At a glance

What is current policy and why change it?

Currently, the OPTN uses Donor Service Areas (DSAs) and Regions to distribute livers for transplant. Transplant candidates in Hawaii have access to regionally shared livers from donors in Region 6, and candidates in Puerto Rico have access to regionally shared livers from donors in Region 3. If the distribution unit for a very sick patient changes to a 500 nautical mile (NM) circle from the donor hospital, there may not be a donor within 500 NM quickly enough for candidates in Hawaii and Puerto Rico who need a liver transplant very urgently. These medically urgent candidates have a high likelihood of death within the first one or two weeks from the time they are listed at this status.

What's the proposal?

- Create a variance for Hawaii and Puerto Rico adding two additional distances for distribution for very sick candidates:
  - An additional distance of 1,100 NM for candidates in Puerto Rico.
  - An additional distance of 2,400 NM for candidates in Hawaii.
- Additional distances will follow 500 NM classifications for candidates with Status 1A and 1B, and 500 NM classifications for candidates with a model for end stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score of 37 or higher.

What's the anticipated impact of this change?

- **<u>What it's expected to do</u>**
  - Medically urgent liver candidates listed at transplant hospitals in Hawaii and Puerto Rico will have additional access to donated

organs that become available in the closest parts of the continental U.S.

- **What it won't do**
  - The variance will not apply to:
    - donors 70 years or older or donors who donate after cardiac death (DCD)
    - blood type A or AB candidates when the donor blood type is O
    - livers allocated for therapeutic treatments other than organ transplantation
    - candidates outside of Hawaii or Puerto Rico
    - affect the allocation sequence for donors in Hawaii or Puerto Rico.

Terms you need to know

- **Nautical Miles (NM)**: A unit of measure equal to 1.1508 miles.
- **Variance**: An experimental policy that tests methods of improving allocation.
- **Candidate**: A person registered on the organ transplant waiting list.
- **Donor Service Area (DSA)**: The geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals.
- **Region**: For administrative purposes, OPTN membership is divided into 11 geographic regions. Members belong to the Region in which they are located.
  - Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Puerto Rico
  - Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, and Washington

- Click here to search the OPTN glossary

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Public Comment Proposal

Access for Urgent Liver Candidates in Hawaii and Puerto Rico

OPTN Liver and Intestinal Organ Transplantation Committee

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Access for Urgent Liver Candidates in Hawaii and Puerto Rico

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Sponsoring Committee:	*Liver and Intestinal Organ Transplantation*
Public Comment Period:	*December 5, 2019 – January 9, 2019*

Executive Summary

For liver candidates listed in Hawaii or Puerto Rico who need a liver transplant very urgently, there may not be a donor of compatible blood type within 500 nautical miles (NM) in the time frame they need. This proposal would create additional geographic units that only apply to these candidates in order to broaden the pool of donors for whom these candidates would be likely to receive offers. For candidates in Hawaii, there would be an additional unit of distribution of 2,400 NM between the donor and transplant hospitals. For candidates in Puerto Rico, there would be an additional unit of distribution of 1,100 NM between the donor and transplant hospitals. These additional units of distribution would follow allocation classifications for candidates of similar medical urgency within 500 NM of the donor hospital.

Purpose of the Proposal

The purpose is to reduce the chances that a very sick liver candidate in Hawaii or Puerto Rico will die before receiving an offer of a donated liver. In these locations, there are limited liver donors.[1] For liver candidates with a high likelihood of death within one or two weeks without a liver transplant, the timing of donor availability is particularly important.

This proposal would improve timely access to donors for candidates listed as Status 1A, Status 1B or with a model for end stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score of 37 or higher in Hawaii and Puerto Rico. It would provide additional access to donors that become available in the closest parts of the continental United States by creating additional geographic units of 1,100 NM and 2,400 NM for candidates in Puerto Rico and Hawaii respectively. A candidate in Hawaii or Puerto Rico whose transplant hospital is within these distances of the donor hospital would receive offers right after candidates of similar medical urgency within 500 NM of those donor hospitals. This would increase the likelihood that a donor of an acceptable blood type match would become available for candidates on these islands within the critical timeframe.

Background

The OPTN Board of Directors adopted changes to liver allocation policy in December 2018, which change the units of distribution for livers from a DSA and regional system to a concentric circle system (also known as "Acuity Circles").[2] Questions about what impact the changes to liver distribution would have on medically urgent patients in Hawaii and Puerto Rico were initially raised during public comment for the distribution changes, because Hawaii and Puerto Rico are located outside the reach of the largest (500NM) circle.[3] At that time, the Liver and Intestinal Organ Transplantation Committee (Committee) chose to take more time to consider what the impact would be on this population and develop a solution. The Committee invited representatives from the programs in Hawaii and Puerto Rico to join members of the Committee in a work group to evaluate the problem. The Committee representation included a representative from Washington. The Committee also reached out to members of the community in California and Florida for more information on the potential impact the proposal may have on these areas.

Candidates listed as Status 1A have an estimated 14-day waitlist survival probability of 71%, and those with MELD scores of 36-40 have a 14-day waitlist survival probability of 70%[4]. Most of the waitlist deaths for Status 1A occur in the first 7 days after listing as Status 1A[5]. These candidates cannot wait for weeks or months to get a suitable liver offer.

The transplant programs in Hawaii and Puerto Rico experience a unique scarcity of donors within 500 NM. Table 1 below shows the average number of deceased liver donors within 500 NM in a year, by

[1] In Hawaii, there were 28 livers recovered in 2018 and 26 livers recovered in 2017. In Puerto Rico, 83 livers were recovered in 2018 and 70 were recovered in 2017. Presentation for May 8, 2019 Meeting, OPTN Hawaii and Puerto Rico Workgroup.

[2] *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed November 19, 2019).

[3] *Ibid.*

[4] Sharma, P. , Schaubel, D. E., Gong, Q. , Guidinger, M. and Merion, R. M. (2012), End-stage liver disease candidates at the highest model for end-stage liver disease scores have higher wait-list mortality than status-1A candidates. Hepatology, 55: 192-198. doi:10.1002/hep.24632

[5] Figure 13: Waitlist Mortality Over Time*, Liver and Intestine Distribution Using Distance from Donor Hospital*.

blood type, for the 10 transplant programs in the United States with the lowest averages. As shown in Table 1, there is less than one donor of each blood type on average within a week for the Hawaii and Puerto Rico transplant programs.

