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ATTORNEYS AT LAW

November 26, 2018

**VIA EMAIL & COURIER**

Ms. Ruby Potter
ruby.potter@maryland.gov
Health Facilities Coordination Officer
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore MD 21215

Re: MedStar Franklin Square
Establishment of Liver and Kidney Transplant Services
Matter Nos. 17-03-2405 & 17-03-2406

Dear Ms. Potter:

On behalf of interested party University of Maryland Medical Center ("UMMC"), we are submitting eight copies of UMMC's Reply in Further Support of its Motion for Stay of Certificate of Need Review of Medstar Health, Inc.'s Applications Proposing the Establishment of Liver and Kidney Transplant Services.

Also enclosed is a CD containing searchable PDF files of the filing and its exhibits, along with a WORD version of the filing, which will also be provided to Commission Staff under separate email.

We hereby certify that a copy of this submission has been forwarded to the appropriate local health planning agency as noted below. Thank you for your assistance.

Sincerely,

Ella R. Aiken

Hannah L. Perng

ERA/HLP:blr
Enclosures

#646451
006551-0239

cc: Paul Parker, Director, Center for Health Care Facilities Planning & Development, MHCC
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Thomas C. Dame, Esq.

| | | |
|---|---|---|
| IN THE MATTERS OF | * | |
| | * | |
| MEDSTAR FRANKLIN SQUARE KIDNEY TRANSPLANT SERVICE | * | |
| | * | BEFORE THE MARYLAND |
| Docket No. 17-03-2405 | * | HEALTH CARE |
| | * | |
| -and- | * | COMMISSION |
| | * | |
| MEDSTAR FRANKLIN SQUARE LIVER TRANSPLANT SERVICE | * | |
| | * | |
| Docket No. 17-03-2406 | * | |

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**UNIVERSITY OF MARYLAND MEDICAL CENTER'S REPLY IN FURTHER SUPPORT OF ITS MOTION FOR STAY OF CERTIFICATE OF NEED REVIEW OF MEDSTAR HEALTH, INC.'S APPLICATIONS PROPOSING THE ESTABLISHMENT OF LIVER AND KIDNEY TRANSPLANT SERVICES**

University of Maryland Medical Center ("UMMC"), by its undersigned counsel, submits this Reply in further support of its October 15, 2018 Motion for Stay of the Certificate of Need ("CON") reviews of the applications and related materials filed by MedStar Health, Inc. ("MedStar") proposing to establish liver and kidney transplant services at Franklin Square Hospital Center *d/b/a* MedStar Franklin Square Medical Center ("MFSMC").[1]

[1] MedStar suggests UMMC's request for a stay of these reviews is inconsistent with UMMC's silence in the review of the CON Application of Suburban Hospital, Docket No. 17-15-2400, to establish a liver transplant service. UMMC has not moved for a stay of the Suburban Hospital CON review because UMMC is not an interested party in that case, and therefore lacks standing. Moreover, there is nothing inconsistent about UMMC's failure to request interested party status in that review for the purpose of filing a motion for stay. UMMC's Motion is based on forthcoming significant changes to liver and kidney allocation policy, changes set into motion by the July 31, 2018 letter of the Health Resources and Services Administration ("HRSA") finding that the use of Designated Service Areas cannot be justified under the Final Rule, 42 C.F.R. 121.8. UMMC Motion for Stay, Exhibit A. HRSA's letter is dated three months after the deadline to request interested party status in Suburban Hospital CON review. Id. MARYLAND REGISTER, Vol. 45:7, p. 403 (Mar. 30, 2018) (establishing April 30, 2018 deadline.)

## ARGUMENT

Contrary to MedStar's statements in opposition to UMMC's Motion, there is no uncertainty about when the forthcoming changes to liver and kidney allocation policy will occur. Rather, there is overwhelming evidence that OPTN continues to actively progress toward set deadlines for implementing these significant policy changes. MedStar is also not entitled to review of its CON application based upon the supposed strength of its arguments unrelated to need. The State Health Plan Chapter requires compliance with all standards and criterion, not most of them. Finally, MedStar apparently concedes that the need analysis in its applications for transplant centers will be irrelevant once the liver and kidney allocation policies are changed to eliminate reliance on Donation Service Areas ("DSAs"), as MedStar offers no meaningful, substantive response to UMMC's argument that the elimination of DSAs undermines MedStar's need analysis.

### I. Significant Changes to Liver Allocation Policy Will Occur in December 2018.

MedStar likens the forthcoming liver allocation policy changes to prior slow-moving, internally prompted policy reviews. See MedStar Opp. at 2. That is not at all the situation here. The Health Resources and Services Administration ("HRSA") concluded that current liver allocation policy does not and cannot comply with the Final Rule, a federal regulation governing organ allocation policy; HRSA issued the directive that the Organ Procurement and Transplantation Network ("OPTN") change liver allocation by December 2018; and a federal court is providing oversight in the pending lawsuit against OPTN. A liver allocation policy change that removes the reliance on DSAs is certain and imminent.[2]

[2] MedStar relies on a previous instance in which OPTN approved a policy change that took a year to implement without explaining how the approval process in that previous instance is similar to this one.

For the past several years, OPTN has been considering significantly changing liver allocation policy to reduce or eliminate reliance on DSAs. See generally Exhibit D.[3] Earlier this year, however, prompted by the filing of a critical comment and a lawsuit, HRSA took the definitive step of directing OPTN to approve a new liver allocation policy by December 2018, concluding that OPTN's current liver allocation policy did not and could not comply with the Final Rule, which governs organ allocation policy. See Exhibit A, pp. 1, 4.

