

March 26, 2019

George Sigounas, MS, PhD  
Adminstrator  
Health Resources and Systems Administration  
Department of Health and Human Services  
Rockville, MD 20857

Dear Dr. Sigounas,

On March 14, 2019, you wrote on behalf of the United States Department of Health and Human Services (HHS), requesting the views of the Organ Procurement and Transplantation Network (OPTN) on issues raised in a critical comment submitted to HHS regarding the OPTN's adoption of modifications to liver allocation policy in December 2018. These modifications are known as the "Acuity Circles" policy.

HRSA specifically requested feedback on the OPTN's considerations of and conclusions concerning whether and how the new policy complies with the requirements of the National Organ Transplant Act (NOTA) and the OPTN Final Rule, particularly with regard to the cumulative impact of the policy on socioeconomic inequities, in light of 42 C.F.R. §121.4(a)(3); patient access to transplantation per 42 C.F.R. §121.8(a)(5); the predicted number of liver transplants and deaths under the Acuity Circles policy; and the use of median Model for End-Stage Liver Disease (MELD) score at transplant.

HRSA also requested feedback on the issues raised in the critical comment related to the OPTN's public comment process, and the OPTN's views on any other issues raised in the critical comment, as well as issues raised in other letters HRSA has received from Senators McConnell, Grassley, Blunt, and Moran, Congressman Engel, and other Senators and Members of Congress. The OPTN Executive Committee also reviewed and is responding to issues raised in letters by the law firm of Boies Schiller and the Greater New York Hospital Association. Many of the topics described below appear in more than one of these letters.

The OPTN appreciates the opportunity to provide its views on all of the following:

1. The OPTN policy development process
  - a. The governance structure and composition of the OPTN Board and Committees

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- b. The development of the Acuity Circles policy and the Broader 2 Circle (B2C) policy proposals
  - c. The public comment process, including details of the Fall 2018 public comment cycle
  - d. The Board's decision-making process during its December 3-4, 2018 meeting
  - e. HRSA's response to the Board's December 3-4, 2018 decision
2. OPTN Final Rule considerations
    - a. Socioeconomic inequities in light of 42 C.F.R. §121.4(a)(3)
    - b. Patient access to transplantation in light of 42 C.F.R. §121.8(a)(5)
    - c. Use of median MELD at transplant (MMA<sub>T</sub>) as a metric of access to transplant
  3. Predicted outcomes of the Acuity Circles policy
    - a. Predicted numbers of liver transplants
    - b. Predicted impact on waitlist mortality
  4. Measurement of organ procurement organization (OPO) performance
  5. Transportation costs
  6. Cold ischemic time
  7. Donor participation
  8. Access for patients in Midwestern and Southern states

No policy satisfies all parties, but the OPTN adhered to its well-established and transparent evidence-based process that effectively synthesizes multiple viewpoints to produce policies that comply with regulatory requirements. After appropriately weighing the considerations required by the OPTN Final Rule and evaluating the data analysis, the OPTN Board of Directors (Board) made a fully informed decision to adopt the Acuity Circles policy that will result in a more equitable distribution of livers. The OPTN adopted a robust plan to monitor the post-implementation effects of the Acuity Circles policy, will report the results of these effects publicly and frequently, and will propose modifications to the policy if data suggests changes are warranted.

### **Analysis**

The OPTN Executive Committee met to consider these questions and the OPTN response multiple times since it learned of the critical comment submitted to HRSA on February 13, 2019.<sup>1</sup> During its deliberations, the Executive Committee seriously considered the issues raised in the critical comment. The Executive Committee also reviewed and deliberated on letters submitted to the Secretary of HHS ("the Secretary") by Members of Congress. These include the letter submitted by Senator Blunt and Senator Moran on December 11, 2018, the letter submitted by Senator McConnell on December 20, 2018, the letter submitted on January 24, 2019 by Senator Grassley and 20 additional Senators, and another letter submitted on March 6, 2019, by Representative Engel and 80 additional Members of Congress, expressing support for the OPTN's policy and process.

On behalf of the Board, the OPTN Executive Committee concluded that the policy adopted in December 2018 is compliant with the OPTN Final Rule and will result in more equitable distribution of livers for all liver candidates on the waiting list. The Executive Committee also

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<sup>1</sup> Glenn Krinsky, letter to HHS Secretary Alex Azar, February 13, 2019.

confirmed that the policy development process was deliberative, evidence-based, and transparent consistent with the requirements of NOTA<sup>2</sup> and the OPTN Final Rule.<sup>3</sup>

## **1. The OPTN Policy Development Process**

### **a. The governance structure and composition of the OPTN Board of Directors and Committees**

The OPTN is a unique public-private partnership created by NOTA and further governed by the OPTN Final Rule. NOTA created a national network in the private sector with oversight provided by the federal government through the Secretary. The OPTN is a private not-for-profit entity with a board of directors that must meet the composition requirements of NOTA and the OPTN Final Rule. For example, in addition to organ-specific transplant surgeons and physicians, the OPTN Board must include representatives of the general public, organ procurement organizations, and voluntary health associations, and must be comprised of at least 25 percent transplant candidates, transplant recipients, organ donors and family members.

The OPTN Board is required to establish committees, and the OPTN Final Rule specifies similar composition requirements for those additional committees. Currently the OPTN Board has established over 20 committees with over 400 volunteer committee members to assist it in meeting the statutory requirements of NOTA.

The core of the Board and its committees are constituted through elections in each of the OPTN's 11 regions. Board leadership positions and patient and donor representatives are chosen through national elections, and other positions are filled by professional societies involved in transplantation.

The Liver & Intestinal Organ Transplantation Committee membership is comprised of transplant surgeon and transplant physician representatives of transplant hospitals, OPOs, transplant coordinators, transplant patients, and representatives elected from each OPTN region.<sup>4</sup> When developing policy proposals, committees rely on all available data, and use the benefit of their collective experience as well as the unique and varied individual membership perspectives to interpret and evaluate proposals.

The Board respects and appreciates the work of all its volunteer committee members. Although there is significant delegation of work to these committees, the OPTN Board has the ultimate authority and responsibility to fulfill its charge under NOTA, including the equitable allocation of organs. Any committee created by the Board serves in an advisory capacity to the OPTN Board, which is the only entity authorized to approve allocation policies. The Board's responsibility is to consider not only the perspective and recommendation of the committee, but also perspectives raised during public comment and during discussion by the Board, which includes both patient and HRSA representatives. The Board has exercised its discretion to amend or decline a committee proposal 23 times in the past ten years, including this past December Board meeting.

### **b. The development of the Acuity Circles policy and the Broader 2 Circle (B2C) policy proposals**

In July 2018, a lawsuit was filed against the Secretary and the OPTN alleging that the OPTN's operative and adopted (but not yet implemented) allocation policies for deceased

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<sup>2</sup> 42 USC §274(b)(2)(B).

