The UNOS Region 2 meeting was held on September 8, 2017 in Baltimore, MD. Dr. Matthew Cooper, Region 2 Councillor, convened the meeting and welcomed those in attendance. There were 130 individuals in attendance representing 77 percent of institutional voting members.

**OPTN/UNOS Update**

Yolanda Becker, MD, OPTN/UNOS President provided the OPTN/UNOS Update.

**Non-Discussion Agenda**

**Proposals not presented or discussed**

- **Living Organ Donation by Persons with Certain Fatal Diseases Who Meet the Criteria to Be Living Organ Donors (Ethics Committee)**

  Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the OPTN website. A white paper is an authoritative report or guide that informs readers concisely about a complex issue and presents the issuing body’s philosophy on the matter. It is meant to help readers understand an issue, solve a problem, or make a decision.

  In 2013, the OPTN implemented new informed consent policies (Policy 14.3, Informed Consent Requirements) for living kidney donors. New informed consent policies for other types of living donors followed in 2014. These new policies included absolute contraindications (Living Donor Exclusion Criteria) to living donation.

  Some terminally ill patients may desire to be living donors but may not be afforded the opportunity to donate based on confusion with existing OPTN policies for living donor informed consent, medical evaluation, and post-donation reporting policy requirements. If a potential living donor patient is competent and can provide informed consent, a terminal disease should not preclude organ donation and would not violate existing policy. Based on published and anecdotal reports, members may need guidance regarding how to handle potential living donors with certain fatal diseases who meet the criteria to be living donors.

  **Region 2 Vote – 25 yes, 0 no, 0 abstentions**

  This white paper was approved during the December 2017 OPTN/UNOS Board of Directors meeting.

  **Effective date:** December 4, 2017

  The white paper is available on the OPTN website: https://optn.transplant.hrsa.gov/resources/ethics

- **Review of HLA Tables (2016) (Histocompatibility Committee)**

  The Histocompatibility Committee (the Committee) is charged with reviewing the equivalency tables in Policy 4.10: Reference Tables of HLA Antigen Values and Split Equivalences and recommending any updates as needed. During the 2016-2017 review of the equivalency tables, the Committee identified a need to include HLA-DPB1 equivalences in policy. The Committee created a DPB1 unacceptable antigen equivalency table that includes G allele equivalences, and also made updates the existing tables to reflect advancements in HLA testing since the last comprehensive update. This proposal also updates the nomenclature in all equivalency tables in policy. By updating the equivalency tables, members have a current resource to use when performing and interpreting final crossmatches and considering organ offers. For candidates
with antibodies to newly added antigens, these updates can help improve graft survival. The
table updates in this proposal will provide members with new antigen equivalences that can
help them make more informed transplantation decisions.

Region 2 Vote – 25 yes, 0 no, 0 abstentions
This proposal was approved during the December 2017 OPTN/UNOS Board of Directors
meeting.
Effective date: Pending programming and notice to OPTN members

Addressing Approved Transplant Fellowship Training Programs Bylaws (MPSC)
A number of abdominal key personnel training pathways in the Bylaws require that the training
occurred at a fellowship program “approved by the MPSC,” and that the Membership and
Professional Standards Committee (MPSC) will review training programs “every five years or
any time the program director changes.” The MPSC does not regularly review or formally
approve transplant training programs, nor has it done so historically. This proposal
recommends deleting Bylaws that reference the MPSC’s “approval” and routine review of
transplant fellowship programs to address this discrepancy, while retaining language that
validates the rigor of the training program cited by a key personnel applicant applying through
one of the Bylaws’ “training pathways.” The proposal also recommends some clerical changes
to simplify these Bylaws sections. Making these proposed changes to the Bylaws supports the
OPTN strategic plan goal of promoting the efficient management of the OPTN.
Region 2 Vote – 25 yes, 0 no, 0 abstentions
This proposal was approved during the December 2017 OPTN/UNOS Board of Directors
meeting.
Effective date: March 1, 2018

Guidance for Transplant Program Participation in the Transplantation of non-A1/non-
A1B (A2/A2B) Donor Kidneys into Blood Group B Candidates (Minority Affairs
Committee)
Blood type B candidates, a blood group more common in underrepresented minorities, have
longer kidney waiting times. In December 2014, the new Kidney Allocation System (KAS)
became effective, including Policy 8.5.D: Allocation of Kidneys by Blood Type, which allows for
blood types A, non-A1 and AB, non-A1B kidneys to be transplanted to blood type B recipients
who meet certain criteria.1 Allocation of deceased donor kidneys from blood group A, non-A1
and AB, non-A1B to blood group B kidney recipients has improved transplant rates among
disadvantaged blood group B patients with equivalent long-term graft outcomes compared to
blood type compatible transplants.2, 3 However, the 18 month KAS post- implementation data
analysis revealed that an overwhelming majority of transplant programs (82 percent) do not
perform any non-A1/non-A1B (A2/A2B) transplants and that overall transplant programs have
not taken advantage of this policy change, which provides greater access to deceased donor
kidneys for disadvantaged blood group B candidates.4 Further, a 2016 OPTN/UNOS Minority
Affairs Committee (MAC) survey to all active U.S. kidney transplant programs revealed that
many programs cited difficulty in establishing a protocol for patient enrollment as the major
barrier to performing these transplants. Specifically, the transplant programs identified the
following obstacles when developing the required protocols to participate in non-A1 transplants:

- Difficulty establishing titer thresholds (32 percent)
- Difficulty developing an informed consent policy (21 percent)
- Difficulty determining patient eligibility (18 percent)

OPTN/UNOS policy allows each transplant program to develop and implement protocols for
determining candidate eligibility, but many established programs follow similar practices for protocol. Based on the survey findings, these best practices are offered in a guidance document as an effort to increase the number of kidney transplant programs that perform non-A1/non-A1B (A2/A2B) transplants. An increase in the number of programs using this provision can increase equity in access to transplants for disadvantaged blood group B candidates, due to a greater number of potential donor matches.

