

## At-a-Glance

- **Proposal For Regional Distribution of Livers for Critically Ill Candidates**
- **Affected/Proposed Policy:** Policies 3.6 (Adult Donor Liver Allocation Algorithm)
- **Liver and Intestinal Organ Transplantation Committee**
- **Description:** This proposal would offer livers to combined local and regional candidates with MELD/PELD scores of 35 or higher (“tiered regional sharing”).
- **Specific Requests for Comment:** The Committee asks the following:
  - Do you support a regional share for candidates with MELD/PELD scores of 35 or higher?
  - Do you feel that a Sharing Threshold is needed for regional distribution to of livers to patients with high MELD/PELD scores?
- **Number of Potential Candidates Affected:**

Of all candidates that were waiting for a liver during 2010, 2,032 (7.7% of total) were at some point listed with a MELD/PELD score of 35 or higher.
- **Compliance with OPTN Strategic Goals and Final Rule:**

This meets the OPTN Strategic Goal of increasing access to transplants.
- **Affected Groups:**
  - Directors of Organ Procurement
  - OPO Executive Directors
  - OPO Medical Directors
  - OPO Coordinators
  - Transplant Administrators
  - Transplant Data Coordinators
  - Transplant Physicians/Surgeons
  - PR/Public Education Staff
  - Transplant Program Directors
  - Transplant Social Workers
  - Organ Recipients
  - Organ Candidates
  - Donor Family Members
  - General Public

## Proposal for Regional Distribution of Livers for Critically Ill Candidates

**Affected/Proposed Policy:** Policies 3.6 (Adult Donor Liver Allocation Algorithm)

### Liver and Intestinal Organ Transplantation Committee

#### Summary and Goals of the Proposal:

This proposal would offer livers to combined local and regional candidates with MELD/PELD scores of 35 or higher (“tiered regional sharing”).

In a separate proposal, the Committee is seeking to extend the Share 15 Regional policy to a National Share 15. The Committee is asking for **separate comments and votes** for each proposal. However, the background, rationale, and much of the supporting evidence is common to both proposals, and is included in **Appendix A to this proposal**. Depending on public comment and subsequent Board consideration, the proposals could be incorporated into one algorithm.

#### Problem Statement:

Based on data from 2007-2010, candidates with MELD/PELD scores of 35 or higher have 33.7% risk of death at one year after listing, compared to 17.4% for those in the MELD 15-34, and 8.8% for those with MELD scores less than 15, as shown in Figure 1. Further, the average MELD/PELD score at which patients receive a transplant varies greatly, and this variability exists within and between regions (Figure 2). Waiting list death rates (computed using competing risks) are also variable within and between regions (Figure 3).

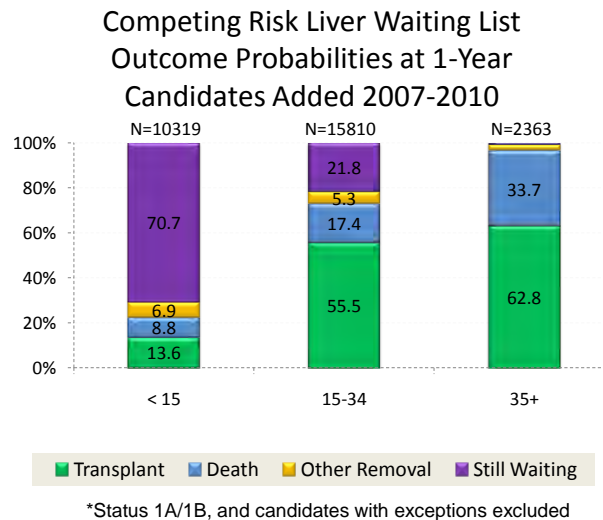
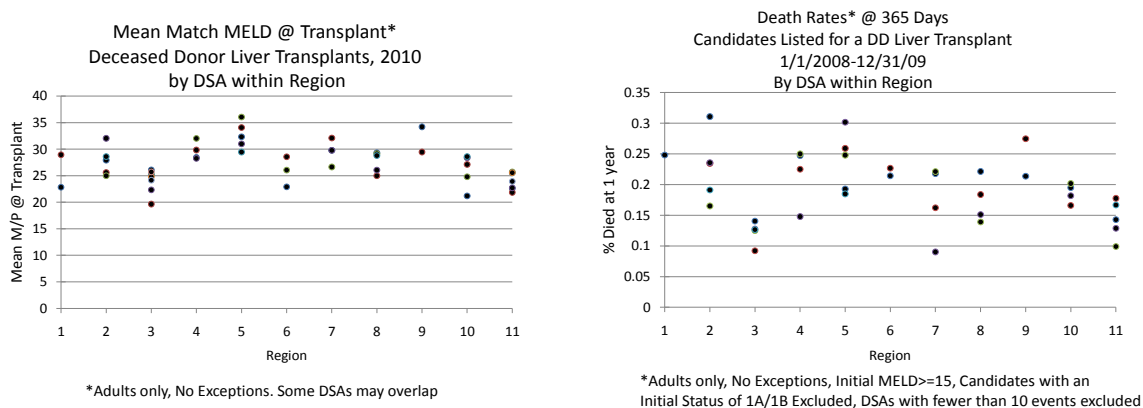


