

**OPTN/UNOS Liver & Intestinal Organ Transplantation Committee
Report to the Board of Directors
December 5-6, 2016
St. Louis, Missouri**

**Ryutaro Hirose, MD, Chair
Julie Heimbach, MD, Vice Chair**

Contents

Action Items	2
1. Changes to HCC Criteria for Auto Approval	2
Committee Projects	3
2. Proposal to Establish a National Liver Review Board (NLRB)	3
3. Redesigning Liver Distribution	5
Meeting Summaries	14

OPTN/UNOS Liver & Intestinal Organ Transplantation Committee
Report to the Board of Directors
December 5-6, 2016
St. Louis, Missouri

Ryutaro Hirose, MD, Chair
Julie Heimbach, MD, Vice Chair

This report reflects the work of the OPTN/UNOS Liver & Intestinal Organ Transplantation Committee between June 2016 and November 2016.

Action Items

1. Changes to HCC Criteria for Auto Approval

The Committee's recommended policy additions and modifications to current criteria for automatic approval of hepatocellular carcinoma (HCC) exceptions was released for public comment on August 15, 2016. The public comment period closed on October 15, 2016 and the Committee discussed public comment and next steps during the full committee meeting on October 24, 2016.

The project contains three major parts, 1) Criteria for Single Small Lesions 2) Downstaging Criteria and 3) High Alpha-fetoprotein (AFP) Criteria. The Committee considered public comment feedback, including the feedback received from the OPTN regions and online. The single small lesion criteria received the most negative feedback during the regional meetings. The downstaging criteria was received well by the majority of the regions however there was some opposition to the criteria. Specifically, that the criteria was too restrictive and patients should be allowed to be eligible for an automatic HCC exception if they present outside of the proposed criteria but are successfully downstaged to within T2. The high AFP criteria was widely accepted at the regional meetings.

The Committee discussed the details surrounding the high AFP criteria. The committee compared an individual who presents with an AFP over 1000 (who wouldn't get the automatic exception) compared to the individual with an AFP of 800 for example that would qualify for an automatic exception. The Committee discussed the need for a response number following the initial presenting AFP. The proposed policy states 500 as the AFP response number, but it was suggested that as long as the individual is downstaged to below 1000 (for example 999) then they should be eligible for an automatic exception. It was also suggested that as the policy is proposed currently, a patient could present with an AFP of 400 that subsequently rose to 980, would still be eligible for an automatic exception although they may have a tumor biology that suggests bad outcomes with transplant. It was agreed by the Committee that the cut-off of 1000 in general is reasonable and a good predictor of bad outcomes.

It was suggested by the Committee that the proposed language could be changed to bring the AFP threshold from 1000 down to 500. This would decrease the number of candidates that would qualify for an automatic exception based on their AFP at the time of their request. Thresholds of 1000, 500, and 200 were all originally discussed by the subcommittee but ultimately the intent of 1000 was to set a threshold that would not be too drastic of a change and one that the community would support. The Committee further discussed the benefits and costs of different AFP thresholds. There was a motion for the proposed AFP policy to go forward to the Committee as written. The vote was 9 yes, 6 opposed, 1 abstention.

The Committee moved on to the downstaging criteria proposed. Currently, there is not standardized downstaging criteria although many regions approve exceptions for downstaged candidates. There was discussion on the merits of policy that could increase the number of HCC candidates that receive transplant, as well as discussion on the merits of using UCSF criteria compared to other established downstaging protocols. It was reinforced by the Committee that this only applies to automatic exceptions and candidates outside of this downstaging criteria will still be able to seek exception points from the review board. The Committee discussed the future need for mandatory reporting of post-transplant pathology forms to ensure accurate data related to HCC. There was a motion made to send the downstaging criteria to the board as written with the provision that the definitions of follow-up and successful downstaging. 17 Yes, 0 opposed, and 0 abstentions.

The feedback on the proposed single small lesion criteria represented the majority of regional feedback and public comment on the proposal. The Committee discussed candidates that fall within the single small lesion criteria, but experience high MELD that prevents their ability to receive treatment. It was emphasized that these candidates would not be eligible for the automatic exception but could go through HCC review board. During the discussion of the outcomes for patients that fall within the single small lesion criteria, the Committee reviewed data that showed the vast majority of these patients have evidence of HCC in their explant pathology form. This suggests that perhaps these candidates don't need reduced priority. The Committee agreed to further explore this data. The Committee discussed that ideally the single small lesion criteria would reduce priority for HCC candidates that likely would not recur following treatment, however it may be "a little early" for such a change. This comment was followed up by the suggestion that this change could take place in a small test group of centers. The merits of transplantation in this single small lesion category were further discussed with conversation on where to set the bar on when HCC candidates are provided priority. There was a motion to remove the small lesion criteria from the proposed HCC policy being sent to the Board of Directors for consideration in December 2016. 17 yes, 0 no, 0 abstentions.

The Committee voted to send the proposal to the board including the AFP and downstaging criteria, but excluding the single small lesion criteria. 17 yes, 0 no, 0 abstentions. The Committee then discussed the potential implementation plan for the proposal. The options were that 1) at time of implementation all existing HCC candidates that do not meet the new criteria would lose exception or 2) upon implementation candidates would need to meet the new criteria at their next exception extension. This is specifically related to candidates, at time of implementation, with an AFP over 1000. The Committee discussed the options and were decidedly in favor of option 2. The Committee voted that upon implementation existing HCC candidates would need to meet the new criteria at their next exception extension. 16 yes, 0 no, 0 abstentions.

RESOLVED, that changes to Policy 9.3.F (Candidates with Hepatocellular Carcinoma (HCC)), as set forth in the Liver and Intestinal Organ Transplantation Committee's Briefing Paper, are hereby approved, effective pending implementation and notice to OPTN members.

Committee Projects

2. Proposal to Establish a National Liver Review Board (NLRB)

The Proposal to Establish an NLRB is a project with multiple components, as described in Table 1 below.

Table 1: Status of NLRB Project Components

Project Component	Status
Modifying policy language to establish the NLRB	<ul style="list-style-type: none"> • Distributed for public comment in January 2016 • Likely to be distributed for a second round of public comment in January 2017
Standardizing exception points assignments for standardized exceptions in <i>Policy 9.3.C: Specific MELD/PELD Exceptions*</i>	<ul style="list-style-type: none"> • Likely to be distributed for public comment as part of the NLRB policy language in January 2017
Expanding upon the existing Guidance on MELD/PELD Exception Review to address multiple other diagnoses that commonly lead to exception requests for adult liver candidates*	<ul style="list-style-type: none"> • Distributed for public comment in August 2016 • Likely to be distributed for a second round of public comment in January 2017
Creating guidance for requesting MELD/PELD or status 1B exceptions for pediatric liver candidates*	<ul style="list-style-type: none"> • Likely to be distributed for public comment in January 2017
Creating guidance for requesting HCC exceptions for candidates with HCC that do not meet the policy qualifications for standardized exceptions*	<ul style="list-style-type: none"> • Likely to be distributed for public comment in January 2017

*Components that can be enacted even if the NLRB is not approved by the OPTN/UNOS Board of Directors

At the Committee's request, the Scientific Registry of Transplant Recipients (SRTR) performed a Liver Simulation Allocation Model (LSAM) analysis to project the impact of adopting a particular value (-1, -3, -4, -5) below the median MELD at transplant (MMA_T) in the Donation Service Area (DSA) as the exception score that must be assigned if the Review Board approves a standardized exception request under *Policy 9.3.C: Specific MELD/PELD Exceptions*. See **Exhibit A** for Data Report. The Committee sought to determine: 1) what are the proportions of exception patients who undergo transplant compared with non-exception patients who undergo transplant in these scenarios?; and 2) what is the waitlist mortality and posttransplant mortality for exception and non-exception patients in these scenarios?. The SRTR presented these data to the Liver Committee. The MELD/NLRB Subcommittee previously received this presentation.