<sup>3</sup> 42 C.F.R. §121.4(a)

<sup>4</sup> As required by OPTN Bylaws Article VII, 7.1: Composition of Standing Committees.

donor livers were legally non-compliant because those policies distributed livers using “arbitrarily-drawn” geographic areas called Donation Service Areas (“DSAs”) and administrative regions (“OPTN Regions”). Other letters written before and after the Board decision, including one by Rep. Engel and 81 House members, called upon the OPTN to promptly amend and implement a liver distribution policy that does not rely on DSAs and provides more equitable access to candidates awaiting liver transplantation.

The Secretary was also separately reviewing a critical comment submitted directly by these same individuals, which raised similar arguments. Despite the OPTN having worked for some time to develop a new liver policy, HRSA concluded that OPTN had not justified and could not justify the use of DSAs or OPTN Regions as units of organ distribution under the OPTN Final Rule. HRSA directed the OPTN Board to adopt a liver allocation policy that eliminated the use of DSAs and OPTN Regions for liver distribution purposes and that complied with the Final Rule.

Following this July directive, the Board charged the Liver Committee to engage in a deliberative process to develop, consider, and propose a new liver allocation policy that would weigh the Final Rule requirements to design geographic units of organ distribution that are constrained only as required by medical urgency, efficiency in organ placement, achieving the best use of donated organs, promoting patient access, avoiding organ wastage, and avoiding futile transplants.<sup>5</sup> After determining that *some* geographic constraint is necessary in order to avoid wasting organs and to promote the efficient management of organ placement, the Liver Committee considered several approaches, and ultimately honed in on two. Both the Acuity Circles and Broader 2 Circle (B2C) frameworks eliminated any use of DSAs/OPTN Regions, and instead use fixed distances from a donor hospital as the applicable geographic limit when weighing the required OPTN Final Rule considerations. These two proposed policies differed, though, in how they respectively grouped candidates for the purposes of the allocation order.

The B2C proposal would have allocated livers to status 1 candidates within 500 nautical miles (NM) of the donor hospital, then to candidates with a model for end-stage liver disease (MELD) score or a pediatric model for end-stage liver disease (PELD) score of at least 29 within 250 NM of the donor hospital, then to candidates with a MELD/PELD score of at least 15 within 150 NM, then 250 NM, then within 500 NM, and finally to candidates throughout the nation.<sup>6</sup>

The Acuity Circles policy uses distance-based circles with small bands of a few MELD/PELD points. The goal of this concept to prioritize the most efficient placement (minimizing transport time and logistics by prioritizing transplant and donor hospitals that are closer together) among candidates with a similar need, and when there is a greater need (shown by higher MELD score), allow candidates who are further away to have increased access. The approach places more emphasis on the difference in MELD/PELD score, even when the differences are smaller.

The Liver Committee considered the predicted results of the Acuity Circles and the B2C concepts produced at the Committee’s request by the Scientific Registry of Transplant Recipients (SRTR). While the SRTR provides many analyses, in recent years the Liver Committee and Board have focused on a few key metrics when considering distribution proposals.

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<sup>5</sup> 42 C.F.R § 121.8(a).

<sup>6</sup> Unless otherwise stated, distances refer to the distance between the donor hospital and the transplant hospital where the candidate is registered.

1. Variance in median MELD at transplant (MMaT): This metric is one of the metrics used by the Liver Committee to assess whether transplant candidates in various groups have comparable access to transplant. This is in line with 42 C.F.R. § 121.8(a)(5) (“promote patient access”) and (a)(8) (“[s]hall not be based on the candidate's place of residence or place of listing”).
2. Transplant Count: This metric is relevant because a goal of the OPTN is to increase the number of transplants. This is in line with the requirement of 42 C.F.R. § 121.8(a)(2) to make the best use of donated organs.
3. Post-transplant Mortality: This metric is relevant in determining futility and the best use of donated organs in line with the requirements of 42 C.F.R. § 121.8(a)(2) and (a)(5).
4. Transportation time: This metric is relevant when considering the fact that the amount of cold ischemic time (CIT) on an organ impacts transplant outcomes, in line with the requirements of 42 C.F.R. § 121.8(a)(5) to make the best use of organs and avoid wasting organs.
5. Percent of Organs Flown: This metric is relevant considering the costs related to efficiency in transporting organs by air instead of ground transportation. This is in line with the requirement of 42 C.F.R. § 121.8(a)(5) to make the best use of organs and avoid wasting organs.

The Liver Committee distributed a proposal for public comment that explained and requested feedback on both B2C and Acuity Circles.

### **c. The public comment process, including details of the Fall 2018 public comment cycle**

The OPTN is required to seek public comment on all proposals to change policies.<sup>7,8</sup> Proposals are posted on the OPTN website and feedback is requested on specific questions related to the proposals. Proposals are also presented at the OPTN Regional Meetings by those members of the Committee that were elected by their regions, at OPTN committee meetings, and on OPTN-sponsored webinars. Attendees of these meetings and webinars are also encouraged to provide feedback to be posted on the OPTN website, with the hope of initiating conversation in an online forum. Throughout the public comment cycle and afterwards, policy analysts provide analysis to the committees regarding the number of comments submitted, the characteristics of the people and organizations that submitted the comments, including their geographic location and their relationship to transplant, themes emerging from the comments, and whether those themes can be associated with the characteristics of the commenters.

All comments and the public comment analysis are considered by the committee sponsoring the proposal, and ultimately by the Board. Consideration of these comments is required by the Final Rule (“the Board of Directors...shall take into account the comments received in developing and adopting policies for implementation by the OPTN...”),<sup>9</sup> and assists the committees and Board in making fully informed decisions regarding the impact of any potential policy change. The sponsoring committee or the Board may opt to modify the proposed policy to account for considerations raised by the public.

The B2C and Acuity Circles proposals were posted for public comment from October 8, 2018, to November 1, 2018. The public comment cycle was condensed due to the expedited timeline

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<sup>7</sup> 42 U.S.C. §274(b)(2)(B).

<sup>8</sup> 42 C.F.R. §121.4(a).

<sup>9</sup> *Id.* at §121.4(b)(1).

upon which the OPTN was charged with removing DSAs and OPTN Regions from liver allocation policy, and due to the need to have modeling available during public comment, while still having a proposal ready to present at the December OPTN Board meeting as directed by the Secretary.

The Liver Committee met several times during the public comment period to hear updates on the comments received. Public comment concluded on November 1, 2018, and the Liver Committee met again in-person on November 2, 2018 to consider the comments and vote on a proposal to recommend to the Board. Despite the condensed timeframe, the OPTN received more than 1,200 responses during the public comment period, the second-highest number of comments ever received on any proposal distributed for public comment by the OPTN.

Due to the overwhelming volume of last-minute comments and the short period of time between the close of public comment and the Liver Committee's review of those comments, 17 of the more than 1,200 submitted comments were inadvertently not presented to the Liver Committee prior to its discussion of the proposal. However, these 17 comments were provided to the Liver Committee on November 7, 2018. All 17 comments aligned with comment themes already identified and presented during the November 2, 2018 meeting; no new or unique feedback, or content emerged. As such, Liver Committee leadership decided that an additional meeting or reconsideration of the Liver Committee's decision from its November 2, 2018 meeting was unnecessary.