Figure 1: Source OPTN Data July 2011



Figures 2 and 3 Source: OPTN Data, July 2011

### Background and Significance of the Proposal:

Liver **allocation** has been based on the model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) scores since 2002. This system prioritizes candidates based on mortality risk while awaiting liver transplantation and has been recognized as a major improvement in the way that candidates are prioritized for a liver transplant. **Distribution** refers to how donor livers are offered to the prioritized list of candidates, and has historically been based on the location of the transplant center relative to where the organ was procured.

The OPTN Final Rule<sup>1</sup>, effective March 2000, is a set of federal regulations that amplify the legal authority for the OPTN contained in the National Organ Transplant Act of 1984 (NOTA)<sup>2</sup>. The Final Rule governs organ allocation and OPTN policy development. The Final Rule specifies the bases upon which organ allocation policies may and may not be predicated, as well as performance goals for equitable organ allocation policies. One of the performance goals in the Final Rule is to distribute “organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency.” The Board has approved several changes to the liver distribution policy since the MELD/PELD allocation system was implemented in 2002 that are in compliance with this aspect of the Final Rule. This proposal seeks to comply with the Final Rule by increasing access for patients with the most medical urgency and decreasing geographic disparity for these patients.

### History of Proposal Development:

This proposal follows nearly two years of committee discussion, evidence gathering, and collaboration with the public and transplant community as described fully in **Appendix A**. Table 1 highlights the steps taken by the Committee to ensure that the community has been included in the policy development process.

<sup>1</sup> 42 CFR Part 121, see [http://optn.transplant.hrsa.gov/policiesAndBylaws/final\\_rule.asp](http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp), hereafter referred to as the “Final Rule”

<sup>2</sup> National Organ Transplant Act (NOTA), 1984 Public Law 98-507, amended in 1988, 1990, and 2008 [http://www.unos.org/SharedContentDocuments/NOTA\\_as\\_amended\\_-\\_Jan\\_2008.pdf](http://www.unos.org/SharedContentDocuments/NOTA_as_amended_-_Jan_2008.pdf)

**Table 1**

<ul style="list-style-type: none"><li>• Request for Information (RFI) Document and Survey, distributed in December 2009<ul style="list-style-type: none"><li>➤ 87 responses received, used to develop agenda and content for Forum</li></ul></li><li>• Public Forum held in Atlanta in April 2010<ul style="list-style-type: none"><li>➤ 160 in attendance plus 70 via LiveMeeting</li></ul></li><li>• Concept Paper and Survey, distributed December 2010<ul style="list-style-type: none"><li>➤ 227 responses</li></ul></li><li>• Presentations at various transplant meetings (AASLD, ASTS Winter Symposium, ATC), in 2010 and 2011</li><li>• Updates to the OPTN/UNOS Board of Directors, 2010-2011</li><li>• Review of survey results at March 2011 Liver/Intestine committee meeting</li><li>• Review of SRTR modeling of National MELD 15 and Tiered Sharing at July 2011 Liver Committee meeting</li></ul>
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**Supporting Evidence and/or Modeling:**