Table 1: Average Number of Deceased Liver Donors Per Week at Donor Hospitals Within 500 Nautical Miles of Liver Transplant Centers, During May 1, 2018 Through April 30, 2019, By Donor Blood Type

Transplant Center Code[6]	A	AB	B	O
HIQM	0.23	0.04	0.15	0.21
PRSJ	0.45	0.02	0.17	0.74
WACH	2.60	0.23	0.55	2.98
WASM	2.60	0.23	0.55	2.98
WAUW	2.60	0.23	0.55	2.98
ORUO	4.15	0.29	1.04	5.45
ORVA	4.15	0.29	1.04	5.45
COCH	5.21	0.44	1.74	6.92
COUC	5.21	0.44	1.74	6.92
COSL	5.26	0.44	1.75	7.04

This analysis is limited to the number of donors, without considering how many compatible candidates might be listed at any given status in an area at any point in time. Although Hawaii and Puerto Rico each have a small numbers of candidates, the goal of this proposal is not to match the population of donors to the population of candidates. Instead, it is focused on increasing the access to timely offers for medically urgent candidates where that access is limited to this degree by extreme geographic isolation of the transplant program.

In order to increase the likelihood that the changes in this proposal will improve access to livers that could be accepted for candidates listed at the transplant programs in Hawaii and Puerto Rico, the Committee considered historical patterns of liver acceptance by those programs.

Figure 1 demonstrates that the closest cluster of donors outside of 500 NM of Puerto Rico is within 1,100 NM. Figure 2 demonstrates that the largest cluster of donors more than 500 NM away from Hawaii is within 2,400 NM. These data informed the Committee's recommendation to adopt an additional classification for urgent liver candidates in Hawaii and Puerto Rico with distances of 2,400 NM and 1,100 NM, respectively between the donor and transplant hospitals. The closest cluster was preferred over the farther cluster for Puerto Rico based on concerns about decreased efficiency and increased cold ischemic time that may impact organ quality. The Committee also sought to avoid over-

[6] In the transplant center codes, the first two letters are the state or territory abbreviation. For example, Auxilio Mutuo Hospital's center code begins with "PR" because it is located in Puerto Rico.

adjusting and providing these candidates an unfair advantage relative to other candidates with the same medical urgency listed within the contiguous United States.

Figure 1: Distances from Donor Hospital to Transplant Hospital, Deceased Donor Liver Transplant Recipients at Auxilio Mutuo Hospital (PRSJ) During 1/1/2012 to 10/31/2019