After the presentation, the Committee provided feedback to the MELD/NLRB Subcommittee. First, the Committee discussed whether the concept of changing policy to assign exception points based on a "fixed floor" (certain value below MMA_T in the DSA) is preferable than the current "elevator" policy that permits exception points assignments to gradually increase at certain intervals. The Committee is generally supportive of adopting a fixed floor because the data show that candidates with exceptions would still have access to transplant, though the percentage of transplants for candidates with exception points would decrease while the percentage of transplants for candidates without exception points would increase. Since the Committee intends for such a shift, the Committee was supportive of continuing to explore the fixed floor concept.

Next, the Committee was asked whether the fixed floor should apply to all diagnoses, some diagnoses, or only to HCC exception candidates. The Committee agreed that the Subcommittee should consider assigning different exception points values to different diagnoses because the exception candidates have disparate waitlist mortality risks. In particular, some standardized exception candidates have a higher waitlist mortality risk than HCC exception candidates. The Subcommittee will determine whether the certain value below MMaT should only apply to HCC candidates, or whether it should apply to some other diagnoses as well. The Committee agreed that no matter the decision, the HCC “cap and delay” policies should remain in place.

Finally, the Committee discussed whether the fixed floor should apply to pediatric exception candidates. The Committee widely agreed that pediatric candidates should be exempt from the change in points assignment, because there is not a good system for predicting pre-transplant mortality currently. The Committee does not want to create a policy that inadvertently disadvantages pediatric candidates. The Subcommittee will continue to discuss the Committee’s recommendations, as well as the other components of the NRLB project, in an effort to develop a policy change and guidance documents in time for public comment in January 2017.

3. Redesigning Liver Distribution

The Committee distributed the Redesigning Liver Distribution proposal for public comment in August 2016,¹ which sought to address geographic disparities in access to liver transplantation. After public comment ended in October 2016, the Committee spent the majority of its time discussing as the history of the problem and proposed solution, the feedback received in response to public comment, potential alternative solutions, and a path forward for this project.

History of the Project

The problem of geographic disparity in access to liver transplantation has long been recognized, but the work towards a solution is often hampered by loss of institutional memory when committee members cycle through their committee terms. A complete timeline of the project is posted on the OPTN’s website.²

In 2000, the Department of Health & Human Services issued the Final Rule, which in part states that access to transplant shall not be based on a candidate’s place of residence or place of listing. By 2009, the Liver Committee explored the concept of broader sharing of livers by adopting full regional sharing for all status 1 patients. The Committee was initially concerned that such a policy may lead to worse post-transplant outcomes, but this worry did not come to fruition. The status 1 patients did well post-transplant, experienced decreased waitlist mortality rates, and increased transplant rates.

The Committee began exploring the idea of changing the boundaries for liver distribution in earnest in 2010. It distributed an RFI and held its first public forum, which resulted in consensus amongst participants that there is a problem of geographically disparate access to transplant, and that the Donation Service Area (DSA), which historically served as the first unit of allocation for most livers, was no longer an appropriate unit for the distribution of livers.

This momentum led to a policy change in 2012 (implemented in 2013), known as “Share 35,” which modified the liver allocation algorithm to offer deceased donor livers from donors 18 and older to local and regional candidates with MELD/PELD scores of 35 or higher before those livers are offered to local candidates with MELD scores less than 35. The policy also offers

¹ <https://optn.transplant.hrsa.gov/governance/public-comment/redesigning-liver-distribution/>

² <https://optn.transplant.hrsa.gov/governance/policy-initiatives/liver-timeline/>

OPTN/UNOS Liver & Intestinal Organ Transplantation Committee

livers to all candidates with MELD/PELD scores of 15 or higher locally, regionally, and nationally before offering to candidates with MELD/PELD scores less than 15.

Review of data two years post-implementation of Share 35 reveals that the policy is achieving its intended consequence of increasing access to transplant for high MELD/PELD patients while decreasing their waitlist mortality. In general, organ discard rates decreased and post-transplant outcomes improved, though these data vary by region.

However, the policy also resulted in unintended consequences related to logistical problems associated with allocation and DonorNet, such as lack of transparency, the need for more communication between OPOs and the transplant programs outside the OPO's DSA, and difficulty with late re-allocations. These are lessons the Committee has learned from and must address in future broader sharing proposals. OPOs and transplant programs are also learning to mitigate some of these problems through agreements about local back-ups. Another lesson the Committee learned from the Share 35 experience is that there are livers that fly over each other for only a few MELD points differences, which the Committee attempted to mitigate in its public comment proposal by proposing proximity points for candidates closer to the donor.

Despite these historic attempts to reduce geographic disparities, the problem persists that median MELD score at transplant by DSA is disparate, and the variance amongst DSAs continues to increase. In 2012, the OPTN/UNOS Board of Directors acknowledged that the geographic disparity in access to organ transplantation remains unacceptably high, and directed all organ-specific OPTN/UNOS committees, including the Liver Committee, to investigate alternatives to using the DSA as a unit of distribution, and to consider optimization as a method for resolving the disparity. The Liver Committee held public forums in 2014 and 2015 to engage the liver community in discussing the problem and potential solutions.

After the first forum in 2014, the Committee established a number of subcommittees to address multiple facets of the geographic disparity problem, including a subcommittee to recommend the metrics by which disparities are measured. The Subcommittee recommended that the Committee analyze solutions based on multiple **supply metrics**, including actual supply (actual liver donors), potential donors (eligible deaths), and total deaths. The Subcommittee recommended the Committee also analyze solutions based on multiple **demand metrics**, including the number of patients on the liver waiting list, and liver patients with a MELD greater than 15. The Committee did not use total burden of liver disease as a demand metric because this metric would be a significant over-estimate of demand for multiple reasons: 1) the number of patients that are good candidates for liver transplant is much smaller than the number of patients with liver disease; 2) patients that are not waitlisted (for any of the many reasons a person does not get registered on the waitlist) are not affected by liver allocation policies. The Committee acknowledges these patients exist and acknowledges their disparate access to hospitals and to Medicaid, but OPTN policy does not govern or apply to these circumstances. Similarly, OPTN policy does not govern individual hospitals' waitlist practices, so even though these practices may affect whether a candidate is added to the waitlist, OPTN policies are not designed to solve these issues.

