Exhibit A

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June 3, 2013

VIA EMAIL

The Honorable Kathleen Sebelius
Secretary of the Department of Health & Human Services
200 Independence Ave., S.W., Room 120F
Washington, D.C. 20201
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Email: Kathleen.Sebelius@hhs.gov

Dear Secretary Sebelius:

This firm has been engaged to represent Janet and Francis Murnaghan, the parents of 10-year-old Sarah Murnaghan, who is now in the intensive care unit at Children's Hospital of Philadelphia ("CHOP") hoping to receive a lung transplant that will save her life. I am writing this letter pursuant to 42 C.F.R. § 121.4(d) to ask that you take immediate action and direct the Organ Procurement and Transplantation Network (the "OTPN") to set aside that portion of OPTN Policy 3.7 that discriminates against children under 12 in the system established by law for allocating donated lungs (the "Under 12 Rule").

We have reviewed your letter of May 31, 2013 directing the OPTN to review Policy 3.7 and the Under 12 Rule in particular as soon as possible but with full consultation with the OPTN membership and other interested parties. Unfortunately, that process will take months and Sarah and other children under 12 currently standing at the back of the line waiting to be considered for donation of adult lungs cannot wait. They will die in the meantime.

As explained below, you have the authority to direct the OPTN to set aside the Under 12 Rule on an emergency basis and you should exercise that authority. The Under 12 Rule has the practical effect of preventing children under 12 from being considered as candidates to receive lungs from the much larger pool of adults lungs even when their doctors have determined that they can receive adult lungs.[1] Data from the OPTN shows that children under 12 waiting for lung transplants are dying at a rate much higher than the rate for adults waiting for lung transplants. Whether the Under 12 Rule is causing or simply permitting that result, this outcome is unacceptable. There is no sound rationale or purpose for the Under 12 Rule that should prevent the OPTN from setting the Rule aside while it studies the matter. The Under 12 Rule is unfair, arbitrary and capricious, inconsistent with the statute and regulations, and stands

[1] In 2011, the last year for which data is available, there were 1,573 available lungs from adults versus 23 from children for the entire country. See Ruddock Dec. ¶ 17.

in the way of Sarah potentially receiving a set of lungs that she needs to live. It violates her rights under the Due Process and Equal Protection Clauses of the United States Constitution.

Please take particular note that the Murnaghans are not asking you to intervene in favor of Sarah to ensure that she receives a set of donated lungs. They are only asking that you exercise your authority to direct that an inflexible policy established by a federally-created organization supervised by your Department be set aside so that medical professionals can exercise their judgment and Sarah can be considered for a set of donated adult lungs under the same requirements that apply to persons aged 12 and over. Sarah wants and deserves equal treatment, without being disqualified because of her age.

I. Background

A. Factual Background

Attached to this letter is the Declaration of Sharon Ruddock. Sharon is the sister of Sarah's mother, Janet Murnaghan. She is very familiar with the background of this matter and has been asked by our clients to work directly with us as they are busy with Sarah and her doctors. As I think you already know, it has been a very tough few months for Sarah. She is now on her 104th straight day in the hospital. Her doctors at CHOP have advised that she may have only weeks to live. If Sarah could be considered for a lung transplant under OPTN Policy 3.7, without regard to the Under 12 Rule, there is a good chance that she would receive a compatible and medically appropriate set of adult lungs that would save her life or at least it would greatly increase her chances. We do not have access to current UNOS data, but based on 2011 data, Sarah's lung allocation score (described below) would put her in the top 6% in the country, greatly increasing her chances of a receiving a donated lung. Indeed, but for the Under 12 Rule she very well might have already received a new set of lungs.

B. Legal Background

The National Organ Transplant Act of 1984 ("NOTA") created the OPTN. The statute has been amended several times. The current version is codified at 42 U.S.C. § 274, *et seq.* Section 274 provides that "the Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b) of this section."

Section 274(b)(2) provides, inter alia, that the OPTN "shall":

(A) establish in one location or through regional centers –

(i) a national list of individuals who need organs, and

> (ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,
>
> . . .
>
> (D) assist organ procurement organizations in the nationwide distribution of organs *equitably* among transplant patients,
>
> . . .
>
> (M) *recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children*
>
> . . . .

42 U.S.C. § 274(b)(2) (emphasis added).

Acting pursuant to its authority under the NOTA, since 1986 the Secretary of the Department of Health and Human Services ("HHS") through the Health Resources and Services Administration ("HRSA") has contracted with the United Network for Organ Sharing ("UNOS"), a non-profit private organization, to operate the OPTN. The Secretary has also promulgated regulations at 42 C.F.R. part 121 that govern the OPTN.

The regulations promulgated by the Secretary provide that the OPTN's Board of Directors shall be responsible for developing policies for the operation of the OPTN, including "[p]olicies for the *equitable* allocation of cadaveric organs . . . ." 42 C.F.R. § 121.4(a)(1).

The regulations also govern the content of the policies to be developed by the OPTN. Section 121.8(a) provides that OPTN's Board of Directors "shall develop, in accordance with the policy development process described in § 121.4, policies for the *equitable allocation* of cadaveric organs among potential recipients. " (Emphasis added). And Section 121.8(b) directs that the allocation policies should be designed to give greatest consideration to allocating organs based on the severity of illness. As noted in the proposed final rule promulgated on April 2, 1998: "The OPTN is required to develop equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment." 63 Fed. Reg. 16296.

The statute and regulations clearly require that OPTN policies for organ allocation must be equitable and must provide organs based on medical severity. The Murnaghans are not seeking special treatment for Sarah. Rather, they ask only for equitable treatment based on sound medical judgment.

II. Discussion

A. OPTN Policy 3.7 Unfairly Discriminates Against Children

Under OPTN Policy 3.7, lungs are allocated by the age of the donor. The Policy essentially sets up three different waiting lines: one for lungs donated by adults (age 18 and over), one for lungs donated by adolescents (age 12-17), and one for lungs donated by children (age 11 and under). Lungs donated by adults are offered preferentially to adults and adolescents based on location, compatibility, and lung allocation score ("LAS"), which is "a calculation of illness severity and projected posttransplant survival that was intended to place the sickest candidates with the best chance of survival at the top of the waiting list." Colvin-Adams, M, Valapour, et al, *Lung and Heart Allocation in the United States*, Am J. Transplant 2012; 12:3213-3234, 3214. The Under 12 Rules prohibits patients under 12 years of age from receiving lung donated by adults unless they have been first offered to and declined by every waiting adult and adolescent in the same geographic zone. *Id.* at 3215. It should be obvious that with a critical need for lung donations, all of the adults and adolescents on the waiting list in a zone are not going to decline a set of lungs unless the lungs are of very poor quality, such as lungs from a heavy smoker or person with a compromised immune system. As a practical matter, being at the very back of the list is nearly the same as not being on the list.

It has been suggested that this system is fair because the demand for donated lungs for children is small and under Policy 3.7 children get preferential access to lungs donated from children as well as preference behind adolescents to lungs donated from adolescents. The May 30, 2013 letter to you from John P. Roberts, M.D., of the OPTN suggests (at page 4) that this was the OPTN's thinking when it developed Policy 3.7 and the Under 12 Rule in 2004. There is no suggestion that the OPTN has tested or re-analyzed that conclusion and we think there is strong evidence that it is wrong.

First, it stands to reason that any time a system allocates health resources by segmenting the population based on age, significant disparities could result. In fact, disparities are what you would expect. A simple review of UNOS data proves this. I asked Sharon Ruddock to help me analyze some UNOS data in support of this letter. You can see at paragraph 18 of her declaration that UNOS data shows that in 2011, the last year for which data is available, segmentation by age could lead to significant disparities. For example, in that year, persons aged 18-34 provided 50% of the donated lungs and received 12% of the transplants while persons 65 and over provided 1% of the donated lungs and received 27% of the

transplants. This shows that it would be extremely unfair to allocate lungs within the adult population based on age. It is unfair to children as well.

Sharon Ruddock's review of the UNOS data shows that disparate outcomes for children are not just likely, they are real. The death rate (*i.e.*, the percentage of people on the waiting list that die while waiting for a lung transplant) for children in 2011 (the last year for which data is available) is 62% versus 26% for adults. Ruddock Dec. ¶ 15. The 2009-11 three year average death rate for children is 46% versus 27% for adults. These results are statistically significant. When we plot the death rates on a chart for the years 1999 to 2011, we see that since 2005, the year that OPTN implemented the Under 12 Rule, the death rate for children has gone up while the death rate for adults has gone down. We believe that when you or your staff review the data, you will reach the same conclusions.

When we look at UNOS data on the share of patients receiving a donated lung the story is similar. In every year since 2005 the rate of adults receiving a donated lung is much higher than the rate of children receiving a donated lung. Ruddock Dec. ¶ 16.

The data proves that outcomes are much worse for children than for adults under Policy 3.7 and the Under 12 Rule. It makes no difference whether Policy 3.7 and the Under 12 Rule are causing this disparity or simply permitting it. Either way, it is clear violation of the statutory command that the organ allocation system must be equitable.

In summary, the data shows that children are not being treated equitably. They are being treated very differently and worse than adults. In the next section of this letter, we demonstrate that there is no sound reason to justify discrimination against children in the system for allocating lungs.

B. There Is No Sound Reason For Discriminating Against Children in Lung Allocation

It has been very difficult for us to understand any purpose for the Under 12 Rule. None of the OPTN policies were published in the Federal Register. This is a violation of 12 C.F.R. § 121.4(b), which requires the OPTN to provide its policies to the Secretary at least 60 days in advance of their implementation and requires the Secretary to "refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the Federal Register for public comment." Apparently the policies were published on the OPTN website, but we can find no record of any public comments or the OPTN's response to any comments.

As best we can discern from the May 30 letter from Dr. Roberts of the OPTN to you (at page 3), when the OPTN developed Policy 3.7 in 2004 it decided that "waiting time for

this population [i.e., children] should remain the method of prioritizing patients in this group"[2] because there were not that many of them and some of them had diseases not found in the adult population. We understand him to be suggesting that the OPTN felt it did not have a basis to make a decision about using the LAS with children. Elsewhere in the same letter (at page 2), he suggests that the LAS is used for adults and adolescents and "[i]ts applicability among pre-adolescents is unknown." Our clients' experience at CHOP and in communications with many different hospitals suggests that in the real world medical professionals use the LAS with children as a measure of severity. See Ruddock Aff. ¶ 11.

In any event, it makes no sense for the OPTN to continue to subject children to unfair discrimination in lung allocation simply because it could not prove that the LAS system worked for children when it developed the LAS system in 2004. Sarah's case proves the point. There is no question that she is very sick. Her doctors have said so and have also told her parents that she may soon die if she does not get a lung transplant. But, without ever reviewing her case, UNOS/OPTN presume that they cannot tell how sick she really is in comparison to adults and adolescents, and on that basis continue to deny her access to the much larger pool of lungs donated from adults. This is truly arbitrary. It also violates the OPTN's duty to allocate lungs according to medical severity.

In the past, it may have been the case that complications involved with downsizing an adult lung for transplantation into a child presented a serious obstacle to the surgery, but that is no longer the case. Doctors do these surgeries and, as the May 30 OPTN letter recognizes, "[m]edical literature suggests that outcomes (survival, complications) are comparable when lobes rather than whole lungs are transplanted," although it notes that the studies involve small numbers.[3]

OPTN would satisfy its legal obligations by making lung allocation decisions for children based on LAS scores determined by medical professionals without disqualifying children from being considered as candidates for lung donations in the larger pool of adult lung donors. The number of children seeking lung donations is so small[4] that making this change immediately on an experimental basis has virtually no risk of upsetting the overall system. It's only a portion of children under 12 that would even be considered for donation of an adult lung, based on medical determinations made by their doctors. This immediate change would help a small number of children and it would do little to affect the chances of adult and adolescent

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[2] This clearly violated the Secretary's announced policy decision in favor of "equitable allocation policies that provide organs to those with the greatest medical urgency, in accordance with sound medical judgment." 63 Fed. Reg. 16296.

[3] *See, e.g.,* Keating DT, et al, *Long-term outcomes of cadaveric lobar lung transplantation: helping to maximize resources* J Heart Lung Transplant; 2010 Apr; 29(4):439-44.

[4] Review of UNOS data suggests that this number is very small, probably twenty or less, as compared to the number of adults currently seeking lung transplants, which is 1,637. Ruddock Dec. ¶ 22.

candidates to receive donated lungs because the number of children is very small in relation to the number of adults and adolescents.

You raised the issue of medical judgment in your letter of May 31, 2013 to Dr. Roberts of the OPTN. You stated that "decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety and urgency that must be judged by transplant professionals." That is precisely what is *not* happening at present. No one from UNOS/OPTN has reviewed Sarah's case. The OPTN is an inflexible system that treats children much differently and worse than adults and precludes transplant professions from exercising any discretion in the matter.

There is no question that Sarah needs a lung transplant; the question is why does OPTN continue to enforce the Under 12 Rule when it severely prejudices children, who should at the very least be treated equally with adults, when the only justification for the Rule is that OPTN did not know if the LAS system would be useful for children when it developed Policy 3.7 back in 2004. The answer seems to be that the OPTN built no flexibility into the Under 12 Rule when it developed it or at any time since and cannot see its way clear to develop any flexibility now.

The OPTN has categorically refused to consider any exception in Sarah's case and has taken the position that Policy 3.7 does not permit special exceptions to the Under 12 Rule. See Ruddock Aff. ¶ 20. In a statement issued by the OPTN on May 27, 2013, the OPTN stated: "OPTN policies allow status adjustments for specifically defined groups of candidates with unique medical circumstances not addressed by the overall policy. A request to adjust the status of a patient under age 12 so that they may be included in the allocation sequence for adolescents and adults is not within the scope of the existing lung allocation policy." See http://optn.transplant.hrsa.gov/news/newsDetail.asp?id=1595.[5]

But if the Under 12 Rule is hurting children – and doing so for no good reason – then it is the very definition of arbitrariness for the OPTN to refuse to set it aside on an emergency basis. And if the OPTN will not do so, then as discussed in the next section, the Secretary has the power and the duty to direct it to do so.

[5] In contrast to the inflexibility of the Under 12 Rule, OPTN Policy 3.7.6.4 provides for "special review of exceptional cases when the treating transplant team believes that the assigned LAS or priority level does not appropriately reflect the severity of the case, or when essential clinical values must be estimated to assign a score." Colvin-Adams, M, Valapour, M, et al, *Lung and Heart Allocation in the United States*, Am J. Transplant 2012; 12:3213-3234, 3218.

C. The Secretary Has the Authority to Direct the OPTN to Set Aside the Under 12 Policy On an Emergency Basis

The Secretary has the clear authority to direct UNOS and/or OPTN to disregard Sarah's age as a disqualifying factor in considering her as a candidate for lung donation, without upsetting any of the other factors, on the grounds that the policy is inequitable, fails to take into consideration the unique needs of children, is arbitrary and capricious, and otherwise violates legal and regulatory requirements. UNOS and the OPTN may have private non-profit charters, but Congress created the OPTN by statute and established the legal requirements that govern it. The Secretary also established legal requirements for the OPTN when it promulgated 42 C.F.R. part 121.[6] And UNOS operates the OPTN pursuant to a contract with HRSA.

The regulations promulgated by the Secretary recognize that the Secretary has the authority to direct the OPTN to take action, even on an emergency basis. Section 121.4(d) of the regulations provides as follows:

> Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices. *Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety.* The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under § 121.12. After this review, the Secretary may:
>
> (1) Reject the comments;
>
> (2) *Direct the OPTN to revise the policies or practices* consistent with the Secretary's response to the comments; or
>
> (3) Take such other action as the Secretary determines appropriate.

[6] On April 8, 1998, Claude Earl Fox, M.D., Acting Administrator of HRSA testified before the House Committee on Government reform and Oversight, Subcommittee on Human Resources, that "HHS has the responsibility to oversee the OPTN to ensure that its policies conform to technological advances and are consistent with the intent of the statute." See http://www.hhs.gov/asl/testify/t980408a.html. He also testified that "[i]t would be illegal to deny an organ to patients solely because of their race, gender, or age." *Id.* Yet that is the effect of the Under 12 Rule.

The italicized language recognizes that the Secretary has the authority to direct the OPTN to revise Policy 3.7 and also has the authority to set it aside based on possible risks to the health of patients. Sarah has only weeks to live unless she receives a set of donated lungs, which obviously establishes a risk to the health of patients, as does the data showing that children waiting to receive donated lungs are dying at a rate much higher than the rate for adults. Under the circumstances, it would be arbitrary and capricious and inconsistent with law for the Secretary not to direct the OPTN and/or UNOS to disregard Sarah's age as a disqualifying factor in considering her as a candidate for lung donation and instead to treat her equally with persons over 12.

An alternative would be for the OPTN to develop a variance to the policy, in accordance with section 121.8(g), which provides that the "OPTN may develop, in accordance with § 121.4, experimental policies that test methods of improving allocation." Given the exigencies of Sarah's circumstances, the OPTN could implement the variance immediately, while it prepares to submit the variance for comment. When it published the regulation in the Federal Register in 1999, referring to section 121.8, the Secretary emphasized that the changes to that section of the regulation "are not intended to limit the ability of the OPTN to address special situations such as the unique needs of young children." 64 Fed. Reg. 56650, 56651.

III. Conclusion

The Murnaghans appreciate that you responded to their public petition by directing OPTN to review Policy 3.7 as soon as possible after giving the OPTN membership and others a chance to comment. But any changes as a result of that process will be too late for Sarah. She has only weeks to live. It's not too late for her to receive a lung donation and undergo transplant surgery. Her parents are not asking that you direct that OPTN provide her with a set of donated lungs. They are asking you to immediately direct OPTN to set aside the Under 12 Policy that is causing or at the very least permitting children needing lung transplants to die at a rate much higher than the rate for adults so that Sarah and a few other similarly situated children can have a fair shot at obtaining donated lungs.

It cannot possibly be the case that the system is so rigid that despite the compelling facts set forth in this letter Sarah must die rather than getting a fair chance to receive a donated lung. Discretion and power rests with the Secretary to direct the OPTN to disregard the Under 12 Rule until the OPTN can devise a better system after proper notice and comment to the public.

I hope that you will exercise your discretion in this matter as requested. In any event, I would appreciate it if you would ask the Department's counsel to call me so that we may make arrangements for delivery of any further papers or materials related to this matter.

Respectfully,

Stephen G. Harvey

Stephen G. Harvey

cc:

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DECLARATION OF SHARON RUDDOCK

I, Sharon Ruddock, hereby declare and state as follows:

1. Sarah Murnaghan is a 10-year-old girl who was diagnosed with Cystic Fibrosis when she was 18 months old. She is now in the intensive care unit at Children's Hospital of Philadelphia ("CHOP").

2. I am Sarah Murnaghan's aunt. Her mother Janet is my sister. I am a business executive with an engineering degree from Cornell University and an MBA from Duke University.

3. Janet and her husband Francis have been very busy dealing with Sarah and her doctors. They also have been busy dealing with requests from the press about Sarah's case. As a result, they asked me to work with the lawyers who represent them to prepare this declaration. I have been communicating closely with Janet and Fran as well as Sarah's doctors for many months about Sarah's condition and the effort to obtain a donated set of lungs for Sarah.

4. Sarah has been in and out of hospitals since she was first diagnosed, with multiple trips to the hospital each year for 3 to 4 days at a time. She has also needed additional medical care at home. Despite her condition, until about 18 months ago she attended school and had a relatively normal life.

5. Sarah's condition grew worse about 18 months ago as her lung capacity diminished to about 30% of its normal capacity. She has required supplemental oxygen 24 hours a day since then. On December 7, 2011, Sarah was put on the pediatric lung transplant list, which means that she was then eligible to receive donated lungs preferentially from a child donor under 12 years of age.

6. Organ donation in the United States is controlled by the United Network for Organ Sharing ("UNOS"), a private entity that has a contract with the Department of Health and Human Services ("HHS") to operate the Organ Procurement Transplantation Network ("OPTN"), which was created by Congress. The OPTN has developed and published organ transplant policies which can be found on the OPTN's website. The specific policy at issue in Sarah's case is Policy 3.7 entitled "Allocation of Thoracic Organs."

7. Under Policy 3.7, Sarah is eligible for lungs donated from children under 12 based on time on the waiting list and severity (children are categorized as priority 1 or 2 based on severity) assuming the lung is compatible in size and blood type, lungs donated from adolescents aged 12 to 17 based on time on the waiting list and severity again assuming the lung is compatible in size and blood type but only after the lung is declined by all adolescents in the zone, and for lungs donated by adults based on time on the waiting list and severity again assuming the lung is compatible in size and blood type but only after the lung is declined by all adults and adolescents in the zone (the "Under 12 Rule"). As a practical matter, the Under 12 Rule prevents children like Sarah from being considered for a donation of a lung from the much larger pool of adult donated lungs or if children are offered adults lungs after they have been declined by all adults and adolescents in the zone the lungs are damaged or otherwise medically unsuitable.

8. In November of 2012 in order to increase the size of the donor pool Sarah's doctors increased the height range for Sarah's listing thus allowing her to receive organs from larger donors. If Sarah were to receive an offer from a larger donor then her surgeons would downsize the donor lungs to fit Sarah's smaller body.

9. For lung transplants, the size of the donated lung has to fit the thoracic cavity of the candidate for donation, but we have been advised that an adult lung can be downsized by the doctors and that, although this may be a complicating factor, the likely outcome is the same or nearly the same as with a lung that did not need to be downsized. I am aware of an Australian medical study that also validated that medical outcomes are the same or nearly the same with downsized lungs.

10. My understanding is that adults lungs are allocated based on several factors, including lung compatibility (based on size and blood type), geography (i.e., consideration of how far the donated organ has to be transported), and something called the lung allocation score ("LAS"), which is a formula that UNOS/OPTN uses to weigh severity and posttransplant survivability. I understand that the LAS system was meant to allocate lungs with preference to the most severe cases.

11. Sarah has received a LAS since the date she was listed for a lung transplant. The LAS system is not used for organ allocation but the data is required by UNOS. Sarah is categorized as priority 1 for child lungs. I read in the May 30, 2013 letter from John P. Roberts, M.D. of OPTN to Secretary Sebelius the suggestion that the LAS system is not used with children. This is contrary to our experience at CHOP. The doctors at CHOP have been responsible for providing the results of medical tests which are then used to calculate Sarah's LAS. The calculation is done by UNOS. UNOS has been tracking Sarah's LAS since she was added to the lung transplant organ listing. Further, I have had recent communications with many hospitals about possible lung donors and have discussed Sarah's LAS as a measure of severity of her condition with all of them. When she first went on the adult list it was 40. Over time, we watched that number grow into the 50s, then 60s, as Sarah's condition grew worse.

12. Sarah has been in CHOP for the past 103 days as of today. About two weeks ago, she took a turn for the worse and was admitted into the ICU. At that time, she had a significant and permanent loss of hearing because of the side effects of the antibiotics she must take. At the same time, her LAS went to 60. Since then, her LAS has climbed to 66, where it is today.