OPTN is currently on track to meet its December deadline. OPTN reviewed 1,200 public comments submitted between October 8 and November 1, and on November 2 voted to advance a new liver allocation policy to the OPTN Board of Directors for a vote by the Board on December 3-4, 2018. See "Liver distribution proposal advances for board consideration," November 6, 2018, attached as **Exhibit I**. In just a few weeks from the filing of this Reply, the OTPN Board will vote on this new liver allocation policy, and the policy will be implemented by early 2019. Id.

Also of note, the lawsuit against OPTN that prompted OPTN's immediate action on this issue has been stayed by a Court order until December 21, 2018, while OPTN actively works to revise its liver allocation policy. See August 10, 2018 Court Order, attached as **Exhibit J**. A joint status report is due on December 21 informing the Court of "the steps taken, if any, by Defendant Organ Procurement and Transplantation Network to change is liver allocation policy." Id. Most recently, the plaintiffs in that lawsuit filed a letter with the Court, stating that they

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Indeed, there is no indication that OPTN implemented that policy change at the direction of HRSA, or that the change was motivated by an active lawsuit.

[3] Exhibits A through H are attached to UMMC's initial Motion for Stay. The exhibits attached to this Reply begin with Exhibit I.

would "continue to monitor the ongoing policy development in advance of the OPTN Board of Director meeting in December 2018." October 16, 2018 Letter to Judge Torres, attached as **Exhibit K**, p. 2. Given that the Court is overseeing the progress of this policy change, and that OPTN failure's to meet its December 2018 deadline would trigger a resumption of the litigation against it, OPTN has every incentive to remain on track in this process.[4]

MedStar further attempts to dismiss the significance of the timing of this forthcoming policy change by suggesting that further litigation could delay its implementation, or that more data collection will be need to evaluate it. See MedStar Opp. at 2-3. These arguments are red herrings. Once the liver allocation policy change has been implemented, it will immediately change how livers are distributed. Donation Service Areas will no longer be used. That potential future litigation could impact organ allocation policy is pure self-speculation by MedStar, is unsupported, and could be used to justify any disregard for applicable regulations. The mere possibility that policy could change again in the future does not justify the application of policy that will be defunct before a review of MedStar's application can be completed.

In addition, the argument that "even once a new policy is submitted and implemented, it is unlikely that reliable and valid data . . . would allow the Commission to meaningfully evaluate the impact on existing and proposed translation services . . . for months, perhaps years," MedStar Opp. at 3-4, is inaccurate. The Commission and CON applicants regularly create models to view historical data in order to project future results. MedStar should be able to project how the

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[4] In fact, OPTN faced a similar situation in 2017, when patients in New York challenged the use of DSAs in lung allocation. That challenge resulted in a court order directing the OPTN/UNOS Executive Committee to conduct an emergency review of lung allocation policy, which it did. Changes to lung allocation policy were implemented shortly thereafter. See Public Comment Proposal: Liver and Intestine Distribution Using Distance from Donor Hospital, October 8, 2018, attached as **Exhibit L**, at p. 3.

allocation changes will impact its proposed program based on historical data (and future utilization and population projections) because the fundamental data points will not change – that is, which hospitals have programs, what donor organs become available, and the MELD/PELD score of waitlist patients. The allocation policy provides only the framework or model in which to view that data in order to project how organs are likely to be allocated in the future. As described more fully in UMMC's initial motion and Interested Party Comments, that allocation will occur in geographic circles larger than existing DSAs, prioritizing the most ill patients, whom MedStar concedes will not be treated at MFSMC. It will be possible for MedStar to consider the impact of the new allocation framework on its proposed program as soon as the policy is voted on in December. Indeed, OPTN has received significant analysis of the proposed policy changes based on the input of historical data into new models based on the different polices under consideration. See generally, Exhibit H.

Moreover, even if MedStar were correct, Maryland health planning policy does not support marching blindly ahead when there is insufficient data to justify a new program or imminent policy changes.

**II. Significant Changes to Kidney Allocation Policy Will Occur In June 2019.**

A recent update from the Kidney and Pancreas Transplantation Committees states that the OPTN Board of Directors is expected to vote on a proposed kidney allocation change at its June 2019 meeting. See "Updates from kidney and pancreas committees regarding geographic distribution issues," Nov. 5, 2018, attached as **Exhibit M**. The update explains that the Scientific Registry of Transplant Recipients ("SRTR") is currently modeling potential allocation policies, and that from January 21 to March 22, 2019, the proposed change will be available for public comment. Id. at p. 2. Notably, the update report acknowledges that "HRSA has directed

the OPTN to develop policies to replace the donor service area (DSA) and region as units of organ distribution with areas that meet provisions of the OPTN Final Rule." Id. at pp. 1-2.

Although the timeline for kidney allocation change lags a few months behind liver, it is clear that OPTN is marching forward to bring kidney allocation policy in compliance with the Final Rule, which means eliminating reliance on DSAs in kidney allocation policy.

## III. MedStar Must, but Cannot, Demonstrate that its Organ Transplantation Programs are Needed.

COMAR § 10.24.15.04B sets forth the requirements that MedStar's application must satisfy, including need, minimum volume, access, cost effectiveness, impact, and health promotion and disease prevention. MedStar must satisfy each of these requirements in order to receive a Certificate of Need from the Commission. Id. Need for a new project is based, in part, on "[t]he ability of the general hospital to increase the supply or use of donor organs for patients served in Maryland through technology innovations, living donation initiatives, and other efforts." COMAR § 10.24.15.04B(1). MedStar's opposition appears to suggest that its application is entitled to CON review despite its inability to meet the need standard because it (allegedly) meets the other requirements of the State Health Plan standards. See MedStar Opp. at 4 (arguing that "the ability to increase the supply or use of donor organs is just one element of MFSMC's proposal"). The regulations make abundantly clear that MedStar must satisfy the need requirement just as it must satisfy all the other requirements set forth in the State Health Plan chapter. See COMAR § 10.24.15.04B. If MedStar cannot do so, then it is not entitled to a Certificate of Need for its organ transplant centers.