Region 2 Vote – 25 yes, 0 no, 0 abstentions
This guidance document was approved during the December 2017 OPTN/UNOS Board of Directors meeting.
Effective date: December 4, 2017
The guidance document is available on the OPTN website: https://optn.transplant.hrsa.gov/media/2347/mac_guidance_201712.pdf

Guidance on the Benefits of Pancreas After Kidney (PAK) Transplantation (Pancreas Transplantation Committee)
There has been a substantial decline in Pancreas After Kidney (PAK) transplants for more than a decade. PAK transplants have dropped steadily each year, with a 55% decrease from 2004 to 2011, even while 2-year pancreas graft survival increased for PAKs from 69% to 81% for the same time period. PAK transplantation has historically been associated with inferior pancreas allograft survival compared with Simultaneous Pancreas and Kidney (SPK) transplantation. The Pancreas Committee sought to compare PAK transplants with SPK candidates and kidney alone recipients waiting for a pancreas to examine what characteristics resulted in improved outcomes for PAK recipients and to address an influential previous study that demonstrated poor outcomes for PAK recipients.

UNOS research analysis showed that PAK transplant recipients have an increased survival advantage compared to SPK waiting list candidates who receive neither a pancreas nor a kidney. Moreover, compared to uremic diabetic waitlist candidates, SPK and PAK recipients showed similar patient survival benefits. Finally, the analysis showed that both living and deceased donor kidney recipients who subsequently receive a pancreas transplant have better kidney graft survival than those recipients who just received a kidney alone. While the analysis does not include recipients that had a kidney graft loss before the pancreas transplant, which can bias the results to those healthy enough to get a PAK that are included in the PAK group, the results still indicate that PAK transplants are appropriate for certain diabetic uremic candidates, especially those with long SPK waiting list times. The Committee seeks to provide guidance to the community on the benefits of PAK transplants for these candidates.

Region 2 Vote – 25 yes, 0 no, 0 abstentions
This guidance document was approved during the December 2017 OPTN/UNOS Board of Directors meeting.
Effective date: December 5, 2017
The guidance document is available on the OPTN website: https://optn.transplant.hrsa.gov/media/2348/pancreas_guidance_201712.pdf

Revisions to Pediatric Emergency Membership Exception Pathway (Pediatric Transplantation Committee)
In December 2015, the OPTN/UNOS Board of Directors (Board) approved minimum training and experience requirements for key personnel at pediatric heart, kidney, and liver transplant programs. An emergency membership exception pathway (pathway) was included in the
proposal for adult heart and liver transplant programs that did not meet the pediatric key personnel requirements, but wanted to register a patient less than 18 years old on the waiting list. The intent of this pathway was to allow a one-time membership exception for the identified patient under certain exigent circumstances. Members of the Board recognized opportunities for improvement and requested the OPTN/UNOS Pediatric Transplantation Committee (Committee) work on amendments to the pathway.

The Committee collaborated with the OPTN/UNOS Membership and Professional Standards Committee (MPSC) to amend the pathway in 2016. The proposed changes include objective requirements for heart and liver transplant programs that want to register a candidate less than 18 years old. These changes will address concerns over:

- the OPTN's ability to monitor and enforce the requirements,
- subjective and ill-defined language in the prior version of the pathway,
- how the pathways will work operationally, and
- what objective criteria will be used to determine when it is acceptable to transplant a pediatric candidate using one of the pathways.

The scope of this proposal only includes modifications to the emergency membership exception pathways for heart and liver transplant programs. Modifications to the minimum training and experience requirements approved by the Board in 2015 are not being made.

Region 2 Vote – 25 yes, 0 no, 0 abstentions
This proposal was approved during the December 2017 OPTN/UNOS Board of Directors meeting.
Effective date: Pending programming and notice to OPTN members

Regional Review Board Guidance for Adult Congenital Heart Disease Exception Requests (Thoracic Organ Transplantation Committee)
The OPTN Board of Directors recently approved the Thoracic Organ Transplantation Committee’s (Committee) Modification to the Adult Heart Allocation proposal during their December 2016. During the development of the proposal, the Committee received feedback from the heart transplant community during both rounds of public comment voicing concerns that adult congenital heart disease (ACHD) candidates may be disadvantaged by the proposed policy. The Committee considered the following issues in congenital heart disease (CHD) candidates:

- Higher urgency statuses are device-driven
- Variability in review board decision-making for ACHD exception requests
- Challenging to objectively quantify severity of illness

The Committee acknowledged that some ACHD candidates may have higher mortality and may not be candidates for mechanical support options, but ultimately did not change proposed policy. Short-term, the exception and review process will accommodate these candidates, who can apply for an exception in any status as their medical urgency and potential for benefit would warrant. The Committee recognized that CHD expertise may be inconsistent across the regional review boards (RRBs), thus potentially making evaluation and award of ACHD exception requests vulnerable to variability. To help mitigate these inconsistencies, the Committee created guidance for the RRBs with the goal of outlining objective criteria to standardize the evaluation and decision-making of ACHD exception requests.
This proposal aligns with the OPTN strategic goal of improving equity in access to transplants by providing objective criteria to RRBs, potentially making evaluation and award of exception requests for ACHD candidates more consistent, especially for those boards that lack a CHD expert. In addition, developing standardized exception criteria creates an intelligible pathway for more medically urgent ACHD candidates to obtain access to higher urgency statuses, under which they may be transplanted more quickly, thereby potentially reducing waitlist mortality for those candidates.

Region 2 Vote – 25 yes, 0 no, 0 abstentions
This guidance document was approved during the December 2017 OPTN/UNOS Board of Directors meeting.
Effective date: December 5, 2017
The guidance document is available on the OPTN website:

Discussion Agenda

Kidney Transplantation Committee
Improving Allocation of En Bloc Kidneys

Kidney transplantation is the preferred treatment for end stage renal disease (ESRD), yet demand for kidneys far exceeds supply. One strategy to increase the donor pool is to use kidneys from small, pediatric donors. However, programs may be reluctant to transplant single kidneys from small pediatric donors due to technical challenges, which may result in inferior outcomes.