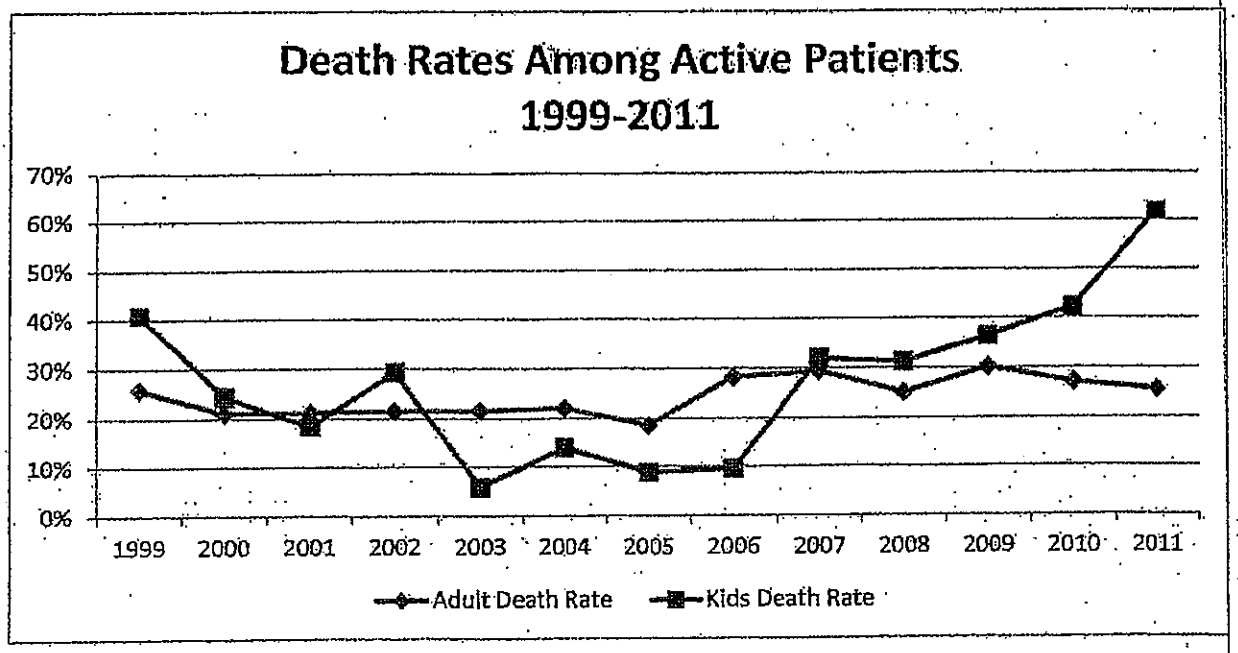
13. With a LAS of 66, if Sarah were an adult she would be very likely to receive a donated lung. Again, looking at the data available on the UNOS website, for 2011 (the last full year for which data is available) a LAS of 50 would put her in the top 6% of organ donor candidates. Assuming those numbers are similar for 2013, Sarah would be very near the top of the list, based on the severity of her condition.

14. Unfortunately, Sarah is not at the top of the list, she is instead at the very back of the list, because OPTN Policy 3.7 discriminates against children under 12.

15. I have reviewed the information on the UNOS website and the website of the Scientific Registry of Transplant Recipient ("SRTR"), a national database of transplantation statistics based on data from the OPTN. The SRTR works closely with UNOS and is responsible for ongoing data analyses designed to provide policy makers with information needed to make decisions. The data shows that children active on the lung transplant waiting list die at more than twice the rate as adults active on the lung transplant waiting list.[1] Attached hereto as Exhibit B is a table based on SRTR data that shows that the death rate for children is 62% vs 26% for adults in 2011. Also, the 2009-11 three-year average death rate is 46% for children versus 28% for adults. These conclusions are statistically significant. This same data for the

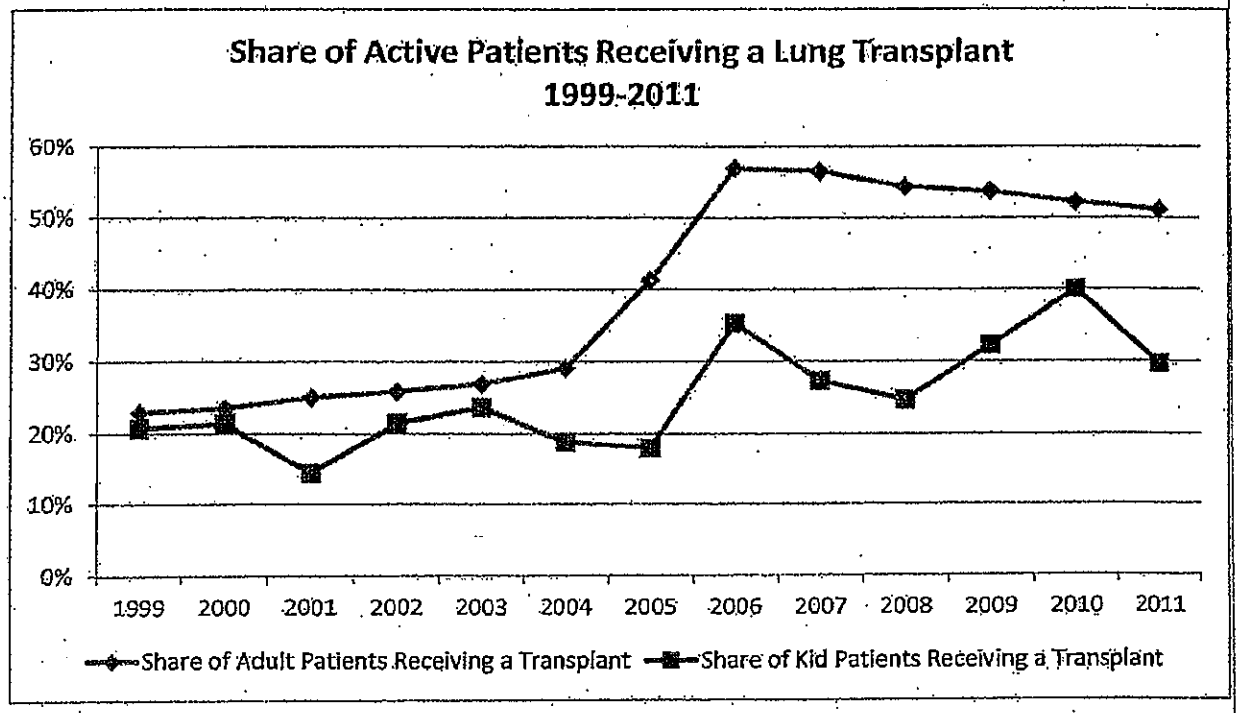
[1]Exhibit A attached hereto explains the use of active vs inactive patients in analyzing death rates.

years 1999 – 2011 shows a marked increase in the death rate for children since the OPTN implemented the Under 12 Rule in 2005. This can also be represented graphically, as follows:



16. As can be seen from UNOS data, attached hereto as Exhibit C, the success rate for children on the lung transplant list was 32%, while the success rate for the adults was 50%. Success rate is the percentage of people who get a lung transplant as compared to the total number who were on the transplant list at any time during the year. Since the Under 12 Rule was instituted in 2005, adults have experienced a substantial increase in success in receiving a

transplant from 29% in 2004 to 50% in 2011, while children are left behind with a success rate of 30%. This is represented graphically below:



17. The total number of lungs available for children in need of transplant is very small. I do not have access to current data but available UNOS data shows that there were only 23 lungs available in 2011 in the entire country. Given the limitations of blood type, size, and geographic range, a total pool of only 23 lungs is likely to result in few lung donations for a child on the lung transplant waiting list. In comparison, the adult transplant pool had 1,573 lungs available in 2011.

18. We are concerned that the segmentation by age can lead to significant statistical disparities between age groups. UNOS data for 2011 shows that if lungs were allocated within age segments of the 12 and over population, there would be significant statistical disparities.[2]

[2]UNOS data for children under 12 is not available to me.

Age Group	Percentage of Lungs Donated by Group	Percentage of Lung Transplants Received by Group
18-34 Yr Old	50%	12%
35-49 Yr Old	30%	13%
50-64 Yrs Old	19%	48%
65+ Yrs Old	1%	27%

19. To date, Sarah has not had any suitable offers of donated adult lungs through OPTN.

20. Through Sarah's doctors at CHOP, we have twice asked the Thoracic Committee of UNOS/OPTN if an appeal could be made to the OPTN Lung Review Board. UNOS/OPTN rejected both requests on the grounds that the OPTN Lung review Board has no discretion to set aside the Under 12 Rule.

21. On Thursday, May 16, 2013, Sarah's parents and I decided to fight this inequity and started a media campaign. We began actively looking for counsel shortly thereafter and on May 31 engaged the law firm of Pepper Hamilton.

22. We are asking the Department of Health and Human Services (HHS) to direct UNOS and the OPTN to set aside the Under 12 Rule on an emergency basis so that Sarah and other children can be considered for a lung donation on the same basis as persons over 12. We are not seeking preferential treatment, we only want her and the other children to be treated equally with persons over 12. This should not cause any significant disruption to the OPTN because there are very few children under 12 seeking donations of adult lungs. The UNOS data does not show the number of children under 12 seeking donation of adult lungs, but it does show the number of children aged 6-10 seeking lungs from any age donor, which is currently 16. In 2011, that number was 18. What this shows is that there are not many children seeking lung

donations overall, and the number seeking adult lungs would be even less. There may be a few more such children between 10 and 12, but in any event, it is a very small number in relation to the number of adults seeking lung transplants which is currently 1,637.

23. Sarah's doctors have told us that if Sarah could be considered as a candidate for an adult lung, without regard to her age, all other factors remaining equal, the chance of her receiving a compatible and medically appropriate adult lung would be greatly increased. They have also advised us that at this time Sarah's chances for successful lung transplant surgery are good.

24. Sarah has now been in Children's Hospital of Philadelphia for the last 103 days. Sarah's parents have been advised by her doctors that the medical outcome is uncertain and it's possible that she only has weeks to live.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Sharon Ruddock 6/2/13

Sharon Ruddock

EXHIBIT A

Active Wait List vs Inactive

Because the pediatric waiting list system uses the amount of time a patient has accrued on the list is an important factor in determining when a patient will be eligible to receive an available donor organ, pediatric patients are incentivized to get on the waiting list as early as possible in order to accrue time and increase their standing on the list. As a result, there are many "inactive" patients on the pediatric list. "Inactive" patients are those who are on the waiting list accruing time though they are not currently seeking a donor organ. They may change their status to "active" when and if they are sick enough to need a transplant without losing their "place" on the list. Sixty-five percent of the children on the official waiting list today are "inactive."

Prior to 2005, the adult list was handled the same way as the pediatric list -- on a first come, first served basis. But in 2005, the approach used for the adult waiting list was changed to one that determines a patient's position on the list based on the severity of illness. Patients are assigned a LAS. This score is then used to determine who should receive donor lungs that become available. As a result, most adult transplant patients are not placed on the wait list until they are actually sick enough to need a transplant. The result of this is that there are now far fewer patients on the adult wait list who are "inactive" at any given time. In 2005, sixty-five percent of patients on the adult list were "inactive"; today, that number has dropped to twenty-two percent.

This causes a problem in determining if pediatric patients fare as well as adult patients under the current system. UNOS includes statistics from both "active" and "inactive"

patients on each wait list to calculate death rates. As a result, the percentage of pediatric patients who die each year while awaiting transplant *appears* to be lower than it actually is. Examining statistical data from two systems that operate under such different rules without making an adjustment to accommodate for those differences leads to inaccurate and misleading results. To obtain an accurate comparison of the death rates of patients on the adult list with those on the pediatric list I used *only* the data of "active" patients from each list.

EXHIBIT B

Death Rates for Children and Adults Active on the Lung Transplant Waiting List

Adult Active Patients

	Total Active Patients (beginning of year)	Total Deaths	Death Rate
1999	[redacted]	[redacted]	26%
2000	[redacted]	[redacted]	21%
2001	[redacted]	[redacted]	21%
2002	[redacted]	[redacted]	25%
2003	[redacted]	[redacted]	22%
2004	[redacted]	[redacted]	22%
2005	[redacted]	[redacted]	19%
2006	[redacted]	[redacted]	28%
2007	[redacted]	[redacted]	29%
2008	[redacted]	[redacted]	25%
2009	[redacted]	[redacted]	30%
2010	[redacted]	[redacted]	27%
2011	1368	351	26%

Pediatric Active Patients

	Total Active Patients (beginning of year)	Total Deaths	Death Rate
1999	[redacted]	[redacted]	4%
2000	[redacted]	[redacted]	25%
2001	[redacted]	[redacted]	18%
2002	[redacted]	[redacted]	29%
2003	[redacted]	[redacted]	6%
2004	[redacted]	[redacted]	14%
2005	[redacted]	[redacted]	9%
2006	[redacted]	[redacted]	10%
2007	[redacted]	[redacted]	32%
2008	[redacted]	[redacted]	31%
2009	[redacted]	[redacted]	36%
2010	[redacted]	[redacted]	42%
2011	21	13	62%

EXHIBIT C

Success Rates for Children and Adults Active on the Lung Transplant Waiting List

	Adult Total Patients (Active)[3]	Adults Getting Lungs	Adult Transplant Rate	Kids Total Patients (Active)[4]	Kids Getting Lungs	Kid Transplant Rate
1999	4,013	919	23%	130	27	21%
2000	4,193	984	23%	112	24	21%
2001	4,284	1,070	25%	118	17	14%
2002	4,092	1,055	26%	98	21	21%
2003	4,080	1,095	27%	89	21	24%
2004	4,102	1,193	29%	101	19	19%
2005	3,446	1,422	41%	106	19	18%
2006	2,470	1,407	57%	82	29	35%
2007	2,618	1,481	57%	66	18	27%
2008	2,739	1,490	54%	61	15	25%
2009	3,107	1,670	54%	62	20	32%
2010	3,418	1,785	52%	65	26	40%
2011	3,580	1,830	51%	64	19	30%

[3] Total Adult Patients equals the count of active adult patients at the beginning of the year plus new active adult patients during the course of the year.

[4] Total Kid Patients equals the count of active kid patients at the beginning of the year plus new active kid patients during the course of the year.

Exhibit B

3.7 **ALLOCATION OF THORACIC ORGANS.** This policy describes how thoracic organs (hearts, heart-lung combinations, single and double lungs) are to be allocated to candidates awaiting a thoracic organ transplant.

3.7.1 **Exceptions.** Unless otherwise approved according to Policy 3.4.8 (Variances), or specifically allowed by the exceptions described in this Policy 3.7.1, all thoracic organs must be allocated in accordance with Policy 3.7.

3.7.1.1 **Exception for Sensitized Candidates.** The transplant surgeon or physician for a candidate awaiting thoracic organ transplantation may determine that the candidate is "sensitized" such that the candidate's antibodies would react adversely to certain donor cell antigens. It is permissible not to use the allocation policies set forth in Policy 3.7 for allocation of a particular thoracic organ when all thoracic organ transplant centers within an OPO and the OPO agree to allocate the thoracic organ to a sensitized candidate because results of a crossmatch between the blood serum of that candidate and cells of the thoracic organ donor are negative (i.e., the candidate and thoracic organ donor are compatible). The level of sensitization at which a candidate may qualify for this exception is left to the discretion of the listing transplant center, and subject to agreement among all thoracic organ transplant centers within an OPO and the OPO. Sensitization is not a qualifying criterion for assigning a candidate to a heart status category as described in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status).

3.7.2 **Geographic Sequence of Thoracic Organ Allocation.** Thoracic organs are to be allocated locally first, then within the following zones in the sequence described in Policy 3.7.10 and Policy 3.7.11. Five zones will be delineated by concentric circles of 500, 1,000, and 1,500 and 2,500 nautical mile radii with the donor hospital at the center. Zone A will extend to all transplant centers which are within 500 miles from the donor hospital but which are not in the local area of the donor hospital. Zone B will extend to all transplant centers that are at least 500 miles from the donor hospital but not more than 1,000 miles from the donor hospital. Zone C will extend to all transplant centers that are at least 1,000 miles from the donor hospital but not more than 1,500 miles from the donor hospital. Zone D will extend to all transplant centers that are located beyond 1,500 miles from the donor hospital, but not more than 2,500 miles from the donor hospital. Zone E will extend to all transplant centers that are located beyond 2,500 miles from the donor hospital.

3.7.3 **Adult Candidate Status.** Each candidate awaiting heart transplantation receives a status code corresponding to the candidate's medical urgency for transplant. A heart transplant candidate at least 18 years of age at the time of listing receives a status code as follows:

Status	Definition
Status 1A	A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for a 1A(b) candidate) and has at least one of the following devices or therapies in place:

(a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:

(i) left and/or right ventricular assist device implanted Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating

physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.

(ii) total artificial heart;

(iii) intra-aortic balloon pump; or

(iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(b) Mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure or life-threatening ventricular arrhythmias. A transplant center can report a complication not listed here. The report of an "other" complication will result in a review by the respective heart regional review board. (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).)

Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(d) Continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures.

Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate. The OPTN contractor shall maintain in the heart status justification form in UNet℠ a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

Status 1A by Exception

A candidate who does not meet criterion (a), (b), (c), or (d) may nevertheless be Status 1A upon application by his or her transplant physician. The transplant physician must justify to the applicable Regional Review Board why the candidate is considered, using acceptable medical criteria, to have an

urgency and potential for benefit as other candidates in Status 1A. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of Status 1A. ~~Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board.~~ Regional Review Boards will retrospectively review requests for Status 1A exceptions.

A candidate's listing under this exceptional provision is valid for 14 days. Any further extension of the Status 1A listing by exception requires ~~prospective~~ retrospective review and approval by ~~a majority of~~ the Regional Review Board ~~Members~~. If Regional Review Board approval is not given, the candidate's transplant physician may override the Regional Review Board and list the candidate as Status 1A~~, subject to automatic referral to the Thoracic Organ Transplantation Committee~~. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1A Justification Form
A completed Heart Status 1A Justification Form must be submitted in UNet[SM] in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B

A candidate listed as Status 1B has at least one of the following devices or therapies in place:

(aa) left and/or right ventricular assist device implanted; or
(bb) continuous infusion of intravenous inotropes.

Status 1B by Exception
A candidate who does not meet the criteria for Status 1B may nevertheless be listed as Status 1B upon application by his or her transplant physician. The transplant physician must justify to the applicable Regional Review Board why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other Status 1B candidates. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. Regional Review Boards will retrospectively review requests for Status 1B exceptions. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1B Justification Form
A completed Heart Status 1B Justification Form must be submitted to UNet[SM] in order to list a candidate as Status 1B.

Status 2

A candidate who does not meet the criteria for Status 1A or 1B

is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet℠ within 24 hours of the change in medical condition.

3.7.4 **Pediatric Candidate Status.** Each candidate awaiting heart transplantation receives a status code corresponding to the candidate's medical urgency for transplant. Pediatric heart transplant candidates who have not received a heart transplant before their 18th birthday shall continue to qualify for medical urgency status based on Policy 3.7.4. A heart transplant candidate who is less than 18 years of age at the time of listing receives a status code as follows:

Status	Definition
Status 1A	A candidate listed as Status 1A meets at least one of the following criteria:

(a) Requires assistance with a ventilator;

(b) Requires assistance with a mechanical assist device (e.g., ECMO);

(c) Requires assistance with a balloon pump;

(d) A candidate less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;

(e) Requires infusion of high dose or multiple inotropes (The OPTN contractor shall maintain in the heart status justification form in UNet℠ a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.); or,

(f) A candidate who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a retrospective conference with the applicable Regional Review Board. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ

Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Qualification for Status 1A under criteria (a) through (e) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

Submission of Status 1A Justification Form
A completed Heart Status 1A Justification Form must be submitted in UNet[SM] in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B A candidate listed as Status 1B meets at least one of the following criteria:

(a) Requires infusion of low dose single inotropes (The OPTN contractor shall maintain in the heart status justification form in UNet[SM] a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.);

(b) Less than six months old and does not meet the criteria for Status 1A; or

(c) Growth failure *i.e.,* less than 5th percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either < 5th percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the candidate's growth at two different times, second, calculating the candidate's growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.,* (candidate's growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

Status 1B by Exception
A candidate who does not meet the criteria for Status 1B may be listed as Status 1B upon application by his transplant physician to the applicable Regional Review Board. The transplant physician must justify why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other candidates listed as Status 1B. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1B Justification Form
A completed Heart Status 1B Justification Form must be submitted in UNet℠ to list a candidate as Status 1B.

Status 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet℠ within 24 hours of the change in medical condition.

3.7.5 Allocation of Pediatric Donor Hearts to Pediatric Heart Candidates. Within each heart status, a heart retrieved from a pediatric organ donor shall be allocated to a pediatric heart candidate (i.e., less than 18 years old at the time of listing) before the heart is allocated to an adult candidate. For the purpose of Policy 3.7, a pediatric organ donor is defined as an individual who is less than 18 years of age.

3.7.6 Lung Allocation. Candidates waiting for lung transplants receive priority for deceased donor lung offers based on Lung Allocation Score (LAS) if they are at least 12 years of age. Candidates less than 12 years of age receive deceased donor lung offers based on medical urgency priority.

3.7.6.1 Lung Allocation Score (LAS) System for Candidates at Least 12 Years of Age

Candidates who are at least 12 years of age receive offers for deceased donor lungs based on LAS, as well as geography and blood type. Candidates with higher LASs receive higher waiting list priority.

3.7.6.1.1 The LAS Calculation
The LAS calculation uses *all of* the following:

- Waitlist Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list
- Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant

- Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waitlist Urgency Measure

The LAS is determined by normalizing the Raw Allocation Score to a continuous scale of 0 to 100. The Raw Allocation Score is the difference between the Transplant Benefit Measure and the Waitlist Urgency Measure.

The equation for the LAS calculation is:

$$LAS = \frac{100 * [PTAUC - 2 * WLAUC + 730]}{1095}$$

Where... **Includes...**

$$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$$

PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year.

β_i: the coefficient for characteristic i from the waiting list model, according to Table 1.

$$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$$

$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate.

Y_i = the value of the j^{th} characteristic for an individual candidate

α_j = the coefficient for characteristic j from the post-transplant model, according to Table 2.

$$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$$

WLAUC = the area under the waiting list survival probability curve during the next year.

Where...

$$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p}}$$

Includes...

$S_{WL,0}(t)$ = the baseline waiting list survival probability at time t, according to Table 3.

$S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to Table 4.

$S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate

X_i = the value of the i^{th} characteristic for an individual candidate.

