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

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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

From: Patti Niles <patniles@organ.org <mailto:patniles@organ.org>>
Sent: Wednesday, December 9, 2020 8:23 AM
To: MCBRIDE, Ginny <Ginny.Mcbride@ourlegacyfl.org <mailto:Ginny.Mcbride@ourlegacyfl.org>>
Cc: Engels, Thomas (HRSA) <TEngels@hrsa.gov <mailto:TEngels@hrsa.gov>>; Diane Brockmeier <dbrockmeier@midamericatransplant.org <mailto:dbrockmeier@midamericatransplant.org>>; Jan Whaley <jwhaley@dnwest.org <mailto:jwhaley@dnwest.org>>; Matt Wadsworth <mwadsworth@lifeconnection.org <mailto:mwadsworth@lifeconnection.org>>; Meeks, Chris B <cmeeks@legacyofhope.org <mailto:cmeeks@legacyofhope.org>>; Kyle Herber <kyleh@nedonation.org <mailto:kyleh@nedonation.org>>; Kevin Stump <kstump@msora.org <mailto:kstump@msora.org>>
Subject: Re: Urgent Request: Suspend Implementation of Revised OPTN/UNOS Kidney Allocation Policy Until Pandemic Subsides

Thank you for your leadership on this.

Patti Niles

President/CEO

Southwest Transplant Alliance

Sent from my iPhone

Please forgive typo blunders

> On Dec 9, 2020, at 6:46 AM, MCBRIDE, Ginny <Ginny.Mcbride@ourlegacyfl.org <mailto:Ginny.Mcbride@ourlegacyfl.org>> wrote:
>
> **Message Originated Outside STA**

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

—

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