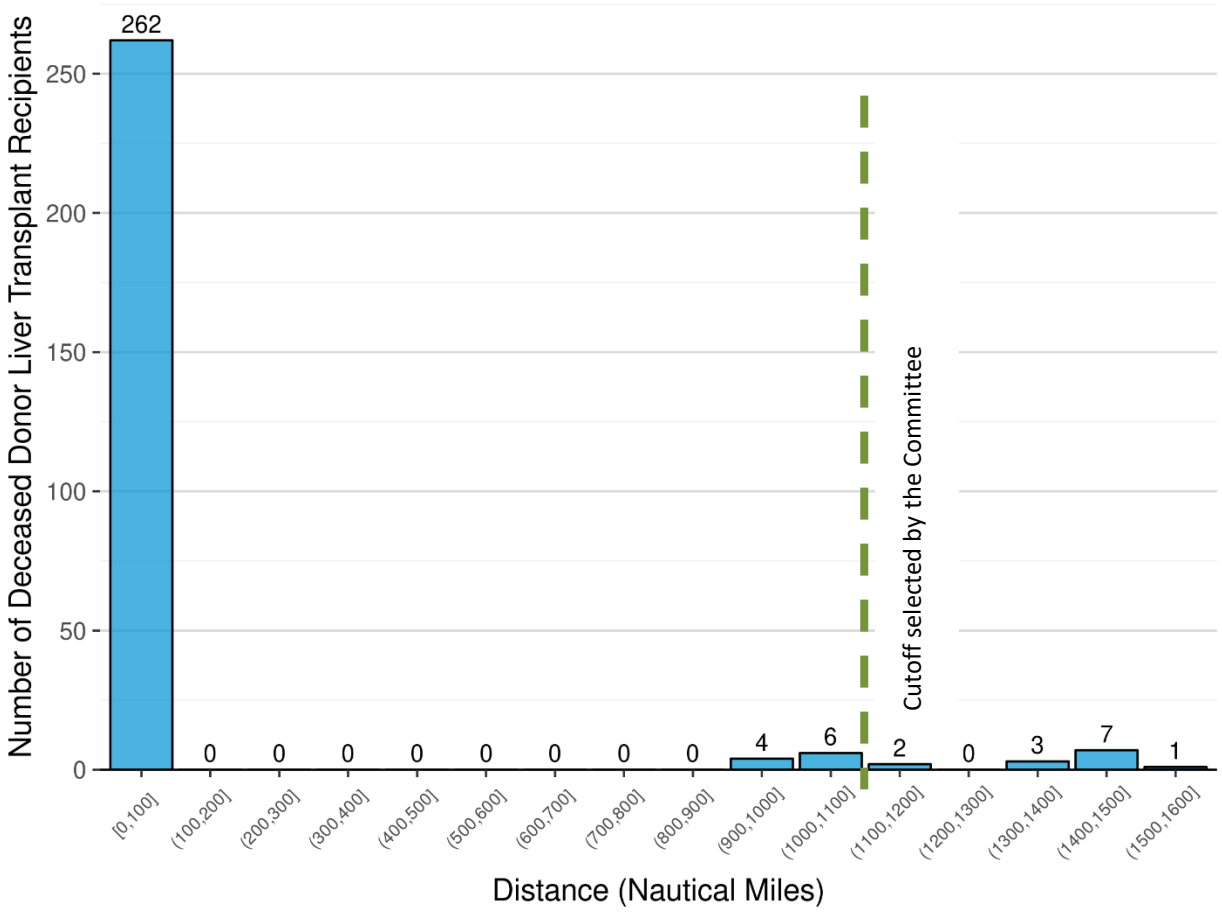
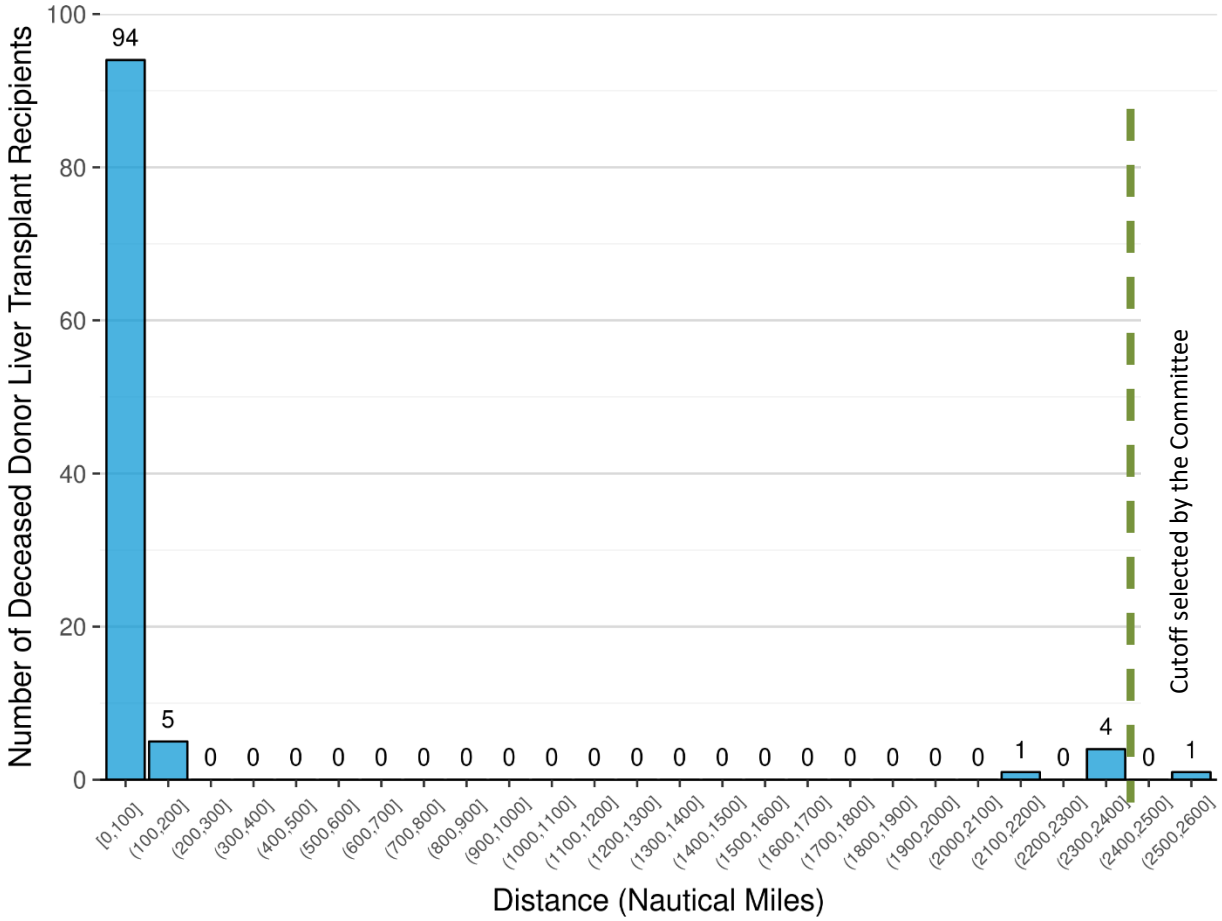
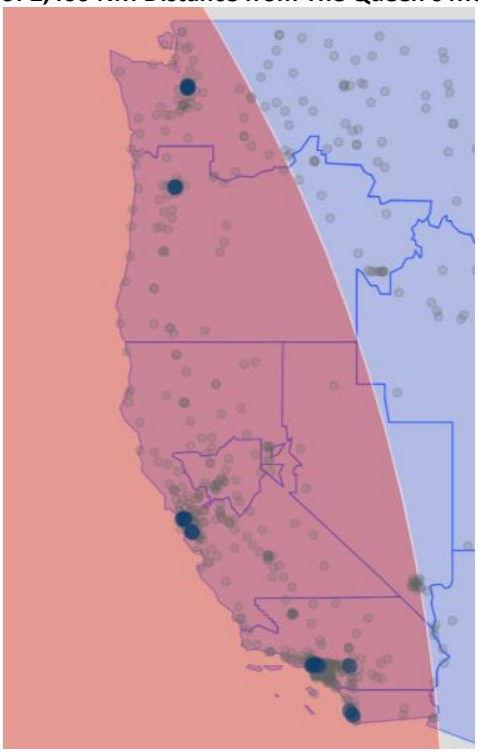


Figure 2: Distances from Donor Hospital to Transplant Hospital, Deceased Donor Liver Transplant Recipients at The Queen's Medical Center (HIQM) During 1/1/2012 to 10/31/2019