Table 1
Factors Used in the Waiting List Morality Calculation: Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (year)	0.0083990318885565*age
2. Bilirubin (mg/dL)	0.0431682188302477*(bilirubin – 1) if bilirubin is more than 1.0 mg/dL (see Policy 3.7.6.1.4) 0 when bilirubin is 1.0 mg/dL or less
3. Bilirubin increase of at least 50%	1.4144058906830200 for Group B (see Policy 3.7.6.1.4) 0 for Groups A, C, and D (see Policy 3.7.6.1.2)
4. Body mass index (BMI; kg/m^2)	0.1261444133358100*(20 – BMI) for BMI less than 20 kg/m^2 0 if BMI is at least 20 kg/m^2
5. Cardiac index prior to any exercise	0.5435368888028200 if the cardiac index is less than 2 $L/min/m^2$ 0 if the cardiac index is at least 2 $L/min/m^2$
6. Central venous pressure (CVP; mm Hg) at rest, prior to any exercise	0.0173841981251578*(CVP – 7) for CVP greater than 7 mm Hg (Group B only – see Policy 3.7.6.1.2.b) 0 if less than or equal to 7 mm Hg for Group B (see Policy 3.7.6.1.2.b) 0 for candidates in Groups A, C, and D (see Policy 3.7.6.1.2)

For this covariate:	The following coefficient is used in the LAS calculation:
7. Ventilation status if candidate is hospitalized	1.6771121096052300 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
8. Creatinine (serum, mg/dL)	0.5034346761960600*creatinine if at least 18 years of age (see Policy 3.7.6.1.5) 0 if less than 18 years of age
9. Diabetes	0.4680254026735700 if diabetic 0 if not diabetic
10. Diagnosis Group A (see Policy 3.7.6.1.2.a for the diseases included in this group)	0
Diagnosis Group B (see Policy 3.7.6.1.2.b for the diseases included in this group)	1.5774243292137200
Diagnosis Group C (see Policy 3.7.6.1.2.c for the diseases included in this group)	1.2313926484343600
Diagnosis Group D (see Policy 3.7.6.1.2.d for the diseases included in this group)	0.6259577164157700
11. Detailed diagnosis: Bronchiectasis (Group A – see Policy 3.7.6.1.2.a)	0.6680518055684700
Detailed diagnosis: Eisenmenger's syndrome (Group B – see Policy 3.7.6.1.2.b)	-0.6278657824830000
Detailed diagnosis: Lymphangioleiomyomatosis (Group A – see Policy 3.7.6.1.2.a)	-0.3162937838984600
Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Group D – see Policy 3.7.6.1.2.d)	0.4453284411081100
Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Group D – see Policy 3.7.6.1.2.d)	-0.2091170018125500
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Group D – see Policy 3.7.6.1.2.d)	-0.4577749354638600

For this covariate:	The following coefficient is used in the LAS calculation:
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Group A – see Policy 3.7.6.1.2.a)	0.9330846239906700
12. Forced vital capacity (FVC)	0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Group D (see Policy 3.7.6.1.2.d) 0 if FVC is greater than or equal to 80% for Group D (see Policy 3.7.6.1.2.d) 0 for candidates in Groups A, B, and C (see Policy 3.7.6.1.2)
13. Functional Status	-0.4471034284458400 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
14. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0213187586203456*O_2 for Group B (see Policy 3.7.6.1.2.b) 0.1188479817592500 for Groups A, C, and D (see Policy 3.7.6.1.2)
15. PCO_2 (mm Hg): current	0.1104609835819100*PCO_2/10 if PCO_2 is at least 40 mm Hg (see Policy 3.7.6.1.3)
16. PCO_2 increase of at least 15% (see Policy 3.7.6.1.3)	0.2331149280428300 if PCO_2 increase is at least 15% (see Policy 3.7.6.1.3) 0 if PCO_2 increase is less than 15% (see Policy 3.7.6.1.3)
17. Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.4155116686114300*(PA systolic – 40)/10 for Group A if the PA systolic pressure is greater than 40 mm Hg (see Policy 3.7.6.1.2.a) 0 for Group A if the PA systolic pressure is 40 mm Hg or less (see Policy 3.7.6.1.2.a) 0.0462410402627318*PA systolic/10 for Groups B, C, and D (see Policy 3.7.6.1.2)

For this covariate:	The following coefficient is used in the LAS calculation:
18. Six minute walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	-0.0844896372724000*Six-minute walk distance/100

~~Table 1~~
~~Factors Used to Predict Risk of Death on the Lung Transplant Waitlist~~

~~1. Forced vital capacity (FVC)~~
~~2. Pulmonary artery (PA) systolic pressure (Groups A, C, and D[4] — see 3.7.6.1.a)~~
~~3. O_2 required at rest (Groups A, C, and D[4] — see 3.7.6.1.a)~~
~~4. Age~~
~~5. Body mass index (BMI)~~
~~6. Diabetes~~
~~7. Functional Status~~
~~8. Six-minute walk distance~~
~~9. Continuous mechanical ventilation~~
~~10. Diagnosis~~
~~11. PCO_2 (see 3.7.6.1.b)~~

Table 2
Factors Used in the Post-Transplant Survival Calculation:
Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (years)	0.0246579831271869*(age – 45) if greater than 45 years of age 0 if 45 years of age or younger
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if at least 18 years of age (see Policy 3.7.6.1.5) 0 if less than 18 years of age

For this covariate:	The following coefficient is used in the LAS calculation:
3. Creatinine increase of at least 150%	0.7708616024698100 if increase in creatinine is at least 150%, and when the higher value determining this increase is at least 1 mg/dL (see Policy 3.7.6.1.5) 0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL (see Policy 3.7.6.1.5) 0 if increase in creatinine less than 150% or creatinine decreases (see Policy 3.7.6.1.5)
4. Cardiac index (L/min/m^2) at rest, prior to any exercise	0.3499381679822400 if less than 2 L/min/m^2 0 if at least 2 L/min/m^2
5. Ventilation status if candidate is hospitalized	0.6094478988424900 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
6. Diagnosis Group A (see Policy 3.7.6.1.2.a for the diseases included in this group)	0
Diagnosis Group B (see Policy 3.7.6.1.2.b for the diseases included in this group)	0.6115547319209300
Diagnosis Group C (see Policy 3.7.6.1.2.c for the diseases included in this group)	0.3627014422464200
Diagnosis Group D (see Policy 3.7.6.1.2.d for the diseases included in this group)	0.4641392063023200
7. Detailed diagnosis: Bronchiectasis (Group A – see Policy 3.7.6.1.2.a)	0.1889100379099400
Detailed diagnosis: Eisenmenger's syndrome (Group B – see Policy 3.7.6.1.2.b)	0.9146727886744700
Detailed diagnosis: Lymphangioleiomyomatosis (Group A – see Policy 3.7.6.1.2.a)	-1.5194416206749400
Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Group D – see Policy 3.7.6.1.2.d)	-1.2050508750702600

For this covariate:	The following coefficient is used in the LAS calculation:
Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Group D – see Policy 3.7.6.1.2.d)	-0.0723596761367600
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Group D – see Policy 3.7.6.1.2.d)	-0.0437880049066331
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Group A – see Policy 3.7.6.1.2.a)	-0.1389363636019300
8. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0747978926517300*O_2 for Group A (see Policy 3.7.6.1.2.a) 0.0164276945879309 for Groups B, C, and D (see Policy 3.7.6.1.2)
9. Functional Status	-0.1900086366785100 if no assistance needed with activities for daily living 0 if some or total assistance needed with activities for daily living
10. Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	0.0004594953809594*(1200-6mw) 0 if six-minute-distance-walked is at least 1200 feet

~~Table 2~~
~~Factors that Predict Survival after Lung Transplant~~

~~1. FVC (Groups B and D – see 3.7.6.1.a)~~
~~2. PCW pressure ≥ 20 (Group D – see 3.7.6.1.a)~~
~~3. Continuous mechanical ventilation~~
~~4. Age~~
~~5. Serum Creatinine~~
~~6. Functional Status~~
~~7. Diagnosis~~

Tables 3 and 4 provide the baseline waiting list and post-transplant survival probabilities, which are used in the LAS calculation.

Table 3: Baseline Waiting List Survival ($S_{WL}(t)$) Probability

Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$
0	1.000000	50	0.956543	99	0.913086	148	0.869629	197	0.826172
1	0.999267	51	0.955811	100	0.912354	149	0.868896	198	0.825439
2	0.998535	52	0.955078	101	0.911621	150	0.868164	199	0.824707
3	0.997803	53	0.954346	102	0.910889	151	0.867432	200	0.823975
4	0.997070	54	0.953613	103	0.910156	152	0.866699	201	0.823242
5	0.996338	55	0.952881	104	0.909424	153	0.865967	202	0.822510
6	0.995605	56	0.952148	105	0.908691	154	0.865234	203	0.821777
7	0.994873	57	0.951416	106	0.907959	155	0.864502	204	0.821045
8	0.994141	58	0.950684	107	0.907227	156	0.863770	205	0.820312
9	0.993408	59	0.949951	108	0.906494	157	0.863037	206	0.819580
10	0.992676	60	0.949219	109	0.905762	158	0.862305	207	0.818848
11	0.991943	61	0.948486	110	0.905029	159	0.861572	208	0.818115
12	0.991211	62	0.947754	111	0.904297	160	0.860840	209	0.817383
13	0.990479	63	0.947021	112	0.903564	161	0.860107	210	0.816650
14	0.989746	64	0.946289	113	0.902832	162	0.859375	211	0.815918
15	0.989014	65	0.945557	114	0.902100	163	0.858643	212	0.815186
16	0.988281	66	0.944824	115	0.901367	164	0.857910	213	0.814453
17	0.987549	67	0.944092	116	0.900635	165	0.857178	214	0.813721
18	0.986816	68	0.943359	117	0.899902	166	0.856445	215	0.812988
19	0.986084	69	0.942627	118	0.899170	167	0.855713	216	0.812256
20	0.985352	70	0.941895	119	0.898438	168	0.854980	217	0.811523
21	0.984619	71	0.941162	120	0.897705	169	0.854248	218	0.810791
22	0.983887	72	0.940430	121	0.896973	170	0.853516	219	0.810059
23	0.983154	73	0.939697	122	0.896240	171	0.852783	220	0.809326
24	0.982422	74	0.938965	123	0.895508	172	0.852051	221	0.808594
25	0.981689	75	0.938232	124	0.894775	173	0.851318	222	0.807861
26	0.980957	76	0.937500	125	0.894043	174	0.850586	223	0.807129
27	0.980225	77	0.936768	126	0.893311	175	0.849854	224	0.806396
28	0.979492	78	0.936035	127	0.892578	176	0.849121	225	0.805664
29	0.978760	79	0.935303	128	0.891846	177	0.848389	226	0.804932
30	0.978027	80	0.934570	129	0.891113	178	0.847656	227	0.804199
31	0.977295	81	0.933838	130	0.890381	179	0.846924	228	0.803467
32	0.976562	82	0.933105	131	0.889648	180	0.846191	229	0.802734
33	0.975830	83	0.932373	132	0.888916	181	0.845459	230	0.802002
34	0.975098	84	0.931641	133	0.888184	182	0.844727	231	0.801270
35	0.974365	85	0.930908	134	0.887451	183	0.843994	232	0.800537
36	0.973633	86	0.930176	135	0.886719	184	0.843262	233	0.799805
37	0.972900	87	0.929443	136	0.885986	185	0.842529	234	0.799072
38	0.972168	88	0.928711	137	0.885254	186	0.841797	235	0.798340
39	0.971436	89	0.927979	138	0.884521	187	0.841064	236	0.797607
40	0.970703	90	0.927246	139	0.883789	188	0.840332	237	0.796875
41	0.969971	91	0.926514	140	0.883057	189	0.839600	238	0.796143
42	0.969238	92	0.925781	141	0.882324	190	0.838867	239	0.795410
43	0.968506	93	0.925049	142	0.881592	191	0.838135	240	0.794678
44	0.967773	94	0.924316	143	0.880859	192	0.837402	241	0.793945
45	0.967041	95	0.923584	144	0.880127	193	0.836670	242	0.793213
46	0.966309	96	0.922852	145	0.879395	194	0.835938	243	0.792480
47	0.965576	97	0.922119	146	0.878662	195	0.835205	244	0.791748

Table 3: Baseline Waiting List Survival ($S_{WL}(t)$) Probability (Continued)

Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$
241	0.981773	276	0.968560	304	0.961837	318	0.957951	342	0.952507
242	0.981773	277	0.968560	305	0.961837	319	0.957951	343	0.952507
243	0.981773	278	0.968560	306	0.961837	320	0.957951	344	0.952507
244	0.981773	279	0.968560	307	0.961837	321	0.957951	345	0.952507
245	0.981773	280	0.968560	308	0.961837	322	0.957951	346	0.952507
246	0.981773	281	0.968560	309	0.961837	323	0.957951	347	0.952507
247	0.981773	282	0.968560	310	0.961837	324	0.957951	348	0.952507
248	0.981773	283	0.968560	311	0.961837	325	0.957951	349	0.952507
249	0.981773	284	0.968560	312	0.961837	326	0.957951	350	0.952507
250	0.981773	285	0.968560	313	0.961837	327	0.957951	351	0.952507
251	0.981773	286	0.968560	314	0.961837	328	0.957951	352	0.952507
252	0.981773	287	0.968560	315	0.961837	329	0.957951	353	0.952507
253	0.981773	288	0.968560	316	0.961837	330	0.957951	354	0.952507
254	0.981773	289	0.968560	317	0.961837	331	0.957951	355	0.952507
255	0.981773	290	0.968560	318	0.961837	332	0.957951	356	0.952507
256	0.981773	291	0.968560	319	0.961837	333	0.957951	357	0.952507
257	0.981773	292	0.968560	320	0.961837	334	0.957951	358	0.952507
258	0.981773	293	0.968560	321	0.961837	335	0.957951	359	0.952507
259	0.981773	294	0.968560	322	0.961837	336	0.957951	360	0.952507
260	0.981773	295	0.968560	323	0.961837	337	0.957951	361	0.952507
261	0.981773	296	0.968560	324	0.961837	338	0.957951	362	0.952507
262	0.981773	297	0.968560	325	0.961837	339	0.957951	363	0.952507
263	0.981773	298	0.968560	326	0.961837	340	0.957951	364	0.952507
264	0.981773	299	0.968560	327	0.961837	341	0.957951	365	0.952507
265	0.981773	300	0.968560	328	0.961837	342	0.957951	366	0.952507
266	0.981773	301	0.968560	329	0.961837	343	0.957951	367	0.952507
267	0.981773	302	0.968560	330	0.961837	344	0.957951	368	0.952507
268	0.981773	303	0.968560	331	0.961837	345	0.957951	369	0.952507
269	0.981773	304	0.968560	332	0.961837	346	0.957951	370	0.952507
270	0.981773	305	0.968560	333	0.961837	347	0.957951	371	0.952507
271	0.981773	306	0.968560	334	0.961837	348	0.957951	372	0.952507
272	0.981773	307	0.968560	335	0.961837	349	0.957951	373	0.952507
273	0.981773	308	0.968560	336	0.961837	350	0.957951	374	0.952507
274	0.981773	309	0.968560	337	0.961837	351	0.957951	375	0.952507
275	0.981773	310	0.968560	338	0.961837	352	0.957951	376	0.952507
276	0.981773	311	0.968560	339	0.961837	353	0.957951	377	0.952507
277	0.981773	312	0.968560	340	0.961837	354	0.957951	378	0.952507
278	0.981773	313	0.968560	341	0.961837	355	0.957951	379	0.952507
279	0.981773	314	0.968560	342	0.961837	356	0.957951	380	0.952507
280	0.981773	315	0.968560	343	0.961837	357	0.957951	381	0.952507
281	0.981773	316	0.968560	344	0.961837	358	0.957951	382	0.952507
282	0.981773	317	0.968560	345	0.961837	359	0.957951	383	0.952507

Table 4: Baseline Post-Transplant Survival ($S_T(t)$) Probability

Time (days): t	$S_T(t)$	Time (days): t	$S_T(t)$	Time (days): t	$S_T(t)$	Time (days): t	$S_T(t)$	Time (days): t	$S_T(t)$
0	1.000000	42	0.961324	84	0.927414	126	0.899243	168	0.875884
1	0.999426	43	0.960824	85	0.926997	127	0.898924	169	0.875617
2	0.998853	44	0.960324	86	0.926580	128	0.898605	170	0.875350
3	0.998279	45	0.959824	87	0.926163	129	0.898286	171	0.875083
4	0.997706	46	0.959324	88	0.925746	130	0.897967	172	0.874816
5	0.997132	47	0.958824	89	0.925329	131	0.897648	173	0.874549
6	0.996559	48	0.958324	90	0.924912	132	0.897329	174	0.874282
7	0.995985	49	0.957824	91	0.924495	133	0.897010	175	0.874015
8	0.995412	50	0.957324	92	0.924078	134	0.896691	176	0.873748
9	0.994838	51	0.956824	93	0.923661	135	0.896372	177	0.873481
10	0.994265	52	0.956324	94	0.923244	136	0.896053	178	0.873214
11	0.993691	53	0.955824	95	0.922827	137	0.895734	179	0.872947
12	0.993118	54	0.955324	96	0.922410	138	0.895415	180	0.872680
13	0.992544	55	0.954824	97	0.921993	139	0.895096	181	0.872413
14	0.991971	56	0.954324	98	0.921576	140	0.894777	182	0.872146
15	0.991397	57	0.953824	99	0.921159	141	0.894458	183	0.871879
16	0.990824	58	0.953324	100	0.920742	142	0.894139	184	0.871612
17	0.990250	59	0.952824	101	0.920325	143	0.893820	185	0.871345
18	0.989677	60	0.952324	102	0.919908	144	0.893501	186	0.871078
19	0.989103	61	0.951824	103	0.919491	145	0.893182	187	0.870811
20	0.988530	62	0.951324	104	0.919074	146	0.892863	188	0.870544
21	0.987956	63	0.950824	105	0.918657	147	0.892544	189	0.870277
22	0.987383	64	0.950324	106	0.918240	148	0.892225	190	0.870010
23	0.986809	65	0.949824	107	0.917823	149	0.891906	191	0.869743
24	0.986236	66	0.949324	108	0.917406	150	0.891587	192	0.869476
25	0.985662	67	0.948824	109	0.916989	151	0.891268	193	0.869209
26	0.985089	68	0.948324	110	0.916572	152	0.890949	194	0.868942
27	0.984515	69	0.947824	111	0.916155	153	0.890630	195	0.868675
28	0.983942	70	0.947324	112	0.915738	154	0.890311	196	0.868408
29	0.983368	71	0.946824	113	0.915321	155	0.889992	197	0.868141
30	0.982795	72	0.946324	114	0.914904	156	0.889673	198	0.867874
31	0.982221	73	0.945824	115	0.914487	157	0.889354	199	0.867607
32	0.981648	74	0.945324	116	0.914070	158	0.889035	200	0.867340
33	0.981074	75	0.944824	117	0.913653	159	0.888716	201	0.867073
34	0.980501	76	0.944324	118	0.913236	160	0.888397	202	0.866806
35	0.979927	77	0.943824	119	0.912819	161	0.888078	203	0.866539
36	0.979354	78	0.943324	120	0.912402	162	0.887759	204	0.866272
37	0.978780	79	0.942824	121	0.911985	163	0.887440	205	0.866005
38	0.978207	80	0.942324	122	0.911568	164	0.887121	206	0.865738
39	0.977633	81	0.941824	123	0.911151	165	0.886802	207	0.865471
40	0.977060	82	0.941324	124	0.910734	166	0.886483	208	0.865204
41	0.976486	83	0.940824	125	0.910317	167	0.886164	209	0.864937
42	0.975913	84	0.940324	126	0.909900	168	0.885845	210	0.864670
43	0.975339	85	0.939824	127	0.909483	169	0.885526	211	0.864403
44	0.974766	86	0.939324	128	0.909066	170	0.885207	212	0.864136
45	0.974192	87	0.938824	129	0.908649	171	0.884888	213	0.863869
46	0.973619	88	0.938324	130	0.908232	172	0.884569	214	0.863602
47	0.973045	89	0.937824	131	0.907815	173	0.884250	215	0.863335
48	0.972472	90	0.937324	132	0.907398	174	0.883931	216	0.863068
49	0.971898	91	0.936824	133	0.906981	175	0.883612	217	0.862801
50	0.971325	92	0.936324	134	0.906564	176	0.883293	218	0.862534
51	0.970751	93	0.935824	135	0.906147	177	0.882974	219	0.862267
52	0.970178	94	0.935324	136	0.905730	178	0.882655	220	0.862000
53	0.969604	95	0.934824	137	0.905313	179	0.882336	221	0.861733
54	0.969031	96	0.934324	138	0.904896	180	0.882017	222	0.861466
55	0.968457	97	0.933824	139	0.904479	181	0.881698	223	0.861199
56	0.967884	98	0.933324	140	0.904062	182	0.881379	224	0.860932
57	0.967310	99	0.932824	141	0.903645	183	0.881060	225	0.860665
58	0.966737	100	0.932324	142	0.903228	184	0.880741	226	0.860398
59	0.966163	101	0.931824	143	0.902811	185	0.880422	227	0.860131
60	0.965590	102	0.931324	144	0.902394	186	0.880103	228	0.859864
61	0.965016	103	0.930824	145	0.901977	187	0.879784	229	0.859597
62	0.964443	104	0.930324	146	0.901560	188	0.879465	230	0.859330
63	0.963869	105	0.929824	147	0.901143	189	0.879146	231	0.859063
64	0.963296	106	0.929324	148	0.900726	190	0.878827	232	0.858796
65	0.962722	107	0.928824	149	0.900309	191	0.878508	233	0.858529
66	0.962149	108	0.928324	150	0.899892	192	0.878189	234	0.858262

Table 4: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability (Continued)

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
244	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	317	[illegible]	341	[illegible]
245	0.953???	270	0.950??1	294	0.948???	318	0.94????	342	0.943??1
246	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	319	[illegible]	343	[illegible]
247	0.953074	272	0.950???	296	0.948126	320	0.94???4	344	0.943418
248	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	321	[illegible]	345	[illegible]
249	0.953???	274	0.950774	298	0.947?75	322	0.94????	346	0.943106
250	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
251	0.953???	276	0.950121	300	0.947?47	324	0.94????	348	0.943030
252	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
253	0.953???	278	0.949???	302	0.947???	326	0.94???7	350	0.942718
254	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
255	0.952712	280	0.949???	304	0.947???	328	0.94?457	352	0.942719
256	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
257	0.952484	282	0.949452	306	0.947???	330	0.94????	354	0.942595
258	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
259	0.952???	284	0.949???	308	0.947???	332	0.94????	356	0.942172
260	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
261	0.952???	286	0.949???	310	0.94????	334	0.94????	358	0.941713
262	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
263	0.951879	288	0.949126	312	0.94????	336	0.944???	360	0.941627
264	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	361	[illegible]
265	0.951649	290	0.948???	314	0.94?744	338	0.944104	362	0.941540
266	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	363	[illegible]
267	0.951672	292	0.948???	316	0.94????	340	0.94????	364	0.941315
268	[illegible]								

3.7.6.1.2 Lung Disease Diagnosis Group Classification in the Lung Allocation Score (LAS)

The LAS calculation includes four diagnosis groups: A, B, C, and D. The diagnoses that comprise each group are:

a. Group A
- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

b. Group B
- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: Patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: Ventricular septal defect (VSD)
- Portopulmonary hypertension
- Primary pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

c. Group C
- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

d. Group D
- ABCA3 transporter mutation
- Alveolar proteinosis

- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchoalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with one or more of the following disease entities:
  - Acute interstitial pneumonia
  - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
  - Desquamative interstitial pneumonia
  - Idiopathic pulmonary fibrosis
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia
  - Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- Scleroderma – restrictive
- Secondary pulmonary fibrosis (specify cause)
- Silicosis
- Sjogren's syndrome
- Surfactant protein B mutation
- Surfactant protein C mutation
- Teratoma
- Wegener's granuloma – restrictive

3.7.6.1.3 PCO_2 in the Lung Allocation Score (LAS)

UNet[SM] will use two measures of PCO_2 in a candidate's lung allocation score calculation: current PCO_2, and change in PCO_2. There are two types of PCO_2 change calculations: "threshold change" and "threshold change maintenance." The following explanations (a-f) and illustrations (Figures 1-3) detail how UNet[SM] uses PCO_2 in the lung allocation score.

a. *Use of Arterial, Venous, or Capillary PCO_2 Values*
In UNet[SM], a center may enter a PCO_2 value from an arterial, venous, or capillary blood gas test. UNet[SM] will convert a venous or capillary value to estimate an arterial value as follows:
   - a capillary value will equal an arterial value; and,
   - UNet[SM] will subtract 6 mmHg from a venous value to equal an arterial value.

