TO: George Sigounas, MS, Ph.D.
Administrator
Health Resources and Services Administration
Department of Health and Human Services

FROM: Yolanda Becker, MD
President, OPTN/UNOS Board of Directors

Brian Shepard
OPTN Executive Director
CEO, United Network for Organ Sharing

DATE: November 24, 2017

RE: Review of Lung Allocation Policy by the OPTN/UNOS Executive Committee

Executive summary:

On behalf of the United States Department of Health and Human Services (HHS), on November 21, 2017, Health Resources and Services Administration (HRSA) Administrator George Sigounas directed the Organ Procurement and Transplantation Network (OPTN) to conduct an emergency "review of the use of DSAs [donation service areas] in Lung Allocation Policy in accordance with the requirements of the OPTN final rule" and "inform HHS whether the use of DSAs in Lung Allocation Policy is consistent with the requirements of the OPTN final rule."[1]

Specifically, the OPTN was asked to explain whether the current adult donor allocation sequence that allocates lungs to candidates in the DSA in the first six allocation classifications is more consistent with the Final Rule than an allocation policy that instead removes the DSA as the first unit of allocation and initially allocates lungs to all candidates within Zone A (500 nautical miles of the donor hospital). HRSA further requested that if the OPTN concludes that changes should be made, to describe to what extent and how it proposes lung allocation policies be modified and provide timetable for implementing changes.

The OPTN/UNOS Executive Committee has conducted the emergency review as requested and has determined that the current lung allocation policy contains an over-reliance on DSA as the primary unit of lung allocation. The OPTN/UNOS Executive Committee also concluded that a policy that does not depend on DSA as the primary unit of allocation of lungs is more consistent with the OPTN Final Rule than a policy that shares lungs first exclusively within the DSA. Therefore, the OPTN/UNOS Executive Committee further concluded that lung allocation policy could be revised by replacing the DSA as the first element of lung allocation with a 250 mile circle measured from the donor hospital. Implementation of this change can be made expeditiously as outlined below.

[1] Letter from HRSA Administrator to Yolanda Becker, MD, President of the OPTN. November 21, 2017.

Use of DSAs in Lung Allocation Policy and the Final Rule

Currently, lung candidates greater than 12 years old are prioritized for offers from donors within their DSA according to their lung allocation score (LAS), which is an estimate of the candidate's medical urgency and likelihood of post-transplant success.[2] Because of the way these two factors are used in the calculation, a higher LAS generally reflects a higher likelihood of death on the waiting list. Offers from adult donors are sent to all candidates in the DSA before any offers are sent to candidates in Zone A, which encompasses all candidates within 500 nautical miles of the donor hospital but outside of the donor hospital's DSA.[3] Under the current sharing system for lungs, for example, a candidate with a very high LAS in Zone A will not receive a lung offer until all candidates in the local DSA, including those with a relatively low severity of illness, are first offered the lungs.

Recent literature suggests that changing the DSA-first allocation system would increase the number of organs allocated to the most medically urgent candidates. One study found that "organs are commonly allocated to local candidates with a lower LAS while regional candidates with a higher LAS continue to wait and/or die without the benefit of transplantation."[4] For example, "waiting list survival among patients with an LAS less than 50 is approximately 4 years, those with an LAS 50 to 74 is approximately 6 months, and those with an LAS 75+ is less than 30 days." [5] This finding supports the notion that other geographic considerations might be more consistent than current policy with the requirement in the OPTN Final Rule that organs be allocated "over as broad a geographic area as feasible…and in order of decreasing medical urgency."[6] Another study, supported by the Scientific Registry for Transplant Recipients' (SRTR) Thoracic Simulation Allocation Modeling (TSAM), demonstrated that broader sharing would lead to decreased waitlist mortality.[7]

In addition to supporting broader sharing due to the likely effect of transplanting more urgent candidates more quickly without resulting in worse post-transplant outcomes, another study also suggested that allocating lungs to the DSA first results in "disparities in outcomes for transplant candidates depending on where they reside."[8] This finding further supports that removing DSA-first sharing may make OPTN policy more consistent with the requirements of the Final Rule.