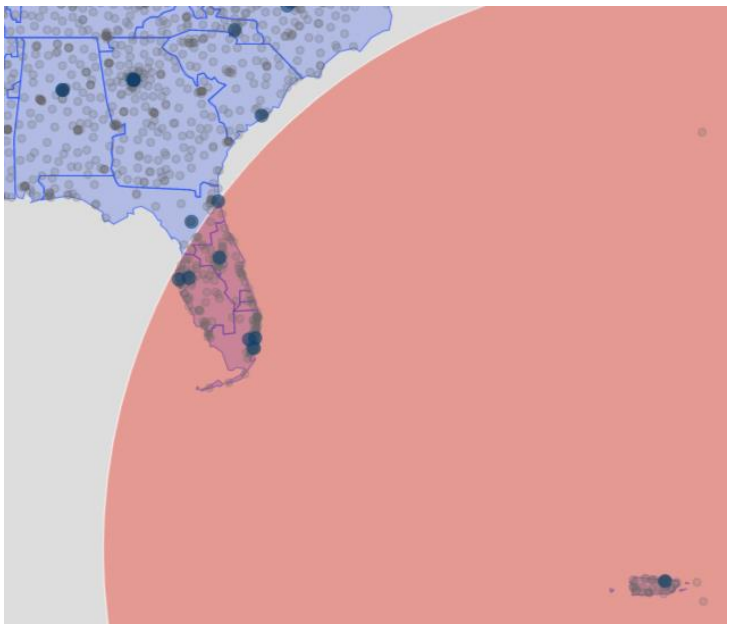
In Figure 3, grey dots represent donor hospitals and navy dots represent other liver transplant programs. Donors located at donor hospitals within the red shaded portion of the United States would have match runs that include the proposed classifications for potential transplant recipients in Hawaii that are Status 1A, Status 1B, or have a MELD or PELD score of 37 or higher.

Figure 3: Illustration of 2,400 NM Distance from The Queen's Medical Center (HIQM)



In Figure 4, grey dots represent donor hospitals and navy dots represent other liver transplant programs. Donors located at donor hospitals within the redshaded portion of the United States would have match runs that include the proposed classifications for potential transplant recipients in Puerto Rico that are Status 1A, Status 1B, or have a MELD or PELD score of 37 or higher.

Figure 4: Illustration of 1,100 NM Distance from Auxilio Mutuo Hospital (PRSJ)



Historical patterns of acceptance are limited in their ability to predict which organs are the most likely to be able to be accepted once the Acuity Circles changes to allocation are implemented because they are based on data from the current allocation system, which uses regions as a unit of distribution in allocation of livers. This proposed change would be part of an allocation system that does not use regions for allocation.[7] Because of the small numbers of candidates affected, modeling would not provide sufficient inferences to determine the optimal distance to extend allocation. The Final Rule allows sound medical judgment to drive decision-making.[8] In the Committee's judgment, the selected distances are an appropriate balance between ensuring access, minimizing logistical challenges and treating candidates similarly.

To address these limitations, the Committee proposes this change as a variance that the Committee will evaluate for five years. After five years, the Committee will make a recommendation to the Board of Directors (Board) regarding whether to make this change a regular function of policy, make changes to the way it functions, or end the variance. The Committee chose a period of five years because the number of candidates affected by this variance is expected to be small, and a five year period is likely to provide more data for evaluation than a shorter time period would.

Proposed Solution

The Committee proposes a closed variance to liver allocation for five years. Under the variance, two additional distances for distribution will be added, creating additional classifications in the already approved classification tables. An additional distance of 1,100 NM will only apply for the most medically urgent candidates listed at a transplant hospital located in Puerto Rico. An additional distance of 2,400 NM will only apply for the most medically urgent candidates listed at a transplant hospital in Hawaii.

These additional distances will follow the 500 NM classifications for Status 1A and 1B candidates, and 500 NM classifications for candidates with a MELD or PELD of 37. The additional distances will not apply when the donor is 70 years old or older, or is a DCD donor due to the reduced likelihood of acceptance at the greater distances. When the donor is less than 18 years old, the additional distances will only apply to the most medically urgent candidates listed before their 18th birthday because these organs are not offered to any adult candidates until they have been offered to all of the candidates registered before their 18th birthday in the nation. The additional distances will not apply to blood type A or AB candidates when then donor blood type is O because at the point that these offers are made, the liver has already been offered to all of the O candidates in the nation and all of the B candidates with a MELD or PELD of at least 30 in the nation. Further, the additional distances will not apply for livers allocated for other methods of hepatic support because livers are only offered for other methods of hepatic support after then have been offered to all eligible candidates in the nation. For these groups where the allocation classification priority would not occur until after a significant number of offers were made, the Committee did not believe those donors were likely to be accepted from that distance.

[7] OPTN Policy Notice, *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, January 2019, https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf (accessed November 21, 2019).

[8] 42 CFR 121.8.

Potential Impact on Select Patient Populations

There are only a limited number of candidates listed in Hawaii or Puerto Rico as Status 1A, Status 1B or MELD or PELD of at least 37. From July 2013-July 2018 in Hawaii, there were two Status 1A candidates and six candidates with a MELD or PELD of at least 35 transplanted.[9] In that same time, there were ten Status 1A candidates and 15 candidates with a MELD or PELD of at least 35 transplanted in Puerto Rico.[10] This amounts to less than two candidates per year in Hawaii and roughly five candidates per year in Puerto Rico. These candidates would receive increased access to certain livers in the continental United States.

Other Solutions Considered

The Committee considered other approaches to broadening the likely donor pool for these candidates.

Virtual Listing

The Committee considered creating secondary virtual locations for listing these candidates, such as the Seattle-Tacoma International Airport and Miami International Airport. The Committee was concerned that choosing the airport that has been used most often historically would not allow as much flexibility once distribution changes take effect. The Committee decided against this solution because the Committee's goal was to solve the problem in the most direct and consistent way possible. Additionally, the program in Hawaii did not think it would be likely to accept livers from 500 NM away from the airport location due to additional cold time and travel logistics associated connecting flights or significant driving to get the liver to a major airport.[11]

Distances

The Committee considered several distances, and the option of using the same distance for Hawaii and Puerto Rico. However, the Committee preferred not to choose even larger circle sizes because it hopes to maximize placement efficiency by ensuring that organ offers are made to candidates for whom they are most likely to be accepted, in part based on the logistical and geographic feasibility of transporting the organ from the donor to the distant candidate. This also helps mitigate concerns about cold ischemic time resulting from the travel, which could potentially lead to a lost opportunity to transplant the organ, or futile transplant due to poor post-transplant outcomes based on the increased cold ischemic time.[12]

The Committee was concerned that using shorter distances might fail to exclude the donors that were most likely to able to be accepted for the candidates in Hawaii and Puerto Rico due to inherent logistical challenges. Cold ischemic time, or even travel time are not precisely correlated with distance, especially in the case of these isolated islands. Transportation to Hawaii or Puerto Rico relies on the use of a major airport with several flights a day between the contiguous states and the islands. It is possible that a liver

[9] Presentation for May 8, 2019 Meeting, OPTN Hawaii and Puerto Rico Workgroup.