**Options Modeled and Results:**

Of the 227 responses to the Concept Paper survey, **178 (78%) answered ‘Yes’ to the question: “Do you think broader sharing for patients with high waiting list mortality is reasonable?”**. Based on all the feedback received from the efforts described above, the Committee voted to pursue modeling of regional distribution for candidates with MELD/PELD scores of 35 and higher. The reason this threshold was chosen is because the waiting list mortality for patients with a MELD score of 35 or high is similar to the mortality for candidates listed in Status 1<sup>3</sup>, and there is currently regional sharing for Status 1A and 1B candidates.

The Committee also asked the SRTR to model an extension of the Share15 Regional system, which is described in a separate proposal. These two potential options were modeled separately, as well as in combination. LSAM modeling outputs reviewed included:

- Decrease in Total Deaths vs. Percent Shared;
- Decrease in Waiting List Deaths vs. Percent Shared;
- Decrease in Total Deaths vs. Median Distance;
- Death rate vs. Median Distance; and
- Percent Of Liver Transplants That Benefit from The Sharing Thresholds System Among All Transplants.

LSAM modeling demonstrated that Share35 (by itself) could reduce total deaths by 32 deaths per year, 22 of which would be waiting list deaths. The greatest decreases in total deaths (70-80 per year) resulted from the combined Share 15 National/Share 35 Regional, followed by the Share 15 National alone, and then the individual regional sharing scenarios (Figure 4). Thus, these represent incremental changes. Figure 5 displays the change in median distance organs would travel under these algorithms.

<sup>3</sup> Sharma P, Schaubel DE, Gong Qi, Guidinger MK, Merion RM. End stage liver disease (ESLD) patients with high MELD have higher wait list mortality than Status 1 patients. Am J Transplantation, 2009, Vol 9, Suppl2, p 347.