   In the lung allocation score calculation, UNet[SM] will use the PCO_2 value with the most recent test date, regardless of the blood gas type. Exception: if an arterial value and either a venous or capillary value have the same test date, UNet[SM] will use the arterial value in the lung allocation score calculation.

b. *Definition of Current PCO_2*
Current PCO_2 is the PCO_2 value with the most recent test date entered in UNet[SM].

c. *Expiration of Current PCO_2 Value*
UNet[SM] will evaluate a current PCO_2 value as expired according to Policy 3.7.6.3.

d. *Use of Normal Clinical Value for Current PCO_2*
The normal clinical value of PCO_2 is 40 mmHg. UNet[SM] will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO_2 is less than 40 mmHg, missing, or expired.

e. *PCO_2 Values Used in the Change Calculations*
There are two types of PCO_2 change calculations: threshold change and threshold change maintenance.
The threshold change calculation evaluates whether the PCO_2 change is 15% or higher. In this calculation, UNet[SM] will use highest and lowest values of PCO_2. The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet[SM] will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNet[SM] will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is:

$$\frac{\textbf{Highest } PCO_2 \textbf{-Lowest } PCO_2}{\textbf{Lowest } PCO_2}$$

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact

from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current PCO_2 value must be at least 15% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is:

$$\frac{\text{Current } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

UNet[SM] will perform the threshold change maintenance calculation either when the current PCO_2 value expires (Policy 3.7.6.3) or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the threshold change calculation. If a current PCO_2 value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current PCO_2 value expires, UNet[SM] will substitute that expired value with the normal clinical value of 40 mmHg. This normal value, therefore, cannot be 15% *higher* than the lowest value in the threshold change calculation.

If a center enters a new current PCO_2 value for a candidate who has lost the impact from threshold change, UNet[SM] will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the threshold change calculation, UNet[SM] will *reapply* the impact from threshold change to the candidate's lung allocation score.

f. *Impact of PCO_2 Threshold Change in the Lung Allocation Score*

A change in PCO_2 that is 15% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current PCO_2 is at least 15% higher than the lowest value used in the threshold change calculation.

Figure 1
Use of Current PCO_2 in the Lung Allocation Score

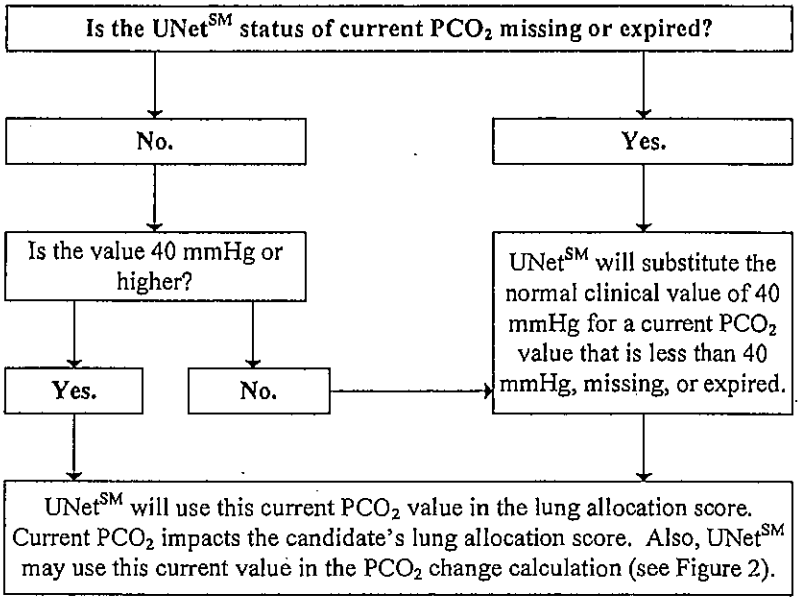


Figure 2
PCO_2 Threshold Change Calculation

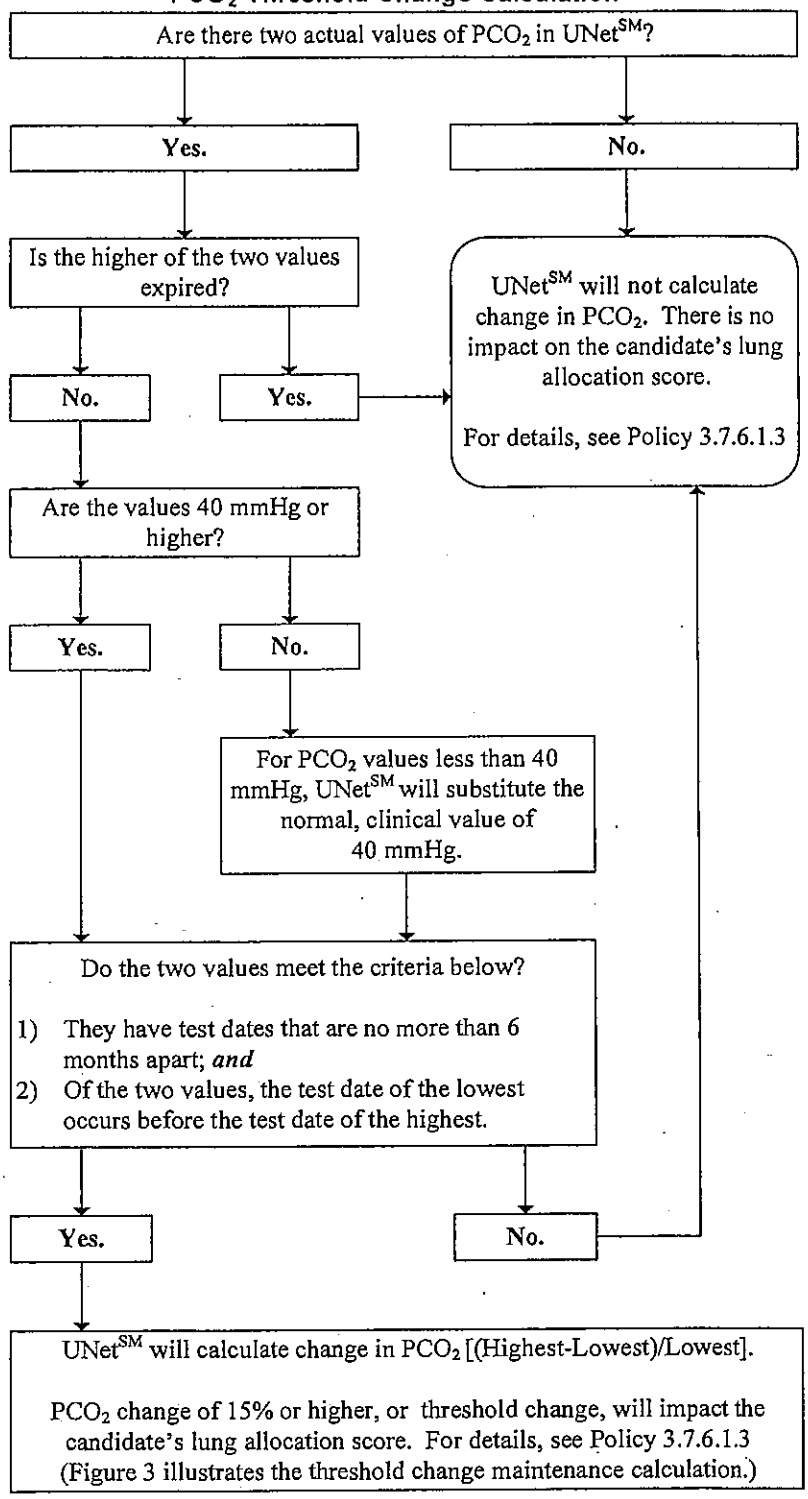
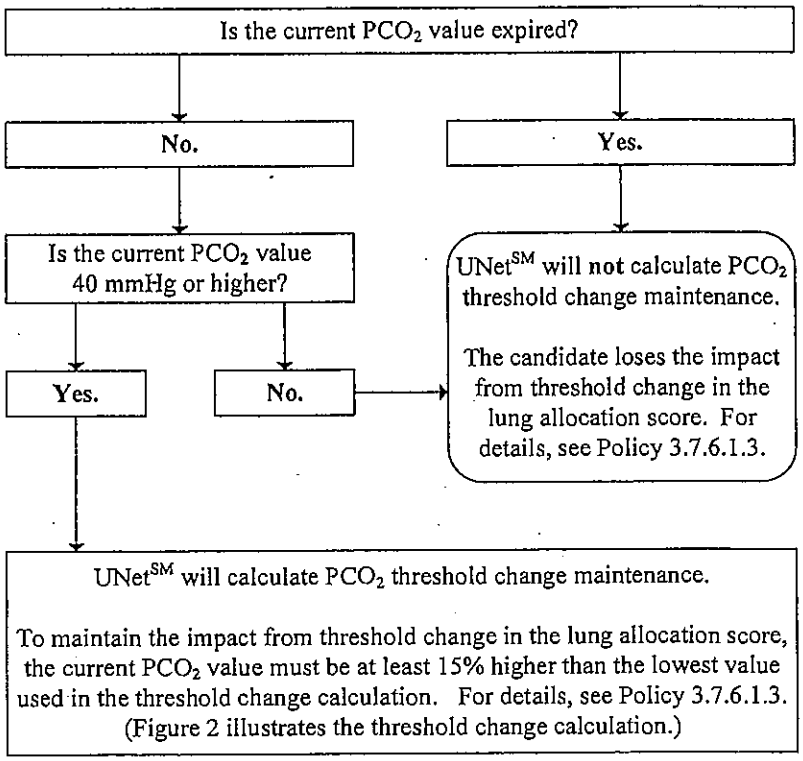


Figure 3
PCO_2 Threshold Change Maintenance Calculation



3.7.6.1.4 Bilirubin in the Lung Allocation Score (LAS)

UNet℠ will use two measures of total bilirubin in a candidate's lung allocation score calculation: current bilirubin (for all candidates), and change in bilirubin (for Group B only). There are two types of bilirubin change calculations: "threshold change" and "threshold change maintenance." This section of Policy 3.7.6.1 explains how UNet℠ uses bilirubin in the lung allocation score.

a. *Definition of Current Bilirubin*
Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNet℠. UNet℠ will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

b. *Expiration of Current Bilirubin Value*
UNet℠ will evaluate a current bilirubin value as expired according to Policy 3.7.6.3.

c. *Use of Normal Clinical Value for Current Bilirubin*
The normal clinical value of current bilirubin is 0.7 mg/dL. UNet℠ will substitute this normal clinical value in the lung allocation score calculation when the value of current bilirubin is less than 0.7 mg/dL, missing, or expired.

d. *Bilirubin Values Used in the Change Calculations (Group B Only)*

There are two types of bilirubin change calculations: threshold change and threshold change maintenance.
The threshold change calculation evaluates whether the bilirubin change is 50% or higher. In this calculation, UNet[SM] will use highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet[SM] will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNet[SM] will substitute the normal clinical value of 0.7 mg/dL before calculating change. The equation for threshold change is:

$$\frac{\text{Highest Bilirubin-Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current bilirubin value must be at least 50% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is:

$$\frac{\text{Current Bilirubin-Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

UNet[SM] will perform the threshold change maintenance calculation either when the current bilirubin value expires (Policy 3.7.6.3) or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the threshold change calculation. If a current bilirubin value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current bilirubin value expires, UNet[SM] will substitute that expired value with the normal clinical value of 0.7 mg/dL. This normal value, therefore, cannot be 50% *higher* than the lowest value in the threshold change calculation.

If a center enters a new current bilirubin value for a candidate who has lost the impact from threshold change, UNet[SM] will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the threshold change calculation, UNet[SM] will *reapply* the impact from threshold change to the candidate's lung allocation score.

e. *Impact of Bilirubin Threshold Change in the Lung Allocation Score (Group B only)*
A change in bilirubin that is 50% or higher, or threshold

change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current bilirubin is at least 50% higher than the lowest value used in the threshold change calculation.

3.7.6.1.5 Creatinine in the Lung Allocation Score (LAS)

The LAS calculation uses two measures of creatinine: current creatinine and increase in creatinine.

a. Current Creatinine
Current creatinine is the serum creatinine value from the most recent test date and time reported to the OPTN Contractor. The LAS calculation only uses current creatinine for candidates who are at least 18 years of age.

b. Increase in Creatinine
An increase in creatinine will influence a candidate's LAS only if it is at least 150%. The Increase-In-Creatinine calculation uses the highest and lowest values of creatinine. For this variable to impact a candidate's LAS, the test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of the highest and lowest values cannot be more than 6 months apart. The Increase-In-Creatinine calculation can use an expired lowest value, but not an expired highest value. The equation for this increase-in-creatinine calculation is:

$$\frac{\text{Highest Creatinine-Lowest Creatinine}}{\text{Lowest Creatinine}}$$

If a candidate's LAS is influenced by an increase in creatinine, then the LAS calculation will assess whether to maintain that influence. To maintain the influence of the increase in creatinine, the candidate's current creatinine value must be at least 150% higher than the lowest value used in the Increase-In-Creatinine calculation. The equation for this maintenance calculation is:

$$\frac{\text{Current Creatinine-Lowest Creatinine}}{\text{Lowest Creatinine}}$$

If the current creatinine value expires or a new creatinine value is entered, then the increase maintenance calculation will occur.

3.7.6.2 Candidates Age 0 - 11. UNet^{SM} ranks candidates who are 0 – 11 years old for lung offers according to the priorities defined below. Within each priority, UNet^{SM} will rank candidates by ABO (according to Policy 3.7.8.2) and then by waiting time, in descending order. For Priority 1, UNet^{SM} will only consider the most current period of time a candidate has spent as Priority 1, i.e, UNet^{SM} will not tally the time waiting during multiple Priority 1 periods. For Priority 2, and if there is ever a tie among Priority 1 candidates, UNet^{SM} will use these candidates' total waiting time to determine the order for receiving lung offers. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive.

A program may update clinical data used to justify a candidate's priority at any time it believes a candidate's medical condition warrants such modifications. For a candidate listed as Priority 1, a program must update each qualifying criterion, except that which is obtained only by heart catheterization, at least once in each six month period following the candidate's registration on the lung Waitlist[SM]. If more than six months elapse without data updates after the candidate's last six-month "anniversary" of his or her Waitlist[SM] registration, then the candidate's Priority 1will revert to Priority 2. UNet[SM] will assess the currency of lung variables for each candidate on every six-month "anniversary" date. (For example, if a candidate is first registered on the Waitlist[SM] on January 1, 2011, and the most recent six-month "anniversary" is January 1, 2012, then UNet[SM] will consider any variables collected on or after July 1, 2011 as current until June 30, 2012. UNet[SM] will reassess the currency of the lung variables on July 1, 2012, and then any variables with test dates that are on or after January 1, 2012 would be considered current.)

Priority 1: Candidates with one or more of the following criteria:

- **Respiratory failure, defined as:**
  - Requiring continuous mechanical ventilation; *or*
  - Requiring supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% in order to maintain oxygen saturation levels greater than 90%; *or,*
  - Having an arterial or capillary PCO_2 greater than 50 mmHg, or a venous PCO_2 greater than 56mmHg.

- **Pulmonary hypertension, defined as:**
  - Having pulmonary vein stenosis involving 3 or more vessels; *or*
  - Exhibiting any of the following, in spite of medical therapy: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index less than 2 L/min/M^2, syncope, or hemoptysis

    Examples of accepted medical therapy for pulmonary hypertension will be listed in UNet[SM]. Transplant centers must indicate which of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant center must submit an exception request to the Lung Review Board as described below.

- **An exception case approved by the Lung Review Board:**
  - In its review of exception requests, the Lung Review Board will follow the ~~prospective~~ retrospective review process described in Policy 3.7.6.4 (Lung Candidates with Exceptional Cases).

Priority 2: Candidates who do not meet the criteria for Priority 1 must be listed as Priority 2.

3.7.6.3 Reporting Data for Candidates Who Receive Lung Allocation Scores (LAS)

When registering a candidate who is at least 12 years of age for lung transplantation, transplant programs must report to the OPTN Contractor clinical data corresponding to the covariates shown in Tables 1 and 2 in Policy 3.7.6.1.1. Data reported upon registering the candidate must be no more than six months older than the registration date. The transplant program must maintain source documentation for

the reported data in the candidate's chart.

Except as noted in Policy 3.7.6.3.1, transplant programs must report to the OPTN Contractor each element of a candidate's clinical data at every six-month anniversary date. A six-month anniversary date first occurs six months after the date of initial registration, then every six months after. A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. Actual values or estimated values for pulmonary pressures are valid until the transplant program submits new actual values or new estimated values to the OPTN Contractor according to Policy 3.7.6.4.

Transplant programs may determine how often to update clinical data that must be obtained through heart catheterization. However, if a transplant program performs a heart catheterization on the candidate during any six month interval, then it must report the relevant results to the OPTN Contractor. The transplant program must maintain source documentation of all heart catheterization test results in the candidate's chart.

If values for certain covariates are missing, expired, or below a threshold as defined by Table 5, then the LAS calculation will substitute normal or least beneficial values to calculate the candidate's LAS. A normal value is one that a healthy individual is likely to exhibit. A least beneficial value is one that will calculate the lowest LAS for a candidate. Table 5 lists the normal and least beneficial values that will be substituted.

Table 5
Data Substituted for Missing, Expired, or Below Threshold Actual Values in Calculating the LAS

If this covariate's value is missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
Bilirubin:	0.7 mg/dL if the actual value is missing, expired, or less than 0.7 mg/dL
Body mass index (BMI)	100 kg/m^2 if the actual value is missing or expired
Cardiac index	3.0 L/min/m^2 if the actual value is missing
Central venous pressure (CVP)	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	No mechanical ventilation in the waiting list model if the actual value is missing or expired Continuous mechanical ventilation in the post-transplant model if the actual value is missing or expired
Creatinine: serum	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post-transplant model for candidates at least 18 years of age if the actual value is missing or expired

If this covariate's value is missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
	0 mg/dL in the post-transplant model for candidates less than 18 years of age if the actual value is missing or expired
Diabetes	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	150% for Group D if the actual value is missing or expired, according to Policy 3.7.6.1.2(d)
Functional status	No assistance needed in the waiting list model if the actual value is missing or expired Some or total assistance needed in the post-transplant model if the actual value is missing or expired
Oxygen needed at rest	No supplemental oxygen needed in the waiting list model if the actual value is missing or expired 26.33 L/min in the post-transplant model if the actual value is missing or expired
PCO_2:	40 mm Hg if the actual value is missing, expired, or less than 40 mm Hg
Pulmonary artery (PA) systolic pressure	20 mm Hg if the actual value is missing or less than 20 mm Hg
Six minute walk distance	4000 feet in the waiting list urgency model if the actual value is missing or expired 0 feet in the post-transplant survival model if the actual value is missing or expired

Programs are permitted to enter a medically reasonable estimated value if a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a candidate. Before entering such estimated values, programs must receive approval from the Lung Review Board, which will determine whether the estimated values are appropriate. Estimated values will remain valid until those values are either updated with an actual value, or a new estimated value is entered according to Policy 3.7.6.4.

~~**3.7.6.3 Candidate Variables in UNet℠.** Entry into UNet℠ of candidate clinical data corresponding to the variables shown in Tables 1 and 2 in Policy 3.7.6.1 is required when listing a candidate for lung transplantation. Diagnosis, birth date (used to calculate age), height and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. Candidates will receive a Lung Allocation Score of zero if the Functional Status class or assisted ventilation variable is missing a value at any time.~~

~~If values for pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure are missing, then a default value will be assigned that represents a normal clinical value for these missing pulmonary pressure variables. A default value of 20 mm Hg will be assigned for missing pulmonary artery systolic pressure, a default value of 5 mm Hg will be assigned for missing pulmonary capillary wedge pressure, and a default value of 15 mm Hg will be assigned for missing pulmonary artery mean pressure. The default values for pulmonary pressures will also be used in the calculation of Lung Allocation Scores for those candidates whose actual values are provided, but are lower than the default value. If any other candidate variables are missing, then a default value, which will be the value that results in the lowest contribution to the Lung Allocation Score for that variable field ("Least Beneficial Value"), will be selected for the candidate.~~

~~Programs are permitted to enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Prior to entering such estimated values, programs must request review and approval from the Lung Review Board to determine whether the estimated values are appropriate. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to Policy 3.7.6.4.~~

3.7.6.3.1 Reporting Data for Candidates with LASs of 50 or Greater

A program must report three key variables to the OPTN Contractor no more than 14 days after a candidate's LAS becomes 50 or greater:

a. Assisted ventilation,
b. Supplemental oxygen
c. Current PCO_2.

If a program does not perform a PCO_2 test in that time, then it does not need to report this updated value to the OPTN Contractor. While the candidate's LAS remains 50 or greater, the program must continue to assess and report any observed change in the three clinical variables every 14 days.

The transplant program must maintain source documentation for each assessment in the candidate's chart.

~~**Updating Candidate Variables.** Programs may update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification. Programs must update each element of a candidate's clinical data in UNet℠ every six months, except those data obtainable only by heart catheterization. Also, as described further below, programs must update three clinical variables more frequently than six months for candidates with LAS of 50 or higher.~~

~~UNet℠ defines a "six month anniversary date," which first occurs six months from the date of initial listing, then every six months thereafter. UNet℠ will consider a variable to be expired if the variable's test date is six months older than the most recent anniversary date.~~

~~If the test dates of the Functional Status or assisted ventilation~~

~~variable expire, then the candidate's Lung Allocation Score will be zero. If any other candidate variable expires — excluding pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure — then the candidate will receive the Least Beneficial Value for that variable. The transplant center determines the frequency of updating those candidate variables that are required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) If a transplant center repeats a heart catheterization test, it must report the results in UNet℠.~~

~~UNet℠ will consider actual values or estimated values for pulmonary pressures to be valid until the transplant center updates them with new actual values or new estimated values pursuant to Policy 3.7.6.4.~~

~~A program must update three key variables in UNet℠ no more than 14 days after a candidate's LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO_2. If a program does not perform a PCO_2 test in that time, then it does not need to update this value in UNet℠. While the candidate's score remains 50 or higher, a program must continue to assess and report any observed change in the three clinical variables no less frequently than 14 days from the date of the previous assessment.~~

3.7.6.4 Lung Candidates With Exceptional Cases. Special cases require prospective review by the Lung Review Board. Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The transplant center will accompany each request for special case review with a supporting narrative. Once complete, the request must be sent to the OPTN contractor. The Lung Review Board will have seven (7) calendar days to reach a decision, starting from the date that the contractor sends the request to the Lung Review Board. If a request is denied by the Lung Review Board upon initial review, then the center may choose to appeal the decision for reconsideration by the Lung Review Board. The center will have seven (7) calendar days from the date of the initial request denial to appeal. The Lung Review Board will have seven (7) calendar days to reach a decision on the appeal, starting from the date that the contractor sends the appealed request to the Lung Review Board. If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will not receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the Thoracic Organ Transplantation Committee for further review.

Should the Lung Review Board deny a transplant center's initial request or appealed request for an estimated value or a specific Lung Allocation Score, the transplant center has the option to override the decision of the LRB. If the transplant center elects to override the decision of the Lung Review Board, then the request or appeal will be automatically referred to the Thoracic Organ Transplantation Committee for review; this review by the Thoracic Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

Estimated values will remain valid until an actual value is entered in the

system or a new estimated value is entered pursuant to the procedures described in this policy. A diagnosis that has been approved by the Lung Review Board or the Thoracic Organ Transplantation Committee will remain valid indefinitely or until an adjustment is requested and, if necessary, approved by the Lung Review Board. Lung Allocation Scores will remain valid for six (6) months from the entry date (or the candidate's twelfth birthday, whichever occurs later). If the candidate continues to be on the Waiting List six months after the entry date, then the candidate's Lung Allocation Score will be computed as described in Policy 3.7.6.1 and Policy 3.7.6.3 unless a new Lung Allocation Score request is entered pursuant to the procedures described in this policy or the center chooses to use the computed Lung Allocation Score instead.

The Thoracic Committee shall establish guidelines for special case review by the Lung Review Board.

3.7.7 Allocation of Thoracic Organs to Heart-Lung Candidates. When the candidate is eligible to receive a heart in accordance with Policy 3.7, or an approved variance to this policy, the lung shall be allocated to the heart-lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart. Heart-lung candidates shall use the ABO matching requirements described in Policy 3.7.8 when they are included in the heart match run results. Heart-lung candidates shall use the ABO matching requirements described in policy 3.7.8.2 when they are included in the lung match run results.