Most importantly, all 1,200 of the comments, including the 17 that were not presented to the Liver Committee during its November 2, 2018 meeting, were provided to the Board with ample time for the Board's consideration. The Board's consideration of these comments satisfies the Final Rule requirement that the Board consider all comments received prior to adopting a policy change.

After evaluating the public comment responses and discussing the merits of both models, the Liver Committee voted on which model to recommend to the Board. 11 Committee members preferred the B2C model, and 9 preferred the AC model.<sup>10</sup>

#### **d. The Board's decision-making process during its December 3-4, 2018 meeting**

The Board's careful consideration of the Liver Committee's recommendations is demonstrated through the robust discussion and questioning during the Board meeting, the materials available for review, and that much of the substance of the proposal recommended by the Liver Committee was passed by the Board.

Two weeks prior to the Board meeting, the Liver Committee sent an extensive liver proposal to the Board for consideration.<sup>11</sup> The Liver Committee's proposal included the B2C model for distribution, as well as a detailed discussion of the merits of the Acuity Circles model. The proposal also included all the evidence the Liver Committee considered throughout the policy development process, as well as the data modeling results and public comment analysis considered by the Liver Committee.

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<sup>10</sup> Meeting Summary for November 2, 2018 meeting, OPTN/UNOS Liver and Intestinal Transplantation Committee, <https://optn.transplant.hrsa.gov/members/committees/liver-and-intestine-committee/>.

<sup>11</sup> *Eliminate the Use of DSA and Region in Liver and Intestine Allocation*, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2018, [https://optn.transplant.hrsa.gov/media/2766/liver\\_boardreport\\_201812.pdf](https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf) (Accessed March 19, 2019).

At the Board meeting, the Chair of the Liver Committee presented the Committee's proposal to the Board, including an explanation of the Liver Committee's ultimate recommendation for B2C, the process in which the Liver Committee deliberated to develop such a recommendation, and the narrow margin by which its recommendation passed over the Acuity Circles option. The Chair answered the Board's questions over a nearly four-hour period of robust discussion. After this Board-level discussion, during which some Directors also provided presentations in favor of the B2C and Acuity Circles models, the OPTN Board voted to amend the proposal to adopt Acuity Circles by a vote of 24 in favor, 14 against, and 0 abstentions.<sup>12</sup>

#### **e. HRSA's response to the Board's December 3-4, 2018 decision**

Following the Board meeting, the HRSA Administrator acknowledged that "[t]he OPTN engaged in an intense and deliberative process to develop, consider, and adopt a new liver allocation policy. HRSA recognizes that the policy approved by the OPTN Board on December 3, 2018, builds on years of discussion and input from the community and the public on other previously considered concepts and draft policies. The OPTN Board, the entity authorized to make decisions on behalf of the OPTN and its membership, is comprised of dedicated individuals who possess renowned expertise and represent the diversity of transplant stakeholders."<sup>13</sup> The HRSA Administrator stated that the OPTN "provided a reasoned rationale for the use of geographic boundaries in the Acuity Circles proposal" and "that Acuity Circles as adopted reflect[s] an appropriate balance of regulatory factors."<sup>14</sup>

## **2. OPTN Final Rule considerations**

The OPTN Final Rule details the types of policies that the OPTN should develop, and the considerations that the OPTN should factor in its decision-making process. The February 2019 critical comment questioned whether the OPTN appropriately considered socioeconomic inequities when it adopted the Acuity Circles proposal, and whether it appropriately considered whether the Acuity Circles policy appropriately promotes patient access to transplantation. The OPTN has considered these comments and, for the reasons stated below, believes it appropriately considered these Final Rule requirements.

#### **a. Socioeconomic inequities in light of 42 C.F.R. §121.4(a)(3)**

The OPTN Final Rule charges the OPTN with developing policies addressing multiple issues, including "policies for the equitable allocation of cadaveric organs," "policies...for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases;" and "policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs..."<sup>15</sup>

Additionally, as previously explained in the proposal and considered by the Board, "[t]he OPTN Final Rule charges the OPTN to develop 'policies that reduce inequities resulting from socioeconomic status, including ... [the] reform of allocation policies.'<sup>16</sup> However, this requirement does not specify that all proposals specifically reduce inequities. Sec. 121.4 lists a

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<sup>12</sup> This vote reflects the Board's decision to opt for the Acuity Circles amendment sponsored by one of the Directors. The final vote count for the proposal in full, after considering other technical amendments, was 30 in favor, 7 against, and 2 abstentions.

<sup>13</sup> George Sigounas, letter to Sue Dunn, OPTN President, December 19, 2018.

<sup>14</sup> *Id.*

<sup>15</sup> 42 C.F.R. §121(a)(1),(2), and (4).

<sup>16</sup> *Id.* at §121(a)(3).

variety of policy proposals that that OPTN must develop, but it is unreasonable to expect that every proposal will simultaneously [advance] all of these goals.”<sup>17</sup>

The reform of allocation policies is but one strategy that the OPTN may consider using to address socioeconomic inequities. It is not the only strategy or method available to the OPTN, nor is it required that the OPTN only consider socioeconomic inequities every time it revises allocation policies. The OPTN has adopted policies in the past that are intended to address socioeconomic inequities, notably the significant revision to kidney allocation to credit candidates with waiting time from the point they began dialysis, rather than their date of listing for transplant, to avoid penalizing candidates who had a more difficult time gaining access to a transplant hospital.

The goal of the Acuity Circles policy is to grant access to liver candidates more equitably based on medical urgency. It is designed to help medically urgent candidates, regardless of whether those candidates are of low or high socioeconomic status.

Nevertheless, in order to ensure that the policy would not have unintended negative effects on socioeconomically disadvantaged candidates, the OPTN did consider the impact Acuity Circles policy may have from a socioeconomic perspective. The Board relied upon inferential modeling results performed by the SRTR and presented in a 320-page report containing multiple metrics broken down by different demographics.

As explained in the proposal presented to the Board:

Overall, modeling showed that, for candidates registered on the waiting list for liver, ‘the trends for the socio-economic status characteristics (education, insurance type, cumulative community risk score, and urbanicity) subgroups were similar between frameworks to the total population.’

For example, the modeling shows similar results for transplant rates, waitlist mortality, and post-transplant mortality regardless of public or private insurance...