Finally, the Subcommittee recommended that potential solutions be analyzed using multiple **disparity metrics**, with variance in median MELD at transplant as the primary disparity metric. Other disparity metrics include variance in overall mortality, and variance in transplant rates. Every proposed solution has been analyzed based on all of these disparity metrics. Notably, the original 8 district solution was designed around the demand metric of number of people on the waitlist with a MELD higher than a certain threshold, and the supply metric was the number of

livers available for transplant. The original 8 district solution was not designed around the variance in median MELD at transplant, but was developed by minimizing the difference in the number of livers a DSA should receive (ideally) and the number of livers a DSA actually receives.

Reviewing the history of the project helped provide background for the subsequent public comment discussion, as many themes that arose during public comment were concepts previously considered or addressed by the Committee.

Themes in Response to August 2016 Redesigning Liver Distribution Public Comment Proposal

The Committee received a significant amount of public comment feedback in response to the proposal to modify liver distribution by creating eight optimized districts (to replace the 11 regions), with a 150 mile proximity circle, granting candidates within the proximity circle 3 additional MELD or PELD points, and applying the district-wide sharing to anyone with a MELD or PELD of 29 or higher. In total, 1,155 commenters, including individuals, professional societies, transplant programs, and the regions, submitted substantive feedback. All comments can be reviewed on the OPTN's public comment website.³ The regional voting is reflected in Table 2 below. A summary of the responses from each of the regions is included in **Appendix A**.

Table 2: Regional Votes in Response to the Proposal to Redesign Liver Distribution

Region	Vote
1	Support
2	Oppose
3	Oppose
4	Oppose
5	Support
6	Oppose
7	Oppose
8	Oppose
9	Support
10	Oppose
11	Oppose

While it is important to consider the regional votes, it is the Committee's duty to learn more about what aspects of the proposal are supported or opposed by considering the substance of the comments submitted. The Committee therefore reviewed the following themes and responded to each:

- **Theme:** The Committee should analyze the problem using lab MELD instead of allocation MELD
- **Response:** There are differences in opinion regarding what MELD score is more reflective of the severity of illness of a transplant candidate, and there are differences in the way in which MELD scores are assigned within different regions. This issue was discussed in great detail by the Committee, and feedback during the forums was also taken into consideration. The most compelling reason the Committee selected allocation

³ <https://optn.transplant.hrsa.gov/governance/public-comment/redesigning-liver-distribution/>

MELD for use in the modeling is because this is an *allocation* policy that is being developed. Since allocation MELD is what is used for allocation, it seems logical to design the new distribution system around the realities of the current system. An additional consideration is that the liver community decided long ago that lab MELD does not fully represent all candidates' priority for transplant, and exceptions should be granted for such individuals, including those with HCC. Focusing only on lab MELD would therefore ignore the reality that there are many exception patients in this country who are transplanted because they benefit from their exception.

The Committee did consider ways to mitigate the effect of exception points in the proposed allocation, such as only exposing lab MELD patients to broader sharing. If the Committee and community support such a policy, the Committee may include this type of provision in the next iteration of the proposal. Importantly, in response to feedback regarding the regional variation in allocation MELD, the Committee is simultaneously pursuing other efforts to minimize "inflation" related to HCC exceptions: 1) modifying the criteria for qualifying for a standardized HCC exception (which was distributed for August 2016 public comment and will be presented to the Board of Directors for approval in December 2016); 2) establishing the NLRB to award exceptions in a more uniform manner nationally; and 3) modifying the way in which points are assigned for various exceptions.

- **Theme:** Disagreement with supply, demand, and disparity metrics
- **Response:** The Committee discussed the way in which the decision to use each of these metrics was made during the discussion of the history of the project, as described above.

Some believe that waitlist mortality should be analyzed as a disparity metric. The Committee discussed how waitlist mortality is a difficult metric to go with, because it does not have a direct relationship with access to transplant. For example, currently there are two different liver transplant programs in the same DSA that have widely different waitlist mortality rates, even though they have similar access to transplant as they use the same OPO. This is because waitlist mortality rates are tied closely to the composition of a program's waitlist, which is dependent upon who the program chooses to list and not to list, and the comorbidities of those people the program does list.

Despite the challenges with analyzing variance in waitlist mortality as a disparity metric, the Committee agrees that considering waitlist mortality is important. Variance in overall (pre- and post-transplant) mortality was examined for all policy scenarios, as was waitlist mortality rate, post-transplant mortality rate, waitlist deaths prevented (compared to current policy) and post-transplant deaths prevented (compared to current policy). The Committee has assessed and continues to consider the predicted impact of these policy concepts on waitlist mortality.

- **Theme:** The Committee should have analyzed a more contemporary cohort in the modeling to reflect recent policy changes
- **Response:** The cohort the models analyzed included all candidates added to the waitlist as of December 31, 2006 and candidates that were added between January 1, 2007 and December 31, 2011, as well as all donors that donated between January 1, 2007 and December 31, 2011. The reason this cohort was chosen was to allow for the analysis of

post-transplant outcomes. In order to analyze post-transplant outcomes, it is necessary to allow for post-transplant follow-up data to accrue. It is important to note that SRTR ran the simulations using Share 35 policy rules. Therefore, even though an older cohort was included in the models, within these models organs were allocated using Share 35/Share 15 allocation rules.

The Committee ultimately agreed to request modeling based on a more recent cohort, with the understanding that the analysis will not be able to include post-transplant outcomes. The Redistricting Subcommittee will continue to hone the request before officially submitting it to the SRTR.

- **Theme:** There were conflicts of interest in developing the proposal
- **Response:** The Committee determined that one way to eliminate the perception that there is a conflict of interest is to make sure that all the data used and all the modeling used are open to the public. The Committee also acknowledged it can do an even better job of communicating the status of this project to the community. Committee members are also responsible for communicating these changes to their hospitals and to their regions.

The Committee also acknowledged that to a certain degree, every member of the Committee is conflicted in the sense that each Committee member has his or her patients' well-being in mind when evaluating the solutions for this problem. To allow completely "un-conflicted" people to develop the proposal would be to completely dismiss the OPTN policy development process and place decision-making in the hands of people who are not experts in the field of transplantation. The Committee also acknowledged that another underlying problem leading to potential "conflicts" is that it benefits centers to do transplants financially, so centers that are likely to perform more transplants under the new solution are more likely to support the solution, while those that may see a decrease in transplants are more likely to oppose it. The challenge to the Committee members and the community at large is to consider the solution that is best for the country at large, as the Committee's charge is to design a national policy.

Additionally, it is important to clarify the relationship between the SRTR, HRSA, the OPTN, and UNOS. There are two HRSA contracts related to policy development and analysis: the SRTR contract and the OPTN contract. The OPTN contract is operated by UNOS, while the SRTR contract is operated by the Minneapolis Medical Research Foundation (MMRF). The SRTR provides inferential data analyses at the request of OPTN/UNOS committees, while the OPTN provides descriptive data analyses at the request of the OPTN/UNOS committees. Both contractors maintain robust conflict of interest policies and high ethical standards of scientific research and conduct.