3.7.8 ABO Typing for Heart Allocation. Within each heart status category, hearts will be allocated to patients according to the following ABO matching requirements:

(i) Blood type O donor hearts shall only be allocated to blood type O or blood type B patients;

(ii) Blood type A donor hearts shall only be allocated to blood type A or blood type AB patients;

(iii) Blood type B donor hearts shall only be allocated to blood type B or blood type AB patients;

(iv) Blood type AB donor hearts shall only be allocated to blood type AB patients.

(v) If there is no patient available who meets these matching requirements, donor hearts shall be allocated first to patients who have a blood type that is compatible with the donor's blood type.

(vi) Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in 3.7.10, by heart status category to born Status 1A or 1B pediatric heart candidates who are eligible to receive a heart from any blood type donor. Allocation to *in utero* candidates eligible for any blood type donors is initiated after all eligible born candidates have received offers.

A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if one of the following conditions is met:

(i) Candidate is *in utero*;

(ii) Candidate is less than 1 year of age, and meets all of the following:

a. Listed at Status 1A or 1B, and
b. Current isohemagglutinin titer information for A and/or B blood type antigens reported in UNet[SM].

(iii) Candidate is greater than or equal to 1 year of age, and meets all of the following:

a. Is listed prior to age 2;
b. Is listed at Status 1A or 1B;
c. Has current isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNet[SM]; and,
d. Has *not* received treatments within the prior 30 days that may have reduced titer values to 1:4 or less.

3.7.8.1 Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type. A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if the eligibility requirements set forth in Policy 3.7.8 are met.

Anti-A and/or Anti-B titers must be reported:

(i) At time of listing (except for *in utero* candidates);

(ii) Every 30 days after listing (**all** eligible born candidates);

(iii) At transplant; and

(iv) In the event of graft loss or death within one year after transplant (for all candidates transplanted with other than blood type identical or compatible donor hearts).

Listing and transplant outcomes for candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.

3.7.8.2 ABO Typing for Lung Allocation. Candidates who have the identical blood type as the donor and are awaiting an isolated lung transplant will be allocated thoracic organs before candidates who have a compatible (but not identical) blood type with that of the donor and are awaiting an isolated lung transplant

3.7.9 Time Waiting for Thoracic Organ Candidates. Calculation of the time a candidate has been waiting for a thoracic organ transplant begins with the date and time the candidate is first registered as active on the Waiting List. Waiting time will not be accrued by candidates awaiting a thoracic organ transplant while they are registered on the Waiting List as inactive, except as specified in Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age). When time waiting is used for thoracic organ allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same status/priority category. Where applicable, waiting time accrued by a candidate for a single thoracic organ transplant (heart or single lung) while

waiting on the Waiting List also may be accrued for a second thoracic organ, when it is determined that the candidate requires a multiple thoracic organ (heart-lung or double lung) transplant. In addition, where applicable, waiting time accrued by a candidate for a multiple thoracic organ transplant while waiting on the Waiting List may be transferred to the Waiting List for a single thoracic organ transplant.

3.7.9.1 **Waiting Time Accrual for Heart Candidates.** Candidates listed as a Status 1A, 1B, or 2 will accrue waiting time within each heart status; however, waiting time accrued while listed at a lower status will not be counted toward heart allocation if the candidate is upgraded to a higher status. For example, a candidate who is listed as a Status 2 for 3 months and then is upgraded to a Status 1A for one week will accrue one week of waiting time as a Status 1A. If the candidate is downgraded to a Status 2 for another 3 weeks, then the candidate will have 4 months of total accrued time. If the candidate subsequently is upgraded for another week as a Status 1A, then the candidate's Status 1A waiting time will be 2 weeks.

3.7.9.2 **Waiting Time Accrual for Lung Candidates liat Least 12 Years of Age Following Implementation of Lung Allocation Scores (LAS) System** ~~**Described in Policy 3.7.6 Waiting time accrued by lung candidates age 12 and older at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 and thereafter will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores that have been approved by the Lung Review Board pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by their total active waiting time accrued.**~~

** **BOLD** *language that appears in Policy 3.7.9.2 was approved by the Executive Committee on March 11, 2005, and was implemented on May 4, 2005.*

In the event that multiple candidates receive identical computed Lung Allocation Scores greater than zero, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time of each candidate's most recent update in UNet[SM] by the member, of variables used in calculation of the Lung Allocation Score. (For example, if Candidate A and Candidate B have an identical Lung Allocation Score and identical priority for a lung offer, and Candidate A's data variables were most recently updated by the transplant center on May 1, 2005, and Candidate B's data variables were most recently updated by the transplant center on June 1, 2005, then Candidate A would receive higher priority for the lung offer because his most recent data update by the transplant center occurred first and the same set of data variables has been used to calculate Candidate A's Lung Allocation Score for the longest amount of time.)

In the event that multiple candidates receive identical assigned Lung Allocation Scores pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time that each candidate's most recent approval of that Lung

Allocation Score by the Lung Review Board was entered in UNet[SM] (For example, if Candidate X and Candidate Y have identical Lung Allocation Scores assigned to them by the Lung Review Board and identical priority for a lung offer, and the approval for Candidate X's score was entered in UNet[SM] on June 1, 2005, and the approval for Candidate Y's score was entered in UNet[SM] on July 1, 2005, then Candidate X would receive higher priority for the lung offer because his most recent Lung Allocation Score was approved and entered in UNet[SM] first.)

~~Candidates that receive a Lung Allocation Score of zero due to missing or expired candidate variables as described in Policy 3.7.6.3 will be screened from the lung match following notification of the listing center, and will not receive isolated lung offers. Upon the entry or update of previously missing or expired candidate variables as described in Policy 3.7.6.3, those candidates will appear on the lung match.~~

Candidates awaiting a lung transplant on the Waiting List at inactive status will be subject to the same requirements for updating candidates' clinical data as indicated in Policy 3.7.6.3 and Policy 3.7.6.4 and will not accrue any waiting time while at inactive status.

NOTE: Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6) (BOLDED and as of the June 24, 2005 Board of Directors Meeting) shall be approved and implemented pending distribution of appropriate notice and programming on UNet[SM], if and as applicable.

3.7.9.3 Waiting Time Accrual for Lung Candidates Less than 12 Years of Age. Candidates listed as a Priority 1 or Priority 2 will accrue waiting time within each priority. Priority 1 and Priority 2 candidates will receive a preference over other candidates within a match run classification who have accumulated less waiting time. For Priority 1 candidates, UNet[SM] will only consider the most recent time spent as Priority 1, i.e., UNet[SM] will not tally the time waiting during multiple Priority 1 periods.

For Priority 2 candidates, and if there is ever a tie among Priority 1 candidates, UNet[SM] will use total waiting time. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive.

3.7.10 Sequence of Adult Heart Allocation. Donor hearts recovered from donors age 18 and older shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

Local
1. Status 1A candidates
2. Status 1B candidates

Zone A
3. Status 1A candidates
4. Status 1B candidates

Local
5. Status 2 candidate s

Zone B
6. Status 1A candidates
7. Status 1B candidates

Zone A
8. Status 2 candidates

Zone B
9. Status 2 candidates

Zone C
10. Status 1A candidates
11. Status 1B candidates
12. Status 2 candidates

Zone D
13 Status 1A candidates
14. Status 1B candidates
15. Status 2 candidates

Zone E
16. Status 1A candidates
17. Status 1B candidates
18. Status 2 candidates

3.7.10.1 Sequence of Pediatric Heart Allocation. Hearts recovered from pediatric donors shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

1. Common OPO and Zone A Status 1A ABO Primary Ped Candidates for Pediatric Donor
2. Common OPO and Zone A Status 1A ABO Secondary Ped Candidates for Pediatric Donor
3. Common OPO Status 1A ABO Primary Candidates
4. Common OPO Status 1A ABO Secondary Candidates
5. Common OPO and Zone A Status 1B ABO Primary Ped Candidates for Pediatric Donor
6. Common OPO and Zone A Status 1B ABO Secondary Ped Candidates for Pediatric Donor
7. Common OPO Status 1B ABO Primary Candidates
8. Common OPO Status 1B ABO Secondary Candidates
9. Zone A Status 1A ABO Primary Candidates
10. Zone A Status 1A ABO Secondary Candidates
11. Zone A Status 1B ABO Primary Candidates
12. Zone A Status 1B ABO Secondary Candidates
13. Common OPO Status 2 ABO Primary Ped Candidates for Pediatric Donor
14. Common OPO Status 2 ABO Secondary Ped Candidates for Pediatric Donor
15. Common OPO Status 2 ABO Primary Candidates
16. Common OPO Status 2 ABO Secondary Candidates
17. Zone B Status 1A ABO Primary Ped Candidates for Pediatric Donor
18. Zone B Status 1A ABO Secondary Ped Candidates for Pediatric Donor
19. Zone B Status 1A ABO Primary Candidates
20. Zone B Status 1A ABO Secondary Candidates
21. Zone B Status 1B ABO Primary Ped Candidates for Pediatric Donor
22. Zone B Status 1B ABO Secondary Ped Candidates for Pediatric Donor
23. Zone B Status 1B ABO Primary Candidates
24. Zone B Status 1B ABO Secondary Candidates
25. Zone A Status 2 ABO Primary Ped Candidates for Pediatric Donor
26. Zone A Status 2 ABO Secondary Ped Candidates for Pediatric Donor
27. Zone A Status 2 ABO Primary Candidates
28. Zone A Status 2 ABO Secondary Candidates
29. Zone B Status 2 ABO Primary Ped Candidates for Pediatric Donor
30. Zone B Status 2 ABO Secondary Ped Candidates for Pediatric Donor
31. Zone B Status 2 ABO Primary Candidates
32. Zone B Status 2 ABO Secondary Candidates
33. Zone C Status 1A ABO Primary Ped Candidates for Pediatric Donor
34. Zone C Status 1A ABO Secondary Ped Candidates for Pediatric Donor

35. Zone C Status 1A ABO Primary Candidates
36. Zone C Status 1A ABO Secondary Candidates
37. Zone C Status 1B ABO Primary Ped Candidates for Pediatric Donor
38. Zone C Status 1B ABO Secondary Ped Candidates for Pediatric Donor
39. Zone C Status 1B ABO Primary Candidates
40. Zone C Status 1B ABO Secondary Candidates
41. Zone C Status 2 ABO Primary Ped Candidates for Pediatric Donor
42. Zone C Status 2 ABO Secondary Ped Candidates for Pediatric Donor
43. Zone C Status 2 ABO Primary Candidates
44. Zone C Status 2 ABO Secondary Candidates
45. Zone D Status 1A ABO Primary Ped Candidates for Pediatric Donor
46. Zone D Status 1A ABO Secondary Ped Candidates for Pediatric Donor
47. Zone D Status 1A ABO Primary Candidates
48. Zone D Status 1A ABO Secondary Candidates
49. Zone D Status 1B ABO Primary Ped Candidates for Pediatric Donor
50. Zone D Status 1B ABO Secondary Ped Candidates for Pediatric Donor
51. Zone D Status 1B ABO Primary Candidates
52. Zone D Status 1B ABO Secondary Candidates
53. Zone D Status 2 ABO Primary Ped Candidates for Pediatric Donor
54. Zone D Status 2 ABO Secondary Ped Candidates for Pediatric Donor
55. Zone D Status 2 ABO Primary Candidates
56. Zone D Status 2 ABO Secondary Candidates
57. Zone E Status 1A ABO Primary Ped Candidates for Pediatric Donor
58. Zone E Status 1A ABO Secondary Ped Candidates for Pediatric Donor
59. Zone E Status 1A ABO Primary Candidates
60. Zone E Status 1A ABO Secondary Candidates
61. Zone E Status 1B ABO Primary Ped Candidates for Pediatric Donor
62. Zone E Status 1B ABO Secondary Ped Candidates for Pediatric Donor
63. Zone E Status 1B ABO Primary Candidates
64. Zone E Status 1B ABO Secondary Candidates
65. Zone E Status 2 ABO Primary Ped Candidates for Pediatric Donor
66. Zone E Status 2 ABO Secondary Ped Candidates for Pediatric Donor
67. Zone E Status 2 ABO Primary Candidates
68. Zone E Status 2 ABO Secondary Candidates
69. Common OPO and Zone A Status 1A ABO Incompatible Ped Candidates for Pediatric Donor
70. Common OPO and Zone A Status 1B ABO Incompatible Ped Candidates for Pediatric Donor
71. Common OPO Status 2 ABO Incompatible Candidates
72. Zone B Status 1A ABO Incompatible Candidates
73. Zone B Status 1B ABO Incompatible Candidates
74. Zone C Status 1A ABO Incompatible Candidates
75. Zone C Status 1B ABO Incompatible Candidates
76. Zone D Status 1A ABO Incompatible Candidates
77. Zone D Status 1B ABO Incompatible Candidates
78. Zone E Status 1A ABO Incompatible Candidates
79. Zone E Status 1B ABO Incompatible Candidates
80. Common OPO and Zone A ABO Primary In Utero Candidates
81. Common OPO and Zone A ABO Secondary In Utero Candidates
82. Common OPO and Zone A ABO Incompatible In Utero Candidates
83. Zone B ABO Primary In Utero Candidates
84. Zone B ABO Secondary In Utero Candidates
85. Zone B ABO Incompatible In Utero Candidates
86. Zone C ABO Primary In Utero Candidates
87. Zone C ABO Secondary In Utero Candidates
88. Zone C ABO Incompatible In Utero Candidates
89. Zone D ABO Primary In Utero Candidates
90. Zone D ABO Secondary In Utero Candidates
91. Zone D ABO Incompatible In Utero Candidates
92. Zone E ABO Primary In Utero Candidates
93. Zone E ABO Secondary In Utero Candidates
94. Zone E ABO Incompatible In Utero Candidates

3.7.11 Sequence of Adult Donor Lung Allocation. Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung

allocation. If one lung is allocated to a candidate needing a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0 – 11 years old. Lungs from adult donors will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for adult donor lungs is as follows:

1. Local ABO identical candidates age 12 and older according to Lung Allocation Score in descending order;
2. Local ABO compatible candidates age 12 and older according to Lung Allocation Score in descending order;
3. Local ABO identical Priority 1 candidates 0 – 11 years old according to length of waiting time;
4. Local ABO compatible Priority 1 candidates 0 – 11 years old according to length of waiting time;
5. Local ABO identical Priority 2 candidates 0 – 11 years old according to length of waiting time;
6. Local ABO compatible Priority 2 candidates 0 – 11 years old according to length of waiting time;
7. ABO identical candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
8. ABO compatible candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
9. ABO identical Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
10. ABO compatible Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
11. ABO identical Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
12. ABO compatible Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
13. ABO identical candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
14. ABO compatible candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
15. ABO identical Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;
16. ABO compatible Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;
17. ABO identical Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;
18. ABO compatible Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;
19. ABO identical candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
20. ABO compatible candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
21. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;

22. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;
23. ABO identical Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;
24. ABO compatible Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;
25. ABO identical candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
26. ABO compatible candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
27. ABO identical Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;
28. ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;
29. ABO identical Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;
30. ABO compatible Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;
31. ABO identical candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;
32. ABO compatible candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;
33. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time;
34. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time;
35. ABO identical Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time; and
36. ABO compatible Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time.

3.7.11.1 Sequence of Pediatric Donor Lung Allocation. Candidates 0 – 11 years old awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Candidates 12 – 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 – 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0 – 11 years old will first be offered to candidates age 0 – 11; then to candidates age 12 – 17; then to candidates 18 years and older. Candidates will be grouped so that those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

- Offers for 0-11 year-olds will first be made to **combined** local, Zone A and Zone B candidates by priority and waiting time. After adolescent and adult offers are completed through Zone B, offers will continue to these younger candidates in Zones C, D and E prior to adolescents and adults within in each zone.

- Offers for 12-17 year-olds will first be made to combined local and Zone A candidates according to lung allocation score in descending order after the completion of 0-11 year-old offers through Zone B. Once adult Zone A offers are completed, offers will continue to adolescent candidates in Zones B, C, D and E after the younger 0-11 candidates and before the adult candidates within each zone.

- Offers to adult candidates (18 years and older) will be made after the completion of 0-11 year old offers through Zone B and adolescent offers through Zone A. After local and Zone A adult offers are completed, offers will continue in Zones B, C, D and E after the completion of all pediatric offers within each zone.

In summary, the allocation sequence for lungs from donors 0-11 years old is as follows:

1. Combined local, Zone A and Zone B ABO identical Priority 1 candidates 0-11 years old according to length of waiting time;
2. Combined local, Zone A and Zone B ABO compatible Priority 1 candidates 0-11 years old according to length of waiting time;
3. Combined local, Zone A and Zone B ABO identical Priority 2 candidates 0-11 years old according to length of waiting time;
4. Combined local, Zone A and Zone B ABO compatible Priority 2 candidates 0-11 years old according to length of waiting time;
5. Combined local and Zone A ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
6. Combined Local and Zone A ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
7. Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
8. Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
9. ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
10. ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
11. ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
12. ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
13. ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
14. ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
15. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
16. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
17. ABO identical Status 2 candidates 0-11 years old in Zone C according to length of waiting time;
18. ABO compatible Priority 2 candidates 0-11 years old in Zone C according to length of waiting time;
19. ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
20. ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
21. ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;

22. ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
23. ABO identical Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
24. ABO compatible Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
25. ABO identical Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
26. ABO compatible Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
27. ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
28. ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
29. ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
30. ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
31. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
32. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
33. ABO identical Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
34. ABO compatible Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
35. ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
36. ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
37. ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
38. ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

Lungs from donors 12 – 17 years old will first be offered to candidates age 12 – 17 years old; then to candidates age 0 – 11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

In summary, the allocation sequence for lungs from donors 12 – 17 years old is as follows:

1. Local ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
2. Local ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
3. Local ABO identical Status 1 candidates 0 – 11 years old according to length of time waiting;
4. Local ABO compatible Status 1candidates 0 – 11 years old

according to length of time waiting;
5. Local ABO identical Status 2 candidates 0 – 11 years old according to length of time waiting;
6. Local ABO compatible Status 2 candidates 0 – 11 years old according to length of time waiting;
7. Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
8. Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
9. ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
10. ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
11. ABO identical Priority 1 candidates 0 – 11 years old in Zone A according to length of time waiting;
12. ABO compatible Priority 1candidates 0 – 11 years old in Zone A according to length of time waiting;
13. ABO identical Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
14. ABO compatible Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
15. ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
16. ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
17. ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
18. ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
19. ABO identical Priority 1candidates 0 – 11 years old in Zone B according to length of time waiting;
20. ABO compatible Priority 1 candidates 0 – 11 years old in Zone B according to length of time waiting;
21. ABO identical Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
22. ABO compatible Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
23. ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
24. ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
25. ABO identical candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
26. ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
27. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
28. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
29. ABO identical Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
30. ABO compatible Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
31. ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
32. ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
33. ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
34. ABO compatible candidates 12 – 17 years old in zone D according

to Lung Allocation Score in descending order;
35. ABO identical Priority 1candidates 0 – 11 years old in Zone D according to length of time waiting;
36. ABO compatible Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
37. ABO identical Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
38. ABO compatible Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
39. ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
40. ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
41. ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
42. ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
43. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
44. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
45. ABO identical Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
46. ABO compatible Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
47. ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
48. ABO compatible candidates 18 years old and older in Zone E.

3.7.12 Minimum Information for Thoracic Organ Offers.

3.7.12.1 Essential Information. The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

(i) The cause of brain death;
(ii) The details of any documented cardiac arrest or hypotensive episodes;
(iii) Vital signs including blood pressure, heart rate and temperature;
(iv) Cardiopulmonary, social, and drug activity histories;
(v) Serologies as indicated in 2.2.4.1 (qualified specimens preferred as noted in Policy 2.2.3.1);
(vi) Accurate height, weight, age and sex;
(vii) ABO type;
(viii) ABO subtype when used for allocation;
(ix) Interpreted electrocardiogram and chest radiograph;
(x) History of treatment in hospital including vasopressors and hydration;
(xi) Arterial blood gas results and ventilator settings;
(xii) Echocardiogram, if the donor hospital has the facilities; and
(xiii) Human leukocyte antigen (HLA) type if requested by the transplant center.

If a transplant center requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO; the transplant center must document this request. If a transplant center requests donor HLA type prior to submitting a final organ acceptance, the OPO must provide the following, identified splits before the organ's final acceptance:

HLA-A, HLA-B, HLA-Bw4, HLA-Bw6, HLA-Cw, HLA-DR, and HLA-DQ antigens. The transplant center may request HLA-DP type, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document provision of HLA type to the requesting transplant center.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

3.7.12.2 Desirable Information for Heart Offers. With each heart offer, the donor center is encouraged to provide the recipient center with the following information:

(i) Coronary angiography for male donors over the age of 40 and female donors over the age of 45;
(ii) CVP or Swan Ganz instrumentation;
(iii) Cardiology consult; and
(iv) Cardiac enzymes including CPK isoenzymes.

With each heart offer, it is reasonable for the transplanting center to request a heart catheterization of the donor where the donor history reveals one or more of the following:

(a) The donor is a male over the age of 40 or a female over the age of 45;
(b) Segmental wall motion abnormality;
(c) Troponin elevation;
(d) History of chest pain;
(e) Abnormal EKG consistent with ischemia or myocardial infarction; or
(f) Two or more of the following:

i. History of hypertension
ii. History of significant smoking
iii. Intra-cerebral bleed
iv. Strong family history of coronary artery disease
v. History of Hyperlipidemia
vi. History of diabetes
vii. History of cocaine or amphetamine use

3.7.12.3 Essential Information for Lung Offers. In addition to the essential information specified above for a thoracic organ offer, the Host OPO shall provide the following specific information with each lung offer:

(i) Arterial blood gases on 5 cm/H_20/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2 within 2 hours prior to the offer;

(ii) Bronchoscopy results. Bronchoscopy of a lung donor is recognized as an important element of donor evaluation. The Host OPO must document if it is unable to provide bronchoscopy results. Confirmatory bronchoscopy may be performed by the lung retrieval team provided unreasonable delays are avoided. A lung transplant program may not insist upon performing its own bronchoscopy before being subject to the 60 minute response time limit as specified in Policy 3.4.2;

(iii) Chest radiograph interpreted by a radiologist or qualified physician within 3 hours prior to the offer;

(iv) Sputum gram stain with a description of the sputum character; and

(v) Smoking history.

3.7.12.4 Desirable Information for Lung Offers. With each lung offer, the Host OPO is encouraged to provide the transplant center with the following information:

(i) Mycology smear;
(ii) Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested; and
(iii) Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant center.

3.7.13 Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased. If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

3.7.14 Local Conflicts Involving Thoracic Organ Allocation. Regarding allocation of hearts, lungs and heart-lung combinations, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the Thoracic Organ Transplantation Committee and the Board of Directors.

3.7.15 Allocation of Domino Donor Hearts. A domino heart transplant occurs when the native heart of a combined heart-lung transplant recipient is procured and transplanted into a candidate who requires an isolated heart transplant. First consideration for donor hearts procured for this purpose will be given to the candidates of the participating transplant program from which the native heart was procured. If the program elects not to use the heart, then the heart will be allocated according to Policy 3.7, or an approved variance to this policy. For the purpose of Policy 3.7.16, the Local Unit of allocation for the domino heart shall be defined as the CMS-designated service area of the OPO where the domino heart is procured.

3.7.16 Crossmatching for Thoracic Organs. The transplant program and its histocompatibility laboratory must have a joint written policy that states when a crossmatch is necessary. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D of Policy 3.

Exhibit C

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Working together. Saving lives.