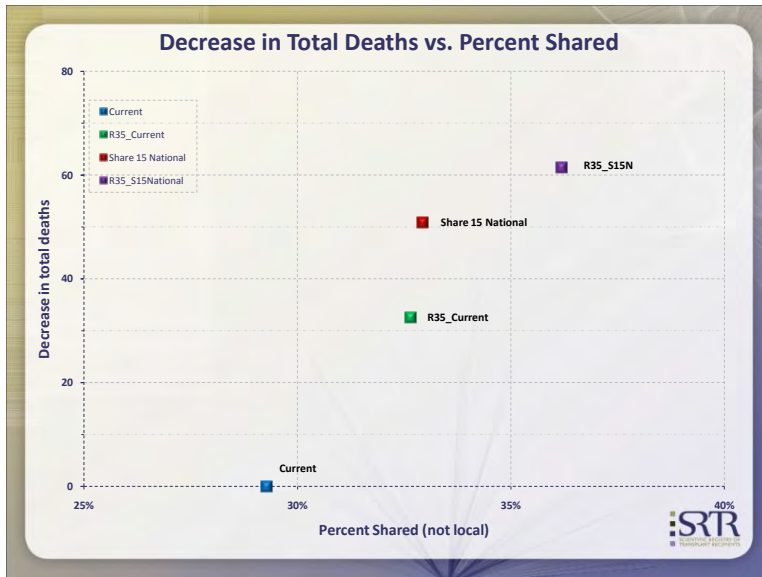


Figure 4: Source SRTR LSAM Data 2011

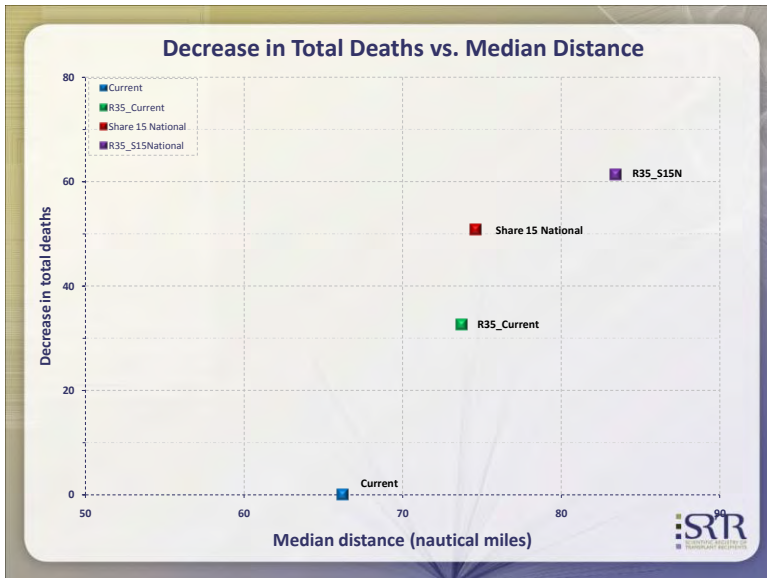
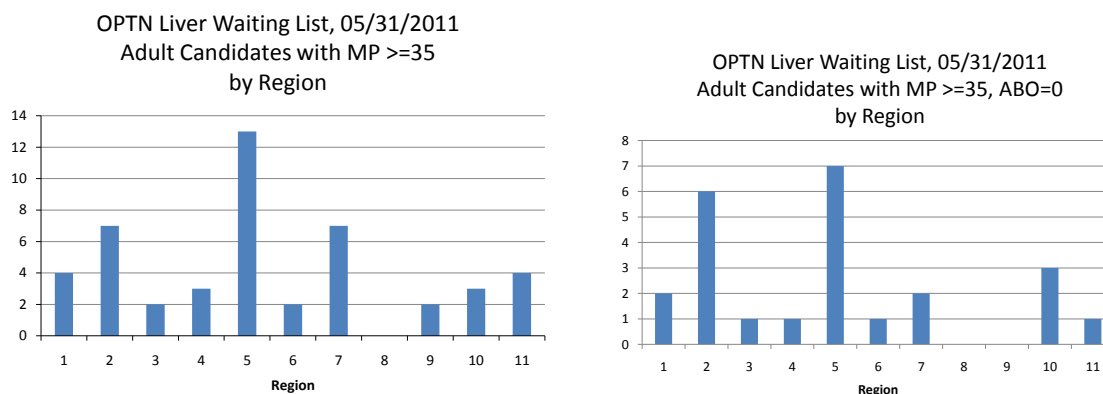


Figure 5: Source SRTR LSAM Data 2011

**Option Being Proposed: Regional Share 35:**

The Committee believes that there is strong evidence to select a MELD score threshold of 35, and that this threshold is likely to be supported by the community at this time. Committee members felt that a regional share should include standard national MELD/PELD exceptions (i.e., those specifically mentioned in the policy, such as HAT) and patients awaiting a liver-kidney transplant, but should not include non-standard MELD/PELD exceptions granted by RRBs. The transplant community is already comfortable with this level of distribution for Status 1 candidates, and, as noted earlier, the mortality risk for candidates in this MELD score range is comparable to Status 1 candidates.

The number of patients waiting and/or transplanted with MELD scores of 35 and higher is typically very small, especially when blood type compatibility is considered (Figures 6 and 7). The modeling was based on the algorithm shown in Table 2, which is a Share 35 algorithm. Within each MELD/PELD score, local candidates would receive the offer before regional candidates. Thus, if there are local and regional candidates with the same MELD/PELD score, the local candidate(s) would be offered the liver before anyone in the region with that same score. This may allay concerns about sending livers outside the local area when there is an equally urgent patient locally.