To mitigate the complications associated with transplanting kidneys from small pediatric donors singly, both kidneys, including the vena cava and aorta, can be transplanted en bloc into a single recipient. However, there are currently several challenges to allocating en bloc kidneys:

- There is currently no OPTN policy regarding allocation of en bloc kidneys
- The Kidney Donor Profile Index (KDPI) programmed into DonorNet® doesn’t consider how kidneys will be used (en bloc or single) or acknowledge the improved function of en bloc kidneys, which could screen medically suitable candidates off the match run. In addition, there are other programming limitations that make en bloc kidney allocation a challenge

The proposed policy resolves these problems by providing explicit direction to organ procurement organizations (OPOs) on when to allocate en bloc kidneys. The policy includes donor criteria regarding the type of kidneys that can be allocated en bloc and mandates that programs must indicate in WaitListSM that they accept en bloc kidneys, thus expediting placement of en bloc kidneys to programs that will transplant them. In addition, the Kidney Transplantation Committee (Committee) proposes masking the KDPI score for en bloc kidney offers to prevent potentially eligible candidates from being screened off the match run for kidneys from high KDPI donors.

This proposal aligns with three OPTN strategic goals. First, it should increase the number of transplants by utilizing kidneys previously left unrecovered or discarded. Second, it should improve outcomes for waitlisted kidney candidates and transplant recipients as studies indicate when kidneys from a small pediatric donor are transplanted into a recipient en bloc versus singly, they confer comparable to superior outcomes. In addition, accepting kidneys en bloc may shorten a candidate’s time on the waitlist, conferring not only a survival advantage, but
also several other additional benefits. Finally, this proposal should increase efficiency in management of the OPTN as OPOs should no longer have to contact the Organ Center for guidance or assistance in allocating en bloc kidneys.

Region 2 Vote – 31 yes, 1 no, 0 abstentions

Region 2 Comments: The region supported the proposal but was concerned that pediatric programs interested in using kidneys singly from donors <=20 kg would need to indicate that they would accept en bloc kidneys for their candidates knowing that they were going to split the kidneys prior to acceptance. If the policy is approved, the pediatric community will need education to make sure they know that they need to opt in to receive these offers. In addition, there was concern that once the KIs are split, the pediatric candidates will be screened from the match for the remaining Ki if the KDPI is >=85%. The region again strongly suggested that that despite the policy calling for the second kidney to be allocated according to current allocation policy, the best opportunity for utilization of that kidney for a split en-bloc pair is for the kidney to remain at the center that split the kidneys. There was also concern that the data used for the proposal was pre-KAS, since these organs with a KDPI of >=85% have not been offered to pediatric candidates since the implementation of KAS. There was some support for lowering the weight threshold to 15 kg; however, an amendment to decrease the threshold was not supported.

Committee Response: While the Committee acknowledged the concern over added cold ischemia on the second kidney, the members agreed that confusion or lack of exposure to the application of Policy 5.9 in practice might be driving some to oppose its inclusion in this project. Policy 5.9 is current practice for OPOs and transplant programs. As shown in Figure 7 [page 12], for donors less than 18kg, just 1.6% of offers, in which both kidneys were accepted between 2010 and 2015, had at least one kidney transported outside of the accepting center. The OPO Committee, NATCO, and Regions 2, 8, and 9 submitted comments that advocate for the accepting program to keep both kidneys upon splitting kidneys originally allocated as en bloc kidney offers. The reason given was to lessen cold ischemia time on the second kidney, thereby preventing possible discard of the organ. OPTN data shows that over six years, 56 kidney pairs from donors under 18kg were split, and only 21 offers had at least one kidney travel to a new center for transplant. It’s important to note that none of the transplanted kidneys from the previously mentioned 21 donors left the accepting candidate’s DSA. The Committee reinforced during each presentation that alignment with Policy 5.9 is the most transparent and patient-centered method to managing released kidneys, even if rare. The Committee feels that every effort should be made to follow the OPTN’s established allocation sequences. Deviating from these sequences without conducting due diligence to the next candidate on a given match run would be in opposition to the core values of the OPTN.

There were several comments (from members on Patient Affairs Committee, Regions 2 and 6) directed at the potential effect of the en bloc kidney proposal on the pediatric population receiving small single kidneys. If the en bloc kidneys are split and the KDPI of the remaining kidney is above 85 percent, then pediatric candidates do not receive that offer. A select number of pediatric programs (in select regions) are transplanting small single kidneys into pediatric patients routinely. Although en bloc kidneys are not typically transplanted into (small) pediatric candidates, they can be transplanted into adolescents. Pediatric programs will still have access to small kidneys, providing they opt-in to receiving en bloc kidney offers. Screening pediatric candidates off KDPIs of 85 percent or above is not a new practice, it is current allocation, and does not change with this proposal. The Committee decided that education for pediatric
programs is essential to prepare them for the opt-in system changes, as well as monitoring the effect of the policy changes on the pediatric population.

This proposal was approved during the December 2017 OPTN/UNOS Board of Directors meeting.
Effective date: Pending programming and notice to OPTN members

Improving Dual Kidney Allocation
By the conclusion of 2016, a record-setting 12,245 deceased donor kidneys transplants were performed nationwide. However, there were still 98,962 candidates waiting for a kidney transplant. One strategy to increase the number of kidney transplants is to reduce the number of discards of high Kidney Donor Profile Index (KDPI) kidneys through double kidney transplantation. The OPTN/UNOS Kidney Transplantation Committee (“the Committee”) is proposing amendments to OPTN policy to improve dual kidney allocation. Dual transplants and high KDPI transplants are disproportionately performed more often in older recipients; expanding the use of dual transplantation of high KDPI kidneys could serve to counterbalance the modest decline in access for older patients post-KAS. Amending current OPTN policy and enhancing programming could increase usage of high KDPI kidneys that are currently at increased risk for discard.

Members say that current policy is ambiguous, out-of-date, and does not enable them to identify and allocate dual kidneys in a timely manner. As a result, dual kidneys are often offered only after the wait list has been exhausted, leading to longer cold ischemia. Transplant programs, especially those with high dual transplantation volume, say that they would prefer to receive dual kidney offers earlier (ideally before organ recovery), to allow time for logistical planning and to minimize cold ischemia. Likewise, OPOs tell us that they favor pre-recovery criteria to facilitate allocation more efficiently.

