

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

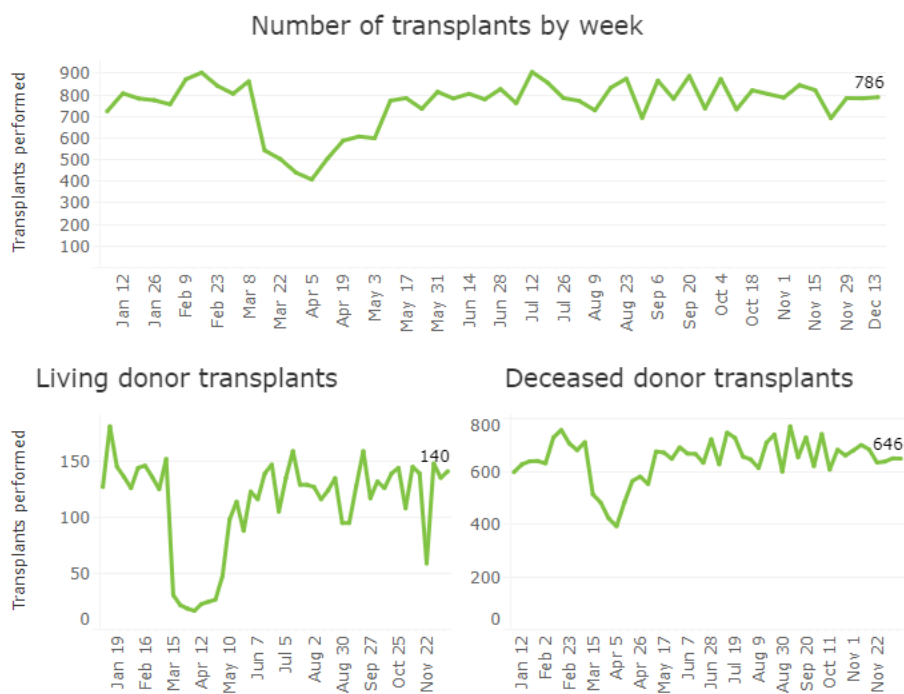
³ Letter from HRSA Administrator Thomas J. Engels to the Dr. David Mulligan, President of the OPTN, and Brian Shepard, Executive Director of the OPTN, December 14, 2020.

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 2020⁴



Transplant hospitals have 24 hours to report a transplant to the OPTN. This data includes only full weeks and reflects a two day lag. Pancreas islets and VCA transplants omitted.
Based on OPTN data as of 12/22/2020 01:05. Data subject to change based on future data submission or correction.

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

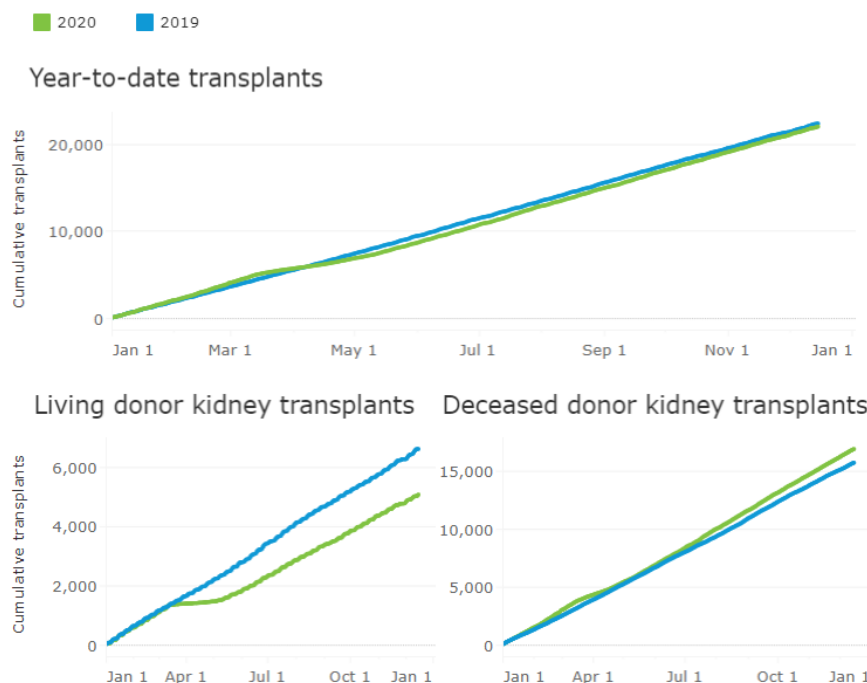
⁴ OPTN data, <https://unos.org/covid/>, accessed on December 22, 2020 at 3:34PM.