MedStar's erroneous dismissal of the need requirement is an attempt to deflect from its lack of substantive response to the fact that its need analysis relies entirely on the existence of

DSAs, and that DSAs will be eliminated with the organ allocation changes. MedStar's application contends that it can satisfy the need requirement of the State Health Plan Chapter because MedStar's proposed new transplantation program at MFSMC will create more donor livers in the Baltimore-area DSA, thus benefitting recipients in this DSA. Without DSAs as the foundation upon which organ allocation decisions are made, however, MedStar's need argument falls apart.

Moreover, as demonstrated in UMMC's initial motion, the new policies will result in organs travelling farther to prioritize the most ill patients. Because MedStar proposes a low-volume project that will not treat the most critically ill patients, there is a serious risk MedStar's proposed programs will be unable to meet other standards as well, such as Minimum Volume, once the forthcoming changes to organ allocation policies are implemented.

## CONCLUSION

Liver allocation policy will change significantly in just a few weeks, and kidney allocation policy will similarly change in six months. Both policy changes will eliminate DSAs as the basis for organ allocation decisions. For these reasons and the additional reasons set forth in UMMC's Motion for Stay and in this Reply, UMMC respectfully requests that the Commission stay the CON review of MedStar's applications proposing to establish liver and kidney transplant services at MedStar Franklin Square Medical Center until these allocation policy changes are passed, and then request that MedStar update its analyses to be consistent with those changes.

Respectfully submitted,

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*Attorneys for University of Maryland Medical Center*

November 26, 2018

**Table of Exhibits**

| Exhibit | Description |
|---|---|
| I | UNOS November 6, 2018 news release on liver distribution proposal |
| J | August 10, 2018 Court Order |
| K | October 16, 2018 Letter to Judge Torres |
| L | Excerpt from OPTN/UNOS Public Comment Proposal: Liver and Intestine Distribution Using Distance from Donor Hospital, pp. 1-6; full document available at https://optn.transplant.hrsa.gov/media/2687/20181008_liver_publiccomment.pdf |
| M | UNOS November 5, 2018 update from kidney and pancreas committee |

## CERTIFICATE OF SERVICE

I hereby certify that on the 26th day of November 2018, a copy of University of Maryland Medical Center's Reply in Support of its October 15, 2018 Motion for Stay of Certificate of Need Review was sent:

***via email and first-class mail to***

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Ella R. Aiken

# EXHIBIT I

Organ Procurement and Transplantation Network (/)

# Liver distribution proposal advances for board consideration



**UNOS News Bureau**

(804) 782-4730

newsroom@unos.org (mailto:newsroom@unos.org)

Chicago – The OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, at its meeting Nov. 2, voted to advance a proposal to revise liver distribution policy for a final vote by the OPTN/UNOS Board of Directors at its Dec. 3-4 meeting. The proposal is intended to establish greater consistency in the geographic areas used to match liver transplant candidates with available organs from most adult deceased donors and reduce geographic differences in liver transplant access.

"We believe this reflects a commitment to transplant the most urgent candidates while balancing a number of key issues affecting the liver transplant process," said committee chair Julie Heimbach, M.D. "We're committed to closely monitoring the impact of this policy and to making modifications if further optimizations are identified."

The proposal would replace fixed, irregular local and regional geographic boundaries historically used to match liver candidates based on the donor location. It would initially prioritize liver offers from most deceased adult donors in the following sequence:

- the most medically urgent candidates (Status 1A and 1B) listed at transplant hospitals within a radius of 500 nautical miles of the donor hospital
- candidates with a MELD or PELD score of 29 or higher listed at transplant hospitals within a radius of 250 nautical miles from the donor hospital
- candidates with a MELD or PELD score between 15 and 28 listed at transplant hospitals within a radius of 150 miles from the donor hospital

Livers from deceased donors older than age 70, and/or those who die as a result of cardiorespiratory failure, will be exempt from this distribution. Most of these organs are accepted for local candidates, since they are most viable when the preservation time between recovery and transplantation is short. In addition, this distribution sequence would not apply to livers from deceased donors younger than age 18, which are preferentially considered for pediatric transplant candidates.

The committee further recommended that the implementation of revised liver distribution policy occur no sooner than three months from the pending implementation of a new National Liver Review Board (NLRB), which is scheduled to occur in early 2019. Also, upon NRLB implementation, the committee recommended that standardized exception scores for liver candidates be capped at 28, so that candidates with these scores would not outgain priority for urgent candidates based on calculated MELD/PELD scores. Transplant hospitals, using their medical judgment, may request exception scores higher than 28 from the NLRB for individual candidates.

Simulation modeling of the proposed changes indicate they would reduce variation in transplants by MELD score that exist in various areas of the country under the current liver distribution system. Modeling further predicts

that the changes should reduce pre-transplant deaths and increase access for liver transplant candidates younger than age 18. In addition to modeling results, the committee reviewed opinions, recommendations and questions from more than 1,200 public comments submitted between Oct. 8 and Nov. 1.

