN news item | Kidney and pancreas committees refine distribution policy options | https://optn.transplant.hrsa.gov/news/kidney-and-pancreas-committees-refine-distribution-policy-options/ | 291 page views |
| 7/26/2019 | Member email | Subject line: Kidney, pancreas distribution proposals set for public comment | Reminder of public comment beginning Aug. 2, link to SRTR modeling, regional meeting schedule. Sent to all Kidney and pancreas transplant program directors, Kidney and pancreas transplant program administrators, and OPO executive directors. | Sent to 962 addresses |
| 8/2/2019-10/2/2020 | OPTN website | Public comment period for the proposal "Eliminate the use of DSA and region in kidney allocation policy" | https://optn.transplant.hrsa.gov/governance/public-comment/eliminate-the-use-of-dsa-and-region-in-kidney-allocation-policy/ | 8086 page views |
| 8/7/2019 | OPTN news item | Kidney and Pancreas Distribution Modeling: Analysis at a Glance | https://optn.transplant.hrsa.gov/news/kidney-and-pancreas-distribution-modeling-analysis-at-a-glance/ | 1503 page views |
| 8/8/2019 | Member email | Subject line: Update on geographic | Sent on behalf of Maryl Johnson re: distribution for all organs. Sent to all OPTN member representatives and alternates, Transplant | Sent to 2413 addresses |

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| | | distribution initiatives | program directors and administrators, OPO executive directors and HLA lab directors and supervisors. With regard to kidney and pancreas distribution, Johnson notes that the committees have issued proposals for public comment to replace the DSA system, and that the recommended approach combines circle-based distribution with proximity points for candidates. | |
| 9/16/2019 | OPTN webinar | Transplant patient webinar addresses proposed changes to kidney and pancreas distribution | https://optn.transplant.hrsa.gov/news/transplant-patient-webinar-addresses-proposed-changes-to-kidney-and-pancreas-distribution/<br><br>Transplant candidates, recipients and their families are invited to learn more about the proposed polices and are encouraged to comment on the proposals out for public comment. | |
| 10/16/2019 | Member email | Subject line: Policy development update: Kidney and pancreas proposals | Post-public comment update, link to public comments sent to Kidney and pancreas transplant program directors and administrators, OPO Executive Directors, and recent members of the Kidney Transplantation and Pancreas Transplantation Committees | Sent to 1064 addresses |
| 10/18/2019 | OPTN news item | Committees to review kidney and pancreas proposals Oct. 21 | https://optn.transplant.hrsa.gov/news/committees-to-review-kidney-and-pancreas-proposals/ | |
| 10/25/2019 | Member email | Subject line: Update: kidney and pancreas proposals modified | Update about key changes that include reduction of the local allocation circle size to a 250 nautical mile radius, as well as reduction of proposed proximity points (a maximum of two points for candidates at transplant programs within the circle and a maximum of four points for candidates listed outside the circle). Sent to kidney and pancreas transplant program directors and administrators, OPO Executive Directors, OPTN member representatives and alternate representatives and recent members of the Kidney Transplantation and Pancreas Transplantation Committees | |

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| 10/28/2019 | OPTN news item | Kidney and pancreas allocation proposals modified to advance 250 nautical mile distribution circle, fewer proximity points | https://optn.transplant.hrsa.gov/news/kidney-and-pancreas-allocation-proposals-modified-to-advance-250-nautical-mile-distribution-circle-fewer-proximity-points/ | 458 page views |
| 11/1/2019 | Member email | Subject line: Additional updates: Kidney and pancreas proposals | Additional details about changes to the proposals regarding import backup, medical urgency and special provisions for Alaska donors. Additional proposals will be developed after the December 2019 board meeting to address those matters. Sent to kidney and pancreas transplant program directors and administrators, OPO Executive Directors, OPTN member representatives and alternate representatives and recent members of the Kidney Transplantation and Pancreas Transplantation Committees | |
| 11/9/2019 | Member email | Subject line: Updates: Kidney and pancreas proposals | Additional reminder ahead of the board meeting. | |
| 11/17/2019 | OPTN news item | Modifications made to kidney and pancreas allocation proposals | https://optn.transplant.hrsa.gov/news/modifications-made-to-kidney-and-pancreas-allocation-proposals/ | |
| 11/26/2019 | OPTN news items | Revised kidney and pancreas proposals going to the OPTN Board of Directors | https://optn.transplant.hrsa.gov/news/revised-kidney-and-pancreas-proposals-going-to-the-optn-board-of-directors/ | 191 page views |
| 12/5/2019 | OPTN news item | New policy adopted to | https://optn.transplant.hrsa.gov/news/new-policy-adopted-to-improve-kidney-pancreas-distribution/ | 1282 page views |

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| | | improve kidney, pancreas distribution | | |
| 12/5/2019 | Member email | Subject line: Update: OPTN board adopts new kidney, pancreas allocation policies | Information about board approval of policies to replace DSA and region in kidney and pancreas allocation with a 250 nautical miles circle. | |
| 6/9/2020 | OPTN news item | Additional provisions adopted to upcoming kidney, pancreas distribution system | https://optn.transplant.hrsa.gov/news/additional-provisions-adopted-to-upcoming-kidney-pancreas-distribution-system/ | 475 page views |
| 9/4/2020 | OPTN Pro-fessional Education section | Policy toolkits are published | https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/<br><br>https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/removal-of-dsa-and-region-from-kidney-allocation-policy/<br><br>https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/modifications-to-released-kidney-and-pancreas-allocation/<br><br>https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/addressing-medically-urgent-candidates-in-the-new-kidney-allocation-system/ | |
| 9/11/2020 | OPTN news item | Changes to kidney and pancreas allocation to be implemented | https://optn.transplant.hrsa.gov/news/changes-to-kidney-and-pancreas-allocation-to-be-implemented-later-this-year/ | 1626 page views |