The Committee distributed a concept paper during the spring 2017 public comment period in order to seek public input on three proposed concepts that aim to address the above problems. This initial round of public comment revealed support for a modification to the allocation tables that incorporate dual kidney allocation to centers that have opted in to receive these offers. The Committee now seeks additional community feedback on the selected policy solution.

Region 2 Vote – 33 yes, 1 no, 0 abstentions
No comments
This proposal was approved during the December 2017 OPTN/UNOS Board of Directors meeting.
Effective date: Pending programming and notice to OPTN members

Pancreas Transplantation Committee
Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types
Pancreas transplants continue to decline and the majority of pancreata that are transplanted are done so as part of a simultaneous pancreas-kidney (SPK) transplant. Current blood type restrictions on kidney-pancreas allocation prevent clinically compatible SPK transplants from occurring. Preventing clinically compatible SPK transplants results in many of these pancreata being discarded or not recovered. Modifying current blood type restrictions could lead to an increase in the utilization of pancreata, an overall increase in SPK transplants, and could promote a more efficient allocation system.
This proposal modifies Policy 11.4.D *Blood Type for Kidney-Pancreas Allocation* to loosen restrictions on blood type compatibility for kidney-pancreas (KP) and pancreas alone (PA) allocation: allowing blood type A, non-A1 and AB, non-A1B kidney-pancreas and pancreas offers to B candidates, allowing blood type B kidney-pancreas and pancreas offers to AB candidates, and removing restrictions on blood type O compatibility. The proposal also modifies allocation to prioritize high-cPRA ABO-identical candidates above high-cPRA ABO-compatible candidates, then among candidates with cPRA < 80%, prioritize ABO-identical candidates above ABO-compatible candidates.

The Pancreas Committee is pursuing an allocation change that maximizes the increase of KP transplants and minimizes negative impacts on blood type, age, or ethnicity. While the modeling by the Scientific Registry of Transplant Recipients (SRTR) did not project that candidates would be disadvantaged based on age or ethnicity, the modeling projected that blood type O candidates would be disadvantaged by a reduced access to transplant, including a simulated 2% decrease for blood type O kidney transplants. There was also a decrease for KP blood type O transplants but an increase of KPs overall. However, the modeling projected a significant increase in the number of SPKs, an increase in the number of median years of benefit, and a net increase in transplants if the blood type restrictions were loosened. The simulation chosen by the Committee predicts the least impact on blood type O candidates except one (Run 6), which showed a smaller increase in the median years of benefit and life years from transplant (LYFT). The increase in SPKs and net increase in transplants projected by the proposal aligns with OPTN Goal 1, to increase the number of transplants.

**Region 2 Vote – 32 yes, 1 no, 1 abstentions**

*Region 2 Comments:* The region supported the proposal but there was concern from the pediatric programs that pediatric candidates with ABO "O" may be disadvantaged due to KI’s going to KP candidates. There was a suggestion that the committee may want to try this as a pilot program before implementing nationally.

*This proposal was not approved during the December 2018 Board of Directors meeting*

The committee is asking for additional analysis and will continue to work on the project.

**OPO Committee**

**Improving the Efficiency of Organ Placement**

On April 30, 2007, mandatory use of DonorNet® began with the goal to facilitate and expedite organ placement using an electronic organ placement system. This system allows organ procurement organizations (OPOs) to electronically notify transplant hospitals about organ offers and provide donor information. During recent discussions and proposals that seek to increase the broader sharing of organs, the transplant community has acknowledged the need to make improvements to the organ placement system in order to place organs more efficiently.

Many factors lead to inefficiencies in the organ allocation process. Some of these, such as logistical issues, are difficult to control while OPOs and transplant programs can control other issues, such as communication. This proposal is the first step to improve the organ placement process by proposing the following:

- Reduce the current time limits for responding to organ offers
- Establish a new time limit for the primary transplant hospital to make a final decision on organ offers
- Limit the number of organ acceptances for one candidate at any given time
- Require OPOs to manage organ acceptances in real time.

This proposal will also address the required deceased donor information by simplifying the language and reducing redundancies and inconsistencies in *Policy 2.11: Required Deceased*
**Donor Information.**

This proposal primarily supports OPTN/UNOS Strategic Goal 1: Increasing the number of transplants by improving the placement of organs and potentially reducing organ discards, leading to an overall increase in the number of transplants.

**Region 2 Vote – 20 yes, 12 no, 0 abstentions**

**Region 2 Comments:** Region 2 supported this proposal, although there was concern from some of the transplant centers that 30 minutes is not a reasonable time frame to make a final acceptance for an organ offer. There was a suggestion that the committee should look more closely at the 10% of centers who are not currently responding within 30 minutes and address this issue with those centers rather than making this a national policy. Some members supported only allowing centers to accept one organ for any one candidate, adding that if the policy is approved and allows the center to accept two organs, there should be a set point in time when the center has to make a decision between the two organs. There was a suggestion that DonorNet be modified to allow OPOs to see how many acceptances one candidate has for organs so they have the full picture. There was also support from the OPO members to modify DonorNet to allow OPOs to regulate how many offers they can send at one time regionally and nationally. The thought is that the current cap is too tight and prolongs allocation time for hard to place organs. There was some support for limiting the number of backup offers a center can accept for the same candidate. If this proposal is approved, the transplant centers would like the committee to closely monitor the acceptance data so that the policy can be revised if the timeframes cannot be met.

**Committee Response:** There were several recommendations to create transparency in the system so OPOs can view how many offers are being considered for a certain candidate. There were several recommendations to create an exception for sicker candidates, such as fulminant liver and heart/lung failure candidates. The Committee ultimately decided that an exception was not necessary because transplant hospitals can still receive offers even if they already have two organ offer acceptances. They would just need to notify one of the host OPOs and release one of the previously accepted organs.

This proposal was approved during the December 2017 OPTN/UNOS Board of Directors meeting.