Published on: Tuesday, November 6, 2018

Viewers & Players
(http://www.hhs.gov/plugins.html)

## CONTACT

Organ Procurement and Transplantation Network (https://optn.transplant.hrsa.gov/)

United Network for Organ Sharing (http://www.unos.org/)

Post Office Box 2484 (http://www.unos.org/)

Richmond, Virginia 23218 (http://www.unos.org/)

# EXHIBIT J

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

WILNELIA CRUZ; SUSAN JACKSON; DEBORAH MCNEILL; ROBERT NOURSE; LUIS TORRES; and MARILYN WALTO,

Plaintiffs,

-against-

UNITED STATES DEPATMENT OF HEALTH AND HUMAN SERVICES through ALEX M. AZAR II in his official capacity as Secretary of the United States Department of Health and Human Services; ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK; and UNITED NETWORK FOR ORGAN SHARING,

Defendants.

18 Civ. 6371 (AT)

**ORDER**

ANALISA TORRES, United States District Judge:

Plaintiffs' motion to stay, ECF No. 26, is GRANTED. It is hereby ORDERED that:

1. The action is STAYED until **December 21, 2018**;
2. The initial pretrial conference scheduled for September 17, 2018 is ADJOURNED pending the stay; and
3. By **December 21, 2018**, the parties shall file a joint status report informing the Court of (a) the steps taken, if any, by Defendant Organ Procurement and Transplantation Network to change its liver allocation policy; and (b) how they wish to proceed in this action.

SO ORDERED.

Dated: August 10, 2018
New York, New York

ANALISA TORRES
United States District Judge

# EXHIBIT K

BSF | BOIES SCHILLER FLEXNER

October 16, 2018

**Via ECF**

Honorable Analisa Torres
United States District Court
Southern District of New York
500 Pearl Street
New York, N.Y. 10007

**Re:** ***Cruz et. al. v. U.S. Dept. of Health and Human Serv. et. al.*****18-CV-06371 (AT)**

Dear Judge Torres:

We write on behalf of Plaintiffs to provide the Court with an interim status report regarding this currently stayed matter.

1. Plaintiff Wilnelia Cruz

This past weekend, Plaintiff Wilnelia Cruz passed away from complications relating to end-stage liver disease. Ms. Cruz, 38, lived in New York City and was the mother of two children. She contracted Hepatitis C as an infant from a blood transfusion she received in her native Puerto Rico. Ms. Cruz was added to the liver transplant waiting list in January 2017. Ms. Cruz's death is particularly tragic because she had a MELD score that could have gotten her transplanted in many places in the United States. She is the unfortunate victim of a system that wrongly prioritizes where a person lives or whether they have the financial resources to travel over legitimate medical need.

Given that there remain other suitable plaintiffs in this action, Plaintiffs will deal with any amendment or Rule 25 substitution of parties following the December 21, 2018 status report.

2. OPTN/UNOS Liver and Intestine Transplantation Committee

On October 8, 2018, the OPTN/UNOS Liver and Intestine Transplantation Committee published a policy proposal on how to bring the OPTN liver policy into compliance with the law. The Committee proposed a new policy called "Broader 2-Circle" that makes cosmetic changes to the revised policy proposed in December 2017, which HHS previously recognized as not complying with the law. The Broader 2-Circle

BSF



proposal remains geography based and prioritizes a patient with a MELD score of 16 (a three month mortality risk of 10% or less) over a patient with a MELD score of 31 (over 50% three month mortality risk) that lives a mere twenty or thirty miles away.[1]

The Committee also modeled a more promising policy, based on "acuity circles," which if properly implemented can lead to meaningful change and bring OPTN policy into compliance with the law. We will continue to monitor the ongoing policy development in advance of the OPTN Board of Director meeting in December 2018.

Consistent with this Court's August 10, 2018 Order, we will file a joint status report by no later than December 21, 2018.

Respectfully submitted,

*s/Motty Shulman*

Motty Shulman

cc: Counsel of Record via ECF

[11] For example, a liver that becomes available in Carthage, TX would go to a patient in Dallas, TX with a MELD score of 16 before it went to a patient in Houston, TX with a MELD score of 31.

# EXHIBIT L

OPTN | UNOS

## Public Comment Proposal

# Liver and Intestine Distribution Using Distance from Donor Hospital

*OPTN/UNOS Liver and Intestine Transplantation Committee*

*Prepared by: Elizabeth C. Miller*
*UNOS Policy Department*

## Contents

# Liver and Intestine Distribution Using Distance from Donor Hospital

| | |
|---|---|
| *Affected Policies:* | *1.2 Definitions; 1.3.A Acceptable Variances; 1.4.E OPTN Computer Match Program Outages; 5.4.B Order of Allocation; 5.10.C Other Multi-Organ Combinations; 7.3.B Allocation of Intestines; Policy 9: Allocation of Livers and Liver-Intestines; and Bylaws Appendix M: Definitions* |
| *Sponsoring Committee:* | *Liver and Intestine Transplantation* |
| *Public Comment Period:* | *October 8, 2018 – November 1, 2018* |

## Executive Summary

The United States Secretary of Health and Human Services (HHS) received critical comments regarding compliance with the National Organ Transplant Act (NOTA)[1] and associated regulations under the OPTN Final Rule[2] with respect to the geographic units used in liver distribution. As of July 2018, HHS and the OPTN are named defendants in a lawsuit regarding this issue.[3]

The OPTN Final Rule sets requirements for allocation polices developed by the OPTN, including sound medical judgement, best use of organs, ability for transplant hospitals to decide whether to accept an organ offer, avoiding wasting organs, and promoting efficiency. The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required"[4] by the other requirements of the Final Rule listed above.

The liver organ distribution policies currently use donation service areas (DSAs) and OPTN regions as geographic units. These are not good proxies for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs and regions result in an inconsistent application for all candidates. This presents a potential conflict with the Final Rule.