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| | | later this year (links to toolkits) | | |
| 9/15/2020 | Member email | Subject line: Policy changes to remove DSA and region from kidney and pancreas allocation to be implemented at end of 2020, policy toolkits now available | Recap of board actions to date, with links to older news items about adoption of policies. Email provided links to policy toolkits on the OPTN site. Final implementation date is not set, but audience is told that it will occur at the end of 2020. Professional education will be released in November. Email was sent to a deep list of transplant and OPO professionals, in addition to lab positions and OPTN member representatives and alternates. | Sent to 9097 addresses |
| 10/12/2020 | Member email | Subject line: Preview available for all OPOs ahead of removal of DSA and region: New kidney and kidney-pancreas distribution match lists | All OPOs are invited to prepare for upcoming changes by participating in a test site from Nov. 2-13. Participating will allow them to preview the news kidney, kidney-pancreas and released kidney match lists as they will function in UNet. | Sent to 363 addresses |
| 10/14/2020 | OPTN news item | Preview available for OPOS: New kidney and pancreas distribution match lists | https://optn.transplant.hrsa.gov/news/preview-available-for-opos-new-kidney-and-pancreas-distribution-match-lists/ | |
| 10/16/2020 | Member email | Subject line: Dec. 15 implementation date set for changes to kidney, pancreas allocation | This email communicated the final implementation date to members, and outlined what OPOs and transplant programs can do to prepare for the changes, including building relationships and accessing professional education resources in November. Email was sent to a deep list of transplant and OPO professionals, in addition to lab positions and OPTN member representatives and alternates. | Sent to 7182 addresses |
| 10/20/2020 | OPTN news item | Policy changes to kidney and pancreas allocation to | https://optn.transplant.hrsa.gov/news/policy-changes-to-kidney-and-pancreas-allocation-to-implement-dec-15/ | 1268 page views |

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| | | implement Dec. 15 | Announces implementation dates, outlines two phases of kidney medical urgency policy implementation. Links to toolkits. | |
| 10/20/2020 | Member email | Subject line: Upcoming changes to medical urgency prioritization for kidney candidates | Communicated details specific to the changes to medical urgency, outlined what kidney programs would need to do during Phase I. Provides links to toolkits and other resources. | Sent to 6701 addresses |
| 10/28/2020 | Member email | Subject line: Upcoming changes for OPOs: New released organ allocation policies for kidney, pancreas | Communicated details specific to how OPOs will allocate released organs in the new system. Provides links to toolkits and other resources. | Sent to 7011 addresses |
| 11/3/2020 | Member email | Subject line: Implementation pre-notice: Phase I of new kidney medical urgency requirements to implement Dec. 1, professional education now available | Notice sent four weeks ahead of Phase I implementation, with information about professional education to help members update their candidates. Provides links to toolkits and other resources. | Sent to 6732 addresses |
| 11/10/2020 | OPTN news item | Patient webinar announced (to occur Nov. 23) | https://optn.transplant.hrsa.gov/news/transplant-patient-webinar-addresses-upcoming-changes-to-kidney-and-pancreas-distribution/ | 174 page views of news item |
| | | | Notice that the chairs of the Kidney and Pancreas Committee were to host a webinar for patients and their caregivers and describe the upcoming changes. Patient questions to be addressed as time permits. | 569 people registered for webinar |
| 11/12/2020 | OPTN news item | Phase I pre-implementation notice for new | https://optn.transplant.hrsa.gov/news/pre-implementation-notice-phase-i-of-new-kidney- | 1024 page views |

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| | | medical urgency reqs | medical-urgency-requirements-to-implement-dec-1/ | |
| 11/16/2020 | Member email | Subject line: Pre-implementation notice: Removal of DSA and region from kidney and pancreas allocation | 30-day notice ahead of final implementation, with information about professional education to help members be informed about the new system. Provides links to toolkits and other resources. | Sent to 7307 addresses |
| 11/16/2020 | OPTN news item | Pre-implementation notice of removal of DSA/regions | https://optn.transplant.hrsa.gov/news/pre-implementation-notice-removal-of-dsa-and-region-from-kidney-and-pancreas-allocation-to-go-into-effect-dec-15/ | 258 page views |
| 11/23/2020 | OPTN | Patient webinar recording made available | https://optn.transplant.hrsa.gov/news/transplant-patient-webinar-recording-now-available/ | 504 views of the patient webinar recording |
| 11/25/2020 | Member email | Subject line: Upcoming changes for OPOs: Modifications to released organ allocation policies for kidney, pancreas | Reminder sent to OPO audience about upcoming changes to released organs. Provides links to toolkits and other resources. | Sent to 7022 addresses |
| 11/25/2020 | Member email | Subject line: Important updates to submitting supporting documentation for Phase I of new kidney<br><br>medical urgency requirements. | Reminder email sent to kidney audiences about upcoming changes to medical urgency requirements. Provides links to toolkits and other resources. | Sent to 6745 addresses |

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| 12/1/2020 | Member email | Subject line: Implementation notice of Phase I of medical urgency | This email communicated the start of a two-week transition period to allow kidney staff to update candidate records ahead of final policy implementation. This policy change provides a consistent definition of medical urgency and also ensures medically urgent candidates receive allocation priority in the new system. | Sent to 6761 addresses |

*****Not all webpages have metrics provided, but they are available upon request