Figures 6 and 7. Source: OPTN Data as of July 2011

**Table 2**

<ol style="list-style-type: none"> <li>1. Combined Local and Regional Status 1A</li> <li>2. Combined Local and Regional Status 1B</li> <li>3. Local and Regional M/P &gt;=35</li> <li>4. Local M/P 15-34</li> <li>5. Regional M/P 15-34</li> <li>6. Local M/P &lt; 15</li> <li>7. Regional M/P &lt;15</li> <li>8. National Status 1A</li> <li>9. National Status 1B</li> <li>10. National M/P ≥ 15</li> <li>11. National M/P &lt; 15</li> </ol>		<ol style="list-style-type: none"> <li>3.1 Local M/P 40</li> <li>3.2 Regional M/P 40</li> <li>3.3 Local M/P 39</li> <li>3.4 Regional M/P 39</li> <li>3.5 Local M/P 38</li> <li>3.6 Regional M/P 38</li> <li>3.7 Local M/P 37</li> <li>3.8 Regional M/P 37</li> <li>3.9 Local M/P 36</li> <li>3.10 Regional M/P 36</li> <li>3.11 Local M/P 35</li> <li>3.12 Regional M/P 35</li> </ol>
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*MELD/PELD Exceptions*

The Committee agreed this would include patients with **standard** MELD/PELD exception scores of 35 or higher as well as those with calculated MELD/PELD scores at that level. It was recognized that some

candidates with MELD exceptions in this range are those with HAT that do not meet the Status 1A criteria but qualify for a MELD/PELD score of 40.

**Potential Concerns:**

Based on all feedback received dating to 2009, the Committee has identified several concerns that may be raised with respect to these proposals:

- Longer distance traveled, increased cold ischemia time (CIT);
- Increased length of stay/poorer post-transplant outcomes due to transplantation of sicker patients;
- Increased cost of travel and patient care;
- Impact on local donation; and
- Concerns that the proposal does not “go far enough.”

Data provided by the OPTN, SRTR, and several presentations and published papers are used to address most of these issues.

- Longer distance traveled, increased cold ischemia time (CIT). Data provided by the SRTR indicate that the median CIT does not correlate well with distance, ranging from 6 hours for very short distances (less than 5 hours) to 7 hours for livers that traveled greater than 250 miles.
- Concern for criss-crossing of livers across regions for patients with similar MELD scores. The Committee considered the concept of a “sharing threshold” (ST) that would mitigate this concern. This was fully described in the Concept Document. In summary, a “sharing threshold” could be employed such that a share is only invoked if there are one or more regional candidates with a MELD/PELD score of more than 1, 2, or 3 points higher than the sickest local candidate(s). However, LSAM modeling of this concept indicated that only 5% of all transplants would be affected by utilization of an ST. Further, the concept of an ST is not utilized in the current regional distribution of livers for candidates in Status 1A and 1B, this concern does not appear to be an issue for these patients. Figures 8 and 9 display the reduction in deaths and change in median organs traveled using sharing thresholds of 0, 1, 2, and 3. The current proposal uses a threshold of zero. However, the Committee will consider changing this threshold if public feedback indicates support.