**Effective date:** March 1, 2018 for: Policies 2.2 (OPO Responsibilities), 2.11 (Required Deceased Donor 1 Information, and 2.12 (Requested Deceased Donor Information)

**Effective date:** Pending implementation and notice to OPTN members for: Policies 1.2 (Definitions), 5.6.B (Time Limit for 5 Acceptance), and 5.6.C (Effect of Acceptance)

**Liver and Intestinal Organ Transplantation Committee**

**Enhancing Liver Distribution**

Over a 5-year period during the 1990’s, the OPTN tried and failed to reach consensus on liver allocation policy revisions aimed at broader sharing for liver allografts, particularly for the most urgent patients. The Secretary of Health and Human Services became involved and one result was implementation of federal transplant regulations, the OPTN Final Rule in March 2000. The Rule stipulates that OPTN allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and shall not be based on the candidate’s place of residence or place of listing except to the extent needed to satisfy other regulatory requirements. The Rule stipulates additional OPTN requirements and restrictions that previously did not exist.

During the years immediately following Final Rule implementation, the MELD and PELD disease severity scoring systems were developed, seen as the first necessary step before
readdressing broader liver sharing. Additional liver allocation policies followed, with the understanding that the OPTN was moving toward broader sharing to reduce the observed geographic inequity in access to liver transplant for the sickest candidates. On November 13, 2012, the OPTN/UNOS Board of Directors directed all OPTN organ-specific committees to identify allocation equity metrics appropriate to their organ types. The Liver and Intestinal Organ Transplantation Committee (hereafter called “the Committee”) selected variance in median MELD at time of transplant (for exception and non-exception candidates), among other metrics, and observed continued and significant variance in this metric across regions. The Board instructed the Committee to develop evidence-based policy proposals aimed at reducing this variance in accordance with the Final Rule.

The OPTN recognizes that there are not enough organs for patients in need of lifesaving transplants and is invested in increasing the number of transplants each year by increasing donation, reducing organ discards, and improving OPO performance. However, these efforts will not change the fact that current regional boundaries often physically separate urgent candidates from donors in close proximity.

The result is that in some areas of the United States, candidates must reach a higher MELD or PELD score in order to get a transplant.

In progress for the last 5 years, the current proposal strives to balance equity in access while limiting the impact on travel and logistics. The Committee proposes a solution that implements a 150 nautical mile radius sharing circle around the donor hospital and increased sharing within the region. The 150 mile circle may include candidates outside of the region. Candidates at transplant hospitals within the circle will receive 5 additional MELD or PELD points. The Committee proposes sharing in the initial broader classification to be limited to candidates with a calculated MELD of at least 29 (candidate age greater than 18 at time of registration) and allocation MELD or PELD of at least 29 (candidate age less than 18). The Committee also proposes a separate allocation classification for DCD donors or donors at least 70 years old. The new allocation for these donors is expected to increase utilization and address concerns with the broader sharing of specific donor livers.

**Region 2 Vote – The region did not support the liver proposal 5 yes, 22 no, 4 abstentions.**

**Region 2 Comments:**
There was a lot of feedback about why the current proposal was not the right proposal to move forward:

- Variance in MELD score is not all geographic and includes factors such as listing practices, OPO performance, supply and demand and acceptance behavior
- Concern about transportation including availability of planes, increased risk to teams flying and cost
- Utilization, declines and discards are not considered
- The proposal would jeopardize relationships cultivated between the OPO and Tx Centers in the DSA by involving multiple OPOs and Transplant centers in all allocation.

**Ideas for future proposals:**
- Focus on decreasing death on the waiting list
- Consider moving candidates to centers with shorter waiting times instead of organs to centers with longer waiting time
- The committee should review listing practices and focus on the most controversial. There could be policy developed to address these practices.
- Collaborate with professionals in the aviation industry to determine if there would be enough planes to ship organs
- Consider survival benefit
- Seek input from experts in the field of Population Health

Support for the following points outlined in the current proposal:
- Should be based on population density. A 150 mile circle in Region 2 includes many transplant centers and OPOs compared to a 150 mile circle in the Midwest that may only include one OPO and a few transplant centers.
- 5 proximity points should only apply to DSA
- If the proximity points only apply to the DSA then the region supports a sharing threshold of 29
- DCD Candidates and those >= 60 (vs. 70) should be excluded from broader sharing (also asked for data for how many livers from donors >=60 are shared outside of the DSA under current policy)
- The cap of 40 should remain in place. There are candidates now with a MELD of 40 who have a greater severity of illness than others listed at 40 but don’t get additional points. The cap should apply to all candidates regardless of proximity points.
- Points and sharing should apply to candidates with a MELD >15

Other feedback:
- If approved, there should be a waiting period prior to implementation to determine if the NLRB and HCC policies change the data. If the data shows a reduction in variation after implementation of these policies, than the redistribution policy should be revisited prior to implementation.
- If implemented, there need to be stop measures in place so that the committee can move quickly to make changes if there are unintended consequences
- Committee should review data on utilization/declines and discards pre and post Share 35.

Committee Response: Commenters covered many different topics. The committee focused on the following seven themes:
1. MELD or PELD Sharing Threshold
2. Proximity Circle
3. Proximity Points
4. Proximity Points Added to Candidates with a MELD/PELD of at least 15
5. Allowing MELD Scores to go Above 40 to Candidates in the Circle
6. Allocating to Adult Hepatic Artery Thrombosis (HAT) Candidates Based on their Allocation MELD
7. DSA Performance
8. Effect on Vulnerable Populations
9. Variances

1. MELD or PELD Sharing Threshold
The Committee had two goals with the implementation of a sharing threshold. First, to prioritize broader sharing to candidates with the greatest medical urgency on the waiting list. Second, to restrict the amount of the waiting list exposed to broader distribution, thus constraining the amount of broader distribution to address logistical concerns of moving to a new system. The public comment proposal included a sharing threshold within the initial broader sharing classification for the allocation of non-DCD donors at least 18 years old and
less than 70 years old. After allocating to Status 1A and 1B candidates within the Region or Circle, the initial broader sharing classification in the public comment proposal was restricted to candidates at least 18 years old with a calculated MELD of at least 29, and candidates less than 18 years old (pediatrics) with an allocation MELD or PELD of at least 29.