In developing this proposal, the Committee with UNOS and SRTR staff examined several different methodologies to perform SES [socioeconomic status] analysis. They reviewed data currently collected by the OPTN and also merging OPTN geographic data with other data sets. Their analysis began with patient level data that the OPTN currently collects. The OPTN does not classify patients’ SES nor does the OPTN collect variables typically necessary to determine an individual’s SES (ex. income level); however, the OPTN does collect patients’ education level and insurance status. In assessing education level, the SRTR grouped populations by high school or less against more than high school. In assessing insurance status, the SRTR grouped populations by public vs. private insurance. In looking at the variance in MMaT, the broader 2-circle and acuity circle models will, compared to the current and 2017 Board approved systems, improve the variance in MMaT for all education levels. The same is true for both public and private insurance...

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<sup>17</sup> Eliminate the Use of DSA and Region in Liver and Intestine Allocation, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2018, [https://optn.transplant.hrsa.gov/media/2766/liver\\_boardreport\\_201812.pdf](https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf) (Accessed March 19, 2019).



The SRTR research report describes the limitations of this analysis.

‘The CCRS [Cumulative Community Risk Score] is based on population-level attributes, and the authors recommend caution in its interpretation: “it is...important for interpretation of our study findings that ascribing broad area risks to each individual within that area is an ecological fallacy. Thus...it is inappropriate to directly assign risks to individuals within that community.” Thus, readers should think of CCRS results as applying to candidates in high-risk counties, not to high-risk candidates.’<sup>18,19</sup>

The OPTN appropriately considered socioeconomic impact when developing and adopting the Acuity Circles policy.<sup>20</sup>

#### **b. Patient access to transplantation in light of 42 C.F.R. §121.8(a)(5)**

When developing allocation policies, the OPTN is charged with considering whether the policy will promote patient access to transplantation, among other factors.<sup>21</sup> As provided to the Board in the proposal, “[t]he group of patients for whom the proposal is intended to promote access are liver and intestine candidates on the waitlist, as this is an allocation policy developed under the auspices of §121.8(a) of the OPTN Final Rule, requiring the OPTN to develop ‘policies for the equitable allocation of cadaveric organs among potential transplant recipients.’”<sup>22</sup>

The decision whether to register a candidate on the waitlist is made exclusively by a transplant hospital. It is not possible for an organ allocation policy to improve access to transplant for patients who are not registered for a transplant on the waitlist by a transplant hospital. Put simply, there is no allocation policy that will allocate an organ to patient who is not listed for transplantation. Improving transplant access for the group of patients who are not listed as candidates for transplantation requires other types of initiatives. Therefore, the group of patients for whom the proposal is intended to promote access are liver and intestine candidates registered on the transplant waitlist. This position was confirmed by HRSA at the Board meeting in December, stating “it’s appropriate to maintain that the reference to promote patient access to transplantation is limited to promoting access to transplantation for persons on the waiting list.”<sup>23</sup>

#### **c. Use of median MELD at transplant (MMA<sub>T</sub>) as a metric of access to transplant**

The OPTN uses median MELD at transplant as an indicator of equity in access to transplant amongst liver candidates. It is one of several metrics selected by the Liver Committee to inform

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<sup>18</sup> *Id.*

<sup>19</sup> Schold, J. D., Buccini, L. D., Kattan, M. W., Goldfarb, D. A., Flechner, S. M., Srinivas, T. R., ... & Sehgal, A. R. (2012). The association of community health indicators with outcomes for kidney transplant recipients in the United States. *Archives of surgery*, 147(6), 520-526.

<sup>20</sup> Scientific Registry of Transplant Recipients, *SRTR LI\_2018\_01*, Sept. 24, 2018, [https://optn.transplant.hrsa.gov/media/2640/li2018\\_01\\_analysis-report\\_20180924.pdf](https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf) (accessed March 25, 2019).

<sup>21</sup> 42 C.F.R. §121.8(a)(5).

<sup>22</sup> *Eliminate the Use of DSA and Region in Liver and Intestine Allocation*, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2018, [https://optn.transplant.hrsa.gov/media/2766/liver\\_boardreport\\_201812.pdf](https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf) (Accessed March 19, 2019), citing 42 C.F.R § 121.8(a). See also *id.* at §121.2 (defining “potential transplant recipient” as “a transplant candidate who has been ranked by the OPTN computer match program as the person to whom an organ from a specific cadaveric organ donor is to be offered; and defining “transplant candidate” as “an individual who has been identified as medically suited to benefit from an organ transplant and has been placed on the waiting list by the individual’s transplant program.” (emphasis added)).

<sup>23</sup> Remarks by Christopher McLaughlin, Chief, Organ Transplantation Branch, OPTN Project Officer, Division of Transplantation, HRSA, at the OPTN Board of Directors Meeting on December 3, 2018.

the modeling for, and monitor the post-implementation results of, the new policy.<sup>24</sup> It is not the only metric by which the Liver Committee and Board evaluated potential changes to liver allocation policies over the years: the Liver Committee also considered the impact on transplant rates, waitlist mortality and multiple other factors.

As explained in the proposal presented to the Board:

The Committee used MMaT by DSA as a metric to evaluate the difference in candidate access to transplant in different areas of the country...The MELD score is calculated using relevant medical criteria to prioritize candidates for liver transplants based on medical urgency.<sup>25</sup> Within each geographic unit of distribution, candidates are prioritized for offers in order of decreasing MELD score...

The MMaT represents the "middle" point of transplanted MELD scores...If two candidates are in different areas of the country, but have the same objective clinical factors, they will have the same MELD score, so in an equitable system, they should also have the same likelihood of transplant. Since MELD score is a surrogate for medical urgency, variation in MMaT shows that candidates in some geographic areas have to reach a higher level of medical urgency to receive a transplant compared to others...<sup>26</sup>

Modeling showed that both B2C and acuity circles would result in less variance in MMaT than the current allocation system.<sup>27</sup> However, acuity circles improved the variance more significantly, and also showed an increase in the overall MMaT, with more candidates with higher MELD/PELD scores getting transplanted.<sup>28</sup>

The SRTR provided a detailed explanation of the use of MMaT as a measure of equity in candidate access to transplant, as well as several other questions related to the modeling performed at the request of the Liver Committee. That detailed explanation is included as an attachment to the OPTN response.

As measured by the OPTN's adopted metric for identifying patient access for liver transplantation, the Acuity Circles policy is predicted to achieve its intended result of promoting access to transplantation for liver candidates on the waitlist.

### **3. Predicted outcomes of the Acuity Circles policy**

The OPTN regularly relies on predictive modeling prepared at committees' request by the SRTR when developing allocation policy changes. The simulation allocation models, or SAMs, are

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<sup>24</sup> "The Committee was polled in December 2012 regarding the metrics that are most important for reducing geographic inequities in liver allocation, the number of geographic units or regions that would be desirable, and the maximum organ transport times that would be acceptable. Dr Gentry reviewed the results of that poll. For those Committee members who responded to the poll (n=14), the two most important metrics for geographic disparity in liver distribution were the variance in median MELD at transplant across DSA and the variance in waitlist mortality rate across DSAs." January 24, 2013 Meeting Minutes ([link](#)).