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 Type⁸



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-pXVnhKiUI> (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 traveled¹⁰

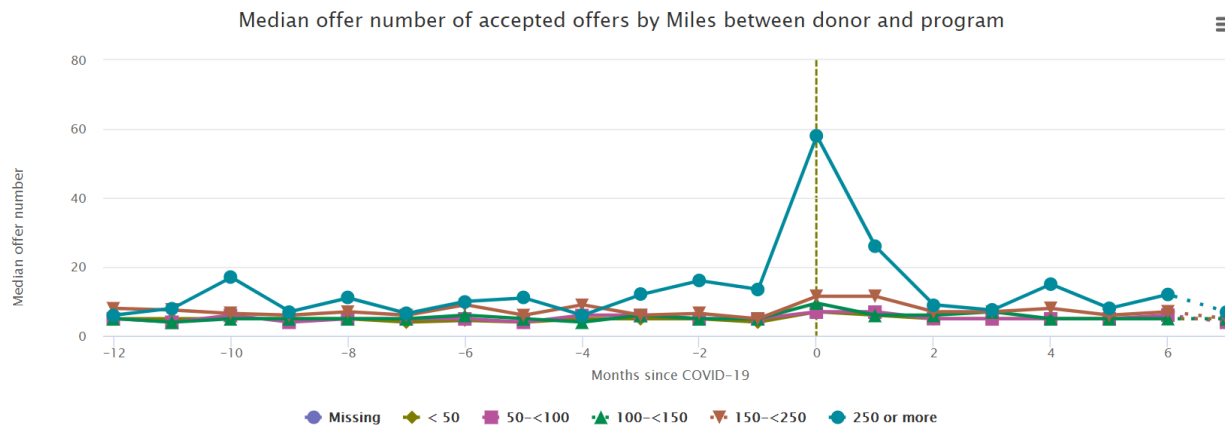


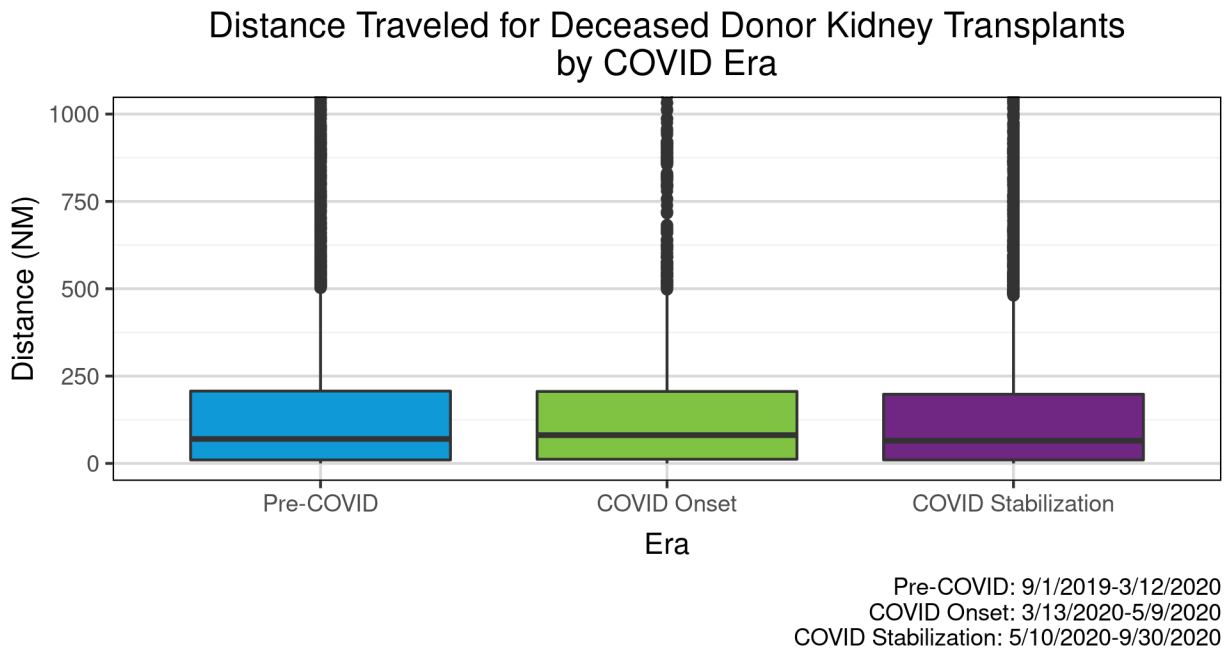
Figure 3 demonstrates the resiliency of the transplant network and shows that acceptance behavior reverted to pre-pandemic norms. The OPTN is confident that that the transplantation and donation community will similarly adapt to other changes to the system, such as the Revised Kidney Policy.