There were at least 37 public comments regarding the inclusion of a sharing threshold of 29 within the initial broader sharing classification of donors at least 18 years old and less than 70 years old (donors >70 are allocated in the new DCD/Age>70 allocation). The community was split between individuals wanting a lower sharing threshold, supporting the threshold at 29, and wanting a higher sharing threshold. A higher sharing threshold was supported in public comment for a few reasons. A higher sharing threshold will reduce the amount of the waiting list exposed to broader distribution, thus minimizing the overall effect of this proposal with regards to the current system. There was discussion that in areas which do not see increased ‘out-of-region’ livers into the Region (Region 5), that a lower threshold may increase sharing within the region but not have much of an effect on MELD at transplant, or waitlist mortality. Finally, there was public comment around the idea that a threshold of 29 may minimize the prioritization to candidates with a 35 or above in the current system. A lower sharing threshold was supported in regions that would like to expand distribution beyond what is anticipated by this proposal. The exception to this is Region 5, which certainly wants to broaden liver distribution, however a larger circle (or other distribution area) and a corresponding influx of out-of-region livers is necessary to make a significant impact for Region 5. A lower sharing threshold would expose more of the waiting list to the proposed changes, and would increase the amount of sharing within the region and proximity circle. However, the modeling and public comment supports the sentiment that a lower sharing threshold would de-prioritize higher MELD candidates.

During the committee’s meeting in Chicago on October 10th, they responded to the feedback received during public comment. The Committee’s discussion on the appropriate sharing threshold focused on two significant themes:

1) The effect of the threshold on geographic disparity and the amount of travel
2) The effect of the threshold on prioritizing medically urgent candidates

As discussed above, the sharing threshold is used to identify a subset of candidates to be exposed to the initial broader sharing classification based on their MELD or PELD score. The Committee discussed the effect of the sharing threshold on the key metrics identified by the Committee in the SRTR modeling results. The Committee requested modeling of a sharing threshold of 29, 22, and no threshold. Previously, the Committee has requested modeling of 35, 29, and 25 in relation to the 8-district model. The recent modeling showed a small decrease in variance in median MELD/PELD at transplant in the 22 threshold, compared to the 29 threshold (5.8 to 4.3) and a small decrease in waitlist mortality rate in the 22 threshold, compared to the 29 threshold (0.09 to 0.087). Median transport distance (102.1 to 113.8 miles) and percent of organs flown (55.6 to 59.9) also see similar changes when comparing a sharing threshold of 29 to 22. For a full overview of metrics see Figures 5 and 6 above. The Committee expects that a sharing threshold between 22 and 29 (for example a 27) would fall in the middle of these results. Additionally, a threshold above 29 (for example a 32) would see a comparatively reduced impact on these same metrics compared to a threshold of 29. Those members on the Committee in support of a higher sharing threshold (32) view it as a positive increase in distribution to current Share35 policy, while having a smaller impact on travel and logistics compared to 29.

The Committee discussed the concern with lowering the sharing threshold and the corresponding effect on the most medically urgent candidates (MELD 35+) who currently
receive priority through the Share 35 policy. Transplant counts for the MELD/PELD 35+ group decrease with the 22 and 29 sharing threshold scenarios. This could suggest that a lowered threshold will deprioritize higher MELD candidates. In many ways this is intentional, due to the goal of broadening distribution to candidates before they reach higher MELD/PELD scores which correlate with higher predicted waitlist mortality. However, it is still a concern the Committee considered in identifying a final sharing threshold. After discussing the entirety of public comment on the appropriate sharing threshold and reviewing the data and concepts above, the Committee decided on a sharing threshold of 32. A sharing threshold of 32 is a compromise to address concerns on the effect of the 29 sharing threshold proposed in public comment. Additionally, it alleviates the potential negative effect on candidates with the greatest medical urgency (MELD/PELD 35+). Finally, it serves as a gradual increase in regional distribution and identifies a subset of the waiting list exposed to the initial broader distribution classification. Both of these changes are expected to reduce the effect of geography on access to transplant and increase access to transplant for candidates with the greatest waitlist mortality.

2. Proximity Circle
There were at least 84 public comments regarding the concept of a 150-nautical mile radius circle around the donor hospital. The Committee’s intention behind the current proposed circle was to expand distribution beyond the regional boundaries to candidates listed at a program within close proximity of an out-of-region donor hospital. The size of the circle, 150-nautical miles, was chosen based on the perceived distance to reduce the amount of flying. Additionally, compared to the size of circles looked at previously (250 and 500 miles), the 150 mile size was chosen to be conscious of the logistical and financial concerns of broader sharing.
Regional feedback and public comment included discussion that the size of the proximity circle should be larger. This perspective is supported by previous modeling of large distribution areas (Districts and larger circles) that show an increased effect on geographical disparity and lower waitlist mortality. Additionally, there was sentiment that areas of the greatest disparity in access to transplant (Region 5) are not sufficiently improved by the current proposal. Finally, in support of a larger circle, there was sentiment in public comment that the current proposal is too incremental and the problem requires a more substantial solution.
Regional feedback and public comment on the proximity circle included feedback in opposition to the current circle or proposed the idea of a population based circle. The current proposal does not account for variations in population density or other form of geographical variation, such as being near the coastline or being in extremely isolated areas (Hawaii, Puerto Rico, etc.). The modeling predicts that there will be DSAs and Regions that experience comparatively greater effect from this proposal compared to others based on the density of liver programs within, and outside their respective region.
During the committee’s meeting in Chicago on October 10th, they responded to the feedback received during public comment. Based on previous modeling, the Committee understands that a larger circle (250 mile, 500 mile, etc.) would further decrease the disparity in access to a liver transplant, however, this would correspond with an increase in travel (distance and flying) that has been met with concern by the community. The 150 nautical mile radius distribution circle has been shown with recent modeling to broaden distribution and importantly, decrease the variance in access to transplant by allowing donor livers to travel across regional boundaries to candidates within close proximity of the donor hospital. Based on the positive modeling results, and in light of the concerns for larger distribution areas by the community, the Committee decided to move forward with the currently proposed 150 nautical mile radius proximity circle.
3. Proximity Points
There were at least 36 public comments regarding the geographic area (DSA or circle, or combined) that candidates listed within will receive proximity points. There was also a variety of perspectives on the number of proximity points that should be provided. The committee’s intention of providing proximity points was to expand distribution beyond the regional boundaries, while being conscious of the logistical and financial challenges of broader sharing and provide some priority for candidates within close proximity of the donor hospital.