[10] Ibid.

[11] Figure 1: Distances from Donor Hospital to Transplant Hospital, Deceased Donor Liver Transplant Recipients at Auxilio Mutual Hospital (PRSJ) During 1/1/2012 to 10/31/2019 and Figure 2: Distances from Donor Hospital to Transplant Hospital, Deceased Donor Liver Transplant Recipients at The Queen's Medical Center (HIQM) During 1/1/2012 to 10/31/2019.

[12] 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."

may be recovered closer to one of the transplant programs, but would result in longer travel times or more ischemic time. The transportation could actually take longer if the donor hospital is farther from an acceptable airport, does not have enough operating room beds to accommodate needed flexibility scheduling the recover, or if it takes longer because of traffic or a lack of a direct route to get to the airport. This additional transportation or cold ischemic time could make the liver less likely to be accepted even though it is closer.

The Committee also considered adding an additional unit of distribution for livers recovered in Hawaii that would apply to candidates at transplant programs within 2,400 NM in the continental United States and for livers recovered in Puerto Rico to candidates at transplant programs within 1,100 NM in the continental United States. The Committee members thought making the additional units of distribution bi-directional would be in line with historical practices of distribution units being the same in both directions and appealed to a sense of fairness. However, there are no areas in the continental United States that experience the same degree of scarcity of donors within one or two weeks, so there is no similar need to apply the alternative distribution rules to the candidates in those states.

Final Rule

The Final Rule requires that "experimental policies that test methods of improving allocation" must be developed "in accordance with §121.4", which in turn incorporates the requirements in §121.8.[13] This proposal meets the requirements of the Final Rule.

- **Shall be based on sound medical judgment:** The Committee proposes this change based on the medical judgment and data that support that Status 1 and high MELD or PELD candidates have greater waitlist mortality in a shorter period than those with lower MELD or PELD scores, and data that support that Status 1 and high MELD or PELD candidates in Hawaii and Puerto Rico are likely to have access to fewer compatible donors in a timely manner under the newly adopted liver allocation policy.
- **Shall seek to achieve the best use of donated organs:** The Committee believes that maximizing the gift of organ donation by using each donated organ to its full potential achieves the best use of donated organs. This proposal seeks to make the best use of donated organs by using them for the most medically urgent candidates first, within a rationally determined geographic distribution unit. Historic data demonstrate that livers from up to 2,400 NM away have been successfully transplanted in recipients in Hawaii, and 1,100 NM away in Puerto Rico.
- **Shall be designed to avoid wasting organs, to avoid futile transplants, … and to promote the efficient management of organ placement:** This variance is designed to promote efficient placement and avoid wasting organs by limiting the size of the additional circle to those donors that are more likely to be accepted, based in part on the logistical and geographic feasibility of transporting them to these isolated transplant programs. This may help mitigate poor outcomes or lost opportunities to transplant that may result from excessive cold ischemia times.
- **Shall be reviewed periodically and revised as appropriate:** This variance will be reviewed annually and will be due to expire or be revised if needed in five years. If successful in achieving the goals without adverse results, it will be recommended to become part of standing policy.
- **Shall be designed to…promote patient access to transplantation:** This proposal promotes access to transplant for medically urgent liver candidates in Hawaii and Puerto Rico, on geographically

[13] 42 CFR 121.8.

isolated islands, by providing these urgent candidates access to livers from a greater distance in order to improve the likelihood that they will receive an offer from a medically acceptable donor within a critically short time period.

- **Shall not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:** This proposal is limited to certain candidates based on their place of listing in geographically isolated areas in order to promote access to transplantation within a reasonable time, while:
  - achieving the best use of the organs by ensuring they are offered to these medically urgent candidates before they are offered to less urgent candidates,
  - balancing the goal of promoting efficient placement of organs by minimizing the size of the distribution units to a circle that will reasonably provide access to the candidates without unduly adding logistical or economic challenges
  - Minimizing the risk of organ wastage or futile transplants by ensuring that the circle size is reasonable in its presumed correlation to cold ischemic time.

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);
- Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.

Variance Requirements

In addition to meeting the Final Rule allocation policy requirements, this proposal meets the Final Rule and OPTN policy requirements for variances. The Final Rule requires that variances "be accompanied by a research design and include data collection and analysis plans."[14] Further, OPTN Policy requires that proposed variances include certain information.[15] This variance proposal includes the required information to create a variance.

- **Purpose … and how the variance will further this purpose:** The purpose of this variance is to address a particular scarcity of medically compatible donors within 500 NM of two transplant hospitals that affects the candidates listed at those hospitals who need a liver transplant most urgently.
- **If a member's application to create, amend, or join a variance will require other members to join the variance, the applicant must solicit their support…:** Representatives from the liver transplant programs in Hawaii and Puerto Rico were involved in the development of this proposal and support it. No other members are required to join the variance.
- **A defined expiration date … :** The variance is proposed to expire five years after implementation. Based on the evaluation of the variance, the Committee will then either recommend that the variance be modified, terminated, replaced with a national policy, or extended to collect more data.
- **An evaluation plan … :** The Committee's plan for evaluating the impact of the variance is outlined in the Policy Evaluation section below.

[14] 42 CFR 121.8(g).

[15] OPTN Policy 1.3.B: Application for a Variance

- **Any anticipated difficulties in demonstrating whether the variance is achieving its stated purpose:** Not many candidates are expected to use benefit from this variance, so it may be difficult to evaluate the impact of the variance.
- **Whether this is an open or closed variance … :** This will be a closed variance and apply only to liver transplant programs in Hawaii or Puerto Rico.

Implementation and Operational Considerations

OPTN Actions

Programming changes will be required to implement this variance. Changes will be made to the liver and liver-intestine allocation systems to add the additional classifications.

UNOS will follow established protocols to inform members and provide educational materials regarding any policy changes.