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 Era¹¹



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 17¹³ and April 3, 2020¹⁴, 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.

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

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 UNetSM 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 UNetSM 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

⁵⁸ *Id.*

⁵⁹ 42 U.S.C. §274(a). Scientific Registry.

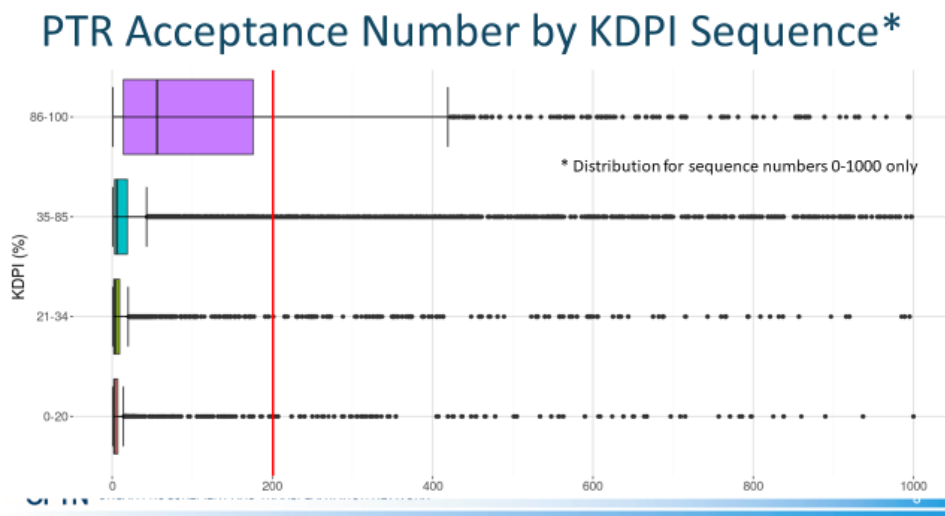
⁶⁰ SRTR. Kidney-Pancreas Simulated Allocation Model – User’s Guide. Version 2015, Last Updated April 20, 2015. <https://www.srtr.org/media/1202/kpsam.pdf> (Accessed on December 23, 2020).

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 kidney⁶⁷ and liver⁶⁸ 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

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

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.

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/Final Map> (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 website¹⁰⁴ 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 webinars¹⁰⁵:
 - 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 policy¹⁰⁷), 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 above¹⁰⁹, 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 dataset¹¹⁶
- 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 DSAs¹¹⁷:

- 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/pancrea s 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

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

		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

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/	Transplant candidates, recipients and their families are invited to learn more about the proposed policies 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	

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

		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 Professional Education section	Policy toolkits are published	https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/ https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/removal-of-dsa-and-region-from-kidney-allocation-policy/ https://optn.transplant.hrsa.gov/learn/professional-education/kidney-allocation-system/modifications-to-released-kidney-and-pancreas-allocation/ 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

		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

		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

		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 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

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