



September 19, 2016

Public Comment Coordinator  
United Network for Organ Sharing  
700 North 4th Street  
Richmond, VA 23218

**Re: CODE Comment on OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Public Comment Proposal Redesigning Liver Distribution**

The Coalition for Organ Distribution Equity (CODE) appreciates the opportunity to comment on the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee’s (Committee) proposal for public comment: Redesigning Liver Distribution. We applaud the Committee’s hard work to address the difficult problem of equitable distribution for the current supply of livers for transplant in the U.S.

The policy encompassed within the proposal will bring tremendous benefit to the thousands of patients who suffer due to the current inequitable distribution scheme. As an organization dedicated to equity in liver distribution, CODE supports the policy as written, encourages its expeditious finalization, and looks forward working with the Committee toward successful implementation.

**I. The Proposed Policy Addresses Long Standing Gaps in Federal Distribution Policy**

The proposed policy addresses a longstanding injustice faced by liver transplant candidates in the U.S. The widely different levels of illness at transplant, varied based on a patient’s location, are unfair to candidates who must wait to become critically ill before they can receive a transplant. This unfairness has been well documented and is well understood by the Committee. The Committee’s has undertaken a thorough, exhaustive, and transparent process for developing this policy, and CODE believes that the Committee’s hard work will pay off and bring equity to those who suffer at the hands of the current system.

Federal law and implementing regulation have long required allocation policies based on need. The Department of Health and Human (HHS) in 2000 implemented the Final Rule, which requires, among other things, that allocation policies “[s]hall not be based on the candidate’s place of residence or place of listing.”<sup>1</sup> The final rule is based on 1999 Institute of Medicine (IOM) recommendations that allocation areas be big enough for medically effective distribution of organs.<sup>2</sup> Despite explicit requirement under the Final Rule for fair allocation policies that are not based on place of residence, and ongoing attention paid to the issue over the years since its finalization, geographic disparity in liver distribution continues. Under the current system, prioritization of liver allocation at the local donation service area (DSA) level has been repeatedly demonstrated to lead to suboptimal results for candidates in areas where there is low supply.

In 2010, the HHS Advisory Committee on Transplantation (ACOT) formally recognized the issue of organ distribution inequity when it unanimously approved a recommendation that HHS ensure that OPTN “develops evidence-based allocation policies which are not determined by arbitrary administrative

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<sup>1</sup> 42 CFR 121.8.

<sup>2</sup> Institute of Medicine. Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule. Washington, DC: The National Academies Press, 1999.



boundaries.”<sup>3</sup> After the 2010 ACOT recommendation, the OPTN/UNOS Board of Directors in June of 2012 adopted an OPTN Strategic Plan that included reducing geographic disparities in access to transplantation as one of its objectives.<sup>4</sup>

Later that year, in November of 2012, the OPTN/UNOS Board resolved that “existing geographic disparity in allocation of organs for transplant is unacceptably high.”<sup>5</sup> As a result, the Board directed the Liver and Intestinal Committee to come up with a way to measure the disparity and identify constraints for the current system.<sup>6</sup> The Liver Committee investigated a variety of ways to measure geographic disparity and identified variance in median Model for End Stage Liver Disease (MELD) score at transplant across DSAs as the key disparity metric because MELD score is generally an accurate reflection of the severity of a candidate’s illness.<sup>7</sup>

Beyond recognition of a disparity metric, the Committee in 2013, working with the OPTN/UNOS Policy Oversight Committee (POC) enumerated a series of principals to address geographic disparity in candidate access to transplants. Among the principals agreed upon were that distribution should begin at a regional level, individual organ-specific committees should be able to revise distribution policies, and measures of utility and efficiency should be considered in any system change.

The Committee’s proposal has stayed true to its own research and modeling, the general principals recommended by the POC, the Board’s findings, and requirements established by Federal law. The proposal reflects the Committee’s findings, based on exhaustive research and upon consideration of a variety of alternatives, that “[s]tatistical modeling strongly suggests that using fewer geographical allocation districts would likely result in reduced waitlist deaths and a reduced variation in the MELD or PELD scores at transplant.”<sup>8</sup> Specifically, in responding to repeated calls for distribution reform and explicit federal policy requiring as much, the Committee predicted that the level of disparity “would be markedly reduced” under an eight district policy.<sup>9</sup>

## **II. The Ongoing Disparity in Liver Distribution is Well Documented and the Personal Costs of Leaving Liver Distribution Reform Outstanding Have Been High**

Contrary to clear federal policy objectives, patients in certain places have had to wait to get very sick or in some cases die before they could get a transplant, while candidates in other areas are able to obtain transplant when they are much less sick.<sup>10</sup> As noted above, pursuant to the OPTN Board’s charge to establish a disparity metric, the Committee decided upon variance in MELD score at the time of transplant. In our current system, across DSAs, research has established that the variation in MELD score at transplant

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<sup>3</sup> Advisory Committee on Organ Transplantation Recommendation 51 Available at: <http://www.organdonor.gov/legislation/acotrecs51.html>.