<sup>25</sup> Leise, Michael D. et al. "A Revised Model for End-Stage Liver Disease Optimizes Prediction of Mortality Among Patients Awaiting Liver Transplantation". *Gastroenterology*, Volume 140, Issue 7, 1952 – 1960. Doi: 10.1053/j.gastro.2011.02.017.

<sup>26</sup> Edwards, E. B., Harper, A. M., Hirose, R., & Mulligan, D. C. (2016). The impact of broader regional sharing of livers: 2-year results of "Share 35". *Liver Transplantation*, 22(4), 399-409. doi:10.1002/lt.24418.

<sup>27</sup> Scientific Registry of Transplant Recipients, *SRTR LI\_2018\_01*, Sept. 24, 2018, [https://optn.transplant.hrsa.gov/media/2640/li2018\\_01\\_analysis-report\\_20180924.pdf](https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf) (accessed March 20, 2019).

<sup>28</sup> *Eliminate the Use of DSA and Region in Liver and Intestine Allocation*, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2018, [https://optn.transplant.hrsa.gov/media/2766/liver\\_boardreport\\_201812.pdf](https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf) (accessed March 19, 2019).

specific to organ type, and provide the committees and Board with insights as to the likely impact a policy will have on many different areas of concern. The Liver Committee reviewed modeling for both the B2C and Acuity Circles proposals and reviewed many metrics, including the predicted numbers of liver transplants and deaths, and the predicted impact on waitlist mortality. These modeling results were also provided to the Board as an attachment to the proposal document.

#### **a. Predicted numbers of liver transplants**

The February 2019 critical comment expressed concern that the number of liver transplants may decline under the Acuity Circles Policy. The models used by the SRTR predict number of transplants based on historical transplant program behavior. The models do not reflect or predict changes in behavior, so it is likely that the modeling results provided regarding the Acuity Circles policy underestimates the number of transplants that will occur when the policy is actually implemented. History supports this interpretation of the modeling results. Using an earlier policy that was a smaller step in broader geographic distribution (called “Share 35”) as an example, the proposal pointed out that:

Both models showed a slight decrease in transplant count. The Liver Simulated Allocation Model (LSAM) accounts for acceptances based on historical acceptance practices related to distance. If historically an organ was not accepted beyond a certain distance, then when modeling changes to distance in distribution, the LSAM assumes that a program is not going to accept that organ if it comes from a further distance. However, in reality, this tends not to bear out in practice because programs do change their acceptance behaviors in response to allocation changes. For example, the LSAM for Share 35 predicted that the transplant count would decrease.<sup>29</sup> Because the LSAM does not account for changes in member behavior, this impact did not occur once Share 35 was implemented.<sup>30</sup>

Additionally, “while both models showed a slight reduction in the number of transplants overall, both showed an increased number of candidates transplanted with MELD scores of 35 or higher and pediatric candidates, and the reduction in the number of transplants was not statistically significant.”<sup>31</sup> The OPTN has evidenced-based reason to believe that the Acuity Circles policy will not, in reality, result in a reduction of liver transplants.

#### **b. Predicted impact on waitlist mortality**

The February 2019 critical comment also expressed doubt about the methodology by which waitlist mortality is determined, and therefore challenged the OPTN’s conclusion that the Acuity Circles policy will achieve the best use of donated organs by reducing the waitlist mortality rate as compared to the current allocation system.

The decrease in waitlist mortality is logically consistent with the modeled increase in the number of higher MELD transplants. If sicker patients are transplanted at an increased rate, fewer people will die on the waiting list. By increasing the priority of the most medically urgent candidates, and decreasing the priority of less urgent candidates, the simulated waitlist deaths

<sup>29</sup> SRTR “Report as of June 26, 2009 to the OPTN Liver-Intestine Transplantation Committee.”

<sup>30</sup> The Impact of Broader Regional Sharing of Livers: 2-Year Results of “Share 35”, Erick B. Edwards, Ann M. Harper, Ryutaro Hirose, and David C. Mulligan, *Liver Transplantation* 22 399-409 2016 AASLD.

<sup>31</sup> Executive Summary of OPTN Approval of Policies to Eliminate the use of DSAs and Regions in Liver Allocation. December 13, 2018, citing Scientific Registry of Transplant Recipients, SRTR LI\_2018\_01, Sept. 24, 2018, [https://optn.transplant.hrsa.gov/media/2640/li2018\\_01\\_analysis-report\\_20180924.pdf](https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf) (accessed Oct. 1, 2018), figure 6.

decrease. Since the number of simulated waitlist deaths decreases under the Acuity Circles policy, it is likely that the Acuity Circles policy does a better job than current policy of offering livers to the most medically urgent candidates, in accordance with the goals of the Final Rule, particularly related to making the best use of donated organs.

Furthermore, there are two different ways to measure "waiting list mortality." A strict definition counts only those patients who were on the list when they died. A broader definition includes both candidates who died while on the list and those removed when they became too sick to transplant and died soon thereafter. Since the two versions of waitlist mortality are nearly always very similar, reviewing both versions is generally redundant, and in the interest of expediting the work of the Liver Committee the SRTR initially provided the strict waitlist mortality counts to the Committee, since that was the metric that the Committee had chosen to consider in the past. Following subsequent concern about not seeing the alternative version, the SRTR also provided the alternate version to the committee prior to their vote on the proposal.<sup>32</sup> As expected, the two metrics provided similar results, and both showed a decrease in mortality under both models.

#### **4. Measurement of organ procurement organization (OPO) performance**

The letter dated January 24, 2019, from Senator Grassley and others asks whether it is appropriate to incorporate the performance of OPOs when considering allocation policies. As previously established, the Final Rule outlines specific factors the OPTN must consider when developing allocation policies. The performance of the OPO in the service area where the candidate is listed is not one of the permissible geographic criteria in the Final Rule.

The OPTN recognizes the Senators' concerns regarding OPO performance, and along with the Centers for Medicare & Medicaid Services (CMS), has measures in place to monitor and facilitate improvements in OPO performance. While there are variations in OPO performance across the nation, those variations are smaller than the variations seen in demographic patterns that currently determine access to transplantation. By moving to a broader distribution system for livers, the Acuity Circles policy will reduce the variations created by those demographic patterns, as well as require better coordination among OPOs and transplant centers outside the OPOs' procurement area. As such, OPOs, transplant centers, and other stakeholders are likely to adjust their behaviors and patterns related to procurements, with the potential for improvement in OPO and system performance overall.

#### **5. Transportation costs**

The OPTN is aware that changes to liver allocation policy that provide for broader distribution of livers will increase transportation costs, assuming current transportation practices are unchanged. The OPTN considers costs under the Final Rule requirement that allocation policies be designed to "promote the efficient management of organ placement."<sup>33</sup>

Cost is one aspect of efficiency, and costs related to the efficient management of organ *placement* are a subset of the total cost of care for end stage organ failure patients or organ transplantation. The OPTN does not routinely collect information on the budgets and expenses

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<sup>32</sup> Scientific Registry of Transplant Recipients, *Analysis Report: Data Request on Circle Based Allocation Supplement: Pre-Transplant Death*, Oct. 26, 2018.

