# OPTN/UNOS Policy Notice Modifications to the Distribution of Deceased Donor Lungs

Sponsoring Committee: Thoracic Organ Transplantation Committee Policy/Bylaws Affected: Policies 1.2 (Definitions), 6.6.F (Allocation of

Heart-Lungs), 10.2.A (Allocation Exception for Sensitized Patients), 10.4.C (Allocation of Lungs from Deceased Donors at Least 18 Years Old), and 10.4.D (Allocation of Lungs from Deceased

Donors Less than 18 Years Old)
January 22, 2018 – March 23, 2018

Board Approval Date: June 12, 2018

**Public Comment:** 

Effective Date: Policies 1.2, 10.2.A, and 10.4: June 12, 2018

Policy 6.6.F: October 18, 2018

#### **Problem Statement**

On November 24, 2017, the OPTN/UNOS Executive Committee approved an emergency change to lung allocation policy to remove the donation service area (DSA) as a unit of distribution, and instead distribute lungs from adult donors to all lung candidates within 250 nautical miles of the donor. DSA level distribution was also removed from the pediatric donor sequence. These changes to policy were implemented immediately, but included an expiration date of November 24, 2018, and were distributed for public comment retrospectively. In addition, two additional changes to policy were required as a consequence of removing the DSA as a unit of distribution from lung allocation policy:

- 1. Modifications to Board-approved heart-lung allocation policy
- 2. Modifications to existing policy for sensitized lung candidates

### **Summary of Changes**

- 1. The Board removed the November 24, 2018 expiration date for the 250 nautical mile distribution unit for deceased donor lungs
- 2. The Board clarified previously approved heart-lung allocation policy that will be implemented in the fall of 2018 by replacing references to the DSA and zones with references to specific allocation classifications
- 3. The Board adopted changes to the policy for sensitized lung candidates

#### What Members Need to Do

Since the 250 nautical mile distribution is already implemented, transplant programs do not need to do anything new for this policy. Transplant programs and OPOs should monitor costs, as broader distribution may increase the number of donor lungs that have to travel, the distance they travel, and the cold ischemic time of these organs. Transplant programs may also increase their use of ex vivo lung perfusion for lungs recovered from donors that are further away, further adding to costs.

The changes to heart-lung allocation policy do not require transplant programs to change their current processes, and transplant programs with candidates in need of a heart and lung should continue to follow

previous guidance distributed by the OPTN advising transplant programs to register those candidates for all three organs (heart, lung, and heart-lung). Transplant programs should also be aware that an exception policy pathway exists for highly sensitized lung candidates.

### **Affected Policy Language**

New language is underlined (<u>example</u>) and language that is deleted is struck through (<u>example</u>).

#### 1.2 Definitions

#### Zone

A geographical area used in the allocation of certain organs.

The allocation of thoracic organs hearts uses the following five concentric bands:

- Zone A Includes all transplant hospitals within 500 nautical miles of the donor hospital but outside of the donor hospital's DSA.
- Zone B All transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone A and the donor hospital's DSA.
- Zone C All transplant hospitals within 1,500 nautical miles of the donor hospital but outside of Zone B and the donor hospital's DSA.
- Zone D All transplant hospitals within 2,500 nautical miles of the donor hospital but outside of Zone C.
- Zone E All transplant hospitals more than 2,500 nautical miles from the donor hospital.

The allocation of lungs uses the following six concentric bands:

Zone A Includes all transplant hospitals within 250 nautical miles of the donor hospital.

Zone B All transplant hospitals within 500 nautical miles of the donor hospital but outside of Zone A.

Zone C All transplant hospitals within 1,000 nautical miles of the donor hospital but outside of Zone B.

Zone D All transplant hospitals within 1,500 nautical miles of the donor hospital but outside of Zone C.

Zone E All transplant hospitals within 2,500 nautical miles of the donor hospital but outside of Zone D.

Zone F All transplant hospitals more than 2,500 nautical miles from the donor hospital.

#### 6.6.F Allocation of Heart-Lungs

When a heart-lung potential transplant recipient (PTR) is offered a heart, the lung from the same deceased donor must be offered to the heart-lung PTR.

When a heart-lung PTR is offered a lung, the heart from the same deceased donor must be offered to the heart-lung PTR according to *Table 6-9* below.