In response to a directive from the HHS Secretary, the Liver and Intestinal Transplantation Committee (Committee) worked to develop a proposal that does not include DSA or region in liver allocation or in scoring liver candidate exceptions. The Board also committed to considering such a proposal in December 2018.

This proposal, developed at that direction, eliminates the use of DSA and region in liver, liver-intestine, intestine, and liver-kidney allocation policies. This proposal would allocate livers to candidates within 150, 250, or 500 nautical miles (nm) of donor hospitals before offering them nationally to allow for efficient placement of donor organs and to avoid organ wastage. (Referred to as the "broader 2-circle" framework.) Livers would be allocated to status 1A and 1B candidates within 500nm first. Candidates with a Model for End-Stage Liver Disease (MELD) score of at least 32 would then be offered livers if they were within 250nm of the donor hospital. Then livers would be offered to candidates with a MELD of 15-31, first within 150nm, then within 250nm, then within 500nm. After that, livers would be offered to status 1A and 1B candidates and candidates with MELD or PELD scores of at least 15 across the nation.

Additionally, the broader 2-circle proposal replaces median MELD at transplant (MMaT) in the DSA or region in the calculation of exception scores with the MMaT within a 250 nm circle around the transplant hospital for patients that are at least 12 years old, and with the median Pediatric End-Stage Liver Disease

[1] NOTA, 42 U.S.C. § 273 et. seq.
[2] OPTN Final Rule, 42 C.F.R. § 121.
[3] Cruz et al v. U.S. Dept. of Health and Human Services, (S.D.N.Y 18-CV-06371).
[4] 42 C.F.R. § 121.

(PELD) at transplant in the nation for patients less than 12 years old. It also recommends changes to existing liver allocation variances, provides additional priority for pediatric candidates when there is a pediatric donor, clarifies treatment of blood type B candidates when the donor is blood type O, simplifies allocation of livers for other methods of hepatic support and MELD <6, and clarifies other references to local, DSA, and region.

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

1. The community is asked what MELD sharing threshold they recommend.
2. The community is asked whether the sizes of the fixed distance circles should be larger, smaller, or remain the same.
3. The community is asked whether they prefer the broader 2-circle model (this is the model preferred by the committee), or the acuity circles model.
4. Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community

# What problem will this proposal address?

The OPTN Final Rule sets requirements for allocation polices developed by the OPTN, including sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, and to promote efficiency.[5] The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by the other requirements of the Rule.[6] Finally, the OPTN Final Rule contains a performance goal for "Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency."[7]

In 2017, patients in New York challenged the use of donation service areas (DSAs) in lung allocation.[8] This challenge contended that the use of DSAs for lung distribution purposes was arbitrary and capricious and not consistent with obligations specified in the OPTN Final Rule. The OPTN/UNOS Executive Committee made emergency changes to remove the use of DSAs in lung allocation.[9] On May 30, 2018, HHS received a critical comment with similar concerns about the liver distribution system.[10] Specifically, the commenter asserted that livers from deceased donors were allocated to candidates based on arbitrary geographic boundaries instead of medical priority. The author then requested that HHS direct the OPTN to revise those distribution policies. Subsequently, HRSA requested a response from the OPTN on the critical comment.[11]

OPTN policy development requires reasoned, evidence-based decision making. In administrative rulemaking, this rationality requirement stems from the concept that changes to regulatory law must be based on reasoned analysis. The courts have developed an "arbitrary and capricious" standard for the review of agency rulemaking.[12] Under this standard, an agency issuing a regulation must "examine the relevant data and articulate a satisfactory explanation for its action" including a 'rational connection between the facts found the choice made.'"[13] An agency regulation is arbitrary and capricious where the agency (1) has relied on factors that Congress did not intend to consider, (2) entirely failed to consider an important aspect of the problem, (3) offered an explanation for its decision that runs counter to the evidence before it, or (4) is so implausible that it could not be the result of a difference in view or agency expertise.[14]

Applying the above test to the current framework for liver distribution, there are concerns with the use of DSAs and regions for organ distribution.[15] First, it appears that at least some members considered factors that Congress did not intend for the OPTN to consider when designing organ allocation rules. During Committee conversations and public comment, some members stated that deceased donor organs should be a local resource as opposed to a national resource. This principle is not included in NOTA or the OPTN Final Rule. Specifically, it is not included in the list of factors for developing organ allocation policies in 42 C.F.R § 121.8. Additionally, several entities have considered this issue, with the consensus understanding that organs are a national resource meant to be allocated based on patient's medical

[5] 42 C.F.R §121.8.
[6] 42 C.F.R §121.8(a)(8).
[7] 42 C.F.R. §121.8(b)(3).

[8] Holman v U.S. Dept. of Health and Human Services, (S.D.N.Y 17-CV-09041).
[9] OPTN/UNOS Thoracic Organ Transplantation Committee, "Modifications to the Distribution of Deceased Donor Lungs." June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf (accessed October 1, 2018).
[10] Motty Shulman, letter to Sec. Alex Azar, May 30, 2018.
[11] George Sigounas, letter to Yolanda Becker, OPTN President, June 8, 2018.
[12] Motor Vehicles Mfrs. Assn. v. State Farm Mut., 463 U.S. 29 (1983).
[13] *Ibid.*
[14] *Ibid.*
[15] Alexandra Glazier, "The Lung Lawsuit: A Case Study in Organ Allocation Policy and Administrative Law." *Journal of Health and Biomedical Law*, no XIV (2018).