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Brian Shepard
Interim Executive Director & CEO

May 30, 2013

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Sebelius:

Thank you for your May 29 letter relating to OPTN lung allocation policy and issues in pediatric lung transplantation. We share in your concern for providing equitable transplant opportunities for all candidates in need. We are reliant on the public trust to provide these opportunities through organ and tissue donation.

We have addressed your specific questions below. We are glad to provide additional information or clarification on these or any additional questions you may have.

1. **What is the current OPTN lung allocation policy for deceased donor lungs from both adult and pediatric donors? Please provide a summary of these policies.**

The OPTN, within the authority and guidance established by the OPTN Final Rule and the National Organ Transplant Act, develops, evaluates and continually seeks to improve allocation policies for each transplantable organ. The lung policy is included within a set of allocation policies addressing thoracic organs, also including heart and heart-lung combinations. While the entire policy is accessible to the public via the OPTN website (and attached for your reference), below is a summary of its essential features, including pediatric prioritization.

While details of organ-specific policy differ due to unique medical considerations for each organ, certain policy commonalities are shared by all, including the lung allocation policy. These include the following:

- a local/zonal/national sequence of organ offers, to minimize organ preservation time and maximize the chance of a successful transplant

- priority in matching for identical blood type matching between donor and candidate, then for compatible but not identical blood types
- use of individual waiting time as an ultimate tiebreaker among two candidates who have otherwise equal priority
- discretion for the individual transplant center to apply individual acceptance criteria for offers for individual candidates, including donor size and age range

The vast majority of lung transplant candidates are adolescents or adults. For all candidates age 12 and older, an individualized lung allocation score (LAS) is calculated and periodically updated to prioritize them for matching organ offers. A lung offer from an adult donor will be considered first for compatible candidates with the highest LAS in the local allocation area, followed by others in declining order of LAS score. The LAS is based on analysis that determined how objective medical tests, a candidate's diagnosis group, and other current health and lung function affect patients' risk of mortality before and survival benefit after transplantation.

The LAS formula is used for adolescent and adult candidates. Its applicability among pre-adolescents is unknown. There are very few of these younger patients, and the diagnosis and progression of lung diseases may be different in this population. There are other unique biologic issues involving pre-adolescents as addressed below. As a result, current lung allocation policy establishes two medical urgency statuses for candidates younger than 12 years old (Priority 1 or Priority 2) based on medical criteria indicating the severity of their condition; Priority 1 is the highest urgency.

Priority 1 pre-adolescent candidates have first priority to receive offers from all donors younger than 12 within a 1,000-mile radius before any older candidates would be considered. In addition, they would be offered lungs from adolescent donors if transplant programs decline them for all candidates between age 12 and 17 within the same allocation area. They would also be offered lungs from adult donors if transplant programs decline them for all candidates after adolescent and adult candidates within the same allocation area have turned them down.

2. **What criteria were used by the OPTN in developing the current lung allocation policy? Please describe the process used to develop the OPTN lung allocation policy.**

The development of lung allocation policy, as with all OPTN allocation policy, follows a deliberative approach consistent with the guidance of the OPTN Final Rule. It considers objective medical evidence, current clinical practice and input from all interested parties.

All allocation policy is developed in detail by a sponsoring OPTN committee (in the instance of lung allocation, the Thoracic Organ Transplantation Committee). A proposal is developed and distributed for public comment by other committees and any interested person or institution. The sponsoring committee considers public comment and may further refine a proposal before presenting it to the OPTN/UNOS Board of Directors for review and a vote. Approved policies are made available to Department of Health and Human Services and are subject to the Secretary's discretion for enforcement or reconsideration, under the provisions of the OPTN Final Rule.

The specific emphasis in developing the LAS score for adolescents and adults was to base organ allocation on a balanced, "net-benefit" concept. There are not enough donated organs currently available to meet all needs. Organs could be offered preferentially to candidates in greatest need, but that would result in reduced survival rates as some candidates may be so debilitated that they will not do well long-term if transplanted. Conversely, organs could be offered preferentially to those with the best opportunity for survival, but this would lead to higher waitlist mortality among urgent candidates who could be helped. The LAS score allows the balance between these two conflicting priorities. At the time of the LAS development, the Thoracic Organ Transplantation Committee recognized that patients under 12 years of age undergoing lung transplant represented both a much smaller number of patients (a total of 376 since 1988 compared to more than 25000 aged 12 and older), and included patients with many diseases not found in the adult population (including, for example diseases involving surfactant protein abnormalities). For this reason, the committee felt that extrapolating the LAS below age 12 was inappropriate and, because of the small numbers, also concluded that waiting time for this population should remain the method of prioritizing patients in this group. Because there was no way to appropriately prioritize 0-11 year old patients with the list of patients ordered by LAS, it was decided to provide 0-11 candidates first priority for organs best suited for them – those from 0-11 year old donors.

As the LAS-based allocation system represented such a substantial change from the prior lung allocation system, a consensus conference was held during the policy development process (in 2003) to obtain broader community input. This conference helped shape the development and future application of the LAS system.

One important aspect of the subsequent policy development related to the treatment of pediatric candidates in the new system. The LAS policy implemented in 2005 included a preference for allocation of adolescent organs to adolescent recipients and subsequently to pediatric (age 0-11) recipients before allocation to adults. The latter aspect of this adjustment was intended to insure that pediatric candidates nearing the age of 12 would have access ahead of adults for appropriate sized lungs from smaller adolescents. As most pediatric centers list their patients with a height range approximately 20% above and below the recipient height, the Thoracic and Pediatric Committees felt that the proposed system would provide equitable access to organs most commonly used for this age group. In addition, in the infrequent circumstance where a center wishes to use downsized lungs or single lobes, it would also have access to organs from adults (albeit behind those patients for whom the organ size is optimal).

Because of concerns that young children (particularly infants) had higher waiting list mortality than adolescents and adults, additional changes to the lung allocation policy were approved by the board in 2008 and implemented in 2010. At the time of these changes, the Pediatric and Thoracic Committees considered whether models similar to those used in the LAS could be created for this age group but ultimately concluded that sufficient data was still not available.

Therefore the policy implemented two priority tiers and broader sharing of 0-11 donor organs (1000 miles from the donor hospital) before offering such organs to adolescents and adults.

3. When was the current OPTN lung allocation policy approved and implemented by the OPTN?

While there have been modifications over time, the framework for the current lung allocation policy (including the establishment of the LAS) was approved by the OPTN/UNOS Board of Directors in June 2004 and was implemented in May 2005. The current pediatric prioritization policy (establishing Priority 1 and Priority 2, as well as changes to the allocation sequence for these candidates) was approved by the OPTN/UNOS Board of Directors in June 2008 and implemented in 2010.

The Board of Directors approved substantial modifications to the LAS calculation in November 2012. These changes currently are being programmed for implementation within the matching system.

4. How frequently does the OPTN consider changes to its lung allocation policy?

The OPTN, through its committee and Board of Directors, continually assesses the performance of all organ allocation policies and may consider amendments or improvements at any time that may improve access and/or outcomes for transplant candidates and recipients. The Board of Directors routinely meets twice a year and considers any proposals that have undergone the established processes of committee review, data analysis and public comment.

As the OPTN's mandate is to develop equitable policies and ensure they are consistently applied for the benefit of all candidates, emphasis is given to new or amended policies that will neither unduly advantage nor disadvantage a specific, identifiable group of candidates based on data or medical evidence.

5. What are the medical risks inherent in transplanting adult donor lungs into a pediatric lung transplant candidate? How are these risks reflected in the OPTN lung allocation policy?

The OPTN Final Rule supports the development of organ allocation polices that are based on sound medical judgment and seek to achieve the best use of donated organs. The individual transplant team is responsible for any decision to accept and use an allocated organ for its candidate according to its medical judgment.

Traditionally, donor lungs are matched to recipients based on the relative height match between donor and recipient. This is reflected within the donor acceptance criteria specified by the transplant program for its individual candidate as part of the OPTN matching algorithm. Matching the lung size well to the chest ensures that the lungs are neither under-inflated nor over-inflated when the recipient takes normal-sized breaths. In addition, size matching ensures that the donor and recipient airways and blood vessels are of similar size, thus reducing the complications of surgically connecting them. It also reduces the risk of infection by providing the normal anatomy of the lungs (three lobes on the right, two lobes on the left).

Some transplant programs, using their individual medical judgment, may opt to accept one or both lungs from a larger donor and excise one or more lobes for the transplant into a smaller (pediatric or adult) recipient. A lobar transplant adds complexity to the operation. The connection between the veins draining the lungs must typically be made to existing pulmonary veins; in a traditional transplant, the pulmonary veins are removed from the donor along with a small patch of the donor

heart (from the left atrium) and connected to the recipient by sewing the patch to the heart (left atrium) of the recipient.

Medical literature suggests that outcomes (survival, complications) are comparable when lobes rather than whole lungs are transplanted, but these studies involve small numbers. By directing younger donors (0-11) to younger recipients first, the system reduces the likelihood that lobar transplant would need to be considered. Nonetheless, because of the relatively small number of patients for whom this approach is considered, the allocation system does not take into account the possibility that lobar transplantation carries additional risk.

Should you need additional assistance or information on these or other topics, please let us know. As always, we are committed to maintaining the OPTN in a way that most equitably meets the needs of all transplant candidates, recipients and living donors.

Sincerely,

John P. Roberts, M.D.
President, OPTN Board of Directors

Attachment: thoracic allocation policy

3.7 **ALLOCATION OF THORACIC ORGANS.** This policy describes how thoracic organs (hearts, heart-lung combinations, single and double lungs) are to be allocated to candidates awaiting a thoracic organ transplant.

3.7.1 **Exceptions.** Unless otherwise approved according to Policy 3.4.8 (Variances), or specifically allowed by the exceptions described in this Policy 3.7.1, all thoracic organs must be allocated in accordance with Policy 3.7.

3.7.1.1 **Exception for Sensitized Candidates.** The transplant surgeon or physician for a candidate awaiting thoracic organ transplantation may determine that the candidate is "sensitized" such that the candidate's antibodies would react adversely to certain donor cell antigens. It is permissible not to use the allocation policies set forth in Policy 3.7 for allocation of a particular thoracic organ when all thoracic organ transplant centers within an OPO and the OPO agree to allocate the thoracic organ to a sensitized candidate because results of a crossmatch between the blood serum of that candidate and cells of the thoracic organ donor are negative (i.e., the candidate and thoracic organ donor are compatible). The level of sensitization at which a candidate may qualify for this exception is left to the discretion of the listing transplant center, and subject to agreement among all thoracic organ transplant centers within an OPO and the OPO. Sensitization is not a qualifying criterion for assigning a candidate to a heart status category as described in Policies 3.7.3 (Adult Candidate Status) and 3.7.4 (Pediatric Candidate Status).

3.7.2 **Geographic Sequence of Thoracic Organ Allocation.** Thoracic organs are to be allocated locally first, then within the following zones in the sequence described in Policy 3.7.10 and Policy 3.7.11. Five zones will be delineated by concentric circles of 500, 1,000, and 1,500 and 2,500 nautical mile radii with the donor hospital at the center. Zone A will extend to all transplant centers which are within 500 miles from the donor hospital but which are not in the local area of the donor hospital. Zone B will extend to all transplant centers that are at least 500 miles from the donor hospital but not more than 1,000 miles from the donor hospital. Zone C will extend to all transplant centers that are at least 1,000 miles from the donor hospital but not more than 1,500 miles from the donor hospital. Zone D will extend to all transplant centers that are located beyond 1,500 miles from the donor hospital, but not more than 2,500 miles from the donor hospital. Zone E will extend to all transplant centers that are located beyond 2,500 miles from the donor hospital.

3.7.3 **Adult Candidate Status.** Each candidate awaiting heart transplantation receives a status code corresponding to the candidate's medical urgency for transplant. A heart transplant candidate at least 18 years of age at the time of listing receives a status code as follows:

Status	Definition
Status 1A	A candidate listed as Status 1A is admitted to the listing transplant center hospital (with the exception for a 1A(b) candidate) and has at least one of the following devices or therapies in place:

(a) Mechanical circulatory support for acute hemodynamic decompensation that includes at least one of the following:

(i) left and/or right ventricular assist device implanted Candidates listed under this criterion, may be listed for 30 days at any point after being implanted as Status 1A once the treating

physician determines that they are clinically stable. Admittance to the listing transplant center hospital is not required.

(ii) total artificial heart;

(iii) intra-aortic balloon pump; or

(iv) extracorporeal membrane oxygenator (ECMO).

Qualification for Status 1A under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(b) Mechanical circulatory support with objective medical evidence of significant device-related complications such as thromboembolism, device infection, mechanical failure or life-threatening ventricular arrhythmias. A transplant center can report a complication not listed here. The report of an "other" complication will result in a review by the respective heart regional review board. (Candidate sensitization is not an appropriate device-related complication for qualification as Status 1A under this criterion. The applicability of sensitization to thoracic organ allocation is specified by Policy 3.7.1.1 (Exception for Sensitized Candidates).)

Admittance to the listing center transplant hospital is not required. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(c) Continuous Mechanical ventilation. Qualification for Status 1A under this criterion is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

(d) Continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, in addition to continuous hemodynamic monitoring of left ventricular filling pressures.

Qualification for Status 1A under this criterion is valid for 7 days and may be renewed for an additional 7 days for each occurrence of a Status 1A listing under this criterion for the same candidate. The OPTN contractor shall maintain in the heart status justification form in UNet℠ a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.

Status 1A by Exception

A candidate who does not meet criterion (a), (b), (c), or (d) may nevertheless be Status 1A upon application by his or her transplant physician. The transplant physician must justify to the applicable Regional Review Board why the candidate is considered, using acceptable medical criteria, to have an

urgency and potential for benefit as other candidates in Status 1A. The justification must be for a candidate admitted to his or her listing transplant center hospital and must include a rationale for incorporating the exceptional case as part of Status 1A. ~~Timing of the review of these cases, whether prospective or retrospective, will be left to the discretion of each Regional Review Board.~~ Regional Review Boards will retrospectively review requests for Status 1A exceptions.

A candidate's listing under this exceptional provision is valid for 14 days. Any further extension of the Status 1A listing by exception requires ~~prospective~~ retrospective review and approval by ~~a majority of~~ the Regional Review Board ~~Members~~. If Regional Review Board approval is not given, the candidate's transplant physician may override the Regional Review Board and list the candidate as Status 1A~~, subject to automatic referral to the Thoracic Organ Transplantation Committee~~. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1A Justification Form
A completed Heart Status 1A Justification Form must be submitted in UNet[SM] in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B

A candidate listed as Status 1B has at least one of the following devices or therapies in place:

(aa) left and/or right ventricular assist device implanted; or
(bb) continuous infusion of intravenous inotropes.

Status 1B by Exception
A candidate who does not meet the criteria for Status 1B may nevertheless be listed as Status 1B upon application by his or her transplant physician. The transplant physician must justify to the applicable Regional Review Board why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other Status 1B candidates. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. Regional Review Boards will retrospectively review requests for Status 1B exceptions. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1B Justification Form
A completed Heart Status 1B Justification Form must be submitted to UNet[SM] in order to list a candidate as Status 1B.

Status 2

A candidate who does not meet the criteria for Status 1A or 1B

is listed as Status 2.

Status 7 — A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet℠ within 24 hours of the change in medical condition.

3.7.4 **Pediatric Candidate Status.** Each candidate awaiting heart transplantation receives a status code corresponding to the candidate's medical urgency for transplant. Pediatric heart transplant candidates who have not received a heart transplant before their 18th birthday shall continue to qualify for medical urgency status based on Policy 3.7.4. A heart transplant candidate who is less than 18 years of age at the time of listing receives a status code as follows:

Status	Definition
Status 1A	A candidate listed as Status 1A meets at least one of the following criteria:

(a) Requires assistance with a ventilator;

(b) Requires assistance with a mechanical assist device (e.g., ECMO);

(c) Requires assistance with a balloon pump;

(d) A candidate less than six months old with congenital or acquired heart disease exhibiting reactive pulmonary hypertension at greater than 50% of systemic level. Such a candidate may be treated with prostaglandin E (PGE) to maintain patency of the ductus arteriosus;

(e) Requires infusion of high dose or multiple inotropes (The OPTN contractor shall maintain in the heart status justification form in UNet℠ a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.); or,

(f) A candidate who does not meet the criteria specified in (a), (b), (c), (d), or (e) may be listed as Status 1A if the candidate has a life expectancy without a heart transplant of less than 14 days, such as due to refractory arrhythmia. Qualification for Status 1A under this criterion is valid for 14 days and may be recertified by an attending physician for one additional 14-day period. Any further extension of the Status 1A listing under this criterion requires a retrospective conference with the applicable Regional Review Board. If Regional Review Board approval is not given, the candidate's transplant physician may list the candidate as Status 1A, subject to automatic referral to the Thoracic Organ Transplantation Committee. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ

Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Qualification for Status 1A under criteria (a) through (e) is valid for 14 days and must be recertified by an attending physician every 14 days from the date of the candidate's initial listing as Status 1A to extend the Status 1A listing.

Submission of Status 1A Justification Form
A completed Heart Status 1A Justification Form must be submitted in UNet[SM] in order to list a candidate as Status 1A, or extend his or her listing as Status 1A in accordance with the criteria listed above in Policy 3.7.4. When a candidate's time at Status 1A expires, the candidate will automatically be classified as Status 1B. The attending physician must classify the candidate as Status 2 or 7 if the candidate's medical condition does not qualify for Status 1A or Status 1B.

Status 1B

A candidate listed as Status 1B meets at least one of the following criteria:

(a) Requires infusion of low dose single inotropes (The OPTN contractor shall maintain in the heart status justification form in UNet[SM] a list of the specific inotropes and doses approved by the Board of Directors to be compliant with this criterion.);

(b) Less than six months old and does not meet the criteria for Status 1A; or

(c) Growth failure *i.e.,* less than 5th percentile for weight and/or height, or loss of 1.5 standard deviations of expected growth (height or weight) based on the National Center for Health Statistics for pediatric growth curves.

Note: This criterion defines growth failure as either < 5th percentile for weight and/or height, or loss of 1.5 standard deviation score of expected growth (height or weight). The first measure looks at relative growth as of a single point in time. The second alternative accounts for cases in which a substantial loss in growth occurs between two points in time. Assessment of growth failure using the standard deviation score decrease can be derived by, first, measuring (or using a measure of) the candidate's growth at two different times, second, calculating the candidate's growth velocity between these times, and, third, using the growth velocity to calculate the standard deviation score (*i.e.,* (candidate's growth rate - mean growth rate for age and sex) divided by standard deviation of growth rate for age and sex).

Status 1B by Exception
A candidate who does not meet the criteria for Status 1B may be listed as Status 1B upon application by his transplant physician to the applicable Regional Review Board. The transplant physician must justify why the candidate is considered, using acceptable medical criteria, to have an urgency and potential for benefit as other candidates listed as Status 1B. The justification must include a rationale for incorporating the exceptional case as part of Status 1B. A report of the decision of the Regional Review Board and the basis for it ~~shall~~ may be forwarded for review by the Thoracic Organ Transplantation Committee. The Thoracic Organ Transplantation Committee may refer the case to the Membership and Professional Standards Committee.

Submission of Status 1B Justification Form
A completed Heart Status 1B Justification Form must be submitted in UNet℠ to list a candidate as Status 1B.

Status 2 A candidate who does not meet the criteria for Status 1A or 1B is listed as Status 2.

Status 7 A candidate listed as Status 7 is considered temporarily unsuitable to receive a thoracic organ transplant.

Change in Status 1A or 1B Criterion or Eligibility
If a change in the candidate's medical condition makes the criterion used to justify a candidate's Status 1A or 1B no longer accurate, the transplant program must report the accurate information in UNet℠ within 24 hours of the change in medical condition.

3.7.5 Allocation of Pediatric Donor Hearts to Pediatric Heart Candidates. Within each heart status, a heart retrieved from a pediatric organ donor shall be allocated to a pediatric heart candidate (i.e., less than 18 years old at the time of listing) before the heart is allocated to an adult candidate. For the purpose of Policy 3.7, a pediatric organ donor is defined as an individual who is less than 18 years of age.

3.7.6 Lung Allocation. Candidates waiting for lung transplants receive priority for deceased donor lung offers based on Lung Allocation Score (LAS) if they are at least 12 years of age. Candidates less than 12 years of age receive deceased donor lung offers based on medical urgency priority.

3.7.6.1 Lung Allocation Score (LAS) System for Candidates at Least 12 Years of Age

Candidates who are at least 12 years of age receive offers for deceased donor lungs based on LAS, as well as geography and blood type. Candidates with higher LASs receive higher waiting list priority.

3.7.6.1.1 The LAS Calculation
The LAS calculation uses *all of* the following:

- Waitlist Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list
- Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant

- Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waitlist Urgency Measure

The LAS is determined by normalizing the Raw Allocation Score to a continuous scale of 0 to 100. The Raw Allocation Score is the difference between the Transplant Benefit Measure and the Waitlist Urgency Measure.

The equation for the LAS calculation is:

$$LAS = \frac{100 * [PTAUC - 2 * WLAUC + 730]}{1095}$$

Where... **Includes...**

$$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$$

PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year.

β_i: the coefficient for characteristic i from the waiting list model, according to Table 1.

$$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$$

$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate.

Y_j = the value of the j^{th} characteristic for an individual candidate

α_j = the coefficient for characteristic j from the post-transplant model, according to Table 2.

$$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$$

WLAUC = the area under the waiting list survival probability curve during the next year.

Where...

$$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p}}$$

Includes...

$S_{WL,0}(t)$ = the baseline waiting list survival probability at time t, according to Table 3.

$S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to Table 4.

$S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate

X_i = the value of the i^{th} characteristic for an individual candidate.