Those in support of proximity points viewed them as a means to constrain travel, provide an advantage to local candidates, and ease the transition to broader liver distribution. Furthermore, the sentiment to provide proximity points to candidates within the circle and to candidates within the DSA is due to maintaining existing relationships between OPOs and their local programs. In some parts of the country, the proximity circle may exclude certain programs within a DSA due to the large size of the DSA. By providing proximity points to the DSA and circle, the potential to prioritize certain candidates within the DSA is eliminated.

During the committee’s meeting in Chicago on October 10th, they responded to the feedback received during public comment. Pertaining to the geographic unit for candidates to receive proximity points, the Committee discussed providing proximity points to candidates within the proximity circle (proposed in public comment) or providing points to candidates within the OPO’s DSA in addition to candidates in the proximity circle. To address relationships between OPO’s and programs in their DSA, as well as the previously mentioned concerns of large DSAs where the circle may exclude certain programs within the DSA, the Committee decided to provide proximity points to candidates in the OPO’s DSA and within the 150 nautical mile proximity circle.

Those in opposition of the number of proximity points (five in the public comment proposal) or the concept of proximity points as a whole, have provided several reasons for this sentiment. It is perceived that proximity points were a concept originating with the 8-district proposal as a means to reduce travel over large geographic areas. However, the public comment proposal had comparatively less travel by only broadening distribution within the region (to candidates with a MELD/PELD of 29) and outside the region through the use of the proximity circle. Therefore, those in opposition of proximity points argue that they may not be necessary (or be much less than five) under the proposal’s comparatively narrower distribution. There was also public comment regarding the idea that five proximity points may reduce the current regional sharing under Share 35. Five proximity points has been perceived as a large advantage to local candidates, and may limit the amount of sharing outside the circle. In large geographic regions, there was comment that proximity points may have an unintended consequence to reduce the amount of regional sharing within the current system of Share 35.

During the committee’s meeting in Chicago on October 10th, they responded to the feedback received during public comment. The Committee discussed the importance of proximity points to prevent livers from traveling within the region, or outside the region, for small differences in MELD or PELD scores. The Committee discussed the number of points necessary to achieve the goal of mitigating small differences in MELD or PELD scores, while also not affecting the clinical implications of a candidates’ score. 5 MELD or PELD points was viewed as a significant clinical advantage to a candidate that may be within close proximity of the donor hospital, over a candidate outside the circle in the region.
An example to illustrate this situation is a candidate within the region (but outside the circle) with a MELD of 35 versus a candidate within the circle with a MELD of 31. In this scenario, the candidate in the circle would be provided 5 MELD proximity points and at the time of the match run, be a MELD 36, thus being prioritized over the candidate with a MELD 35 in the region. The Committee noted that 5 MELD or PELD proximity points represents a significant clinical difference and the comparatively smaller increase in distribution of this proposal does not necessitate such a clinically significant advantage for candidates within close proximity of a donor hospital.

4. Proximity Points Added to Candidates with a MELD/PELD of at least 15
Shortly after public comment began, the Committee identified a concern that the current proposal provided proximity points to all MELD/PELD candidates in the 150-nautical mile circle around the donor hospital. This would include candidates with a MELD or PELD score less than 15, and could potentially provide a MELD or PELD score of 15 to candidates with a score as low as 10 (with 5 proximity points). The Committee expressed concern on the idea of allowing low (less than 15) MELD or PELD candidates to have increased priority for a transplant. The committee solicited feedback during the regional meetings and the vast majority of comment agreed that the proximity points should be provided to candidates with a MELD or PELD score of at least 15.
During the Committee’s in-person meeting following public comment, the Committee reviewed the feedback from the regions and decided to only provide three proximity points to candidates with a MELD or PELD of at least 15. Specifically, candidates at least 18 years old at time of registration will receive three proximity points to their calculated MELD score of at least 15, and candidates less than 18 years old at time of registration will receive three proximity points to their allocation MELD or PELD of at least 15.

5. Allowing MELD Scores to go Above 40 to Candidates in the Circle
The public comment proposal put forth the idea of 5 proximity MELD or PELD points to candidates in the 150 mile circle. With this proposed policy change, candidates in the MELD 35-40 subset will all be capped at 40. For example, two adult candidates within the proximity circle, one with a calculated MELD of 35 and another with a calculated MELD of 39 would both have a 40 within the proximity circle. The tiebreaker would be waiting time, and the differentiation based on MELD would be lost. The Committee solicited feedback from the regions on the idea of uncapping MELD 40 for candidates in the circle to maintain MELD differentiation in the MELD 35-40 population. The majority of comments agreed that the score should be allowed to go above 40 with the inclusion of proximity points.
During the Committee’s in-person meeting following public comment, the Committee reviewed feedback from the regions and decided to allow a candidate’s score to go above 40 at the time of the match run with the introduction of proximity points. With the corresponding change to three proximity points to candidates in the circle and DSA, uncapping MELD for candidates within the circle or DSA would allow continued differentiation between the MELD 37-40 population. For example, two adult candidates within the DSA or circle, one with a calculated MELD of 38 and another with a calculated MELD of 40, would maintain differentiation. The MELD 38 candidate would be a MELD 41, and the MELD 40 candidate would be a 43 at the time of the match run.

6. Allocating to Adult Hepatic Artery Thrombosis (HAT) Candidates Based on their Allocation MELD
The Committee has recently discussed allowing adult candidates with an approved HAT exception, to be allocated based on their allocation MELD. Currently, an adult HAT
candidate with a calculated MELD below the sharing threshold would not be included in Classification 3 for adult donor liver allocation. HAT candidates currently receive an exception score of MELD 40 due to their medical urgency. The Committee has discussed this concept and agree that adult candidates with an approved HAT exception should be included in classification 3, and be allocated to based on their allocation score.