<sup>33</sup> 42 C.F.R. §121.8(a)(5).

of the OPOs and hospitals that participate in donation and transplantation. While simulation modeling also does not predict costs, per se, it can predict the percent of organs flown. The percent of organs flown is relevant because flights add costs to organ placement.<sup>34</sup>

The modeling report provided to the Liver Committee and the Board predicted the Acuity Circles policy will increase the percentage of livers flown from 53.8-54.9% to 71.4-74%, which will result in increases to costs of procurement.<sup>35</sup> The B2C model was predicted to increase flying by less, to only 58.4-60.8%. The modeling demonstrates there is a wide variation across the country and across OPOs in the percentage of organs flown.<sup>36</sup> Additionally, the costs of flights, including charter flights, is also widely variable.<sup>37</sup> Some areas of the country naturally have easier access to travel, which also influences this complicated situation. Organ procurement processes utilize a combination of private, charter, and commercial air travel. Other logistical adjustments will need to be made by OPOs and transplant hospitals as they adjust to the implementation of the new policy, and the OPTN will monitor the impact of those adjustments.

Ultimately, the Board weighed the benefits of broader geographic distribution, such as the promotion of patient access to transplant and making the best use of donated organs, against the increased costs of transportation alone, and a majority of Board members determined the Acuity Circles policy strikes an appropriate balance.

## 6. Cold ischemic time

Broader distribution of organs can potentially lead to increased cold ischemic time (time between procuring the organ from the donor and re-starting blood supply upon transplanting the organ into the recipient). Increased cold ischemic time (CIT) can be associated with poorer graft function and post-transplant outcomes. Therefore, while the Liver Committee considered whether it would be possible to allocate livers without any consideration for geography, thereby fulfilling the Final Rule requirement that allocation policy “not be based on the candidate's place of residence or place of listing...” the Liver Committee determined such a system is not possible without risking organ wastage and efficiency. Prioritizing candidates who are closer to the donor hospital reduces the costs of transportation, reduces the logistical difficulties that could lead to discards, and reduces the amount of CIT for an organ.

All of the options for which the SRTR provided modeling, as well as the current policy, have a median transport time of 2.0 hours or less, well within the conservative recommendation of six hours for livers.<sup>38</sup> The Acuity Circles model increases the median travel time by 0.2 hours: from 1.7 (existing policy) to 1.9 hours (Acuity Circles model).<sup>39</sup> Because literature suggests that total

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<sup>34</sup> Procurement costs include the funds needed to fly a transplant team to the organ recovery hospital. The further recovery teams must travel to procure an organ, the more likely it becomes those teams will need to fly, which leads to increase costs for securing those flights. Additionally, the recovery teams often take chartered flights to recover the organs and transport them back to the hospital where the candidate is registered.

<sup>35</sup> Scientific Registry of Transplant Recipients, SRTR LI\_2018\_01, Sept. 24, 2018, [https://optn.transplant.hrsa.gov/media/2640/li2018\\_01\\_analysis-report\\_20180924.pdf](https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf) (accessed Oct. 1, 2018).

<sup>36</sup> *Id.*

<sup>37</sup> Private Jet Charter Pricing Basics. <https://www.evojets.com/charter-flight-costs-pricing-basics/> (accessed March 20, 2019).

<sup>38</sup> "From a logistics standpoint, an attempt to keep CIT shorter than 6 hours should be made." Croome, Kristopher P., Amit K. Mathur, David D. Lee, Adyr A. Moss, Charles B. Rosen, Julie K. Heimbach, and C. Burcin Taner. "Outcomes of Donation After Circulatory Death Liver Grafts From Donors 50 Years or Older." *Transplantation* 102, no. 7 (2018): 1108-114. doi:10.1097/tp.0000000000002120.

<sup>39</sup> Table 3: Overview of the SRTR Modeling Report, *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2018, [https://optn.transplant.hrsa.gov/media/2766/liver\\_boardreport\\_201812.pdf](https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf).

CIT should not exceed 6 hours, the Board discussion suggested that a projected additional 12 minutes of CIT from increased travel was clinically insignificant.<sup>40</sup>

For donor organs with factors that reduce the viable CIT, e.g. donation after cardiac death (DCD) donors and donors over the age of 70, the classification tables reflect a higher priority on proximity when compared to donors without those factors. The Acuity Circles policy incorporates changes that use a smaller area of distribution for DCD and donors over 70 years old as these organs have better outcomes with shorter cold ischemic times,<sup>41</sup> which “is consistent with the OPTN Final Rule requirement to make the best use of donated organs.”<sup>42</sup> The Liver Committee chose to maintain that approach in [the Acuity Circles policy], and the allocation sequences for this group prioritize candidates within 150 NM of the donor hospital even for higher MELD/PELD candidates than the sequences for other donors.”<sup>43</sup>

Ultimately, the Board adopted a policy that incorporates geography based in part to the effects of CIT, fulfilling the Final Rule requirements to create allocation policies “designed to avoid wasting organs” and to “promote the efficient management of organ placement.”

## **7. Donor participation**

Invariably, when the OPTN proposes changing allocation policies to more broadly distribute organs, anecdotes emerge that the public at large will be less willing to donate their organs if they are going to be distributed nationally rather than to their local community. While this anecdotal mythology persists, objective evidence debunks this fear. Reputable national polling has repeatedly demonstrated that the American public’s support for organ donation is not dependent on local priority. A 2013 Gallup poll found that 81.7% of respondents supported policies designed to give organs to the sickest patients first.<sup>44</sup> Other organ allocation policies already provide priority to pediatric, sensitized, or medically urgent candidates without having reduced donation rates.

## **8. Access for patients in Midwestern and Southern states**

The OPTN is charged with developing national organ allocation policies. Due to the diversity in geography and demographics, any national policy is likely to impact different areas of the country differently. The Liver Committee and the Board scrutinized the modeling provided by the SRTR to understand the potential impact, including the impact on various geographic regions of the country.

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<sup>40</sup> Executive Summary of OPTN Approval of Policies to Eliminate the use of DSAs and Regions in Liver Allocation. December 13, 2018.

<sup>41</sup> Kalisvaart, Marit, Andrea Schlegel, and Paolo Muiesan. "Attitudes and Barriers to the Use of Donation after Cardiac Death Livers: Comparison of a United States Transplant Center Survey to the United Network for Organ Sharing Data." *Liver Transplantation* 24, no. 1 (2017): 144-45. doi:10.1002/lt.24978. Croome, Kristopher P., Amit K. Mathur, David D. Lee, Adyr A. Moss, Charles B. Rosen, Julie K. Heimbach, and C. Burcin Taner. "Outcomes of Donation After Circulatory Death Liver Grafts From Donors 50 Years or Older." *Transplantation* 102, no. 7 (2018): 1108-114. doi:10.1097/tp.0000000000002120. "From logistic standpoint, an attempt to keep CIT shorter than 6 hours should be made."