Table 1
Factors Used in the Waiting List Morality Calculation: Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (year)	0.0083990318885565*age
2. Bilirubin (mg/dL)	0.0431682188302477*(bilirubin – 1) if bilirubin is more than 1.0 mg/dL (see Policy 3.7.6.1.4) 0 when bilirubin is 1.0 mg/dL or less
3. Bilirubin increase of at least 50%	1.4144058906830200 for Group B (see Policy 3.7.6.1.4) 0 for Groups A, C, and D (see Policy 3.7.6.1.2)
4. Body mass index (BMI; kg/m^2)	0.1261444133358100*(20 – BMI) for BMI less than 20 kg/m^2 0 if BMI is at least 20 kg/m^2
5. Cardiac index prior to any exercise	0.5435368888028200 if the cardiac index is less than 2 $L/min/m^2$ 0 if the cardiac index is at least 2 $L/min/m^2$
6. Central venous pressure (CVP; mm Hg) at rest, prior to any exercise	0.0173841981251578*(CVP – 7) for CVP greater than 7 mm Hg (Group B only – see Policy 3.7.6.1.2.b) 0 if less than or equal to 7 mm Hg for Group B (see Policy 3.7.6.1.2.b) 0 for candidates in Groups A, C, and D (see Policy 3.7.6.1.2)

For this covariate:	The following coefficient is used in the LAS calculation:
7. Ventilation status if candidate is hospitalized	1.6771121096052300 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
8. Creatinine (serum, mg/dL)	0.5034346761960600*creatinine if at least 18 years of age (see Policy 3.7.6.1.5) 0 if less than 18 years of age
9. Diabetes	0.4680254026735700 if diabetic 0 if not diabetic
10. Diagnosis Group A (see Policy 3.7.6.1.2.a for the diseases included in this group)	0
Diagnosis Group B (see Policy 3.7.6.1.2.b for the diseases included in this group)	1.5774243292137200
Diagnosis Group C (see Policy 3.7.6.1.2.c for the diseases included in this group)	1.2313926484343600
Diagnosis Group D (see Policy 3.7.6.1.2.d for the diseases included in this group)	0.6259577164157700
11. Detailed diagnosis: Bronchiectasis (Group A – see Policy 3.7.6.1.2.a)	0.6680518055684700
Detailed diagnosis: Eisenmenger's syndrome (Group B – see Policy 3.7.6.1.2.b)	-0.6278657824830000
Detailed diagnosis: Lymphangioleiomyomatosis (Group A – see Policy 3.7.6.1.2.a)	-0.3162937838984600
Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Group D – see Policy 3.7.6.1.2.d)	0.4453284411081100
Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Group D – see Policy 3.7.6.1.2.d)	-0.2091170018125500
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Group D – see Policy 3.7.6.1.2.d)	-0.4577749354638600

For this covariate:	The following coefficient is used in the LAS calculation:
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Group A – see Policy 3.7.6.1.2.a)	0.9330846239906700
12. Forced vital capacity (FVC)	0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Group D (see Policy 3.7.6.1.2.d) 0 if FVC is greater than or equal to 80% for Group D (see Policy 3.7.6.1.2.d) 0 for candidates in Groups A, B, and C (see Policy 3.7.6.1.2)
13. Functional Status	-0.4471034284458400 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
14. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0213187586203456*O_2 for Group B (see Policy 3.7.6.1.2.b) 0.1188479817592500 for Groups A, C, and D (see Policy 3.7.6.1.2)
15. PCO_2 (mm Hg): current	0.1104609835819100*PCO_2/10 if PCO_2 is at least 40 mm Hg (see Policy 3.7.6.1.3)
16. PCO_2 increase of at least 15% (see Policy 3.7.6.1.3)	0.2331149280428300 if PCO_2 increase is at least 15% (see Policy 3.7.6.1.3) 0 if PCO_2 increase is less than 15% (see Policy 3.7.6.1.3)
17. Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.4155116686114300*(PA systolic – 40)/10 for Group A if the PA systolic pressure is greater than 40 mm Hg (see Policy 3.7.6.1.2.a) 0 for Group A if the PA systolic pressure is 40 mm Hg or less (see Policy 3.7.6.1.2.a) 0.0462410402627318*PA systolic/10 for Groups B, C, and D (see Policy 3.7.6.1.2)

For this covariate:	The following coefficient is used in the LAS calculation:
18. Six minute walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	-0.0844896372724000*Six-minute walk distance/100

~~Table 1~~
~~Factors Used to Predict Risk of Death on the Lung Transplant Waitlist~~

~~1. Forced vital capacity (FVC)~~
~~2. Pulmonary artery (PA) systolic pressure (Groups A, C, and D[1] – see 3.7.6.1.a)~~
~~3. O_2 required at rest (Groups A, C, and D[1] – see 3.7.6.1.a)~~
~~4. Age~~
~~5. Body mass index (BMI)~~
~~6. Diabetes~~
~~7. Functional Status~~
~~8. Six-minute walk distance~~
~~9. Continuous mechanical ventilation~~
~~10. Diagnosis~~
~~11. PCO_2 (see 3.7.6.1.b)~~

Table 2
Factors Used in the Post-Transplant Survival Calculation:
Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (years)	0.024657983127186 9*(age – 45) if greater than 45 years of age 0 if 45 years of age or younger
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if at least 18 years of age (see Policy 3.7.6.1.5) 0 if less than 18 years of age

For this covariate:	The following coefficient is used in the LAS calculation:
3. Creatinine increase of at least 150%	0.770861602469810 0 if increase in creatinine is at least 150%, and when the higher value determining this increase is at least 1 mg/dL (see Policy 3.7.6.1.5) 0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL (see Policy 3.7.6.1.5) 0 if increase in creatinine less than 150% or creatinine decreases (see Policy 3.7.6.1.5)
4. Cardiac index (L/min/m^2) at rest, prior to any exercise	0.3499381679822400 if less than 2 L/min/m^2 0 if at least 2 L/min/m^2
5. Ventilation status if candidate is hospitalized	0.6094478988424900 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
6. Diagnosis Group A (see Policy 3.7.6.1.2.a for the diseases included in this group)	0
Diagnosis Group B (see Policy 3.7.6.1.2.b for the diseases included in this group)	0.6115547319209300
Diagnosis Group C (see Policy 3.7.6.1.2.c for the diseases included in this group)	0.3627014422464200
Diagnosis Group D (see Policy 3.7.6.1.2.d for the diseases included in this group)	0.4641392063023200
7. Detailed diagnosis: Bronchiectasis (Group A – see Policy 3.7.6.1.2.a)	0.1889100379099400
Detailed diagnosis: Eisenmenger's syndrome (Group B – see Policy 3.7.6.1.2.b)	0.9146727886744700
Detailed diagnosis: Lymphangioleiomyomatosis (Group A – see Policy 3.7.6.1.2.a)	-1.5194416206749400
Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Group D – see Policy 3.7.6.1.2.d)	-1.2050508750702600

For this covariate:	The following coefficient is used in the LAS calculation:
Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Group D – see Policy 3.7.6.1.2.d)	-0.0723596761367600
Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Group D – see Policy 3.7.6.1.2.d)	-0.0437880049066331
Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Group A – see Policy 3.7.6.1.2.a)	-0.1389363636019300
8. Oxygen needed to maintain adequate oxygen saturation (80% or greater) at rest (L/min)	0.0747978926517300*O_2 for Group A (see Policy 3.7.6.1.2.a) 0.0164276945879309 for Groups B, C, and D (see Policy 3.7.6.1.2)
9. Functional Status	-0.1900086366785100 if no assistance needed with activities for daily living 0 if some or total assistance needed with activities for daily living
10. Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	0.0004594953809594*(1200-6mw) 0 if six-minute-distance-walked is at least 1200 feet

~~Table 2~~
~~Factors that Predict Survival after Lung Transplant~~

~~1. FVC (Groups B and D – see 3.7.6.1.a)~~
~~2. PCW pressure ≥ 20 (Group D – see 3.7.6.1.a)~~
~~3. Continuous mechanical ventilation~~
~~4. Age~~
~~5. Serum Creatinine~~
~~6. Functional Status~~
~~7. Diagnosis~~

Tables 3 and 4 provide the baseline waiting list and post-transplant survival probabilities, which are used in the LAS calculation.

Table 3: Baseline Waiting List Survival Function Probability

Time (days) t	S(t)	Time (days) t	S(t)	Time (days) t	S(t)	Time (days) t	S(t)	Time (days) t	S(t)
0	1.000000	50	0.999538	99	0.999076	148	0.998540	197	0.997755
1	0.999954	51	0.999538	100	0.999076	149	0.998540	198	0.997755
2	0.999954	52	0.999538	101	0.999076	150	0.998540	199	0.997755
3	0.999954	53	0.999307	102	0.999076	151	0.998540	200	0.997755
4	0.999954	54	0.999307	103	0.999076	152	0.998514	201	0.997521
5	0.999838	55	0.999307	104	0.999076	153	0.998514	202	0.997521
6	0.999838	56	0.998191	105	0.998845	154	0.998343	203	0.997521
7	0.999838	57	0.998191	106	0.998845	155	0.998343	204	0.997521
8	0.999838	58	0.998191	107	0.998845	156	0.998245	205	0.997521
9	0.999838	59	0.998191	108	0.998845	157	0.998245	206	0.997521
10	0.999838	60	0.998191	109	0.998845	158	0.998245	207	0.997521
11	0.999838	61	0.998191	110	0.998845	159	0.998245	208	0.997521
12	0.999838	62	0.998191	111	0.998845	160	0.998245	209	0.997521
13	0.999838	63	0.998073	112	0.998845	161	0.998245	210	0.997521
14	0.999838	64	0.998073	113	0.998845	162	0.998245	211	0.997521
15	0.999838	65	0.998073	114	0.998845	163	0.998245	212	0.997521
16	0.999838	66	0.998073	115	0.998845	164	0.998245	213	0.997521
17	0.999838	67	0.998073	116	0.998845	165	0.998245	214	0.997521
18	0.999838	68	0.998073	117	0.998845	166	0.998245	215	0.997521
19	0.999838	69	0.998073	118	0.998845	167	0.998245	216	0.997521
20	0.999838	70	0.998073	119	0.998845	168	0.998245	217	0.997521
21	0.999838	71	0.998073	120	0.998845	169	0.998245	218	0.997521
22	0.999838	72	0.998073	121	0.998845	170	0.998245	219	0.997521
23	0.999838	73	0.998073	122	0.998845	171	0.998245	220	0.997521
24	0.999838	74	0.998073	123	0.998845	172	0.998245	221	0.997521
25	0.999838	75	0.998073	124	0.998845	173	0.998245	222	0.997521
26	0.999838	76	0.998073	125	0.998845	174	0.998245	223	0.997521
27	0.999838	77	0.998073	126	0.998845	175	0.998245	224	0.997521
28	0.999838	78	0.998073	127	0.998845	176	0.998245	225	0.997521
29	0.999838	79	0.998073	128	0.998845	177	0.998245	226	0.997521
30	0.999838	80	0.998073	129	0.998845	178	0.998245	227	0.997521
31	0.999838	81	0.998073	130	0.998845	179	0.998245	228	0.997521
32	0.999838	82	0.998073	131	0.998845	180	0.998245	229	0.997521
33	0.999838	83	0.998073	132	0.998845	181	0.998245	230	0.997521
34	0.999838	84	0.998073	133	0.998845	182	0.998245	231	0.997521
35	0.999838	85	0.998073	134	0.998845	183	0.998245	232	0.997521
36	0.999838	86	0.998073	135	0.998845	184	0.998245	233	0.997521
37	0.999838	87	0.998073	136	0.998845	185	0.998245	234	0.997521
38	0.999838	88	0.998073	137	0.998845	186	0.998245	235	0.997521
39	0.999838	89	0.998073	138	0.998845	187	0.998245	236	0.997521
40	0.999838	90	0.998073	139	0.998845	188	0.998245	237	0.997521
41	0.999838	91	0.998073	140	0.998845	189	0.998245	238	0.997521
42	0.999838	92	0.998073	141	0.998845	190	0.998245	239	0.997521
43	0.999838	93	0.998073	142	0.998845	191	0.998245	240	0.997521
44	0.999838	94	0.998073	143	0.998845	192	0.998245	241	0.997521
45	0.999838	95	0.998073	144	0.998845	193	0.998245	242	0.997521
46	0.999838	96	0.998073	145	0.998845	194	0.998245	243	0.997521
47	0.999838	97	0.998073	146	0.998845	195	0.998245	244	0.997521
48	0.999838	98	0.998073	147	0.998845	196	0.998245	245	0.997521

Table 3: Baseline Waiting List Survival ($S_{WL}(t)$) Probability (Continued)

Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$	Time (days) t	$S_{WL}(t)$
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
218	0.[illegible]	220	0.[illegible]	222	0.[illegible]	224	0.[illegible]	226	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
219	0.[illegible]	221	0.[illegible]	223	0.[illegible]	225	0.[illegible]	227	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
220	0.[illegible]	222	0.[illegible]	224	0.[illegible]	226	0.[illegible]	228	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
221	0.[illegible]	223	0.[illegible]	225	0.[illegible]	227	0.[illegible]	229	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
222	0.[illegible]	224	0.[illegible]	226	0.[illegible]	228	0.[illegible]	230	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
223	0.[illegible]	225	0.[illegible]	227	0.[illegible]	229	0.[illegible]	231	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
224	0.[illegible]	226	0.[illegible]	228	0.[illegible]	230	0.[illegible]	232	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
225	0.[illegible]	227	0.[illegible]	229	0.[illegible]	231	0.[illegible]	233	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
226	0.[illegible]	228	0.[illegible]	230	0.[illegible]	232	0.[illegible]	234	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
227	0.[illegible]	229	0.[illegible]	231	0.[illegible]	233	0.[illegible]	235	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
228	0.[illegible]	230	0.[illegible]	232	0.[illegible]	234	0.[illegible]	236	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
229	0.[illegible]	231	0.[illegible]	233	0.[illegible]	235	0.[illegible]	237	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
230	0.[illegible]	232	0.[illegible]	234	0.[illegible]	236	0.[illegible]	238	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
231	0.[illegible]	233	0.[illegible]	235	0.[illegible]	237	0.[illegible]	239	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
232	0.[illegible]	234	0.[illegible]	236	0.[illegible]	238	0.[illegible]	240	0.[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
233	0.[illegible]	235	0.[illegible]	237	0.[illegible]	239	0.[illegible]	241	0.[illegible]

Table 4: Baseline Post-Transplant Survival ($S_{0,t}$) Probability

Time (days) t	$S_{0,t}$	Time (days) t	$S_{0,t}$	Time (days) t	$S_{0,t}$	Time (days) t	$S_{0,t}$	Time (days) t	$S_{0,t}$
0	1.000000	42	0.981914	84	0.972416	127	0.964078	169	0.954116
1	0.999345	43	0.981914	85	0.972416	128	0.964078	170	0.954116
2	0.998691	44	0.981914	86	0.972416	129	0.964078	171	0.954116
3	0.998691	45	0.981914	87	0.972416	130	0.964078	172	0.954116
4	0.998691	46	0.981914	88	0.972416	131	0.964078	173	0.954116
5	0.998691	47	0.981914	89	0.972416	132	0.964078	174	0.954116
6	0.998691	48	0.981914	90	0.972416	133	0.964078	175	0.954116
7	0.998691	49	0.981914	91	0.972416	134	0.964078	176	0.954116
8	0.998691	50	0.981914	92	0.972416	135	0.964078	177	0.954116
9	0.998691	51	0.981914	93	0.972416	136	0.964078	178	0.954116
10	0.998691	52	0.981914	94	0.972416	137	0.964078	179	0.954116
11	0.998691	53	0.981914	95	0.972416	138	0.964078	180	0.954116
12	0.998691	54	0.981914	96	0.972416	139	0.964078	181	0.954116
13	0.998691	55	0.981914	97	0.972416	140	0.964078	182	0.954116
14	0.998691	56	0.981914	98	0.972416	141	0.964078	183	0.954116
15	0.998691	57	0.981914	99	0.972416	142	0.964078	184	0.954116
16	0.998691	58	0.981914	100	0.972416	143	0.964078	185	0.954116
17	0.998691	59	0.981914	101	0.972416	144	0.964078	186	0.954116
18	0.998691	60	0.981914	102	0.972416	145	0.964078	187	0.954116
19	0.998691	61	0.981914	103	0.972416	146	0.964078	188	0.954116
20	0.998691	62	0.981914	104	0.972416	147	0.964078	189	0.954116
21	0.998691	63	0.981914	105	0.972416	148	0.964078	190	0.954116
22	0.998691	64	0.981914	106	0.972416	149	0.964078	191	0.954116
23	0.998691	65	0.981914	107	0.972416	150	0.964078	192	0.954116
24	0.998691	66	0.981914	108	0.972416	151	0.964078	193	0.954116
25	0.998691	67	0.981914	109	0.972416	152	0.964078	194	0.954116
26	0.998691	68	0.981914	110	0.972416	153	0.964078	195	0.954116
27	0.998691	69	0.981914	111	0.972416	154	0.964078	196	0.954116
28	0.998691	70	0.981914	112	0.972416	155	0.964078	197	0.954116
29	0.998691	71	0.981914	113	0.972416	156	0.964078	198	0.954116
30	0.998691	72	0.981914	114	0.972416	157	0.964078	199	0.954116
31	0.998691	73	0.981914	115	0.972416	158	0.964078	200	0.954116
32	0.998691	74	0.981914	116	0.972416	159	0.964078	201	0.954116
33	0.998691	75	0.981914	117	0.972416	160	0.964078	202	0.954116
34	0.998691	76	0.981914	118	0.972416	161	0.964078	203	0.954116
35	0.998691	77	0.981914	119	0.972416	162	0.964078	204	0.954116
36	0.998691	78	0.981914	120	0.972416	163	0.964078	205	0.954116
37	0.998691	79	0.981914	121	0.972416	164	0.964078	206	0.954116
38	0.998691	80	0.981914	122	0.972416	165	0.964078	207	0.954116
39	0.998691	81	0.981914	123	0.972416	166	0.964078	208	0.954116
40	0.998691	82	0.981914	124	0.972416	167	0.964078	209	0.954116
41	0.998691	83	0.981914	125	0.972416	168	0.964078	210	0.954116
42	0.998691	84	0.981914	126	0.972416	169	0.964078	211	0.954116
43	0.998691	85	0.981914	127	0.972416	170	0.964078	212	0.954116
44	0.998691	86	0.981914	128	0.972416	171	0.964078	213	0.954116
45	0.998691	87	0.981914	129	0.972416	172	0.964078	214	0.954116
46	0.998691	88	0.981914	130	0.972416	173	0.964078	215	0.954116
47	0.998691	89	0.981914	131	0.972416	174	0.964078	216	0.954116
48	0.998691	90	0.981914	132	0.972416	175	0.964078	217	0.954116
49	0.998691	91	0.981914	133	0.972416	176	0.964078	218	0.954116
50	0.998691	92	0.981914	134	0.972416	177	0.964078	219	0.954116
51	0.998691	93	0.981914	135	0.972416	178	0.964078	220	0.954116
52	0.998691	94	0.981914	136	0.972416	179	0.964078	221	0.954116
53	0.998691	95	0.981914	137	0.972416	180	0.964078	222	0.954116
54	0.998691	96	0.981914	138	0.972416	181	0.964078	223	0.954116
55	0.998691	97	0.981914	139	0.972416	182	0.964078	224	0.954116
56	0.998691	98	0.981914	140	0.972416	183	0.964078	225	0.954116
57	0.998691	99	0.981914	141	0.972416	184	0.964078	226	0.954116
58	0.998691	100	0.981914	142	0.972416	185	0.964078	227	0.954116
59	0.998691	101	0.981914	143	0.972416	186	0.964078	228	0.954116
60	0.998691	102	0.981914	144	0.972416	187	0.964078	229	0.954116
61	0.998691	103	0.981914	145	0.972416	188	0.964078	230	0.954116
62	0.998691	104	0.981914	146	0.972416	189	0.964078	231	0.954116
63	0.998691	105	0.981914	147	0.972416	190	0.964078	232	0.954116
64	0.998691	106	0.981914	148	0.972416	191	0.964078	233	0.954116
65	0.998691	107	0.981914	149	0.972416	192	0.964078	234	0.954116
66	0.998691	108	0.981914	150	0.972416	193	0.964078	235	0.954116
67	0.998691	109	0.981914	151	0.972416	194	0.964078	236	0.954116
68	0.998691	110	0.981914	152	0.972416	195	0.964078	237	0.954116
69	0.998691	111	0.981914	153	0.972416	196	0.964078	238	0.954116
70	0.998691	112	0.981914	154	0.972416	197	0.964078	239	0.954116
71	0.998691	113	0.981914	155	0.972416	198	0.964078	240	0.954116
72	0.998691	114	0.981914	156	0.972416	199	0.964078	241	0.954116

Table 4: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability (Continued)

Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$	Time (days): t	$S_{TX}(t)$
344	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
345	[illegible]	375	[illegible]	363	[illegible]	393	[illegible]	347	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
347	[illegible]	377	[illegible]	364	[illegible]	394	[illegible]	348	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
349	[illegible]	378	[illegible]	366	[illegible]	396	[illegible]	349	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
351	[illegible]	379	[illegible]	367	[illegible]	397	[illegible]	350	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
353	[illegible]	380	[illegible]	368	[illegible]	398	[illegible]	351	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
355	[illegible]	382	[illegible]	369	[illegible]	399	[illegible]	352	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
356	[illegible]	384	[illegible]	370	[illegible]	400	[illegible]	353	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
357	[illegible]	385	[illegible]	371	[illegible]	401	[illegible]	354	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
358	[illegible]	386	[illegible]	372	[illegible]	402	[illegible]	355	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
359	[illegible]	387	[illegible]	373	[illegible]	403	[illegible]	356	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
360	[illegible]	388	[illegible]	374	[illegible]	404	[illegible]	357	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
361	[illegible]	389	[illegible]	375	[illegible]	405	[illegible]	358	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
362	[illegible]	390	[illegible]	376	[illegible]	406	[illegible]	359	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
363	[illegible]	391	[illegible]	377	[illegible]	407	[illegible]	360	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
364	[illegible]	392	[illegible]	378	[illegible]	408	[illegible]	361	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
365	[illegible]	393	[illegible]	379	[illegible]	409	[illegible]	362	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
366	[illegible]	394	[illegible]	380	[illegible]	410	[illegible]	363	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
367	[illegible]	395	[illegible]	381	[illegible]	411	[illegible]	364	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

3.7.6.1.2 Lung Disease Diagnosis Group Classification in the Lung Allocation Score (LAS)

The LAS calculation includes four diagnosis groups: A, B, C, and D. The diagnoses that comprise each group are:

a. Group A
- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

b. Group B
- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: Patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: Ventricular septal defect (VSD)
- Portopulmonary hypertension
- Primary pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

c. Group C
- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

d. Group D
- ABCA3 transporter mutation
- Alveolar proteinosis

- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchoalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with one or more of the following disease entities:
  - Acute interstitial pneumonia
  - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
  - Desquamative interstitial pneumonia
  - Idiopathic pulmonary fibrosis
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia
  - Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- Scleroderma – restrictive
- Secondary pulmonary fibrosis (specify cause)
- Silicosis
- Sjogren's syndrome
- Surfactant protein B mutation
- Surfactant protein C mutation
- Teratoma
- Wegener's granuloma – restrictive

3.7.6.1.3 PCO_2 in the Lung Allocation Score (LAS)

UNet[SM] will use two measures of PCO_2 in a candidate's lung allocation score calculation: current PCO_2, and change in PCO_2. There are two types of PCO_2 change calculations: "threshold change" and "threshold change maintenance." The following explanations (a-f) and illustrations (Figures 1-3) detail how UNet[SM] uses PCO_2 in the lung allocation score.

a. *Use of Arterial, Venous, or Capillary PCO_2 Values*
In UNet[SM], a center may enter a PCO_2 value from an arterial, venous, or capillary blood gas test. UNet[SM] will convert a venous or capillary value to estimate an arterial value as follows:
   - a capillary value will equal an arterial value; and,
   - UNet[SM] will subtract 6 mmHg from a venous value to equal an arterial value.

   In the lung allocation score calculation, UNet[SM] will use the PCO_2 value with the most recent test date, regardless of the blood gas type. Exception: if an arterial value and either a venous or capillary value have the same test date, UNet[SM] will use the arterial value in the lung allocation score calculation.

b. *Definition of Current PCO_2*
Current PCO_2 is the PCO_2 value with the most recent test date entered in UNet[SM].

c. *Expiration of Current PCO_2 Value*
UNet[SM] will evaluate a current PCO_2 value as expired according to Policy 3.7.6.3.

d. *Use of Normal Clinical Value for Current PCO_2*
The normal clinical value of PCO_2 is 40 mmHg. UNet[SM] will substitute this normal clinical value in the lung allocation score calculation when the value of current PCO_2 is less than 40 mmHg, missing, or expired.

e. *PCO_2 Values Used in the Change Calculations*
There are two types of PCO_2 change calculations: threshold change and threshold change maintenance.
The threshold change calculation evaluates whether the PCO_2 change is 15% or higher. In this calculation, UNet[SM] will use highest and lowest values of PCO_2. The test date of the lowest value must be earlier than the test date of the highest value. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet[SM] will use an expired lowest value, but not an expired highest value. If a value is less than 40 mmHg, UNet[SM] will substitute the normal clinical value of 40 mmHg before calculating change. The equation for threshold change is:

$$\frac{\textbf{Highest } PCO_2 \textbf{-Lowest } PCO_2}{\textbf{Lowest } PCO_2}$$

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact

from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current PCO_2 value must be at least 15% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is:

$$\frac{\text{Current } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

UNet[SM] will perform the threshold change maintenance calculation either when the current PCO_2 value expires (Policy 3.7.6.3) or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the threshold change calculation. If a current PCO_2 value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current PCO_2 value expires, UNet[SM] will substitute that expired value with the normal clinical value of 40 mmHg. This normal value, therefore, cannot be 15% *higher* than the lowest value in the threshold change calculation.