Upon review of available data and literature, and after consultation with the OPTN/UNOS Thoracic Organ Transplantation Committee (Thoracic Committee), the Executive Committee determined that the current lung allocation policy contains an over-reliance on DSA as a unit of allocation. The Executive Committee further concluded that a policy that does not depend on

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[2] OPTN/UNOS Policies. *10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old.* Accessed November 20, 2017. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_10

[3] OPTN/UNOS Policies. 1.2: Definitions. Accessed on November 20, 2017. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_01

[4] Russo, et.al. Local Allocation of Lung Donors Results in Transplanting Lungs in Lower Priority Transplant Recipients. Ann Thorac Surg 2013;95:1231–5. DOI: 10.1016/j.athoracsur.2012.11.070

[5] *Id.*

[6] 42 C.F.R. § 121.8, available at Electronic Code of Federal Regulations

[7] Mooney, et. al. Effect of Broader Geographic Sharing of Donor Lungs on Regional Waitlist (WL) Mortality and Transplant Center Volume. The Journal of Heart and Lung Transplantation , Volume 36 , Issue 4 , S206 - S207. DOI: http://dx.doi.org/10.1016/j.healun.2017.01.541

[8] Iribarne, et.al. Distribution of donor lungs in the United States: a case for broader geographic sharing. Clin Transplant 2016: 30: 688–693 DOI: 10.1111/ctr.12735

DSA as the primary unit of allocation of lungs is more consistent with the OPTN Final Rule than a policy that shares first only within the DSA.

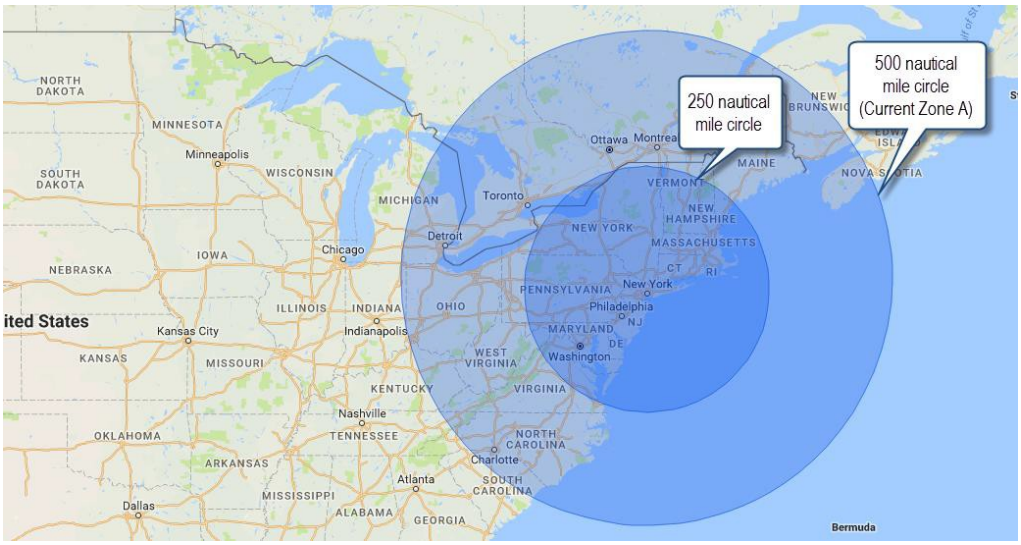
Appropriate Geographic Considerations under the OPTN Final Rule

The Executive Committee also recognized that the size of the initial sharing unit impacts cold ischemic times, which affect post-transplant graft performance. Geography also impacts the timing and costs of the organ recovery and matching processes. The Executive Committee concluded that because of these factors, geographic considerations are consistent with the OPTN Final Rule, so long as those geographic constraints are rationally determined, consistently applied, and do not create inequalities in candidates' access to organ transplantation.