Member Actions

OPOs will continue to follow the match run when allocating livers and liver-intestines. OPOs that serve donor hospitals within 2,400 NM of Hawaii or 1,100 NM of Puerto Rico may work with the transplant programs in Hawaii or Puerto Rico more often, though the volumes affected by this proposed variance are low, as described earlier.

Post-implementation Monitoring

Member Compliance

The proposed language will not change the current routine monitoring of OPTN members. OPTN contractor staff will continue to review deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy and will continue to investigate potential policy violations.

Policy Evaluation

This variance will be formally evaluated each year post-implementation and six months before it is scheduled to end. The following questions, and any others subsequently requested by the Board or Committee, will guide the evaluation of this variance:

- Number of match runs that contain Status 1A, Status 1B, or MELD or PELD 37 or higher potential liver candidates at transplant programs in Hawaii and Puerto Rico
    - Distribution of distance from donor hospital to liver transplant program for these match runs
- Number of deceased donor liver transplants for Status 1A, Status 1B, or MELD or PELD 37 or higher at transplant programs in Hawaii and Puerto Rico
    - Distribution of distance from donor hospital to liver transplant program for deceased liver donor recipients in Hawaii and Puerto Rico
- Number of potential liver candidates removed for death or as too sick to transplant while listed at Status 1A, Status 1B, or MELD or PELD 37 or higher at transplant programs in Hawaii and Puerto Rico.

Conclusion

This proposal would create additional geographic units that only apply for candidates listed in Hawaii or Puerto Rico who need a liver transplant very urgently, in order to broaden the pool of donors for whom these candidates would be likely to receive offers in a timely manner. For candidates in Hawaii, there would be an additional unit of distribution at 2,400 NM. For candidates in Puerto Rico, there would be an additional unit of distribution at 1,100 NM. These additional units of distribution would follow allocation classifications for candidates of similar medical urgency within 500 NM of the donor hospital.

Policy Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

9.8.E Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to *Table 9-11* below.

Table 9-11: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates with a score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Status 1A	500NM	Any	Any
2	Status 1B	500NM	Any	Any
	<u>Status 1A</u>	<u>2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico</u>	<u>Any</u>	<u>Any</u>
	<u>Status 1B</u>	<u>2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico</u>	<u>Any</u>	<u>Any</u>
3	37	150NM	O	O or B
4	37	150NM	Non-O	Any
5	37	250NM	O	O or B
6	37	250NM	Non-O	Any
7	37	500NM	O	O or B
8	37	500NM	Non-O	Any
	<u>37</u>	<u>2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico</u>	<u>O</u>	<u>O or B</u>
	<u>37</u>	<u>2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico</u>	<u>Non-O</u>	<u>Any</u>
9	33	150NM	O	O or B
10	33	150NM	Non-O	Any

Classification	Candidates with a score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
11	33	250NM	O	O or B
12	33	250NM	Non-O	Any
13	33	500NM	O	O or B
14	33	500NM	Non-O	Any
15	30	150NM	O	O or B
16	29	150NM	O	O
17	29	150NM	Non-O	Any
18	30	250NM	O	O or B
19	29	250NM	O	O
20	29	250NM	Non-O	Any
21	30	500NM	O	O or B
22	29	500NM	O	O
23	29	500NM	Non-O	Any
24	15	150NM	O	O
25	15	150NM	Non-O	Any
26	15	250NM	O	O
27	15	250NM	Non-O	Any
28	15	500NM	O	O
29	15	500NM	Non-O	Any
30	Status 1A	Nation	Any	Any
31	Status 1B	Nation	Any	Any
32	30	Nation	O	O or B
33	15	Nation	O	O
34	15	Nation	Non-O	Any
35	Any	150NM	O	O
36	Any	150NM	Non-O	Any
37	Any	250NM	O	O
38	Any	250NM	Non-O	Any
39	Any	500NM	O	O
40	Any	500NM	Non-O	Any
41	Any	Nation	O	O
42	Any	Nation	Non-O	Any
43	29	150NM	O	B

Classification	Candidates with a score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
44	29	250NM	O	B
45	29	500NM	O	B
46	15	150NM	O	B
47	15	250NM	O	B
48	15	500NM	O	B
49	15	Nation	O	B
50	Any	150NM	O	B
51	Any	250NM	O	B
52	Any	500NM	O	B
53	Any	Nation	O	B
54	37	150NM	O	A or AB
55	37	250NM	O	A or AB
56	37	500NM	O	A or AB
57	33	150NM	O	A or AB
58	33	250NM	O	A or AB
59	33	500NM	O	A or AB
60	29	150NM	O	A or AB
61	29	250NM	O	A or AB
62	29	500NM	O	A or AB
63	15	150NM	O	A or AB
64	15	250NM	O	A or AB
65	15	500NM	O	A or AB
66	15	Nation	O	A or AB
67	Any	150NM	O	A or AB
68	Any	250NM	O	A or AB
69	Any	500NM	O	A or AB
70	Any	Nation	O	A or AB
71	Status 1A, for other method of hepatic support	Nation	Any	Any
72	Status 1B, for other method of hepatic support	Nation	Any	Any
73	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

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9.8.F Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Livers from non-DCD deceased donors 11 to 17 years old are allocated to candidates according to *Table 9-12* below.