Table 6-9: Allocation of Heart-Lungs If PTR is Offered the Lung

When a heart-lung PTR	The heart from the same	Within this geographic
in this geographic area is	deceased donor must be	area:
offered a lung:	offered to all the heart-	
	lung PTRs after the heart	
	has been offered to all:	
OPO's DSA or Zone A	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	OPO's DSA or Zone A

When a heart-lung PTR in this geographic area is offered a lung:	The heart from the same deceased donor must be offered to all the heart-lung PTRs after the heart has been offered to all:	Within this geographic area:
Zone B	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone B
Zone C	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	<del>Zone C</del>
Zone D	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	Zone D
Zone E	Pediatric status 1A or 1B, and adult status 1, adult status 2, or adult status 3 isolated heart PTRs	<del>Zone E</del>

If a host OPO is offering a heart and a lung from the same deceased donor, then the host OPO must offer the heart and the lung according to Policy 6.6.F.i: Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old or Policy 6.6.F.ii: Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old.

The blood type matching requirements described in *Policy 6.6.A: Allocation of Hearts by Blood Type* apply to heart-lung candidates when the candidates appear on the heart match run. The blood type matching requirements in *Policy 10.4.B: Allocation of Lungs by Blood Type* applyies to heart-lung candidates when the candidates appear on the lung match run.

### 6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old

If a heart or heart-lung potential transplant recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.

If a lung or heart-lung PTR in allocation classifications 1 through 12 according to Policy 10.4.C: Allocation of Lungs From Deceased Donors at Least 18 Years Old requires a heart, the OPO cannot allocate the heart from the same deceased donor to theat lung or heart-lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 4 according to Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.

## 6.6.F.ii Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old

If a heart or heart-lung potential transplant recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old.

If a lung or heart-lung PTR in allocation classifications 1 through 10 according to Policy 10.4.D: Allocation of Lungs From Deceased Donors Less Than 18 Years Old requires a heart, the OPO cannot allocate the heart from the same deceased donor to theat lung or heart-lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 12 according to Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old.

#### 10.2.A Allocation Exception for Highly Sensitized Patients

Lungs may be allocated to sensitized candidates within a DSA out of the sequence required by the match run if:

- 1. The candidate's transplant surgeon or physician determines that the candidate's antibodies would react adversely to certain human leukocyte antigens (HLA) antigens.
- 2. All lung transplant programs and the OPO within the DSA agree to allocate the lung from a compatible deceased donor to the sensitized candidate because the results of a crossmatch between the blood serum of that the candidate and cells of the lung donor are negative.
- The candidate's transplant program, all lung transplant programs, and the OPO within a DSA agree upon the level of sensitization at which a candidate qualifies for the sensitization exception.

Sensitization alone does not qualify a candidate to qualify for an exception as described in *Policy* 10.2.B: Lung Candidates with Exceptional Cases below.

A lung candidate's transplant physician may use medical judgment to determine that a lung candidate is highly sensitized.

If there is one or more lung transplant programs that have potential transplant recipients (PTRs) who appear on the match run above the highly sensitized candidate, then the highly sensitized candidate's transplant program may request that those transplant programs refuse the offer so that the transplant program can accept the offer for the highly sensitized candidate.

If the only PTRs on the match run are registered at the same transplant program as the highly sensitized candidate, the transplant physician may use medical judgment to accept the offer for the highly sensitized candidate out of sequence.

### 10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old

Single and double lungs from deceased donors at least 18 years old are allocated according to *Table 10-9* below.