- **Theme:** LSAM uses flawed methodology, and the Committee should use an independent model
- **Response:** The Committee also asked whether the SRTR Visiting Committee (SVC), which "advises SRTR on issues such as analytic methodologies to improve its effectiveness and support the Organ Procurement and Transplantation Network (OPTN); objectives, study designs, and statistical methods for research projects performed by

SRTR; and methods used in simulated allocation modeling”⁴ has weighed in on the LSAM and the analysis performed for the public comment proposal. Thus far the SVC has not been engaged, as the SRTR is waiting on guidance from HRSA regarding whether to engage them. In the past the SVC has validated other modeling. The Committee noted it is important for the SVC to provide input about the suitability of LSAM to evaluate the proposed changes, and the suitability of methods.

- **Theme:** This proposal may disadvantage particular populations, such as rural populations, and may disadvantage small centers.
- **Response:** This is a valid concern that people may have, as smaller or more rural transplant centers may provide access to candidates who may otherwise not have access to care. The impact on rural populations is difficult to analyze because it is difficult to define a “rural community” for the purposes of this proposal. For example, many large urban centers, though located in big cities, serve populations from hundreds of miles away that tend to be traditionally rural or agrarian communities. On the other hand, some transplant programs that are located in areas historically considered to be rural transplant patients from cities near and far. Following implementation of any policy proposal, the Committee will closely monitor changes in transplant access, and will revise policies accordingly if any negative impact is seen.
- **Theme:** Concern over predicted decline in the number of transplants
Response: It is true that the modeling indicated up to a 2 percent decrease in the number of transplants, which sounds concerning because one of the OPTN’s strategic goals is increasing the number of transplants. Importantly, data presented during the public comment period did not include modeling of the MELD 29 threshold. New data which presented to the Committee at this meeting indicates that the MELD 29 threshold policy has little estimated change in transplant rate compared to current policy.

Additionally, there is evidence that the potential decrease in transplants is a statistical artifact, and it is unlikely that there will be an actual decrease in the number of transplants. It is important to keep in mind that the model is built upon current acceptance behaviors, which assume that non-local organs are less likely to be accepted for transplant. Based on review of other past policy changes, such as Share 35, it is unlikely that there will be no change in acceptance practices with implementation of this policy change. Importantly, since Share 35 there has also been an overall increase in liver transplants. The Committee also considered that LSAM cannot predict exact numbers or changes in behavior, it is best at projecting the direction of large-scale changes, effects on large patient populations, and the direct impacts of allocation and distribution changes, and not precise and acute effects on smaller populations or more granular stratifications.

- **Theme:** Registered donors will rescind their registrations if their organs are not used locally
- **Response:** Though a number of commenters suggested they would rescind their registered donor status if their organs are not shared locally, this evidence is anecdotal. In past large-scale surveys, the results have revealed that registered donors are in favor of their organs being donated to a person most in need, regardless of where that person

⁴ <http://www.srtr.org/svc/default.aspx>

lives. Additionally, multiple different organ allocation policies share organs broadly (such as sharing for highly sensitized kidney candidates, and broader sharing for pediatric lung and heart candidates), and donor registrations and actual donations have continued to rise.

- **Theme:** Sharing more broadly is likely to lead to worse post-transplant outcomes because the livers will have more cold ischemic time
- **Response:** The Committee acknowledges this risk, especially in instances of suboptimal donors, but also notes that transplant programs are not required to accept offers of organs from farther away. Research has shown that cold ischemic time and distance are not directly correlated. Modeling also did not reveal a significant impact on post-transplant outcomes. Additionally, the inclusion of proximity circles in the 8-district solution would substantially reduce travel time compared to the 8-district solution without proximity circles.
- **Theme:** The best livers will be exported, while only marginal livers will stay local
- **Response:** The Committee agrees this is likely to be true when the candidate most in need is not local, but this is outcome is intentional.
- **Theme:** Broader sharing as proposed will impact the relationship between local transplant programs and their OPO
- **Response:** The Committee agrees this is a likely outcome, as this is a lesson learned from Share 35 as well. However, OPOs' relationships with local donor hospitals should not be affected by the proposal, and OPOs are already learning to establish relationships with transplant programs outside their DSA as a result of Share 35, and these relationships can continue to be built and fostered under the new proposal.
- **Theme:** The Committee and the OPTN should focus on increasing number of donors or improving OPO performance instead of changing allocation policy
- **Response:** In the world of transplantation, an unfortunate reality is that there are currently more people in need of transplantation than organs available for transplant. Even if every OPO increased its conversion rates for potential donors to 100 percent, disparities would persist based on varying population sizes and demographics and the way livers are currently distributed in the U.S. Multiple organizations, including UNOS, are pursuing efforts to increase the number of organ donors, the number of organs transplanted, and helping to improve OPO performance. However, with regard to liver allocation, merely increasing the number of donors and improving OPO performance will still not solve the problem: there is a disparity in a candidate's access to liver transplant depending on where that candidate lives, and this problem will remain as long as livers are allocated within the 11 region model that is currently in place.
- **Theme:** Organs will move from high to low-performing OPOs or areas of high rates of donation to areas of low rates of donation.
- **Response:** The Committee reviewed research on observational⁵ and LSAM data⁶ which indicates that there is no relationship between OPO performance (liver donor conversion

⁵http://www.srtr.org/publications/content/Gentry_Liver%20sharing%20organ%20procurement%20performance_LiverTransplant%202015.pdf

⁶ http://www.srtr.org/publications/content/Gentry_et_al-2015-Liver_Transplantation.pdf

ratio and observed to expected liver yield) and liver flow (import/export). The Committee also requested and reviewed LSAM data to examine if there was a relationship between waitlist mortality rate and liver flow, which reveal that this pattern is not predicted to occur under the proposed 8 district model.

- **Theme:** Concern about the financial impact to transplant centers and OPOs
- **Response:** Financial analyses regarding the impact of this proposal are available.⁷ Summary cost analysis using Medicare claims and University HealthSystem Consortium data indicates that an 8 district model would reduce the cost of pretransplant care, the transplant episode, and posttransplant care. Transportation costs are estimated to increase, as they would with any proposal that would share organs more broadly. This concern will not be resolved through additional analysis. How much and where costs will increase will depend in part on practice patterns. Other costs may decrease, as transplanting patients before they become too sick leads to both a pre-and post-transplant cost savings. The Committee agreed that issues related to reimbursement and Medicaid are important, but outside the scope of the OPTN to solve. Additionally, the inclusion of proximity circles and the MELD threshold are measures specifically intended to reduce the amount of organs traveling.
- **Theme:** New FAA regulations will limit charter flights.
- **Response:** This is a valid concern, but is outside of the control of the Committee or the OPTN.
- **Theme:** Allocation time will increase.
- **Response:** The Committee agrees that this is a likely outcome. This is why the Committee believes it is important to have certain efficiencies built into the allocation system before the changes to liver allocation policy can become effective. The Committee considered these ideas during the System Optimizations to Expedite Organ Allocation and Increase Utilization project discussion, described below in “Other Significant Items.”