need. Specifically, the 1986 Task Force stated that, "The principle that donated cadaveric organs are a national resource implies that, in principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography."[16] The Institute of Medicine (IOM) made this same conclusion in 1999.[17] In 2012, the AMA Code of Medical Ethics stated that, "Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation."[18] HHS has stated this same principle several times in public rulemaking.[19, 20] Most recently, the OPTN/UNOS Board of Directors adopted new Principles of Organ Distribution. Those principles reaffirm that "Deceased donor organs are a national resource to be distributed as broadly as feasible."[21]

Additionally, at least some members offered explanations for the use of DSA and regional boundaries that are unsupported by evidence. During several Committee conversations and public comments, it was posited that DSA boundaries should be used for organ distribution because they result in strengthened relationships between transplant hospitals and OPOs which in turn result in improved utilization rates. While some studies have shown that improved relationships between donor hospitals and OPOs can result in improve organ donation rates,[22] it is conceivable that improved relationships between transplant hospitals and OPOs could result in improved organ placement. However, a literature search identified no research that shows DSA boundaries facilitate these relationships.

The OPTN Final Rule aims to distribute organs to the most medically urgent candidates. The DSA and regional boundaries were not designed with the intent to optimize any of the OPTN goals in NOTA or the Final Rule. Nor have these boundaries been successful in distributing organs to the most medically urgent candidates. Instead, the current distribution framework results in geographic variability in access to transplant. The OPTN/SRTR's 2016 Annual Data Report: Liver stated, "there is wide geographic variability in the degree of sickness, based on median MELD scores, in candidates for deceased donor transplants. The highest reported median MELD score was 39 in Los Angeles, California (CAOP), and the lowest 20 in Indianapolis, Indiana (INOP)."[23] Several articles have repeated this finding over time.[24]

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[16] U.S. Dept. of Health & Human Services, Public Health Service, Health Resources and Services Administration, Office of Organ Transplantation, "Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Transplantation." Rockville, MD., p. 91, 1987, quoting Hunsicker, LG.

[17] National Academies Press, "Organ Procurement and Transplantation." (1999).

[18] American Medical Association, "Opinion 2.16. Organ Transplantation Guidelines." *Journal of Ethics.* March 2012, Volume 14, Number 3: 204-214. doi: 10.1001/virtualmentor.2012.14.3.coet1-1203.

[19] 98 FR 16490, June 22, 1988. Page 33863. "We know that hospitals, OPOs, and tissue and eye banks share our view that organs and tissues are a precious national resource and that only through the collaborative efforts of all parties can lives be saved." https://www.gpo.gov/fdsys/pkg/FR-1998-06-22/html/98-16490.htm

[20] 76 FR 78216. Dec. 16, 2011. Page 78218. "One of the major reasons NOTA was enacted and affirmed by several amendments was to establish an organ allocation system that functions equitably on a nationwide basis with provisions for outcomes reporting and evaluation. Prior to the enactment of NOTA, deceased donor organs were allocated regionally, based on relationships between transplant programs and donor hospitals."

[21] OPTN/UNOS Ad Hoc Committee on Geography. "Geographic Organ Distribution Principles and Models Recommendations Report." June 2018.

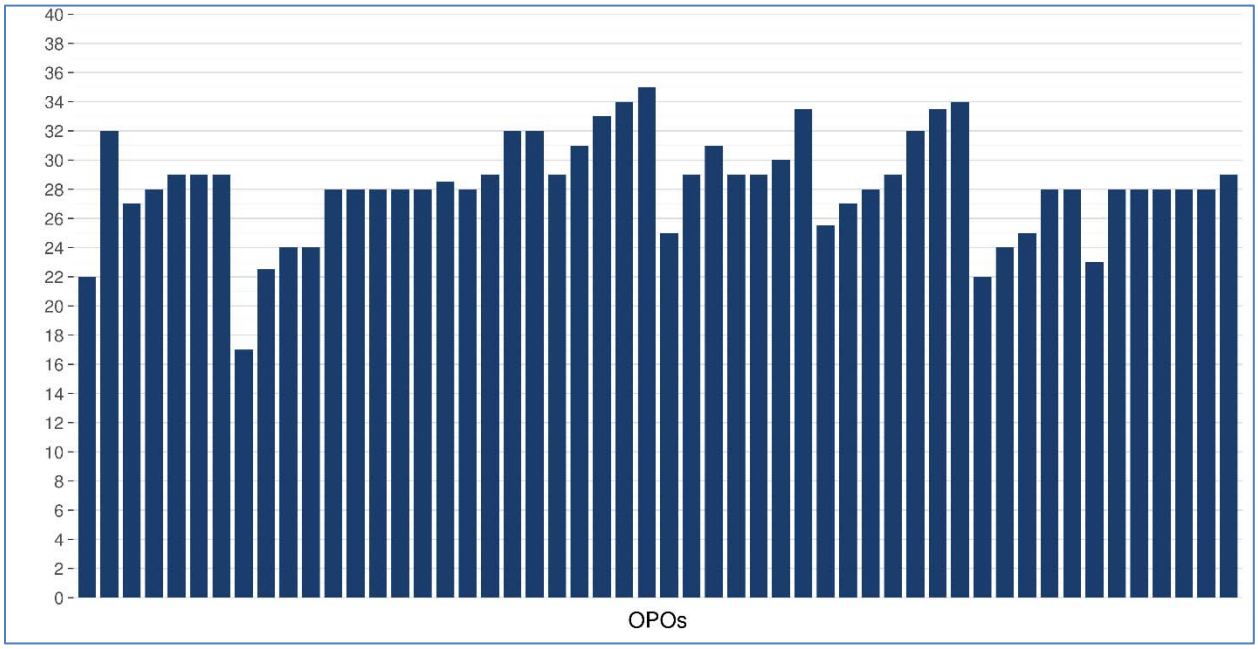
[22] Rayburn, Ann B. "A Multipronged Approach to Addressing the Organ Shortage." *The Journal of Cardiovascular Nursing* No. 20 Supplement (2005). doi:10.1097/00005082-200509001-00003. "The common theme in addressing the problem of organ shortages is relationship building. To be successful, OPOs must develop effective relationships with hospitals, the public and, most importantly, potential donor families."