7. DSA Performance
There was discussion during public comment regarding the relationship of this proposal with the concept of DSA performance. The overall discussion focused on the idea that this proposal would shift organs from “high performing DSAs” to “low performing DSAs” and would discourage the efforts of OPOs and their local transplant centers to increase donation and awareness of transplantation.

The Committee responds to these concerns with the following points.
First, the goal of this proposal has always been to increase equity in access to transplant for candidates on the waiting list. A candidate has no control over the performance of their transplant hospital, other transplant hospitals in the DSA, or their local OPO. Therefore, candidates listed in a low-performing DSA should not be expected to have reduced access to transplant for reasons beyond their control, nor should they be expected to travel to other areas of the country for increased access to a transplant.
Second, the Committee is committed to identifying solutions that improve organ offer and acceptance practices that increase acceptance rates and the overall number of liver transplants. An example of such an initiative can be seen within this proposal in the separate liver allocation policy for DCD donors or donors at least 70 years old. The Committee reviewed data, collaborated with OPO partners, and built consensus within the Committee on a subset of the donor population that would be allocated alternatively to increase utilization and address concerns with broader distribution of these organs. The Committee continues to remain engaged with the OPO Committee’s efforts to improve the efficiency of organ allocation with the goal of increasing the number of transplants.
Finally, the topic of DSA performance is not specific, nor limited to the discussion of liver allocation and distribution. It is a topic related to all organs and one that will require effort outside the scope of this proposal. Of note, the President’s Roundtable, a partnership among the presidents and chief staff officers of the American Society for Histocompatibility and Immunogenetics (ASHI), Association of Organ Procurement Organizations (AOPO), American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), NATCO, The Organization for Transplant Professionals, The Organ Donation and Transplantation Alliance (The Alliance), and the United Network for Organ Sharing (UNOS) met on October 5th to promote collaboration and advance the transplant community. They released the following statement:
“The Presidents’ Roundtable convened on October 5 in Washington, D.C. to address contemporary issues and explore opportunities to work together to solve them. The group supports the OPTN/UNOS process for policy development and the partnership for developing metrics for Donor Service Area (DSA) success. We also fully support the ongoing efforts of AOPO in the development of standard performance metrics to better identify a donation rate based on potential donor deaths and review the elements of successful donor registries. We are committed to work together to develop policies for review of DSA performance.”

The topic of DSA performance will remain a priority for the OPTN.

8. Effect on Vulnerable Populations
As discussed in “How was this proposal developed?”, the effect of this proposal on vulnerable populations remains a priority for the Committee. In addition to the normal subgroup analyses including pediatrics (age younger than 18 years), sex (female), race/ethnicity (African American, Asian/Pacific Islander, Hispanic, white), gender, and race/ethnicity, the Committee requested modeling to determine the effects of the proposal on education level (high school or less, more than high school), insurance type (private, public), and urban/rural (Metropolitan, Micropolitan, Small Town, Rural). The modeling showed that the new subgroups were affected similarly to the overall population. A specific concern was the effect of the proposal on what would be considered as rural or non-metropolitan populations. The modeling shows little evidence of a disproportionate effect on any of the candidate place of residence subgroups. The monitoring plan for this proposal includes an analysis of the effects on socioeconomic factors. Pending Board approval and implementation, the Committee will monitor the effect of the proposal on vulnerable and disadvantaged populations to ensure that the change does not disproportionately affect these groups.

9. Variances
Following the decision on a final board proposal, the Committee addressed the current variances in place. There are four existing variances to current policy. The Committee made a recommendation to the OPTN/UNOS Board of Directors on the four existing liver variances.

Region 1 and 10
Region 1 and 10 use the standard distribution and allocation system with the following exception. The regions share for Status 1 patients on a common regional list. Pediatric donor livers are offered first to Status 1 patients within Region 1 and 10. Current policy has separate classifications for the DSA and Region with regards to allocation to Status 1A candidates for this subset of donor livers. The current proposal allocates regionally for Status 1A candidates for pediatric donors, therefore this variance is encompassed in the current proposal. Due to no longer serving its purpose as a variance to the national system, the Committee voted to terminate the Region 1 and 10 variances pending board approval and implementation of the current proposal.

HIOP
The Hawaii DSA in Region 6 uses the standard distribution and allocation system with the following exception. Liver candidates with compatible blood types are included with identical blood types for blood type O donors. The Hawaii agreement is a unique situation due to its geographical location. Due to its unique application and the variance’s concurrence with the current proposal, the Committee voted to extend the HIOP variance pending board approval and implementation of the current proposal. Policy language has been added to include this variance with other variances in Policy.

Region 9
The region utilizes the standard distribution and allocation system for allocating livers with the following exception. As New York composes most of Region 9, the BOD approved an alternative local unit where “Statewide” classifications replace the DSA and Regional classifications. New York essentially shares all livers throughout Region 9. Vermont is the only state outside of New York in Region 9 and they do not currently have a liver program. The Committee discussed this variance at length. In its current state, the variance does not include references to the proximity circle and does not take into consideration the concept of proximity points. The Committee recognizes that Region 9, and specifically New York have
shared broadly across their DSAs for several years. With the goal of this proposal being to distribute livers more broadly, the Committee sought a way for Region 9 to maintain the sentiment of their current variance, while also being applicable to the current proposal. The Committee voted to amend the current Region 9 variance pending board approval and implementation of the current proposal. The amended variance replaces DSA” with “region” throughout Policy 9.8: Liver Allocation, Classifications, and Rankings. This variance will have two implications:
1) For liver and liver-intestine allocation, all references to the DSA are replaced with “region”. Livers and liver-intestines will be allocated to candidates in the region for all instances in the current proposal that policy would allocate to the DSA.

2) At the time of the match run, a liver or liver-intestine candidate with a MELD or PELD score registered at a transplant hospital within the circle or OPO’s region will receive proximity points. As discussed throughout this proposal, the proposed policy includes proximity points to candidates in the circle or OPO’s DSA.

Policy language has been added to include this variance with other variances in Policy.

This proposal was approved during the December 2017 OPTN/UNOS Board of Directors meeting.
Effective date: Pending programming and notice to OPTN members