Potential Modifications to the 8 District Proposal or Alternative Solutions

The Committee discussed potential modifications to the current proposal, as well as alternative solutions to solving the problem of geographic disparity in access to transplant.

One potential modification for the 8 district solution is to adopt a different sharing threshold, so that only a certain subset of high MELD/PELD candidates are exposed to district-wide sharing. In the public comment proposal, the Committee included a sharing threshold of MELD/PELD 29 or higher. The Committee requested modeling to determine: 1) whether 8 district sharing with a MELD/PELD threshold decreases geographic disparity in the median allocation MELD/PELD at transplant; and 2) how does the impact of geographic disparities differ between the 8 district solution with sharing for all candidates versus 8 district sharing with different MELD/PELD thresholds (35, 29, and 25). The Committee requested this modeling data at the same time as going to public comment with this concept in order to gather both additional data and public comment feedback about the idea, to have as much information as possible going forward. The

⁷http://www.srtr.org/publications/content/Gentry%20SE_Impact%20of%20redistricting%20proposals%20on%20health%20care%20expen_liver%20trans%20candidates%20and%20recip_2016%20Am%20J%20Trans.pdf

results of the modeling were available to the Committee on October 17, 2016, coinciding with the end of the public comment period. See **Exhibit B** for Data Report. The SRTR presented the results of the modeling to the Committee during this meeting. Analysis reveals that with any of the 8 district sharing solutions, including no threshold, or any of the three thresholds, variance in median MELD/PELD at transplant will decrease. No sharing threshold or a sharing threshold of 25 would decrease the variance the most, but even adopting a sharing threshold of 29 or 35 would still significantly decrease the disparity in median MELD at transplant. The Redistricting Subcommittee will continue to discuss this concept and determine whether to modify the 8 district proposal, and if so, which sharing threshold to propose.

The Committee also discussed the Neighborhoods concept, which was presented to the Committee multiple times since between August 2016 and November 2016. See **Exhibit C** for Data Report and **Exhibit D** for Neighborhoods maps. Both Neighborhoods and Redistricting are optimized solutions designed around current DSA boundaries; one of the key differences between the concepts is that redistricting uses static districts (“partitioning”) whereas neighborhoods utilize overlapping districts. The author of the Neighborhoods, Dr. Mehrotra, was present at the Committee’s in-person meeting on October 24, 2016 to answer some questions related to the concept. Dr. Mehrotra stressed that the Committee could suggest additional constraints to be built into the Neighborhoods, in the same way that redistricting was designed to meet Committee constraints. Dr. Mehrotra suggested that an advantage of the Neighborhood solution over the 8 district solution is that the Neighborhoods may be more flexible because they can be based on DSA behavior and is an OPO-centric design. The Committee discussed that such flexibility may be able to be built into any solution, as long as the Committee adopts “guard rails” to alert the Committee when distribution seems to be off-balance again.

The Committee previously seriously considered the concept of Concentric Circles, which eliminates geographic boundaries by focusing distribution in concentric circles (of radii to be determined by the Committee) around the location of the donor recovery hospital. See **Exhibit E** for Data Report. This concept closely mirrors the manner in which thoracic organs are currently distributed. The data showed the outcomes were fairly similar to 8 districts. Ultimately, the Committee opted for the 8 district solution because the districts were optimized, whereas the Concentric Circles were based around somewhat arbitrarily chosen radii.

The Committee believes it should continue exploring all three of these solutions.

Next Steps

The Committee discussed the consequence of not selecting any solution. It understands that if it does not make progress, it is very likely that HRSA or the Board of Directors will remove the decision-making power from the Committee, because the problem exists and it must be solved. During its in-person meeting, the Committee voted on a number of motions at the end of the meeting. First, the following motion was put forth: “The redistricting proposal is non-viable and the Liver & Intestinal Organ Transplantation Committee would like to examine other options.” Four Committee members voted in favor of this motion, 7 opposed it, and 2 abstained.

Next, the Committee took straw man votes on which solutions should continue to be developed. Seven members voted in favor of continuing to develop and further modify the 8 district solution. Nine members voted in favor of continuing to develop and further modify the Neighborhoods solution. Eight members voted in favor of continuing to develop and further modify the Concentric Circles solution.

OPTN/UNOS Liver & Intestinal Organ Transplantation Committee

Ultimately, the Committee voted in favor of the following motion (13 in favor, 0 opposed, 1 abstention):

1. The Committee agrees that there is a geographic disparity in liver distribution and is committed to resolving those geographic disparities
2. The 8 district redistricting proposal the way that it was written and distributed for public comment in August 2016 is not the right solution and needs modification if it were to move forward
3. The Committee is committed to exploring other solutions to solve this problem and will seek input from the liver transplant community prior to selecting one of these options for public comment

The Committee is exploring the feasibility of developing more informational materials to deliver to the community with an opportunity for the community to provide feedback to the committee on which of the three solutions is most supported by the broader community. The Committee will also provide updates at the regional meetings from January 2017 to March 2017.

Meeting Summaries

The committee held meetings on the following dates:

- June 16, 2016
- July 21, 2016
- August 18, 2016
- September 15, 2016
- October 24, 2016
- November 17, 2016

Meetings summaries for this Committee are available on the OPTN website at:
<https://optn.transplant.hrsa.gov/members/committees/>

Appendix A: Summary of Regional Responses to Proposal to Redesign Liver Distribution Region 1

The region strongly supports this proposal and applauds the efforts of the Liver and Intestine Committee in trying to design a fair and balanced allocation system in the face of glaring national disparities in access to liver transplants. The Final Rule disallows a patient's place of listing from determining his or her chances of receiving a lifesaving transplant, and the reality is that a solution to this problem is long overdue. Current regional boundaries, when employed in the allocation of livers, are arbitrary and ineffective. Heart allocation, for example, has adjusted to zonal sharing to accommodate geographic disparities in eligible donors and listed candidates, and liver allocation must follow this lead. Any impact of this proposal on small transplant centers, increased operational costs, or allocation inconveniences cannot dictate the conversation; the priority of the transplant community must focus on making organs available to the sickest patients in time to save their lives. Some members feel that the MELD 29 threshold for zone sharing is too conservative and that the committee should consider lowering the cutoff to MELD 20 or 25. Additionally, many members also indicate that lab MELD scores deserve priority over exception MELD scores. Lab scores more accurately reflect a candidate's medical urgency, and inconsistencies in exception points allowances are created when regions apply different standards in granting exceptions. There is concern that grandfathered exception patients will impact the consistency in distribution of exception scores. The region suggests that each match classification that references a MELD score be broken into two parts: lab MELD and exception MELD. As an example, match classification 3 for donors at least 18 years old would be divided to place lab MELD 29 in the donor's district in a separate classification ahead of exception MELD 29 in the donor's district. One member expressed concern that this proposal would negatively impact smaller programs, causing many to shut down. In areas where patient populations are underserved, this will work to the disadvantage of these patients and very likely result in deaths.