<sup>42</sup> 42 C.F.R § 121.8(a)(2).

<sup>43</sup> *Eliminate the Use of DSA and Region in Liver and Intestine Allocation*, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2018, [https://optn.transplant.hrsa.gov/media/2766/liver\\_boardreport\\_201812.pdf](https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf) (accessed March 19, 2019).

<sup>44</sup> 2012 National Survey of Organ Donation Attitudes and Behaviors, September 2013. See also: 1993 Gallup Organization I. The American Public’s Attitudes Toward Organ Donation and Transplantation. The Partnership for Organ Donation, Inc.; 2005 Gallup Organization I. National Survey of Organ and Tissue Donation Attitudes and Behaviors. HRSA.

Modeling suggests that areas of the country that currently have a relative advantage in access to liver transplant offers, as measured by a lower median MELD at transplant, will move closer to the national average. Regions that currently have above average access and a lower median MELD at transplant are not forecasted to have below average access after the Acuity Circles policy is implemented, but may have less of an advantage over access in other regions as compared to the current state.<sup>45</sup> This is an intended result: patients that are sicker that are currently registered in areas with less access to transplant will experience an improvement in access to transplant, while candidates that are equally sick in areas that currently experience greater access to transplant will experience similar wait times.

## **Conclusion**

The OPTN monitors the effects of new policies as a key part of the policy process. We will publicly and frequently report on key metrics. Using pre vs. post comparisons, analyses will be performed post-implementation at approximate 3-month intervals, up to 2 years, to identify trends and potentially unanticipated consequences of the policy. Analysis of post-transplant outcomes will be performed after sufficient follow-up data has accrued, which is dependent on submission of 6-month follow-up forms. Analyses will be performed nationally and regionally where feasible and appropriate. Metrics to be evaluated include:

- Number of deceased donor liver transplants
- Size and composition of the waiting list
- Variance in the median MELD score at transplant by appropriate geographic areas
- Waiting list mortality rates and transplant rates
- Transplant recipient demographics (age, gender, diagnosis, ethnicity, socioeconomic factors as available for analysis)
- Transplants by exception status (yes/no) and exception type (e.g., HCC, other standard exception, other specify)
- Post-transplant survival rates
- Post-transplant length of stay
- Number of livers recovered for transplant and not transplanted
- Utilization rates (Number of livers transplanted out of all organ donors)
- Organ travel distance, cold ischemia time, donor risk index
- Number and percent of livers transplanted within first classification tier following Status 1s
- Other metrics deemed relevant and necessary to the evaluation of the policy by the Liver and Intestinal Transplantation Committee at time of analysis

In conclusion, the OPTN adhered to its transparent, deliberative, and evidence-based policy-making process. After robust debate prior to and during the Board meeting, the OPTN Board adopted a policy that complies with Final Rule requirements for geographic distribution, fulfills the HRSA directive of July 2018, and provides more equitable access to liver transplantation for candidates across the country.

Sincerely,

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<sup>45</sup> The specific modeling results in each DSA are available on pages 10, 17, 24, 35, and 36 of the SRTR Analysis Report from the Data Request on Circle Based Allocation, available here: [https://optn.transplant.hrsa.gov/media/2640/li2018\\_01\\_analysis-report\\_20180924.pdf](https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf)



Susan M. Dunn  
President, OPTN Board of Directors



Brian Shepard  
OPTN Executive Director



# SRTR Responses

## Responses to Critical Comment Filed February 13, 2019 by Jones Day

**Date:** March 15, 2019

**Submitted To:**

Sue Dunn, President & CEO, Donor Alliance; President, United Network for Organ Sharing / Organ Procurement and Transplantation Network

Brian Shepard, MBA, CEO United Network for Organ Sharing

**CC:**

Cheryl Dammons (HRSA)

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Dear Ms. Dunn and Mr. Shepard,

This document contains SRTR responses to points raised by Jones Day in the critical comment filed with Secretary Azar dated February 13, 2019. The critical comment letter raised several concerns about the liver allocation policy passed by the Board of Directors of the Organ Procurement and Transplantation Network (OPTN) in December 2018, hereafter referred to as the "acuity circles policy". These responses were prepared by staff of the SRTR involved in the policy modeling performed by the SRTR in response to requests by the Liver and Intestinal Transplantation Committee of the OPTN in support of the policy development. Responses are prepared within general themes contained within the critical comment letter.

### **Theme #1: SRTR simulations indicate fewer transplants will be performed if the acuity circles policy is implemented.**

The SRTR strives to provide the most realistic simulations practical, but every simulation has limitations. In order to simulate the allocation of organs, the process of accepting or rejecting offers and the process of discarding organs must be simulated. Historical data are used to build an offer acceptance model and the number of rejected offers before an organ is discarded is chosen in order to generate a realistic total number of transplants under "current policy" simulations. The same

offer acceptance model and offer threshold for discard are used for all simulations so that the results are comparable.

SRTR modeling used real candidate and donor data from July 2013 through June 2016 as the starting point of the simulations (a 3-year simulation). SRTR modeling estimated an average of 6,651 transplants per-year under current policy (serving as a baseline) and 6,594 transplants under the acuity circles policy, a decrease of 57 transplants or a decline of 0.9%.<sup>1</sup> The actual number of deceased-donor liver transplants performed in the United States was 6,450 and 6,768 in calendar years 2014 and 2015<sup>2</sup>, respectively, which is close to the results of the SRTR simulations which contained these calendar years.

Notably, transplant counts declined slightly in each of the 5 policy simulations presented in the SRTR analysis report. The SRTR's offer acceptance and discard models are built upon the behavior inherent in the current allocation system. All policy scenarios modeled broader sharing, and, historically, livers that traveled longer distances tended to have been declined by more programs before reaching more distant candidates. Therefore, livers traveling farther distances had historically lower acceptance probabilities. Under any broader sharing scenario, livers traveling farther may not have already been declined by a number of programs because sicker patients farther away will be nearer the top of the offer list. This nuance alone could result in simulations of broader sharing resulting in fewer accepted livers.

The SRTR could have built alternative acceptance and discard models that attempted to remove this nuance from the simulation; however, doing so would impart an assumption that behavior would change. While the SRTR believes the transplant system would adapt and change as needed, we admittedly have no data to support such an assumption; therefore, we made the modeling decision to stay with acceptance and discard models built on historic behavior, explaining this nuance to the Committee during their deliberations.

## **Theme #2: The decline in waitlist mortality in the SRTR simulation does not seem to make sense.**

The letter notes that the acuity circles policy simulations decrease the number of waitlist deaths, which is correct. Simulation results found a decline from 1,455 waitlist deaths under current policy to 1,341 deaths under the acuity circles policy (a decline of 114 deaths or a 7.8%). The authors then claim that this "on its face does not make sense." The letter correctly notes that, in the long run, the number of available organs determines how many deaths due to organ failure can be prevented. The simulated waitlist death count, however, is not a "long run" prediction, but a "short run" prediction. In the short run, the number of waitlist deaths can be reduced by transplanting

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<sup>1</sup> Scientific Registry of Transplant Recipients, SRTR LI\_2018\_01, Sept. 24, 2018, [https://optn.transplant.hrsa.gov/media/2640/li2018\\_01\\_analysis-report\\_20180924.pdf](https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf).