Table 10-9: Allocation of Lungs from Deceased Donors at Least 18 Years Old

Classification	Candidates that are included within the:	And are:
4	OPO's DSA	At least 12 years old, blood type identical to the donor
2	OPO's DSA	At least 12 years old, blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
3	OPO's DSA	Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers
4	OPO's DSA	Priority 1 and one of the following:  At least 1 year old and blood type compatible with the donor  At least 1 year old and eligible for intended blood group incompatible offers
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7 <u>1</u>	Zone A	At least 12 years old, blood type identical to the donor
8 <u>2</u>	Zone A	At least 12 years old, blood type compatible with the donor
<del>9</del> 3	Zone A	<ul> <li>Priority 1 and one of the following:</li> <li>Less than 12 years old and blood type identical to the donor</li> <li>Less than 1 year old and blood type compatible with the donor</li> <li>Less than 1 year old and eligible for intended blood group incompatible offers</li> </ul>
<del>10</del> 4	Zone A	<ul> <li>Priority 1 and one of the following:</li> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> </ul>
<del>11</del> 5	Zone A	Priority 2, blood type identical to the donor
<del>12</del> 6	Zone A	Priority 2, blood type compatible with the donor
<del>13</del> 7	Zone B	At least 12 years old, blood type identical to the donor
<del>14</del> 8	Zone B	At least 12 years old, blood type compatible with the donor
<del>15</del> 9	Zone B	Priority 1 and <i>one</i> of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers

Classification	Candidates that are included within the:	And are:
<del>16</del> 10	Zone B	<ul> <li>Priority 1 and one of the following:</li> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> </ul>
<del>17</del> 11	Zone B	Priority 2, blood type identical to the donor
<del>18</del> 12	Zone B	Priority 2, blood type compatible with the donor
<del>19</del> 13	Zone C	At least 12 years old, blood type identical to the donor
<del>20</del> 14	Zone C	At least 12 years old, blood type compatible with the donor
<del>21</del> 15	Zone C	Priority 1 and <i>one</i> of the following:  • Less than 12 years old and blood type identical to the donor  • Less than 1 year old and blood type compatible with the donor  • Less than 1 year old and eligible for intended blood group incompatible offers
<del>22</del> 16	Zone C	<ul> <li>Priority 1 and one of the following:</li> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> </ul>
<del>2</del> 3 <u>17</u>	Zone C	Priority 2, blood type identical to the donor
<del>2</del> 4 <u>18</u>	Zone C	Priority 2, blood type compatible with the donor
<del>25</del> 19	Zone D	At least 12 years old, blood type identical to the donor
<del>26</del> 20	Zone D	At least 12 years old, blood type compatible with the donor
<del>27</del> 21	Zone D	<ul> <li>Priority 1 and one of the following:</li> <li>Less than 12 years old and blood type identical to the donor</li> <li>Less than 1 year old and blood type compatible with the donor</li> <li>Less than 1 year old and eligible for intended blood group incompatible offers</li> </ul>
<del>28</del> 22	Zone D	Priority 1 and <i>one</i> of the following:  • At least 1 year old and blood type compatible with the donor  • At least 1 year old and eligible for intended blood group incompatible offers
<del>29</del> 23	Zone D	Priority 2, blood type identical to the donor
<del>30</del> 24	Zone D	Priority 2, blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
<del>31</del> <u>25</u>	Zone E	At least 12 years old, blood type identical to the donor
<del>32</del> 26	Zone E	At least 12 years old, blood type compatible with the donor
<del>33<u>27</u></del>	Zone E	Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers
<del>3</del> 4 <u>28</u>	Zone E	Priority 1 and one of the following:  At least 1 year old and blood type compatible with the donor  At least 1 year old and eligible for intended blood group incompatible offers
<del>35</del> 29	Zone E	Priority 2, blood type identical to the donor
<del>36</del> <u>30</u>	Zone E	Priority 2, blood type compatible with the donor
<u>31</u>	Zone F	At least 12 years old, blood type identical to the donor
<u>32</u>	Zone F	At least 12 years old, blood type compatible with the donor
<u>33</u>	Zone F	Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers
<u>34</u> 	Zone F Zone F	<ul> <li>Priority 1 and one of the following:</li> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> <li>Priority 2, blood type identical to the donor</li> </ul>
36	Zone F	Priority 2, blood type compatible with the donor

## 10.4.D Allocation of Lungs from Deceased Donors Less than 18 Years Old

Single and double lungs from deceased donors less than 18 years old are allocated according to *Table 10-10* below.