Region 2

The region did not support the proposal and voiced the following concerns:

- The proposal does not show a decrease in pre-transplant deaths or an increase in the number of transplants. The projection of fewer transplants may be low when you factor in late re-allocations, inefficiencies in the system, competition and centers having choice of too many livers at once.
- Logistical and financial issues have not been considered.
- The cost of charters will increase based on supply and demand. This will be even more of an issue if there is also broader sharing for hearts.
- There will be more risk to livers and liver teams having to fly
- There need to be rules in place for allocation/acceptance for both OPOs and transplant centers. There would be 38 centers in the new district with the potential to have over 6 offers going on at any given time.
- DonorNet is not an adequate tool for OPOs to allocate more broadly.
- Discards will increase without a system in place to expedite placement if something goes wrong during the allocation process (logistics).
- Geographic differences in waitlisting: Medicaid patients in Ohio and Florida are 30-50% less likely to be waitlisted than in CA, NY, and PA
- Preferential waitlisting HCC patients: 2-4 times higher (exceptions)
- The committee underestimates the relationships between OPOs and Transplant centers. OPOs are structured to react to their local centers and this drives performance and increases donors.

OPTN/UNOS Liver & Intestinal Organ Transplantation Committee

- Severity of illness at transplant is similar across regions. Candidates are just as sick everywhere but made to look worse with exceptions.

Ideas for consideration:

- The modeling should use lab MELD and not allocation MELD.
- Use current data. 2010 data for supply and demand is out dated and doesn't account for new policies (Share 35, MELD-Na, HCC Cap), or new liver programs opened in areas with high demand.
- Implement NLRB first to assess impact on standardizing exceptions
- Standardize listing practices. Published manuscripts show geographic variability in wait listing policies.
- Choose metric that focuses on post-transplant survival and/or survival benefit. System like EPTS in KI for "best" organ.
- Focus more on donation rates and unrealized donors
- Address the issues with logistics in the proposal
- Find a solution that is less costly
- Find a solution that doesn't increase ischemia times
- Share across a smaller area (38 centers and 2,273 livers is too large an area from logistics and cost perspectives)
- One member suggested piloting the system prior to nationwide implementation.
- The committee should develop policy with external consultants outside the transplant community with new, unbiased eye

Region 3

The region agrees that geographic disparity in MELD at transplant exists. The region disagrees that this is the appropriate metric. The proposal does not address the underlying problem - the need for more organ donors. It was specifically pointed out that MELD at transplant is not an appropriate surrogate for prevalence of disease, likelihood of transplant once listed, or death on the waitlist. The proposal predicts a <2% decrease in the number of liver transplants performed annually. This fact likely means that there will be an increase in pre- and post-transplant deaths. The OPTN's #1 strategic plan goal is to increase the number of transplants, and this proposal does not align with that goal. The proposal will shunt more livers from rural areas to metropolitan areas. The clear example is the increase of livers moving from the southeast to the northeast. There was much concern about this and it was pointed out that the median calculated MELD at transplant is equal between these two regions of the country. This will harm the most disadvantaged patients, including minorities and those patients with less economic means. This is a clear discrimination against patients who don't have the means to travel. The IOM recommendations include one paragraph pertaining to race. Sending livers to the northeast will create a racial disparity. It was noted that the liver programs in Mississippi and Puerto Rico were not in existence when the modeling was performed. A member from Puerto Rico commented that the distance from Puerto Rico to Maine is over 1500 miles. Puerto Rico is sending many livers to the mainland under the Share 35 policy, and this proposal will increase the flow of livers from Puerto Rico to other transplant hospitals. Liver candidates in Puerto Rico die before they receive a transplant or wait for a liver until they are so sick that outcomes are not optimal. This member suggested that PR should be carved out from any redistricting. Many small programs have a patient mix that is skewed toward government payers—Medicare and Medicaid. These programs have very small margins and the increased cost associated with the increase in imports/exports may threaten the very survival of these programs. This issue is even more pronounced with Puerto Rico. There is a profound and unequal financial barrier—livers can easily be sent out, but the Puerto Rico program can't afford to import them. The proposal to redesign liver distribution is not agile, and the committee's ability to respond to unintended

consequences of the system will not be timely. The region is very concerned about the increase in cost to implement this proposal and doesn't think the committee has adequately addressed this concern. Examples of increased cost with travel and expansion of Medicaid (in which gives a negative margin currently) will result in unintended financial burdens being placed on smaller and more rural areas. The region felt that a cost effectiveness study outlining the effect on center should be a part of such a radical change. Concern was also expressed as to the lack of an adequate understanding of the potential increased logistical difficulties, in particular for the OPO's. These difficulties could significantly contribute to the increased cost, but also to OPO staff "burn-out" further complicating the OPO's ability to provide service to donors and their families. The community is just now seeing the fallout from the Share 35 policy implementation; how can we go from Share 35 to district-wide sharing without fully understanding the results? The region is aware of the analysis performed but proposes that a more extensive analysis be done to review behavior under the Share 35 policy. Also, concern was raised regarding lack of data from the recently implemented HCC cap and delay in addition to potential implementation of the NLRB. The effect of these will be to lower the MELD discrepancy at transplant in the US. Data on these interventions are needed before proceeding with a costly redistricting plan. The current proposal is unacceptable as written, and it creates more disparity than it repairs. Alternatives to this proposal need to be seriously considered by the Liver Committee. More than one variable of disparity must be considered. Prevalence of liver disease, access to liver care and liver transplant programs, probability of transplant once listed and others were suggested. This should be analyzed with newer data, and the effects of any new system on racial/socioeconomic disparities and cost need to be adequately vetted. Adding variables to the current model will give the same results, and alternative methods must be considered to address the disparity. The region also questioned if we are making the best use of livers that are donated by transplanting the sickest patients first (i.e. are we ignoring the utility portion of the final rule?).

Region 4

Overall the region agrees that the liver distribution system needs to change. However the region opposes the proposal as written and has the following concerns:

- The development of this proposal was not completely transparent nor collaborative.
- The region wasn't aware of the MELD 29 threshold until the fall public comment cycle, nor the plan for a second round of public comment. Initially, the committee began the policy development process openly, by holding two forums and establishing ad hoc subcommittees to look at different aspects of liver distribution. Suggestions from the forums were not taken seriously, and the process afterwards has not been transparent.
- The proposal predicts a <2% decrease in the number of liver transplants performed annually. The OPTN's #1 strategic plan goal is to increase the number of transplants, and this proposal does not align with that goal.
- The proposed districts are too large and will logistically be a challenge and very costly to distribute livers. For example, the distance from Dallas to Florida is 1600 miles. In addition, due to new FAA regulations, there are not enough aircraft or pilots to handle the travel. Costs won't be reimbursed and this proposal will dramatically increase costs.
- DSA performance needs to be addressed before such a proposal is ready for primetime. There should be a hard goal requirement in the model. It was suggested that OPOs that have high donation rates share best practices with areas that do not. There are OPOs that do this well.
- Another component missing from this model is transplant center acceptance rates.

- Current mathematical MELD and allocation MELD needs to be updated first. Allocation MELD does not represent the risk of dying on the waiting list. This is demonstrated by the disparity of mortality on the east and west coast compared to the southeast.