<sup>2</sup> Organ Procurement and Transplantation Network. National Data Reports. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#>, accessed 03/01/2019.

more candidates at high risk of death and transplanting fewer candidates at low risk of death. We agree (and agreed) with Dr. Therneau (in 2011) that "lives saved" is a poor way to describe a decrease in simulated waitlist deaths in the short run. The simulated count of waitlist deaths is, in fact, not a metric of "lives saved", but is a metric of allocation efficiency. By increasing the priority of the most medically urgent candidates, and decreasing the priority of less urgent candidates, the simulated waitlist deaths decrease. Since the number of simulated waitlist deaths decreases under the acuity circles policy, that suggests that the acuity circles policy does a better job of offering livers to the most medically urgent candidates, in accordance with the goals of the Final Rule.

### **Theme #3: SRTR's simulations used national waitlist mortality rates rather than DSA-specific mortality rates.**

The authors note waitlist mortality rates vary across Donation Service Areas (DSAs). The SRTR produces DSA-specific waitlist mortality rates semi-annually as part of the publicly-available program-specific reports. It is true that the waitlist mortality rates are variable from DSA to DSA, but these rates are not adjusted for the characteristics of the candidates on the waitlist within each DSA. If programs in one DSA wait to list patients until they are sicker, the unadjusted waitlist mortality rate for that DSA will be higher, since all the listed candidates will be very sick. If, in another DSA, centers list candidates before they become very sick, the unadjusted waitlist mortality rate for that DSA will be lower, since there will be many listed candidates at low risk of death. The authors suggest that incorporating these unadjusted waitlist mortality rates into the waitlist mortality calculations would improve the simulations. In fact, variability in waitlist mortality is already incorporated into the simulations at the patient level (as opposed to the DSA level), and incorporating DSA-level unadjusted waitlist mortality would make the results of the simulations worse, not better.

In the simulations, the SRTR produces a realistic waitlist history for each simulated candidate based on historical candidates. The candidate histories can include changes in health including advancing disease, deaths, and removals from the waitlist. In DSAs where candidates are sicker, on average, the simulated candidate histories should reflect this already. Since the variability in DSA waitlist mortality is already incorporated into the simulations at the candidate level, the authors are incorrect to claim that failing to incorporate DSA-level variability in waitlist mortality "underestimates the deaths that will result from the Acuity Circle Policy, particularly in areas with higher waitlist mortality rates." The authors reference a "preliminary analysis by the Centers" which "demonstrates that once the variation in waitlist mortality across DSAs is considered, the number of waitlist deaths nationally is higher under the Acuity Circle Policy than the SRTR modeling indicated." It is impossible to be sure without examining this "preliminary analysis", but it does not appear that the Centers understand either the SRTR DSA-level unadjusted waitlist mortality metrics or the way that differences in candidate waitlist mortality rates are incorporated into the SRTR simulations, which suggests that the "preliminary analysis" is likely badly implemented and its claimed results ought to be treated with skepticism.

#### **Theme #4: SRTR's waitlist mortality metrics do not account for patients that are removed for being too sick for transplant.**

The authors note that there are two different ways to measure "waiting list mortality." A strict definition counts deaths for candidates on the waitlist, but not deaths for candidates who have been removed from the waitlist before transplant. A less strict definition includes deaths for all candidates who have been listed (regardless of future removal), but not been transplanted. SRTR has historically provided both formulations of waitlist mortality metrics. Because the Liver committee was trying to act quickly, the SRTR worked with the committee to limit the simulation results to the metrics the committee considered to be the most important. Since the two versions of waitlist mortality are nearly always very similar, reviewing both versions is generally redundant, and in the interest of expediting the work of the committee the SRTR provided the strict waitlist mortality counts to the committee, since that was the metric that the committee had chosen to consider in the past. Following subsequent concern about not seeing the alternative version, the SRTR quickly provided the alternate version to the committee. The authors suggest incorporating historical data on candidates removed from the list in order to "enhance the accuracy" of the simulations, but deaths following removal from the list is already incorporated into the simulations through the candidate histories.

#### **Theme #5: The acuity circles policy will disadvantage patients of lower socioeconomic status.**

The authors conflate reducing the priority of low socioeconomic status (SES) regions and increasing the priority of high SES regions with increasing socioeconomic inequities, and, conversely, conflate increasing the priority of low SES regions and decreasing the priority of high SES regions with reducing socioeconomic inequities. Reducing the relative priority of low SES regions increases socioeconomic inequities if, and only if, low SES regions currently have lower priority than high SES regions. Since the Acuity Circles policy is acuity-based, not region- or DSA-based, it prioritizes sicker candidates that may be farther away than less sick patients nearby the donor. If the candidates in some region have reduced priority under the Acuity Circles policy, that suggests that those candidates are currently benefiting from region- or DSA-based restrictions on the shipment of organs and that there are higher priority candidates nearby.

The acuity circles policy lacks any directionality. If livers tend to be shipped from DSA A to DSA B, it is because the candidates in DSA B tend to be higher priority than the candidates in DSA A. If, at some future time, this pattern reverses so that candidates in DSA A tend to be higher priority than candidates in DSA B, the shipment pattern of livers will also reverse, so that livers tend to be shipped from B to A. This structure ought to demonstrate that the Acuity Circles policy is not designed to disadvantage low SES candidates. The policy is, instead, designed to help high priority candidates, whether those candidates are low or high SES.

Another issue is that the authors treat all candidates within a region as having equivalent socioeconomic status. It is likely true that persons in Region 9 (which includes the state of New York) have higher average SES than persons in some other regions, but it would be wrong to conclude that candidates in other regions are all low SES and that candidates in Region 9 are all high SES. Surely, programs in New York serve both high- and low-SES candidates. Given the OPTN does not collect direct measures of SES in transplant candidates, there is no way to precisely measure which

programs serve the most low-SES candidates. There is no reason to assume, however, that programs in high-SES regions of the country do not serve low-SES candidates. Measures like the Cumulative Community Risk Score (CCRS) are ecologic measures of a group of people and may not necessarily reflect the characteristics of individual candidates. Ascribing broad area risks to each individual within that area may lead to an ecological fallacy. Finally, it is worth noting that while the OPTN does not collect direct measures of SES, e.g., net-worth, total family income, etc., the SRTR has presented metrics based on some factors that are collected by the OPTN and are perhaps representative of SES, e.g., race & ethnicity, age, sex, education level, insurance coverage, CCRS, and urbanicity, and the simulations did not indicate systematic bias against lower SES candidates based on these metrics.