Table 9-12: Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
1	Pediatric Status 1A	500NM	Any	Any
2	Adult Status 1A	500NM	Any	Any
3	Pediatric Status 1B	500NM	Any	Any
	Pediatric Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	Adult Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	Pediatric Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	PELD of at least 37	500NM	O	O or B
	PELD of at least 37	500NM	Non-O	Any
	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
4	PELD of at least 30	500NM	O	O or B
5	Any PELD	500NM	O	O
6	Any PELD	500NM	Non-O	Any
	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	O	O or B

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	Non-O	Any
	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
7	MELD of at least 30 and candidate is less than 18 years old at registration	500NM	O	O or B
8	Any MELD and candidate is less than 18 years old at registration	500NM	O	O
9	Any MELD and candidate is less than 18 years old at registration	500NM	Non-O	Any
10	Pediatric Status 1A	Nation	Any	Any
11	Adult Status 1A	Nation	Any	Any
12	Pediatric Status 1B	Nation	Any	Any
13	PELD score of at least 30	Nation	O	O or B
14	Any PELD	Nation	O	O
15	Any PELD	Nation	Non-O	Any
16	MELD of at least 30 and candidate is less than 18 years old at registration	Nation	O	O or B
17	Any MELD and candidate is less than 18 years old at registration	Nation	O	O

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
18	Any MELD and candidate is less than 18 years old at registration	Nation	Non-O	Any
19	MELD of at least 30 and candidate is at least 18 years old at registration	500NM	O	O or B
20	Any MELD and candidate is at least 18 years old at registration	500NM	O	O
21	Any MELD and candidate is at least 18 years old at registration	500NM	Non-O	Any
22	MELD of at least 30 and candidate is at least 18 years old at registration	Nation	O	O or B
23	Any MELD and candidate is at least 18 years old at registration	Nation	O	O
24	Any MELD and candidate is at least 18 years old at registration	Nation	Non-O	Any
25	Any PELD	500NM	O	B
26	Any MELD and candidate is less than 18 years old at registration	500NM	O	B
27	Any PELD	Nation	O	B
28	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
29	Any MELD and candidate is at least 18 years old at registration	500NM	O	B
30	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
31	Any PELD	500NM	O	A or AB

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
32	Any MELD and candidate is less than 18 years old at registration	500NM	O	A or AB
33	Any PELD	Nation	O	A or AB
34	Any MELD and candidate is less than 18 years old at registration	Nation	O	A or AB
35	Any MELD and candidate is at least 18 years old at registration	500NM	O	A or AB
36	Any MELD and candidate is at least 18 years old at registration	Nation	O	A or AB
37	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any
38	Pediatric Status 1B, for other method of hepatic support	Nation	Any	Any
39	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.8.G Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Livers from non-DCD donors less than 11 years old are allocated to candidates according to *Table 9-13* below.

Table 9-13: Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
1	Pediatric Status 1A	500NM	Any	Any
2	Pediatric Status 1A and candidate is less than 12 years old	Nation	Any	Any

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
3	Adult Status 1A	500NM	Any	Any
4	Pediatric Status 1B	500NM	Any	Any
	Pediatric Status 1A and candidate is at least 12 years old	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	Adult Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	Pediatric Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	PELD of at least 37	500NM	O	O or B
	PELD of at least 37	500NM	Non-O	Any
	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
5	PELD of at least 30	500NM	O	O or B
6	Any PELD	500NM	O	O
7	Any PELD	500NM	Non-O	Any
	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	O	O or B
	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	Non-O	Any
	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
8	MELD of at least 30 and candidate is less than 18 years old at registration	500NM	O	O or B
11	Pediatric Status 1A and candidate is at least 12 years old	Nation	Any	Any
12	Adult Status 1A	Nation	Any	Any
13	Pediatric Status 1B	Nation	Any	Any
14	PELD of at least 30	Nation	O	O or B
15	Any PELD	Nation	O	O
16	Any PELD	Nation	Non-O	Any
17	MELD of at least 30 and candidate is less than 18 years old at registration	Nation	O	O or B
18	Any MELD and candidate is less than 18 years old at registration	Nation	O	O
19	Any MELD and less than 18 years old at registration	Nation	Non-O	Any
20	MELD of at least 30 and candidate is at least 18 years old at registration	500NM	O	O or B
21	Any MELD and candidate is at least 18 years old at registration	500NM	O	O
22	Any MELD and at least 18 years old at registration	500NM	Non-O	Any
23	MELD of at least 30 and at least 18 years old at registration	Nation	O	O or B
24	Any MELD and at least 18 years old at registration	Nation	O	O
25	Any MELD and at least 18 years old at registration	Nation	Non-O	Any
26	Any PELD	500NM	O	B

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
27	Any MELD and candidate is less than 18 years old at registration	500NM	O	B
28	Any PELD	Nation	O	B
29	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
30	Any MELD and candidate is at least 18 years old at registration	500NM	O	B
31	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
32	Any PELD	500NM	O	A or AB
33	Any MELD and candidate is less than 18 years old at registration	500NM	O	A or AB
34	Any PELD	Nation	O	A or AB
35	Any MELD and candidate is less than 18 years old at registration	Nation	O	A or AB
36	Any MELD and candidate is at least 18 years old at registration	500NM	O	A or AB
37	Any MELD and candidate is at least 18 years old at registration	Nation	O	A or AB
38	Status 1A, for other method of hepatic support	Nation	Any	Any
39	Status 1B, for other method of hepatic support	Nation	Any	Any
40	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.8.I Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers and intestines from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to *Table 9-15* below:

Table 9-15: Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates with a score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Status 1A	500NM	Any	Any
2	Status 1B	500NM	Any	Any
	Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
3	37	150NM	O	O or B
4	37	150NM	Non-O	Any
5	37	250NM	O	O or B
6	37	250NM	Non-O	Any
7	37	500NM	O	O or B
8	37	500NM	Non-O	Any
	37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
	37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
9	33	150NM	O	O or B
10	33	150NM	Non-O	Any
11	33	250NM	O	O or B
12	33	250NM	Non-O	Any
13	33	500NM	O	O or B
14	33	500NM	Non-O	Any

15	30	150NM	O	O or B
16	29	150NM	O	O
17	29	150NM	Non-O	Any
18	30	250NM	O	O or B
19	29	250NM	O	O
20	29	250NM	Non-O	Any
21	30	500NM	O	O or B
22	29	500NM	O	O
23	29	500NM	Non-O	Any
24	Status 1A and also registered for an intestine	Nation	Any	Any
25	Status 1B and also registered for an intestine	Nation	Any	Any
26	30 and also registered for an intestine	Nation	O	O or B
27	Any and also registered for an intestine	Nation	O	O
28	Any and also registered for an intestine	Nation	Non-O	Any
29	15	150NM	O	O
30	15	150NM	Non-O	Any
31	15	250NM	O	O
32	15	250NM	Non-O	Any
33	15	500NM	O	O
34	15	500NM	Non-O	Any
35	Status 1A	Nation	Any	Any
36	Status 1B	Nation	Any	Any
37	30	Nation	O	O or B
38	15	Nation	O	O
39	15	Nation	Non-O	Any
40	Any	150NM	O	O
41	Any	150NM	Non-O	Any
42	Any	250NM	O	O
43	Any	250NM	Non-O	Any
44	Any	500NM	O	O
45	Any	500NM	Non-O	Any
46	Any	Nation	O	O
47	Any	Nation	Non-O	Any
48	29	150NM	O	B