<sup>4</sup>OPTN Strategic Plan Available via: [http://optn.transplant.hrsa.gov/ContentDocuments/OPTN\\_Strategic\\_Plan.pdf](http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Strategic_Plan.pdf).

<sup>5</sup> Executive Summary of the Minutes of the OPTN/UNOS Board of Directors Meeting, November 12-13, 2012. Available at [https://optn.transplant.hrsa.gov/media/1801/executivesummary\\_1112.pdf](https://optn.transplant.hrsa.gov/media/1801/executivesummary_1112.pdf). Last accessed August 29, 2016.

<sup>6</sup> Id.

<sup>7</sup> Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation A Concept Paper from the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (June, 2014), p. 9. Available at: [https://optn.transplant.hrsa.gov/media/1269/liver\\_concepts\\_2014.pdf](https://optn.transplant.hrsa.gov/media/1269/liver_concepts_2014.pdf)

<sup>8</sup> Id.

<sup>9</sup> Id.

<sup>10</sup> Massie AB, Caffo B, Gentry SE, et al. MELD exceptions and rates of waiting list outcomes. *Am J Transplant* 2011; 11(11): 2362–2371.



can be as high as 10 points.<sup>11</sup> More recent OPTN data has found regional disparity to be as high as a 12-point difference in median MELD at transplant. The policy put forth by the Committee’s proposal directly addresses this extreme difference in the sickness of candidates at the time of transplant by reducing the current local and regional variation in MELD at transplant.

Further, under the current local distribution system, research indicates that there is wide disparity in a candidate’s chances of receiving a liver.<sup>12</sup> For example, one study found that for patients who were equally sick, 90-day transplant rates ranged from 18% to 86% across DSAs.<sup>13</sup> That study also highlighted that among candidates with MELD scores between 21 and 34, the probability of transplant within 90 days for candidates with the same score varied widely across OPOs, ranging from under 30% to over 90%.<sup>14</sup>

Additional evidence of the ongoing disparity can be seen through the higher overall death rates in places where patients have to wait longer to receive a life-saving transplant.<sup>15</sup> For patients with very high MELD scores, findings indicate a 90-day probability of waitlist death, ranging widely from 14% in some DSAs to 82% in others.<sup>16</sup> Patients who have to wait longer to receive a transplant also have a higher chance of dying after the procedure, as pre-transplant MELD score have been demonstrated to correlate inversely with post-transplant survival.<sup>17</sup> The staggering statistics demonstrate that the costs of waiting for candidates in some areas have indeed been high, lowering their chances of survival both before and after transplant.

Every candidate for a life-saving liver transplant should have an equal shot at getting one. Federal policy intends that livers for transplant from deceased donors be allocated evenly across the entire nation based on need. Despite this noble purpose, evidence clearly demonstrates that critical gaps in our current distribution policy hinders realization of these goals. As the well-documented disparities in liver distribution linger, our shared values of equality in access to organ transplant cannot be achieved, and patients in some places must continue to wait a long time, get too sick, or die before they can receive a transplant.

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<sup>11</sup> Yeh H, Smoot E, Schoenfeld DA, Markmann JF. Geographic inequity in access to livers for transplantation. *Transplantation*. 2011; 91(4):479–486.

<sup>12</sup> Koizumi N, Ganesan R, Gentili M, et al. Redesigning Organ Allocation Boundaries for Liver Transplantation in the United States. *Proceedings of the International Conference on Health Care Systems Engineering / Andrea Matta, Jingshan Li, Evren Sahin, Ettore Lanzarone, John Fowler, editors International Conference on Health Care Systems Engineering (2013 : Milan, . 2014;61:15-27. doi:10.1007/978-3-319-01848-5\_2.*

<sup>13</sup> Massie AB, Caffo B, Gentry SE, et al. MELD exceptions and rates of waiting list outcomes. *Am J Transplant* 2011; 11(11): 2362–2371.

<sup>14</sup> Massie AB, Caffo B, Gentry SE, et al. MELD exceptions and rates of waiting list outcomes. *Am J Transplant* 2011; 11(11): 2362–2371.

<sup>15</sup> Yeh H, Smoot E, Schoenfeld DA, Markmann JF. Geographic inequity in access to livers for transplantation. *Transplantation*. 2011; 91(4):479–486.

<sup>16</sup> Massie AB, Caffo B, Gentry SE, Hall EC, Axelrod DA, Lentine KL, et al. MELD Exceptions and Rates of Waiting List Outcomes. *Am J Transplant*. 2011; 11(11):2362–2371.