[23] Motty Shulman, letter to Sec. Alex Azar, May 30, 2018 citing OPTN/SRTR 2016 Annual Data Report Liver (first published January 2, 2018)

[24] Gentry, S. E., Massie, A. B., Cheek, S. W., Lentine, K. L., Chow, E. H., Wickliffe, C. E., Dzebashvili, N. , Salvalaggio, P. R., Schnitzler, M. A., Axelrod, D. A. and Segev, D. L. (2013), "Addressing Geographic Disparities in Liver Transplantation Through Redistricting." *American Journal of Transplantation*, 13: 2052-2058 doi:10.1111/ajt.12301; Yeh, H., Smoot, E., Schoenfeld, D. A., & Markmann, J. F. (2011). "Geographic Inequity in

Current OPTN data continues to show the variability in organ access. Figure 1 shows the lowest median MELD score by transplant center is 17 and the highest median MELD score is 35.[25]

**Figure 1: MMaT by DSA for Adult Cohort, 7/1/2017-6/30/2018**




The OPTN and others have commented on the use of DSAs and regions for organ distribution. In 2010, the Advisory Council on Organ Transplantation (ACOT) recommended "that the Secretary take steps to ensure that the OPTN develop evidence based distribution policies that are not determined by arbitrary administrative boundaries such as OPO service areas…"[26] In November 2012, the OPTN Board adopted the following resolution… "The existing geographic disparity in access to allocation of organs for transplant is unacceptably high." In 2017, the OPTN Executive Committee recognized that "DSAs might not be the best proxy for geography, as DSAs have disparate sizes, shapes, and populations. DSAs as drawn today do not appropriately address those concerns in a way that is rationally determined, consistently applied, and equal for all candidates."[27]

On July 31, 2018, the Secretary of HHS wrote that "the OPTN has not justified and cannot justify the use of donation service areas (DSAs) and OPTN Regions in the current liver allocation policy and the revised liver allocation policy approved by the OPTN Board of Directors (OPTN Board) on December 4, 2017 under the HHS Final Rule affecting the OPTN."[28] The Secretary continued that "geographic constraints may be appropriate if they can be justified in light of regulatory requirements, but that DSAs and Regions have not and cannot be justified under such requirements.[29] On this basis, the OPTN Board is directed to adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions and that is compliant

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Access to Livers for Transplantation." *Transplantation*, 91(4), 479–486. http://doi. /10.1097/TP.0b013e3182066275; Schwartz A, Schiano T, Kim-Schluger L, Florman S. Geographic disparity: the dilemma of lower socioeconomic status, multiple listing, and death on the liver transplant waiting list; Kilambi, Vikram, and Sanjay Mehrotra. "Improving Liver Allocation Using Optimized Neighborhoods." *Transplantation* 101, no. 2 (2017): 350-59. doi:10.1097/tp.0000000000001505

[25] MMaT by DSA for Adult Cohort, 7/1/2017 to 6/30/2018, excludes national shares, Status 1s, living donors, and DCD donors. Based on OPTN data

[26] ACOT Recommendation 51 (August 2010).

[27] OPTN/UNOS Executive Committee. "Broader Sharing of Adult Donor Lungs". Nov. 2017.

[28] George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

[29] *Ibid.*

with the OPTN Final Rule."[30] The letter contained a deadline for the Board to adopt a new liver allocation policy by its December 2018 meeting.

# Why should you support this proposal?

The problem facing the transplant community is also *who* should make decisions regarding organ distribution policies. The July 2018 HHS letter stated, that "If the OPTN Board fails to adopt a liver allocation policy that eliminates DSAs and Regions and that is otherwise consistent with the requirements of the OPTN Final Rule, the Secretary may exercise further options or direct further action consistent with his authority under 42 C.F.R 121.4(d)." The OPTN believes that organ allocation and distribution decisions are best decided by the experts in the transplant community. Therefore, it is important that the transplant community work together to resolve this issue. In the alternative, we risk having these decisions made by the legislature,[31] the judiciary,[32] or our colleagues in HHS.

The proposed broader 2-circle solution removes the DSAs and Regions as units of distribution in liver allocation policy, and replaces them with rationally determined units of distribution that are intended to ensure that the most urgent candidates are prioritized. It also strikes an appropriate balance of the other Final Rule requirements by mitigating the logistical issues associated with distributing organs across further distances, and ensuring that organs are not wasted. This proposal seeks to make the best use of each donated organ.

## How was this proposal developed?

The Committee was directed by the President of the OPTN Board of Directors on June 25, 2018 to "propose revisions to [approved liver] policy that provide Final Rule compliant replacements for:

1) The use of Region and DSA in liver and liver-intestine allocation
2) The use of DSA in the awarding of proximity points
3) The use of Region and DSA in the median MELD/PELD at transplant scoring for exception patients
4) The use of Region and DSA in simultaneous liver kidney (SLK) allocation" [33]

The Committee collaborated with multiple OPTN/UNOS Committees representing particular patient groups or perspectives during the development of this proposal. Members of the Pediatric Transplantation Committee joined the Committee and contributed to discussions about the impact of each change considered on pediatric candidates. Members of the Kidney Transplantation Committee joined for discussions about how to amend SLK allocation. Members of the Minority Affairs Committee and the Geography Committee provided input on how to address allocation to and from areas of the non-contiguous United States. The Patient Affairs Constituent Council provided feedback to the Committee on how to explain this proposal to the patients who would be affected, and expressed a desire to treat candidates similarly, regardless of their location. The Geography Committee received regular updates on the work of the Committee, and provided feedback about whether some of the solutions the Committee considered were compliant with the OPTN Final Rule.