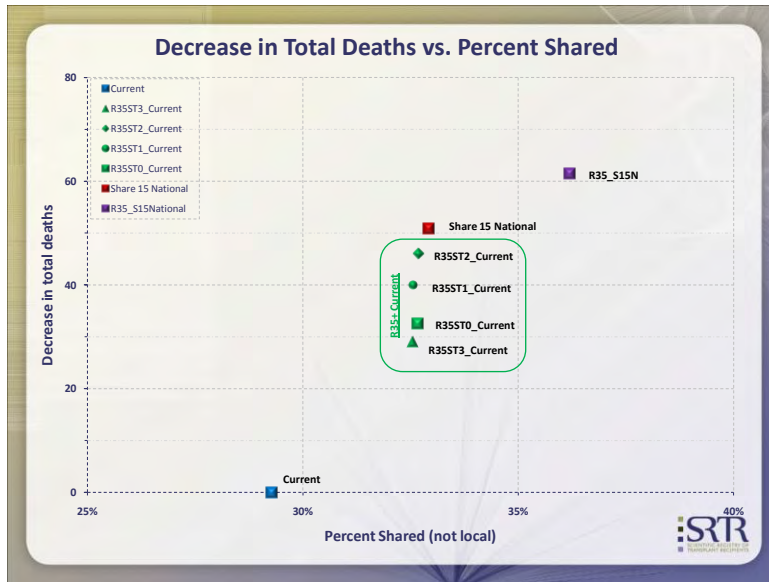


Figure 8: Source SRTR LSAM Data 2011

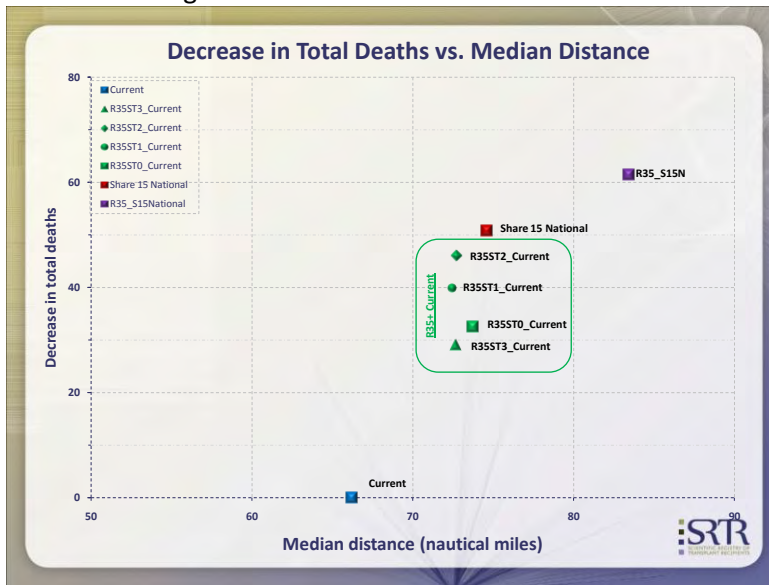


Figure 9: Source SRTR LSAM Data 2011

- Increased length of stay/poorer post-transplant outcomes due to transplantation of sicker patients. This proposal will direct organs to those most in need, so that they will be transplanted more quickly, potentially lowering the length of stay.
- Increased cost of travel and patient care. Axelrod, et al<sup>4</sup>, reported that “Simulation analysis of the reallocation of livers from low MELD patients to high MELD using a two-tiered regional sharing approach (MELD 15/25) resulted in 88 fewer deaths annually at estimated cost of \$17,056 per

<sup>4</sup> D A Axelrod; A Gheorghian; M A Schnitzler; N Dzebisashvili; P R Salvalaggio; J Tuttle-Newhall; D L Segev; S Gentry; S Hohmann; R M Merion; et al. The economic implications of broader sharing of liver allografts. Am J Transplant 2011;11(4):798-807.



*quality-adjusted life-year saved.” and that “The results suggest that broader sharing of liver allografts offers a cost-effective strategy to reduce the mortality from end stage liver disease. “While this proposal is not identical to the model proposed by Axelrod, his analysis was based upon broader distribution than this proposal. Thus, the results should be applicable, but not as dramatic.*

- Impact on local donation. Volk, et al<sup>5</sup> reported that for a probability-based national sample of US adults, *“Only 10% of participants indicated that organs should stay in the community where they are donated, whereas the remainder of participants supported sharing of organs between communities.”*
- Concerns that the proposal does not “go far enough.” It must be recognized that some of the opposition to these two proposals as presented in the Concept Document was from individuals that felt that the sharing level should be set lower than even a MELD score of 29. The Committee felt that based on past community response, a tiered regional share for MELD scores of 29 would not be feasible. This proposal represents a small incremental change to direct livers to a subset of candidates with similar waiting list mortality.

#### **Expected Impact on Living Donors or Living Donation:**

This proposal is not expected to impact living donors or live donor liver transplantation.

#### **Expected Impact on Specific Patient Populations:**

This proposal is expected to impact critically ill liver candidates, directing livers to those most in need.

#### **Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:**

This meets the OPTN Strategic Goal of increasing access to transplants, specifically for the most urgent patients. In June 2010, the Board approved the following: RESOLVED, that the Liver and Intestinal Organ Transplantation Committee shall be charged with making recommendations to reduce geographic disparities in waiting list mortality.