<sup>17</sup> Habib, S., Berk, B., Chang, C.-C. H., Demetris, A. J., Fontes, P., Dvorchik, I., Eghtesad, B., Marcos, A. and Shakil, A. O. (2006), MELD and prediction of post–liver transplantation survival. *Liver Transpl*, 12: 440–447. doi:10.1002/lt.20721.



### **III. The Proposal Put Forth by the Committee Reduces the Ongoing Disparity and Confers Life-Saving an Economic Benefit to Our Healthcare System**

The proposal submitted by the Committee for public comment would establish eight liver distribution districts nationwide. A change from current policy where the allocation sequence prioritizes distribution the local DSA level, the proposal would prioritize distribution at a district-wide level to the sickest candidates before local matching for less sick candidates. In addition, the proposal would implement a system whereby candidates listed at hospitals within 150 miles of the donor's location would receive three additional allocation points to their MELD score. The proposal would not change the current method of determining a candidate's level of sickness (as measured by MELD score).

The eight district solution proposal put forth by the Committee addresses the ongoing and well documented disparity in liver distribution under our current system. The proposal for an eight district model is projected to cut the current variation in illness at transplant in half.<sup>18</sup> While the proposal does not eliminate geographic variation in illness across candidates entirely, CODE cannot underscore enough the significance of this reform. If adopted, under the Committee's proposal, patients who formerly had to wait to become sicker and sicker before receiving a life-saving transplant will be able to receive one at an earlier stage. The earlier receipt of a transplant not only reduces these candidate's chance of death both before and after transplant, but also reduces the significant emotional burden of waiting, including the terrible uncertainty as to when or even if a candidate will receive an organ.

Under the Committee's proposal, variation in a candidate's chances of getting a transplant is reduced. The proposed eight district redistricting scenario with 150-mile proximity circles is projected to have the greatest effect on decreasing the variance in transplant rates out of all the scenarios considered by the Committee. Notably, despite the projected re-allocation of livers under the redistricting proposal, overall pre- and post-transplant deaths are not predicted to increase over the current system.

This proposal is focused on organ distribution equity, and without a doubt, these reforms would move policy in this direction. The proposal, however, has additional ancillary benefits beyond distribution equity. The proposal put forward by the Committee has the potential to save hundreds of lives.<sup>19</sup> Modeling conducted by the Committee has demonstrated that an eight district redistricting policy could save as many as 332 lives over the next 5 years.

In addition, the proposal put forward by the Committee has the potential to produce savings for our healthcare system.<sup>20</sup> The Committee should be commended for the real benefits its policy will confer on patients and the healthcare system at large. While any proposal to use larger regions will increase transportation costs due to the time, distance, and frequency of travel, this proposal is anticipated to decrease the cost of pre-transplant care. Under the proposal, total costs are expected to be reduced, as costs associated with pre-transplant care are anticipated to decrease more than the projected cost increase. Furthermore, any increase in transportation cost is addressed by the portion of the proposal that gives additional points to

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<sup>18</sup> Schladtadt D., J. Pyke, C. Bolch, et al. "Scientific Registry of Transplant Recipients analysis report in response to a data request from the OPTN Liver and Intestinal Organ Transplantation Committee regarding ongoing policy considerations." April 20, 2016.

<sup>19</sup> Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation A Concept Paper from the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (June, 2014). [https://optn.transplant.hrsa.gov/media/1269/liver\\_concepts\\_2014.pdf](https://optn.transplant.hrsa.gov/media/1269/liver_concepts_2014.pdf)

<sup>20</sup> OPTN/UNOS Public Comment Proposal: Redesigning Liver Distribution (August, 2016). Available at: [https://optn.transplant.hrsa.gov/media/1913/liver\\_redesigning\\_liver\\_distribution\\_20160815.pdf](https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf)



patients that are within 150 miles of the hospital where the organ is listed, making it more likely that the organ will be allocated to a patient who is nearby to the hospital.

#### **IV. Minor Issues Raised by the Proposal do not Outweigh the Need for Liver Distribution Reform**

Modeling conducted under the proposal projects a two percent reduction in transplants overall. CODE notes the life-saving importance of every transplant operation. However, we believe strongly that the two percent reduction modeled by the proposal will be offset by behavioral changes and logistical improvements. For example, the Committee highlights that predictive modeling relied upon, while able to project the direction of large-scale changes, is unable to account for behavioral changes, especially acceptance behavior.<sup>21</sup>