A substitute for the disparate sizes, shapes, and populations of DSAs as drawn today could more appropriately address those concerns in a way that is rationally determined, consistently applied, and equal for all lung candidates. Accordingly, while DSAs are not a good proxy for geography, some geographic constraints are appropriately considered in lung allocation policy consistent with the OPTN Final Rule.

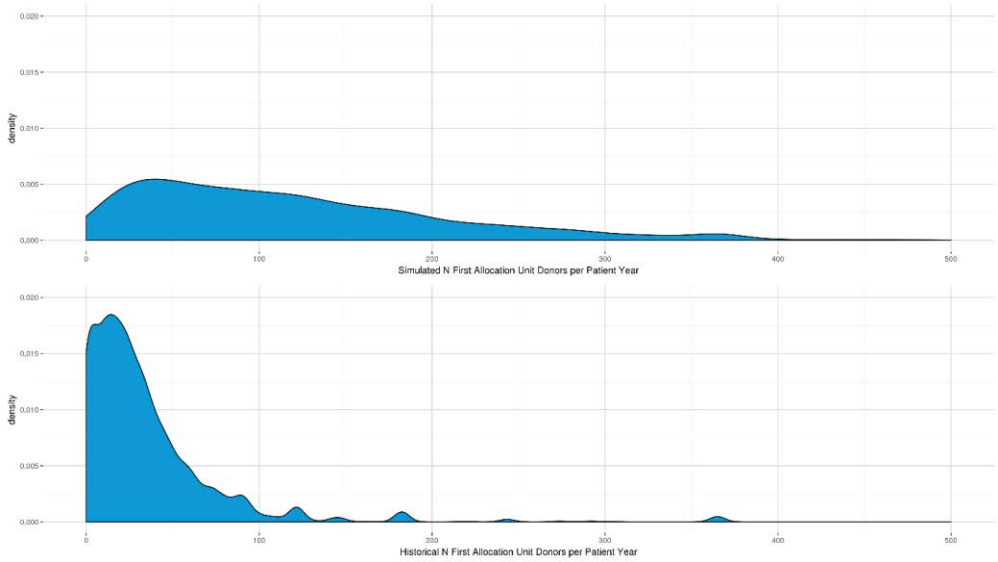
A policy change to replace DSA-first sharing with sharing to a consistent size circle would begin to minimize the effect of geography on a candidate's access to donors in a manner more consistent with the requirements of the Final Rule. Providing urgent candidates access to a broader range of donors across DSA, and sometimes even across regional, borders would appropriately increase the relative importance of medical factors as compared to geographic factors in allocation.

Therefore, the Executive Committee concluded that the lung allocation policy should be revised to replace the use of DSA as the first element of lung allocation with a 250 mile circle, measured from the donor hospital. This policy applies a reasonable geographic constraint in a way that is rational, consistent, and promotes increased equity among candidates. A 250 mile promotes broader geographic access to lungs while reducing the risk of unintended consequences arising to candidates in certain medical or demographic categories that have not yet been modeled.