#### **Plan for Compliance with the Transportation, Housing and Urban Development, and Related Agencies Appropriations Act, 2010:**

The Conference Report associated with H.R. 3288 (the 2010 Transportation, Housing and Urban Development, and Related Agencies Appropriations Act) requires that the OPTN submit a report to the Committees on Appropriations of the House of Representatives and the Senate at least six months prior to implementation of any policy change affecting the distribution of livers. This report must describe the potential impact of these changes, using a list of nine metrics outlined in the report, as well as a description of all public comments received and the plan for addressing those comments. The report also stipulates that such changes must be tested first in demonstrations before nationwide implementation, and that changes should be made in “an incremental manner, reflecting the accumulation and analysis of data on the impact of policy changes.” The OPTN intends to comply with

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<sup>5</sup> Volk ML, Warren GJ, Anspach RR, Couper MP, Merion RM, Ubel PA. Foreigners traveling to the U.S. for transplantation may adversely affect organ donation: a national survey. Am J Transplant. 2010 Jun;10(6):1468-72. Epub 2010 May 10.

these requests. The committee seeks public comment regarding ways to address this in the most appropriate manner.

**Plan for Evaluating the Proposal:**

The hypothesis guiding the proposal is that greater access to organs for sicker candidates will decrease their waiting list mortality, without a demonstrable increase in mortality for other candidates, due to the small number of candidates involved. The committee will examine waiting list mortality rates pre- and post-policy implementation for adult liver candidates. Data will be reviewed every 6 months post-implementation. Data to be reviewed will include:

1. Waiting list mortality by MELD score
2. Post-transplant patient and graft survival
3. Percent shared between OPOs
4. Percent shared nationally
5. Percent of MELD exceptions scores transplanted at high MELDs (35+)

**Additional Data Collection:**

This proposal does not require additional data collection.

**Expected Implementation Plan:**

Additional programming in UNet<sup>SM</sup> will be required to modify the allocation algorithm for adult deceased donor livers. The Liver and Intestinal Organ Transplantation Committee will work with UNOS IT to implement this policy.

**Communication/Education Plan:**

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice following Board Approval	Liver candidates, transplant surgeons, transplant physicians, transplant coordinators, OPO procurement coordinators, OPO executive directors, OPO medical directors, OPO PR/public education staff, public, transplant administrators, and transplant public relations/public education staff	Blast e-mail, OPTN and UNOS websites	1 month after Board approval
System Notice upon implementation	All UNet <sup>SM</sup> Users	Blast e-mail, UNet <sup>SM</sup> notice	TBD

**Monitoring and Evaluation:**

The Department of Evaluation and Quality (DEQ) staff reviews daily all deceased donor liver match runs to determine if the organs were allocated according to the match run sequence as established by liver allocation policy and programmed into the UNet<sup>SM</sup> system. Staff examines any instance where the match run was not followed and makes a written inquiry into any allocations that do not follow the match run sequence.

**Policy or Bylaw Proposal:**

**Adult Donor Liver Allocation Algorithm**

**Combined Local and Regional**

1. Status 1A candidates in descending point order
2. Status 1B candidates in descending order.

**Local and Regional**

3. Candidates with MELD/PELD Scores  $\geq 35$  in descending order of mortality risk (MELD) scores, with Local candidates ranked above Regional candidates at each level of MELD score

**Local**

4. ~~3.~~ Candidates with MELD/PELD Scores  $\geq 15$ -34 in descending order of mortality risk scores (probability of candidate death)

**Regional**

5. ~~4.~~ Candidates with MELD/PELD Scores  $\geq 15$ -34 in descending order of mortality risk scores (probability of candidate death)

**Local**

6. ~~5.~~ Candidates with MELD/PELD Scores  $< 15$  in descending order of mortality risk scores (probability of candidate death)

**Regional**

7. ~~6.~~ Candidates with MELD/PELD Scores  $< 15$  in descending order of mortality risk scores (probability of candidate death)

**National**

8. ~~7.~~ Status 1A candidates in descending point order
9. ~~8.~~ Status 1B candidates in descending point order
10. ~~9.~~ All other candidates in descending order of mortality risk scores (probability of candidate death)

<< No further changes to this section >>