As the Committee notes in the proposal, the current acceptance model “assumes that a transplant program is more likely to turn down livers that are shared outside of the recovering DSA or would need to travel for a long time to reach the transplant center.” The Committee suggests that current practice, where organs shared beyond the local DSA are often rejected, may be less likely under broader sharing.<sup>22</sup> Bolstering this assertion, when a policy was implemented to introduce regional sharing for candidates with MELD scores of 15 or higher, there was an observed acceptance by some centers for organs that were not previously accepted.<sup>23</sup> In addition, while concerns were raised under previous initiatives to introduce broader sharing would increase travel distance and cold ischemia time (CIT), ongoing evaluation of these concerns have not demonstrated such an increase.<sup>24</sup>

While any policy that redistributes organs over a broader area can reasonably be anticipated to raise transport time, distance, and the amount of organs flown, the current proposal minimizes each of these metrics compared to any other potential option.<sup>25</sup> The hypothetical (and modest) reduction in overall transplants modeled under the proposal should not prevent adoption of a policy that would reduce significant disparity inherent in our current system and save lives.

Furthermore, we support the Committee’s plan for evaluating the policy changes suggested. Whenever a new policy is introduced, opportunities for refinement may arise. CODE appreciates the Committee’s eagerness to address unanticipated consequences of the policy and its willingness to engage with stakeholders to consider issues, improvements, and alternatives.

CODE respectfully urges the Committee to stick to the work plan identified in the proposal. Submission for June 2017 Board approval after a second comment period is a generous timeframe, providing stakeholders ample opportunity to work substantively with the Committee toward a shared goal of distribution equity. Further delay toward implementing a fair policy after so many years of injustice is indefensible and inconsistent with Federal directives.

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<sup>21</sup> OPTN/UNOS Public Comment Proposal: Redesigning Liver Distribution (August, 2016). Available at: [https://optn.transplant.hrsa.gov/media/1913/liver\\_redesigning\\_liver\\_distribution\\_20160815.pdf](https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf).

<sup>22</sup> Id.

<sup>23</sup> Pomfret, E. A., Fryer, J. P., Sima, C. S., Lake, J. R. and Merion, R. M. (2007), Liver and Intestine Transplantation in the United States, 1996–2005. *American Journal of Transplantation*, 7: 1376–1389. doi: 10.1111/j.1600-6143.2007.01782.

<sup>24</sup> Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation A Concept Paper from the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (June, 2014) Available at: [https://optn.transplant.hrsa.gov/media/1269/liver\\_concepts\\_2014.pdf](https://optn.transplant.hrsa.gov/media/1269/liver_concepts_2014.pdf)

<sup>25</sup> OPTN/UNOS Public Comment Proposal: Redesigning Liver Distribution (August, 2016). Available at: [https://optn.transplant.hrsa.gov/media/1913/liver\\_redesigning\\_liver\\_distribution\\_20160815.pdf](https://optn.transplant.hrsa.gov/media/1913/liver_redesigning_liver_distribution_20160815.pdf)



## **V. Additional Stakeholder Concerns Should No Longer Obstruct Progress**

CODE would like to take the opportunity to respond to some of the concerns raised by comments on the proposal so far. As the Committee is well aware, CODE reiterates that the proposal relates to reforming the way the existing supply of livers in the U.S. are distributed. The proposal seeks to make sure people everywhere in the U.S. can have a similar chance of receiving an organ based on need rather than their place of residence. It does not have to do with – nor intend to address – the amount of livers donated or the places where livers are donated. CODE is aligned with the Committee in its support for efforts to increase the amount of overall transplants. The overall availability of organs is an important and closely related issue, but the Committee’s work here addresses unfairness in the way we deal with the current shortage.

We note that it is unproductive to speak in terms of the proposal rewarding one community over another. Federal policy dictates that organs for transplant are a resource to be distributed fairly across the entire country.<sup>26</sup> For CODE, rather than rewarding one area at the expense of another, we believe this policy seeks to make sure that patients nationwide who are most in need will have a better chance of accessing organs for transplant no matter where they live.

CODE would also like to express disappointment with comments suggesting the proposal is the result of a conflict of interest or an effort by certain committee members to enrich surgeons and centers in their area. CODE notes that each region has a representative on the Committee responsible for specific issues pertaining to that area. These allegations are unfounded, and amount to a baseless effort to smear the integrity of the Committee and its members – not to mention delay life-saving reforms. These efforts to subvert a needed and required reform are especially harmful, aside from being disrespectful, to the thousands of patients who bear the burden of the current inequity.

## **VI. Conclusion**

CODE appreciates the opportunity to comment on the Committee’s proposal. We understand that the Committee is addressing a difficult problem without an easy solution. We encourage the Committee to hold steadfast to its current trajectory despite the divided nature of the ongoing debate.

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<sup>26</sup> See, Final Rule, ACOT Recommendation, POC Recommendation, UNOS/OPTN Strategic Plan, UNOS/OPTN Board Resolution.