49	29	250NM	O	B
50	29	500NM	O	B
51	Any and also registered for an intestine	Nation	O	B
52	15	150NM	O	B
53	15	250NM	O	B
54	15	500NM	O	B
55	15	Nation	O	B
56	Any	150NM	O	B
57	Any	250NM	O	B
58	Any	500NM	O	B
59	Any	Nation	O	B
60	37	150NM	O	A or AB
61	37	250NM	O	A or AB
62	37	500NM	O	A or AB
63	33	150NM	O	A or AB
64	33	250NM	O	A or AB
65	33	500NM	O	A or AB
66	29	150NM	O	A or AB
67	29	250NM	O	A or AB
68	29	500NM	O	A or AB
69	Any and also registered for an intestine	Nation	O	A or AB
70	15	150NM	O	A or AB
71	15	250NM	O	A or AB
72	15	500NM	O	A or AB
73	15	Nation	O	A or AB
74	Any	150NM	O	A or AB
75	Any	250NM	O	A or AB
76	Any	500NM	O	A or AB
77	Any	Nation	O	A or AB
78	Status 1A, for other method of hepatic support	Nation	Any	Any
79	Status 1B, for other method of hepatic support	Nation	Any	Any
80	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.8.K Allocation of Liver-Intestines from Non-DCD Donors Less than 11 Years Old

Livers and intestines from non-DCD donors less than 11 years old are allocated to candidates according to *Table 9-16* below.

Table 9-16: Allocation of Combined Liver-Intestines from Donors Less than 11 Years Old

Classification	Candidates with a MELD/PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor Type	Candidate Type
1	Pediatric Status 1A	500NM	Any	Any
2	Pediatric Status 1A and candidate is less than 12 years old	Nation	Any	Any
3	Pediatric Status 1A, candidate is at least 12 years old, and candidate is also registered for an intestine	Nation	Any	Any
4	Adult Status 1A	500NM	Any	Any
5	Pediatric Status 1B	500NM	Any	Any
	Pediatric Status 1A and candidate is at least 12 years old	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	Pediatric Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
	PELD of at least 37	500NM	O	O or B
	PELD of at least 37	500NM	Non-O	Any
	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
	PELD of at least 37	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
6	PELD 30	500NM	O	O or B
7	PELD 20	500NM	O	O

8	PELD 20	500NM	Non-O	Any
9	Pediatric Status 1B, and candidate is also registered for an intestine	Nation	Any	Any
10	PELD of at least 30 and candidate is also registered for an intestine	Nation	O	O or B
11	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	O
12	PELD of at least 20 and candidate is also registered for an intestine	Nation	Non-O	Any
13	Any PELD	500NM	O	O
14	Any PELD	500NM	Non-O	Any
	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	O	O or B
	MELD of at least 37 and candidate is less than 18 years old at registration	500NM	Non-O	Any
	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	O	O or B
	MELD of at least 37 and candidate is less than 18 years old at registration	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Non-O	Any
15	MELD of at least 30 and less than 18 years old at registration	500NM	O	O or B
16	Any MELD and less than 18 years old at registration	500NM	O	O
17	Any MELD, candidate is less than 18 years old at registration	500NM	Non-O	Any
18	Pediatric Status 1A and at least 12 years old	Nation	Any	Any
19	Adult Status 1A	Nation	Any	Any
20	Pediatric Status 1B	Nation	Any	Any
21	PELD at least 30	Nation	O	O or B
22	Any PELD	Nation	O	O
23	Any PELD	Nation	Non-O	Any

24	MELD of at least 30 and less than 18 years old at registration	Nation	O	O or B
25	Any MELD and less than 18 years old at registration	Nation	O	O
26	Any MELD and less than 18 years old at registration	Nation	Non-O	Any
27	MELD of at least 30 and at least 18 years old at registration	500NM	O	O or B
28	Any MELD and at least 18 years old at registration	500NM	O	O
29	Any MELD and at least 18 years old at registration	500NM	Non-O	Any
30	MELD of at least 30 and at least 18 years old at registration	Nation	O	O or B
31	Any MELD and at least 18 years old at registration	Nation	O	O
32	Any MELD and at least 18 years old at registration	Nation	Non-O	Any
33	PELD 20	500NM	O	B
34	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	B
35	Any PELD	500NM	O	B
36	Any MELD and candidate is less than 18 years old at registration	500NM	O	B
37	Any PELD	Nation	O	B
38	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
39	Any MELD and candidate is at least 18 years old at registration	500NM	O	B
40	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
41	PELD 20	500NM	O	A or AB
42	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	A or AB
43	Any PELD	500NM	O	A or AB

44	Any MELD and candidate is less than 18 years old at registration	500NM	O	A or AB
45	Any PELD	Nation	O	A or AB
46	Any MELD, candidate is less than 18 years old at registration	Nation	O	A or AB
47	Any MELD, candidate is at least 18 years old at registration	500NM	O	A or AB
48	Any MELD, candidate is at least 18 years old at registration	Nation	O	A or AB
49	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any
50	Pediatric Status 1B, for other method of hepatic support	Nation	Any	Any
51	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

9.11.D Closed Variance for Liver Transplantation in Hawaii and Puerto Rico

This is a closed variance that applies only to liver and liver-intestine candidates registered at transplant programs in Hawaii or Puerto Rico, due to geographic location. This variance provides for additional classifications in the allocation sequences in *Policies 9.8.E-9.8.K.* The additional classifications apply to the following:

- Candidates registered at transplant programs in Hawaii when the transplant hospital is within 2,400 NM of the donor hospital.
- Candidates registered at transplant programs in Puerto Rico when the transplant hospital is within 1,100 NM of the donor hospital.

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