The region agrees change needs to occur, but is the proposal the best way to provide access for patients? The committee needs to identify the endpoints and base the distribution on them. The region also agrees that the liver committee needs to work with the community expeditiously to come to consensus, or HRSA will get involved and the transplant community will not have a choice in the outcome.

Region 5

The region recognizes that a change to the current liver sharing system is long overdue, and a majority feels that this proposal represents a step in the right direction in addressing the disparity of MELD at transplant. However, a number of concerns were raised regarding the effectiveness of the proposal and the modeling utilized to arrive at the suggested district boundaries. While the impact of this proposal appears to balance MELD at transplant across the country, it does not effectively address the problem faced by areas that are currently struggling to transplant their patients, namely California. These areas, whose patients are dying in large numbers waiting for transplants, need more help than is offered by the proposed allocation system. From the time that the liver disparity was recognized and a solution was mandated, the transplant community has taken far too long to arrive at the Redesigning Liver Distribution proposal. The region is concerned that, were this proposal to take effect, it would take the community another extraneous period of time to shift toward an evolved system that more effectively decreases the heights of liver waitlist mortality in California and other areas. This issue should be more adequately resolved in the first change to the allocation system, whatever it may be. Furthermore, the community must be faster to make changes. A potential unintended consequence of this proposal is that it will disadvantage underserved patients at smaller centers (and within smaller DSAs). 40 MELD patients at such centers will be pre-empted by patients from large centers that are currently outside of the higher classifications. While the region acknowledges the importance of basing the model on older data to allow for five year outcome figures, there remains concern that the model cannot be perfectly valid when it relies on severely outdated data.

Additionally, a number of questions were raised about the proposal's model: - The proposal indicates a number of constraints for the modeling. While these constraints seem legitimate, has the committee questioned them? - Does this model take into account patient migration to other centers? - The current model is based on national data. How granular can these models get? What might be the specific implications – in terms of cost and transplant numbers – for particular centers? - Can we predict how center behavior, specific to organ acceptance, change and effect sharing within whatever districts are ultimately approved? The region is curious to learn, in detail, about other sharing alternatives that have been explored by the Liver and Intestine Committee. Specifically, there is interest in the “neighborhoods” proposal and whether it alleviates the liver shortage in California. It is understood that the Committee is currently seeking input on this specific proposal, but the community would be better equipped to evaluate it with more clarity of what other options exist. One member of the region suggests, for comparison's sake, putting multiple (two or three) options on the table at once for public comment.

Region 6

Although Region 6 did not support the proposal as put forth, the members in the region acknowledge the realities of discrepant median MELD scores depending on where patients are listed for liver transplantation. While understanding this discrepancy, it was not clear to

the members of Region 6 that the geographic discrepancy in median MELD at transplant truly reflects geographic disparities in donor liver allocation, nor that the proposed policy would be effective in equalizing such disparities. Specific points of feedback:

- The process itself has become divisive; as this process proceeds, the region advocates putting the highest emphasis on building consensus at every step prior to putting forth proposals
- Whether real or not, a perception has arisen that this proposal has been written and promoted by centers/regions standing to benefit financially from this proposal; going forward the region suggests that every effort is made to avoid this reality or even perception
- It is not clear that median MELD at transplant is the best metric to measure equity in donor liver allocation; the region suggests the Committee examine other metrics and have the regions come to consensus as we craft changes in the future. Suggestions for other metrics include:
 - Numbers of patients dying from liver disease in different geographic localities (demand)
 - Numbers of eligible donors converted to actual donors in different localities (supply)
- Moving livers out of one geographic community to another may diminish community involvement with the donation effort; incentives should be considered to encourage donation that increases community involvement and responsibility for organ donation
- The current proposal would move donor livers away from 5/6 Veterans Administration Hospitals (the VA centers in Texas, Oregon, Virginia, Tennessee and Wisconsin would see a decrease in liver transplants, while the VA center in Pennsylvania would see an increase); going forward we advocate that this special group of Americans be considered in the organ allocation equity equation
- The current proposal does not consider any analysis of changes in policy implemented since the model was developed, namely Share 35 and HCC.
- The current proposal does not provide adequate detail about the logistics and cost of broader sharing.
- Patient/recipient groups need more directed education about the proposal and opportunities for input.

Region 7

There was overarching concern that the proposal is based on flawed methodology, outdated models and does not use current information. The committee needs to focus on these elements. The region is also concerned that the current model predicts fewer transplants. The region commented that any model should include results from implementation of Share 35 and HCC cap and delay. The proposal ignores inefficiency, utility and dropout rates. Broader sharing will increase discards, cost and CIT. OPOs are concerned about logistics as well as longer allocation and recovery times. The committee needs to address late declines in any proposal. The committee needs to ensure that private insurers are on board with any proposal that moves forward. There was some support for implementing NLRB and HCC proposals and analyze results before moving forward with redistribution. There should be an external review of any model presented.

Region 8

The region did not support the proposal and had several comments and concerns. Members commented that the drivers of the discrepancy in MELD at transplant are exception points and poor OPO performance. The level of broader sharing in the proposal would create a disconnect between transplant centers and their OPOs. Relationships between OPOs and

transplant centers drive performance. The benefactors of this proposal are areas with low DSA performance. The committee should consider addressing the problems in these specific areas. There is also an issue with logistics given the large number of liver programs in some of the districts. One of the districts has 38 liver programs. The committee needs to address the problems with cost and logistics before moving forward with a proposal. Until the committee solves the problem with acceptance of multiple offers for a single candidate and late declines, allocation will be significantly delayed. The region was also concerned that the model predicted a decrease in the number of transplants and thought that any proposal that may result in a decrease in transplants requires more work. Some members commented that the assumptions made on the slides had been disputed in other forums, yet the committee continues to make the same assumptions in their presentation. Other models show zero net benefit from the proposed redistricting. The supporting data for the thresholds should have been included in the proposal. Members need the data to assess the proposal. The committee should have all the supporting data prior to sending a proposal out for public comment. There was some support for implementing NLRB and HCC first to determine if making the exceptions more equal across regions would resolve the perceived problem with access. Another issue raised surrounded cost and this was about OPO cost reports. Since all livers will go through the cost report, and are charged overhead by both the exporting OPO and the importing OPO, the cost of each liver could double or triple. This cost will be passed on to the centers. This will affect the transplant programs disproportionately but the model will not change. Even if there is a cost savings for patient care pre and post-transplant, these savings will not be seen by the transplant center. The cost will all be borne by the transplant centers.