Table 10-10: Allocation of Lungs from Deceased Donors Less than 18 Years Old

Table 10-10: Allocation of Lungs from Deceased Donors Less than 18 Years Old		
Classification	Candidates that are included within the:	And are:
1	OPO's DSA, Zone A, er Zone B <u>, or Zone C</u>	<ul> <li>Priority 1 and <i>one</i> of the following:</li> <li>Less than 12 years old and blood type identical to the donor</li> <li>Less than 1 year old and blood type compatible with the donor</li> <li>Less than 1 year old and eligible for intended blood group incompatible offers</li> </ul>
2	OPO's DSA, Zone A, er Zone B <u>, or Zone C</u>	<ul> <li>Priority 1 and <i>one</i> of the following:</li> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> </ul>
3	OPO's DSA, Zone A, er Zone B, or Zone C	Priority 2, blood type identical to the donor
4	OPO's DSA, Zone A, er Zone B, or Zone C	Priority 2, blood type compatible with the donor
5	OPO's DSA, Zone A, er Zone B <u>, or Zone C</u>	12 to less than 18 years old, blood type identical to the donor
6	OPO's DSA, Zone A, er Zone B <u>, or Zone C</u>	12 to less than 18 years old, blood type compatible with the donor
7	OPO's DSA	At least 18 years, blood type identical to the donor
8	OPO's DSA	At least 18 years, blood type compatible with the donor
<del>9</del> <u>7</u>	Zone A	At least 18 years old, blood type identical to the donor
<del>10</del> 8	Zone A	At least 18 years old, blood type compatible with the donor
<del>11</del> 9	Zone B	At least 18 years old, blood type identical to the donor
<del>12</del> 10	Zone B	At least 18 years old, blood type compatible with the donor
<u>11</u>	Zone C	At least 18 years old, blood type identical to the donor
<u>12</u>	Zone C	At least 18 years old, blood type compatible with the donor
13	Zone <u>GD</u>	<ul> <li>Priority 1 and one of the following:</li> <li>Less than 12 years old and blood type identical to the donor</li> <li>Less than 1 year old and blood type compatible with the donor</li> <li>Less than 1 year old and eligible for intended blood group incompatible offers</li> </ul>

Classification	Candidates that are included within the:	And are:
14	Zone <u>CD</u>	<ul> <li>Priority 1 and <i>one</i> of the following:</li> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> </ul>
15	Zone <del>C</del> D	Priority 2, blood type identical to the donor
16	Zone <del>C</del> D	Priority 2, blood type compatible with the donor
17	Zone <del>C</del> D	12 to less than 18 years old, blood type identical to the donor
18	Zone <u>CD</u>	12 to less than 18 years old, blood type compatible with the donor
19	Zone <u>GD</u>	At least 18 years old, blood type identical to the donor
20	Zone <u>GD</u>	At least 18 years old, blood type compatible with the donor
21	Zone Đ <u>E</u>	<ul> <li>Priority 1 and one of the following:</li> <li>Less than 12 years old and blood type identical to the donor</li> <li>Less than 1 year old and blood type compatible with the donor</li> <li>Less than 1 year old and eligible for intended blood group incompatible offers</li> </ul>
22	Zone <del>D</del> <u>E</u>	Priority 1 and one of the following:  • At least 1 year old and blood type compatible with the donor  • At least 1 year old and eligible for intended blood group incompatible offers
23	Zone <del>D</del> E	Priority 2, blood type identical to the donor
24	Zone Đ <u>E</u>	Priority 2, blood type compatible with the donor
25	Zone Đ <u>E</u>	12 to less than 18 years old, blood type identical to the donor
26	Zone Đ <u>E</u>	12 to less than 18 years old, blood type compatible with the donor
27	Zone Đ <u>E</u>	At least 18 years old, blood type identical to the donor
28	Zone Đ <u>E</u>	At least 18 years old, blood type compatible with the donor
29	Zone E <u>F</u>	Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers

Classification	Candidates that are included within the:	And are:
30	Zone <u>E</u> F	Priority 1 and one of the following:
		<ul> <li>At least 1 year old and blood type compatible with the donor</li> <li>At least 1 year old and eligible for intended blood group incompatible offers</li> </ul>
31	Zone <u>E</u> F	Priority 2, blood type identical to the donor
32	Zone <u>E</u> F	Priority 2, blood type compatible with the donor
33	Zone <u>E</u> F	12 to less than 18 years old, blood type identical to the donor
34	Zone <u>E</u> F	12 to less than 18 years old, blood type compatible with the donor
35	Zone <u>E</u> F	At least 18 years old, blood type identical to the donor
36	Zone <u>E</u> F	At least 18 years old, blood type compatible with the donor