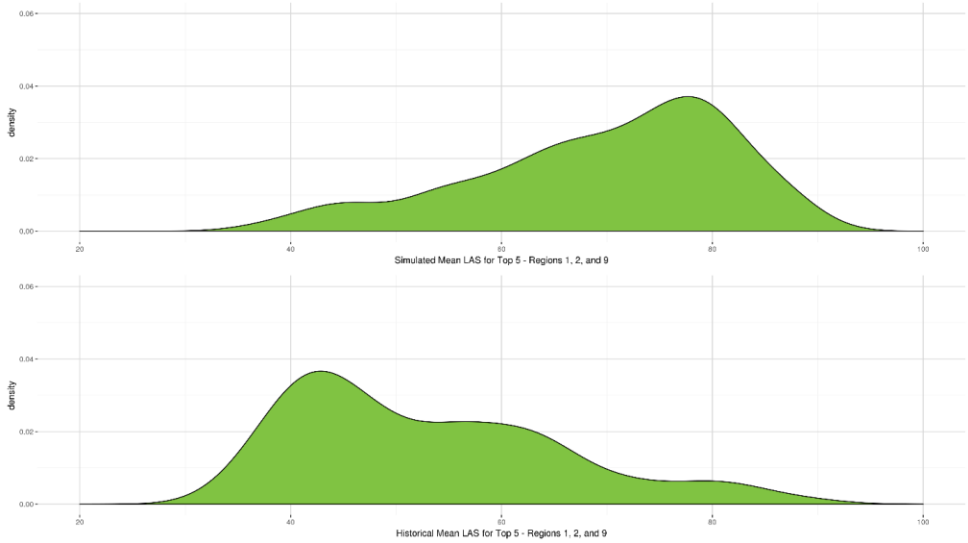


Impact of the Change

The figures below show the increase in the number of donors for which individual candidates would appear on a match run in the first unit of allocation if the DSA-first policy were replaced with a 250 mile circle around the donor hospital. The shift to the right in the top figure (250 mile circle) shows candidates appearing in the first unit of allocation on many more match runs than the lower figure, where most candidates appear on less than 50 match runs.



The top figure in the pair below shows that the mean LAS for the top 5 candidates for any donor in the northeastern United States (OPTN Regions 1, 2, and 9) would increase under a policy that used 250 mile circles as the first unit of allocation. The shift to the right from the mean LAS under the current DSA-first policy (lower figure) represents a shift in access toward the most medically urgent candidates.



Implementation Plan:

At the direction of the HRSA Administrator, the OPTN/UNOS Executive Committee met on November 24, 2017, and adopted the changes to policy described below. The necessary programming in UNet^{SM} to effect these changes to lung allocation are underway and are expected to be completed on November 25, 2017.

Policy changes would typically be presented formally for public comment in the spring and adopted at the OPTN/UNOS board meeting in June 2018. However, the Executive Committee requests that the HRSA Administrator, acting on behalf of the Secretary of HHS, use his authority under the critical comments process of the Final Rule to direct the OPTN to make these changes effective upon completion of the necessary IT programming.

The OPTN will inform members on any policy changes through Policy Notices. After the policy takes effect, the OPTN will distribute a proposal for public comment regarding these changes, and will consider feedback received during public comment for further improvements in the future.

The OPTN will also monitor the effects of the policy change on lung candidates by medical and demographic characteristics, and monitor for any unintended consequences such as poorer graft survival, increased discards, or increased costs.

Change to OPTN Policy

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

RESOLVED, that changes to Policies 1.2 (Definitions), 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), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members and will expire on November 24, 2018.

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.

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:
~~**1**~~	~~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~~
~~**3**~~	~~OPO's DSA~~	~~Priority 1 and *one* of the following:~~ ~~Less than 12 years old and blood type identical to the donor~~

Classification	Candidates that are included within ~~the~~:	And are:
		~~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~~1	Zone A	At least 12 years old, blood type identical to the donor
~~8~~2	Zone A	At least 12 years old, blood type compatible with the donor
~~9~~3	Zone A	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
~~10~~4	Zone A	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
~~11~~5	Zone A	Priority 2, blood type identical to the donor
~~12~~6	Zone A	Priority 2, blood type compatible with the donor
~~13~~7	Zone B	At least 12 years old, blood type identical to the donor
~~14~~8	Zone B	At least 12 years old, blood type compatible with the donor
~~15~~9	Zone B	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
~~16~~10	Zone B	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

Classification	Candidates that are included within ~~the~~:	And are:
~~17~~11	Zone B	Priority 2, blood type identical to the donor
~~18~~12	Zone B	Priority 2, blood type compatible with the donor
~~19~~13	Zone C	At least 12 years old, blood type identical to the donor
~~20~~14	Zone C	At least 12 years old, blood type compatible with the donor
~~21~~15	Zone C	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
~~22~~16	Zone C	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~~17	Zone C	Priority 2, blood type identical to the donor
~~24~~18	Zone C	Priority 2, blood type compatible with the donor
~~25~~19	Zone D	At least 12 years old, blood type identical to the donor
~~26~~20	Zone D	At least 12 years old, blood type compatible with the donor
~~27~~21	Zone D	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
~~28~~22	Zone D	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
~~29~~23	Zone D	Priority 2, blood type identical to the donor
~~30~~24	Zone D	Priority 2, blood type compatible with the donor
~~31~~25	Zone E	At least 12 years old, blood type identical to the donor
~~32~~26	Zone E	At least 12 years old, blood type compatible with the donor
~~33~~27	Zone E	Priority 1 and *one* of the following:

Classification	Candidates that are included within ~~the~~:	And are:
		• 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
~~34~~28	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
~~35~~29	Zone E	Priority 2, blood type identical to the donor
~~36~~30	Zone E	Priority 2, blood type compatible with the donor
31	Zone F	At least 12 years old, blood type identical to the donor
32	Zone F	At least 12 years old, blood type compatible with the donor
33	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
34	Zone F	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
35	Zone F	Priority 2, blood type identical to the donor
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

Classification	Candidates that are included within the:	And are:
1	~~OPO's DSA,~~ Zone A, Zone B, or Zone ~~B~~C	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor

Classification	Candidates that are included within the:	And are:
		• 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
2	~~OPO's DSA,~~ Zone A, Zone B, or Zone ~~B~~C	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
3	~~OPO's DSA,~~ Zone A, Zone B, or Zone ~~B~~C	Priority 2, blood type identical to the donor
4	~~OPO's DSA,~~ Zone A, Zone B, or Zone ~~B~~C	Priority 2, blood type compatible with the donor
5	~~OPO's DSA,~~ Zone A, Zone B, or Zone ~~B~~C	12 to less than 18 years old, blood type identical to the donor
6	~~OPO's DSA,~~ Zone A, Zone B, or Zone ~~B~~C	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~~
~~**9**~~**7**	Zone A	At least 18 years old, blood type identical to the donor
~~**10**~~**8**	Zone A	At least 18 years old, blood type compatible with the donor
~~**11**~~**9**	Zone B	At least 18 years old, blood type identical to the donor
~~**12**~~**10**	Zone B	At least 18 years old, blood type compatible with the donor
11	Zone C	At least 18 years old, blood type identical to the donor
12	Zone C	At least 18 years old, blood type compatible with the donor
13	Zone ~~C~~D	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
14	Zone ~~C~~D	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
15	Zone ~~C~~D	Priority 2, blood type identical to the donor

Classification	Candidates that are included within the:	And are:
16	Zone ~~C~~D	Priority 2, blood type compatible with the donor
17	Zone ~~C~~D	12 to less than 18 years old, blood type identical to the donor
18	Zone ~~C~~D	12 to less than 18 years old, blood type compatible with the donor
19	Zone ~~C~~D	At least 18 years old, blood type identical to the donor
20	Zone ~~C~~D	At least 18 years old, blood type compatible with the donor
21	Zone ~~D~~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
22	Zone ~~D~~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
23	Zone ~~D~~E	Priority 2, blood type identical to the donor
24	Zone ~~D~~E	Priority 2, blood type compatible with the donor
25	Zone ~~D~~E	12 to less than 18 years old, blood type identical to the donor
26	Zone ~~D~~E	12 to less than 18 years old, blood type compatible with the donor
27	Zone ~~D~~E	At least 18 years old, blood type identical to the donor
28	Zone ~~D~~E	At least 18 years old, blood type compatible with the donor
29	Zone ~~E~~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
30	Zone ~~E~~F	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
31	Zone ~~E~~F	Priority 2, blood type identical to the donor

Classification	Candidates that are included within the:	And are:
32	Zone ~~E~~F	Priority 2, blood type compatible with the donor
33	Zone ~~E~~F	12 to less than 18 years old, blood type identical to the donor
34	Zone ~~E~~F	12 to less than 18 years old, blood type compatible with the donor
35	Zone ~~E~~F	At least 18 years old, blood type identical to the donor
36	Zone ~~E~~F	At least 18 years old, blood type compatible with the donor