Region 9

The region unanimously supports the proposal, and appreciates the efforts of the Liver and Intestine Committee to achieve equity in median MELD at transplant across the country. Achieving broad consensus on such a contentious topic will not be possible. A compromise is necessary, and the region thinks the current proposal is just that – a compromise. While not a perfect solution, it is progress and moving in the right direction to ultimately achieve the goal of minimizing the variance in median MELD at transplant. The status quo is unacceptable, and the transplant community needs to be part of the solution, otherwise HRSA may need to address the liver community's inability to address this important issue. Region 9 has shared livers among the four DSAs in the region for >25 years at all MELD scores. Through region-wide sharing, the region is familiar with increased flying, costs, and logistics associated with broader sharing. Organ donation is up in New York and the OPOs continue to work to increase donation with specific efforts focused towards improving the NYS registry. Aligning OPOs with other OPOs outside each region will promote a strong working relationship to increase organ donation, together. The current proposal is the culmination of years of work and is a strong attempt to address the variation in transplant candidates' ability to receive a life-saving transplant. Efforts to derail the policy development process and stall progress is unacceptable. Questioning the data (which has been used for every decision by UNOS including implementation of the MELD system and changes to the kidney allocation system), the simulation model (which has been utilized for >10 years), and the metrics themselves at this juncture is insulting to the efforts to transform what essentially all acknowledge are arbitrary regional boundaries. The argument that Region 9's MELD scores are super inflated by exceptions held no water – as further SRTR analyses demonstrate that the variations in MELD are worse without the exceptions. With the implementation of the kidney allocation system in December 2014, more kidneys are being shared outside of the local donation service area, and OPOs are experienced with shipping kidneys and the logistics and costs associated with this broader sharing. It was not so long

ago that both kidneys were allocated to the transplant hospital where they were procured, and some year's later one kidney was sent out and the other stayed at the transplant center. Today we recognize that kidneys are a shared resource, and are allocated where they are need within a region. Organs are a national resource, and it's time the transplant community begins to think of livers the same way. The region has worked to embrace efforts towards equity and there is a growing sentiment that other areas of the country don't want any change at all. Geographic disparity has been an issue for too long, and it's time for a resolution to this problem.

Region 10

While the region agrees that the liver allocation system needs to change to achieve equity in median MELD at transplant across the country, the proposed solution is not the answer. The region would like the model to include additional metrics including wait list mortality, allocation MELD for non exception patients, and possibly age. Donor risk should be considered in the model which may also account for lower MELD scores at transplant. A new model should give more weight to candidates in the DSA from where the donor originated to continue to incentivize the relationship between local OPOs and transplant hospitals and further efforts to increase organ donation locally. As proposed, the proposal has the potential to lessen the cooperation between transplant centers and the local OPO to increase donation. The proposal predicts a <2% decrease in the number of liver transplants performed annually. The OPTN's #1 strategic plan goal is to increase the number of transplants, and this proposal does not align with that goal. Data from 2010 is not an appropriate measure to redesign liver distribution. The model does not include share 35 data, recent HCC policy changes, or MELD Na data. The median MELD at transplant used in the model is misrepresentative as lower than what occurs clinically. Region 10 has the lowest exception at time of OLT, and as an importer livers are being transplanted into lower MELD candidates. The region accepts livers from areas that are recognized to have a disparity (regions 4 and 7). The lack of data for the proposed MELD threshold of 29 for district-wide sharing and the proximity points assigned to candidates within the 150-mile radius of the donor hospital makes the proposal incomplete. The data needs to be presented before the public comment period is complete. The model has not been substantiated and verified by a third party as many members have requested, and other proposals to redesign liver distribution have not been given fair consideration. The region is very concerned about the increased cost to OPOs and doesn't think the committee has adequately addressed this concern. OPO's time to complete a donor case will also increase. The region thinks it is unclear in the proposal the effect on candidates waiting for a kidney-pancreas transplant and pediatric candidates.

Region 11

Region 11 acknowledges a disparity in MELD at transplant among certain regions of the country, but it unequivocally rejects that the Redesigning Liver Distribution proposal is the appropriate means to address this problem. It is suggested that this proposal is driven by the deficiencies of two specific areas – California and New York. It is unconscionable to support a solution that poses a negative impact on roughly half of the country's transplant regions (4-5 regions) in order to solve a problem that is experienced primarily in a couple of states. Additionally, the proposal projects that the end result will not have improved the median MELD at transplant scores in the areas currently with the biggest deficiency. Any proposal that cannot solve the biggest bull's-eye – California – is seriously flawed. The region believes that this proposal violates a significant principle in The Final Rule which requires the protection of organ access to the underserved. This proposal contradicts this mandate by shifting the allocation of organs from poorer, rural areas of the southeast to

metropolitan northeastern populations which are better served with healthcare options. This shift will severely limit access to care for the poorer demographic in the southeast, which is especially concerning given that these regions currently have comparable calculated median MELD at transplant. The region emphasizes that this proposal is projected to cause a decrease – potentially significantly – in the number of liver transplants performed. This effect is in contradiction with the current primary focus of the OPTN – to increase the number of transplants. The cost impact cannot be understated, and it has not been sufficiently addressed by the committee; the increase in livers flown will be considerable, and major expenditures will accompany this. The cost will be borne by patients and the community. The region suggests that the data behind the claim that 50% of livers will be transplanted within a 150 mile radius of the recovery hospital is based on pre-Share 35 data and is not indicative of current practice. Further, there are other implications to the increased travel: charter planes and pilots have become harder to book because of new FAA regulations limiting pilot hours from 14 hours to 12 hours. On-call time now counts toward these hours, further limiting availability. Crucial challenges reserving charter flights are anticipated. An additional consideration for the increased travel is that charter planes are statistically far less safe than commercial planes, and the hazard posed to recovery teams will be exponentially greater. It is believed that while the 150 mile radius points should theoretically help with the transportation burden, the reality is that the statistic of 50% of livers remaining within the radius is not uniform nationwide. LifePoint (SCOP), for example, has a large number of recovery hospitals in South Carolina that are outside the 150 miles radius from their own as well as neighboring liver transplant centers, meaning that very few livers will stay within their DSA. Therefore, they feel it is likely that they will be sending closer to 75-80% of livers outside of this radius. Allocation will be far more challenging for OPOs, as they'll be frequently offering to centers whose practices are unknown to them. The eastern seaboard consists of 38 liver programs and the OPOs within district 1 will be offering to all of these centers, many of whom will have candidates entertaining multiple offers at once. ORs will be consistently bumped due to late declines, and additional OPO coordinator staff may be required to mitigate the inevitable added hours of donor management while awaiting final liver allocation. This is another component to added costs. The region has been disappointed that data repeatedly requested of the SRTR has not been furnished. DSA-specific data would be helpful to further evaluate the proposal but has thus far been unavailable, and while it is well understood that 2011 data was chosen for 5 year outcomes availability, it is unable to inform on what the current MELD at transplant looks like across the country. It is suggested that this figure is now much higher in region 11. The region is also concerned that this proposal will not curtail multi-listing habits but instead prompt candidates who have the means to list at multiple centers within a district to maximize their standing within multiple 150 mile radiuses. This, again, will serve to disenfranchise the underprivileged populations who cannot afford to travel or list at multiple centers. The region indicates that their support of any proposal seeking to address disparity in MELD at transplant will require more than a tweak or two to the current incarnation; the committee would be advised to look at different metrics. The region feels that this proposal presents a moral hazard and that OPO underperformance in areas struggling with high MELD at transplant should be addressed, along with measures to increase organ donation in general.