While the Liver Committee began work to remove DSAs and regions from liver and intestine distribution, the Executive Committee charged several other Committees to begin similar work. The Kidney and Pancreas Transplantation Committees were charged to remove DSAs and regions from their distribution systems. The Thoracic Organ Transplantation Committee was charged to remove DSAs from heart allocation. The Vascular Composite Allograft (VCA) Transplant Committee was charged to remove

[30] *Ibid.*

[31] For example, see H.R. 6458, 115th Congress, (2018) and H.R. 6517, 155th Congress (2018).

[32] For example, *see* Cruz et al v. U.S. Dept. of Health and Human Services, (S.D.N.Y 18-CV-06371) and Holman v U.S. Dept. of Health and Human Services, (S.D.N.Y 17-CV-09041).

[33] Yolanda Becker, OPTN President, letter to the OPTN Liver and Intestinal Organ Transplant Committee, June 25, 2018.

# EXHIBIT M

*Matching organs. Saving lives.*



Kidney

# Updates from kidney and pancreas committees regarding geographic distribution issues

Nov 5, 2018 | Kidney, Policy

Given the importance of addressing issues of geographic distribution in all organ policies, we want to give you more information about the kidney/pancreas initiative. We will continue to update you periodically as events warrant.

A memo from: Nicole Turgeon, M.D., Chair of the OPTN/UNOS Kidney Transplantation Committee and Jon Odorico, M.D., Chair of the OPTN/UNOS Pancreas Transplantation Committee

To: Kidney and Pancreas transplant program directors and administrators and OPO executive directors.

**Background**

You have already received some general updates from OPTN/UNOS Board leadership on the overall issues of geographic distribution. In short, HRSA has directed the OPTN to develop policies to replace the donor service area (DSA) and region as units of organ distribution with areas that meet

provisions of the OPTN Final Rule and principles adopted by the OPTN/UNOS Board in June.

It is important that we address this within the established OPTN/UNOS policy development process. If we cannot, it makes it much more likely that future issues of similar importance will be decided by legal or regulatory means, which may not reflect the expertise and input of the entire donation and transplant community.

**Timeline and process**

Our two committees are working together on a proposal to revise kidney and pancreas distribution under the guidance of the OPTN/UNOS Executive and Policy Oversight Committees. You may be familiar already with the work in progress on liver and intestine distribution, which is proceeding on a faster timeline.

We are working on a timeline that will include public comment in the regularly scheduled winter/spring cycle and a proposal to bring to the OPTN/UNOS Board in June 2019. This is the same timeline being used to update distribution policies for thoracic organs and vascular composite allografts (VCA).

Below are key policy development milestones as we know them at this point. We will update you with any new or changed dates.
**September 2018** – Modeling request to the SRTR
**December 7, 2018** – Modeling results available
**December 2018** – Public comment proposal finalized
**Jan. 21 – March 22, 2019** – Public comment period
**June 10-11, 2019** – OPTN/UNOS Board meeting

**Frameworks being modeled**

Our individual committees, and a work group representing both committees, have met a number of times by teleconference over the last few months. In September we sent to the SRTR, for kidney/pancreas simulated allocation modeling (KPSAM), a series of alternatives to guide a

policy proposal. We expect to receive the modeling results in December and will share them with you when available.

Because of the timeframe for all of these efforts, the frameworks we recommended for modeling were developed in parallel with the proposed geographic frameworks recently sent for public comment. Our work, however, has been informed by the discussion to date about the geographic principles and the recommended frameworks.

In the immediate term, we are pursuing distribution based on elements of two different distribution frameworks. One framework involves fixed distance (concentric circle) from the donor hospital. The second is a hybrid of the concentric circles and continuous approaches, where all candidates within a circle(s) receive allocation priority based on the current classification tables but with an additional layer of points related to proximity to the donor hospital. While we are focusing on this model to meet the expedited timetable described above, we may consider future policy refinements, such as a full continuous framework proposal, consistent with the outcome of the Board's adoption of one or more frameworks. We have asked for modeling results for various alternatives as summarized here.

As with any simulation modeling, we expect the results to address the scope and direction of impacts more than detailed predictions for all circumstances. Modeling may not represent all behaviors involved in the current transplant process and certainly can't account for potential future behavioral changes. In addition, we may find that the modeling may yield results that affect kidney, pancreas and SPK differently. That said, we will apply the expertise on our committees and seek your input through public comment to determine the best alternative given the current assumptions and timeline. As with any policy, we will closely study its results once implemented and consider any necessary corrections to improve it going forward.

**For questions or further information**

If you'd like to know more about existing policies, contact your Regional Administrator. You can also find additional resource information and updates on the web pages of both the Kidney Committee and the Pancreas Committee. If you'd like to know more about projects or proposals our committee continues to discuss, contact your regional representative to the committee, or send an e-mail to kidney@unos.org or pancreas@unos.org.

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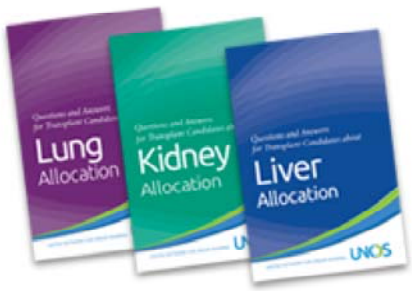


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