If a center enters a new current PCO_2 value for a candidate who has lost the impact from threshold change, UNet[SM] will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the threshold change calculation, UNet[SM] will *reapply* the impact from threshold change to the candidate's lung allocation score.

f. *Impact of PCO_2 Threshold Change in the Lung Allocation Score*

A change in PCO_2 that is 15% or higher, or threshold change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current PCO_2 is at least 15% higher than the lowest value used in the threshold change calculation.

Figure 1
Use of Current PCO_2 in the Lung Allocation Score

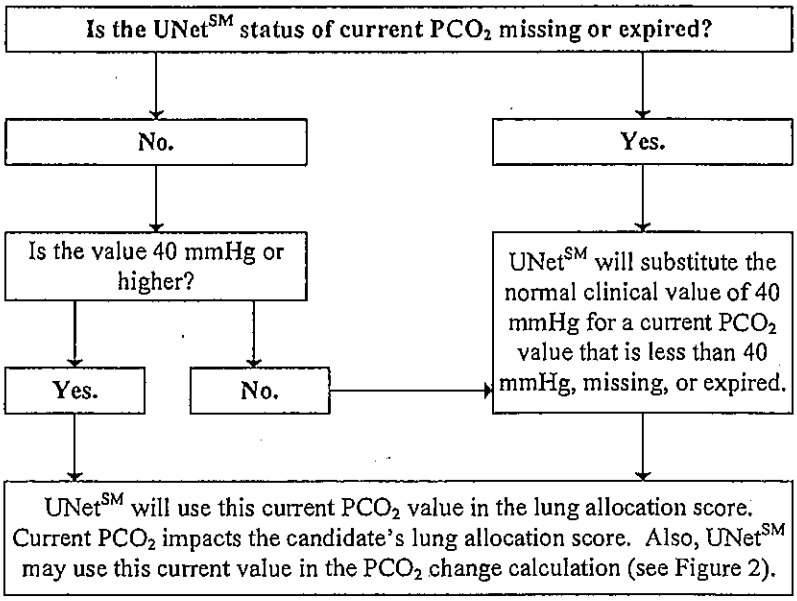


Figure 2
PCO_2 Threshold Change Calculation

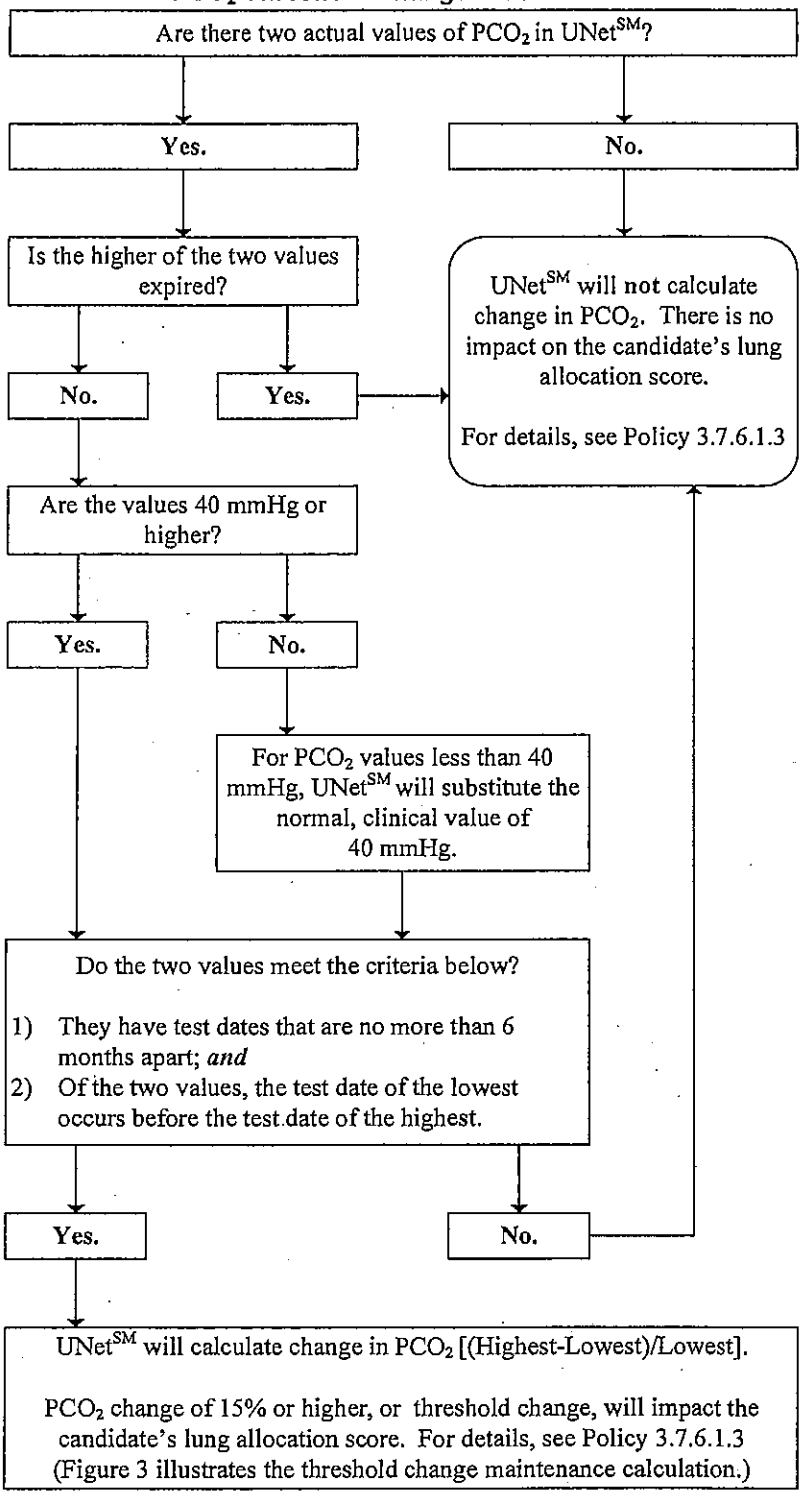
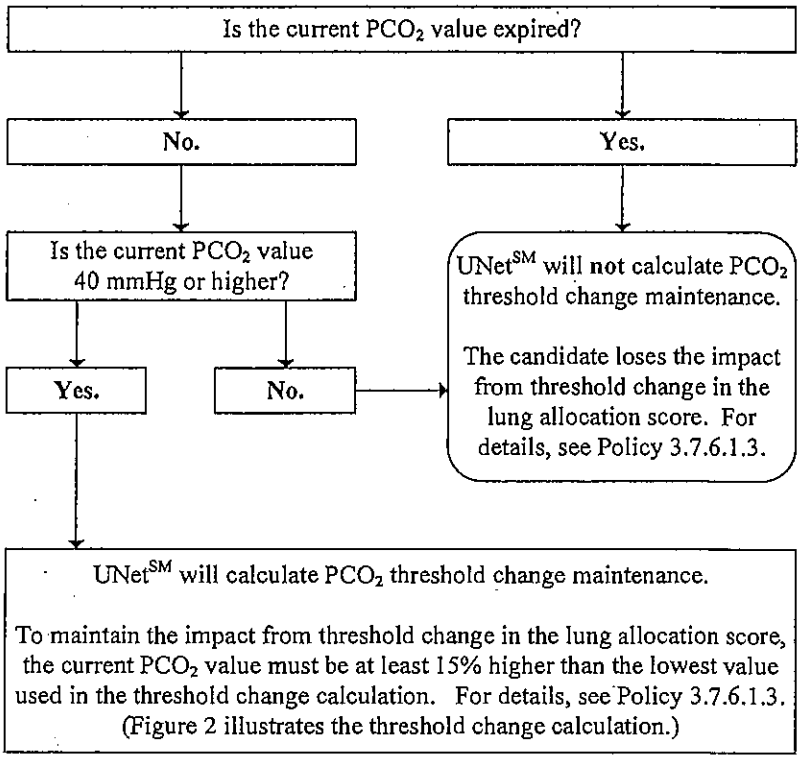


Figure 3
PCO_2 Threshold Change Maintenance Calculation



3.7.6.1.4 Bilirubin in the Lung Allocation Score (LAS)

UNet[SM] will use two measures of total bilirubin in a candidate's lung allocation score calculation: current bilirubin (for all candidates), and change in bilirubin (for Group B only). There are two types of bilirubin change calculations: "threshold change" and "threshold change maintenance." This section of Policy 3.7.6.1 explains how UNet[SM] uses bilirubin in the lung allocation score.

a. *Definition of Current Bilirubin*
Current bilirubin is the total bilirubin value with the most recent test date and time entered in UNet[SM]. UNet[SM] will include in the lung allocation score calculation a current bilirubin value that is at least 1.0 mg/dL.

b. *Expiration of Current Bilirubin Value*
UNet[SM] will evaluate a current bilirubin value as expired according to Policy 3.7.6.3.

c. *Use of Normal Clinical Value for Current Bilirubin*
The normal clinical value of current bilirubin is 0.7 mg/dL. UNet[SM] will substitute this normal clinical value in the lung allocation score calculation when the value of current bilirubin is less than 0.7 mg/dL, missing, or expired.

d. *Bilirubin Values Used in the Change Calculations (Group B Only)*

There are two types of bilirubin change calculations: threshold change and threshold change maintenance.
The threshold change calculation evaluates whether the bilirubin change is 50% or higher. In this calculation, UNet[SM] will use highest and lowest values of bilirubin. The test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of these highest and lowest values cannot be more than 6 months apart. If necessary, UNet[SM] will use an expired lowest value, but not an expired highest value. If a value is less than 0.7 mg/dL, UNet[SM] will substitute the normal clinical value of 0.7 mg/dL before calculating change. The equation for threshold change is:

$$\frac{\text{Highest Bilirubin-Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

The threshold change maintenance calculation occurs *after* the candidate receives the impact from threshold change in the lung allocation score. This maintenance calculation determines the candidate's eligibility for retaining the impact from threshold change in the lung allocation score. To maintain the impact from threshold change in the lung allocation score, the current bilirubin value must be at least 50% higher than the lowest value used in the threshold change calculation. The equation for threshold change maintenance is:

$$\frac{\text{Current Bilirubin-Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

UNet[SM] will perform the threshold change maintenance calculation either when the current bilirubin value expires (Policy 3.7.6.3) or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the threshold change calculation. If a current bilirubin value expires, the candidate's lung allocation score will lose the impact from threshold change. The reason for this loss is that when a current bilirubin value expires, UNet[SM] will substitute that expired value with the normal clinical value of 0.7 mg/dL. This normal value, therefore, cannot be 50% *higher* than the lowest value in the threshold change calculation.

If a center enters a new current bilirubin value for a candidate who has lost the impact from threshold change, UNet[SM] will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the threshold change calculation, UNet[SM] will *reapply* the impact from threshold change to the candidate's lung allocation score.

e. *Impact of Bilirubin Threshold Change in the Lung Allocation Score (Group B only)*
A change in bilirubin that is 50% or higher, or threshold

change, will impact a candidate's lung allocation score. The candidate will not lose the lung allocation score impact from threshold change provided that the current bilirubin is at least 50% higher than the lowest value used in the threshold change calculation.

3.7.6.1.5 Creatinine in the Lung Allocation Score (LAS)

The LAS calculation uses two measures of creatinine: current creatinine and increase in creatinine.

a. Current Creatinine
Current creatinine is the serum creatinine value from the most recent test date and time reported to the OPTN Contractor. The LAS calculation only uses current creatinine for candidates who are at least 18 years of age.

b. Increase in Creatinine
An increase in creatinine will influence a candidate's LAS only if it is at least 150%. The Increase-In-Creatinine calculation uses the highest and lowest values of creatinine. For this variable to impact a candidate's LAS, the test date of the lowest value must be earlier than the test date of the highest value. The highest value must be at least 1.0 mg/dL. Test dates of the highest and lowest values cannot be more than 6 months apart. The Increase-In-Creatinine calculation can use an expired lowest value, but not an expired highest value. The equation for this increase-in-creatinine calculation is:

$$\frac{\textbf{Highest Creatinine-Lowest Creatinine}}{\textbf{Lowest Creatinine}}$$

If a candidate's LAS is influenced by an increase in creatinine, then the LAS calculation will assess whether to maintain that influence. To maintain the influence of the increase in creatinine, the candidate's current creatinine value must be at least 150% higher than the lowest value used in the Increase-In-Creatinine calculation. The equation for this maintenance calculation is:

$$\frac{\textbf{Current Creatinine-Lowest Creatinine}}{\textbf{Lowest Creatinine}}$$

If the current creatinine value expires or a new creatinine value is entered, then the increase maintenance calculation will occur.

3.7.6.2 Candidates Age 0 - 11. UNet^{SM} ranks candidates who are 0 – 11 years old for lung offers according to the priorities defined below. Within each priority, UNet^{SM} will rank candidates by ABO (according to Policy 3.7.8.2) and then by waiting time, in descending order. For Priority 1, UNet^{SM} will only consider the most current period of time a candidate has spent as Priority 1, i.e, UNet^{SM} will not tally the time waiting during multiple Priority 1 periods. For Priority 2, and if there is ever a tie among Priority 1 candidates, UNet^{SM} will use these candidates' total waiting time to determine the order for receiving lung offers. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive.

A program may update clinical data used to justify a candidate's priority at any time it believes a candidate's medical condition warrants such modifications. For a candidate listed as Priority 1, a program must update each qualifying criterion, except that which is obtained only by heart catheterization, at least once in each six month period following the candidate's registration on the lung Waitlist[SM]. If more than six months elapse without data updates after the candidate's last six-month "anniversary" of his or her Waitlist[SM] registration, then the candidate's Priority 1will revert to Priority 2. UNet[SM] will assess the currency of lung variables for each candidate on every six-month "anniversary" date. (For example, if a candidate is first registered on the Waitlist[SM] on January 1, 2011, and the most recent six-month "anniversary" is January 1, 2012, then UNet[SM] will consider any variables collected on or after July 1, 2011 as current until June 30, 2012. UNet[SM] will reassess the currency of the lung variables on July 1, 2012, and then any variables with test dates that are on or after January 1, 2012 would be considered current.)

Priority 1: Candidates with one or more of the following criteria:

- **Respiratory failure, defined as:**
  - Requiring continuous mechanical ventilation; ***or***
  - Requiring supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% in order to maintain oxygen saturation levels greater than 90%; ***or,***
  - Having an arterial or capillary PCO_2 greater than 50 mmHg, or a venous PCO_2 greater than 56mmHg.

- **Pulmonary hypertension, defined as:**
  - Having pulmonary vein stenosis involving 3 or more vessels; ***or***
  - Exhibiting any of the following, in spite of medical therapy: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index less than 2 L/min/M^2, syncope, or hemoptysis

    Examples of accepted medical therapy for pulmonary hypertension will be listed in UNet[SM]. Transplant centers must indicate which of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant center must submit an exception request to the Lung Review Board as described below.

- **An exception case approved by the Lung Review Board:**
  - In its review of exception requests, the Lung Review Board will follow the ~~prospective~~ retrospective review process described in Policy 3.7.6.4 (Lung Candidates with Exceptional Cases).

Priority 2: Candidates who do not meet the criteria for Priority 1 must be listed as Priority 2.

3.7.6.3 Reporting Data for Candidates Who Receive Lung Allocation Scores (LAS)

When registering a candidate who is at least 12 years of age for lung transplantation, transplant programs must report to the OPTN Contractor clinical data corresponding to the covariates shown in Tables 1 and 2 in Policy 3.7.6.1.1. Data reported upon registering the candidate must be no more than six months older than the registration date. The transplant program must maintain source documentation for

the reported data in the candidate's chart.

Except as noted in Policy 3.7.6.3.1, transplant programs must report to the OPTN Contractor each element of a candidate's clinical data at every six-month anniversary date. A six-month anniversary date first occurs six months after the date of initial registration, then every six months after. A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. Actual values or estimated values for pulmonary pressures are valid until the transplant program submits new actual values or new estimated values to the OPTN Contractor according to Policy 3.7.6.4.

Transplant programs may determine how often to update clinical data that must be obtained through heart catheterization. However, if a transplant program performs a heart catheterization on the candidate during any six month interval, then it must report the relevant results to the OPTN Contractor. The transplant program must maintain source documentation of all heart catheterization test results in the candidate's chart.

If values for certain covariates are missing, expired, or below a threshold as defined by Table 5, then the LAS calculation will substitute normal or least beneficial values to calculate the candidate's LAS. A normal value is one that a healthy individual is likely to exhibit. A least beneficial value is one that will calculate the lowest LAS for a candidate. Table 5 lists the normal and least beneficial values that will be substituted.

Table 5
Data Substituted for Missing, Expired, or Below Threshold Actual Values in Calculating the LAS

If this covariate's value is missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
Bilirubin: current	1.0 mg/dL if the actual value is missing, expired, or less than 1.0 mg/dL
Body mass index (BMI)	100 kg/m^2 if the actual value is missing or expired
Cardiac index	3.0 $L/min/m^2$ if the actual value is missing
Central venous pressure (CVP)	5 mm Hg if the actual value is missing or less than 5 mm Hg
Continuous mechanical ventilation	No mechanical ventilation in the waiting list model if the actual value is missing or expired Continuous mechanical ventilation in the post-transplant model if the actual value is missing or expired
Creatinine: serum	0.1 mg/dL in the waiting list model if the actual value is missing or expired 40 mg/dL in the post-transplant model for candidates at least 18 years of age if the actual value is missing or expired

If this covariate's value is missing, expired, or below the threshold value:	Then the LAS calculation will use this substituted value:
	0 mg/dL in the post-transplant model for candidates less than 18 years of age if the actual value is missing or expired
Diabetes	No diabetes if the actual value is missing or expired
Forced vital capacity (FVC)	150% for Group D if the actual value is missing or expired, according to Policy 3.7.6.1.2(d)
Functional status	No assistance needed in the waiting list model if the actual value is missing or expired Some or total assistance needed in the post-transplant model if the actual value is missing or expired
Oxygen needed at rest	No supplemental oxygen needed in the waiting list model if the actual value is missing or expired 26.33 L/min in the post-transplant model if the actual value is missing or expired
PCO_2: current	40 mm Hg if the actual value is missing, expired, or less than 40 mm Hg
Pulmonary artery (PA) systolic pressure	20 mm Hg if the actual value is missing or less than 20 mm Hg
Six minute walk distance	4000 feet in the waiting list urgency model if the actual value is missing or expired 0 feet in the post-transplant survival model if the actual value is missing or expired

Programs are permitted to enter a medically reasonable estimated value if a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a candidate. Before entering such estimated values, programs must receive approval from the Lung Review Board, which will determine whether the estimated values are appropriate. Estimated values will remain valid until those values are either updated with an actual value, or a new estimated value is entered according to Policy 3.7.6.4.

~~**3.7.6.3 Candidate Variables in UNet℠.** Entry into UNet℠ of candidate clinical data corresponding to the variables shown in Tables 1 and 2 in Policy 3.7.6.1 is required when listing a candidate for lung transplantation. Diagnosis, birth date (used to calculate age), height and weight (used to calculate BMI) must be entered for a candidate to be added to the waitlist. Candidates will receive a Lung Allocation Score of zero if the Functional Status class or assisted ventilation variable is missing a value at any time.~~

~~If values for pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure are missing, then a default value will be assigned that represents a normal clinical value for these missing pulmonary pressure variables. A default value of 20 mm Hg will be assigned for missing pulmonary artery systolic pressure, a default value of 5 mm Hg will be assigned for missing pulmonary capillary wedge pressure, and a default value of 15 mm Hg will be assigned for missing pulmonary artery mean pressure. The default values for pulmonary pressures will also be used in the calculation of Lung Allocation Scores for those candidates whose actual values are provided, but are lower than the default value. If any other candidate variables are missing, then a default value, which will be the value that results in the lowest contribution to the Lung Allocation Score for that variable field ("Least Beneficial Value"), will be selected for the candidate.~~

~~Programs are permitted to enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Prior to entering such estimated values, programs must request review and approval from the Lung Review Board to determine whether the estimated values are appropriate. Estimated values will remain valid until those values are either updated with an actual value or a new estimated value is entered pursuant to Policy 3.7.6.4.~~

3.7.6.3.1 Reporting Data for Candidates with LASs of 50 or Greater

A program must report three key variables to the OPTN Contractor no more than 14 days after a candidate's LAS becomes 50 or greater:

a. Assisted ventilation,
b. Supplemental oxygen
c. Current PCO_2.

If a program does not perform a PCO_2 test in that time, then it does not need to report this updated value to the OPTN Contractor. While the candidate's LAS remains 50 or greater, the program must continue to assess and report any observed change in the three clinical variables every 14 days.

The transplant program must maintain source documentation for each assessment in the candidate's chart.

~~**Updating Candidate Variables.** Programs may update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification. Programs must update each element of a candidate's clinical data in UNet℠ every six months, except those data obtainable only by heart catheterization. Also, as described further below, programs must update three clinical variables more frequently than six months for candidates with LAS of 50 or higher.~~

~~UNet℠ defines a "six month anniversary date," which first occurs six months from the date of initial listing, then every six months thereafter. UNet℠ will consider a variable to be expired if the variable's test date is six months older than the most recent anniversary date.~~

~~If the test dates of the Functional Status or assisted ventilation~~

~~variable expire, then the candidate's Lung Allocation Score will be zero. If any other candidate variable expires – excluding pulmonary artery systolic pressure, pulmonary capillary wedge pressure, or pulmonary artery mean pressure – then the candidate will receive the Least Beneficial Value for that variable. The transplant center determines the frequency of updating those candidate variables that are required to be obtained by heart catheterization (pulmonary artery pressures and pulmonary capillary wedge pressure) If a transplant center repeats a heart catheterization test, it must report the results in UNet℠.~~

~~UNet℠ will consider actual values or estimated values for pulmonary pressures to be valid until the transplant center updates them with new actual values or new estimated values pursuant to Policy 3.7.6.4.~~

~~A program must update three key variables in UNet℠ no more than 14 days after a candidate's LAS becomes greater than 50: assisted ventilation, supplemental oxygen, and current PCO_2. If a program does not perform a PCO_2 test in that time, then it does not need to update this value in UNet℠. While the candidate's score remains 50 or higher, a program must continue to assess and report any observed change in the three clinical variables no less frequently than 14 days from the date of the previous assessment.~~

3.7.6.4 Lung Candidates With Exceptional Cases. Special cases require prospective review by the Lung Review Board. Transplant programs may request approval of estimated values, diagnosis, or a specific Lung Allocation Score. The transplant center will accompany each request for special case review with a supporting narrative. Once complete, the request must be sent to the OPTN contractor. The Lung Review Board will have seven (7) calendar days to reach a decision, starting from the date that the contractor sends the request to the Lung Review Board. If a request is denied by the Lung Review Board upon initial review, then the center may choose to appeal the decision for reconsideration by the Lung Review Board. The center will have seven (7) calendar days from the date of the initial request denial to appeal. The Lung Review Board will have seven (7) calendar days to reach a decision on the appeal, starting from the date that the contractor sends the appealed request to the Lung Review Board. If the Lung Review Board has not completed its review of an initial request or an appeal within seven (7) calendar days of receiving it, then the candidate will not receive the requested Lung Allocation Score, diagnosis, or estimated value, and the request or appeal will be forwarded to the Thoracic Organ Transplantation Committee for further review.

Should the Lung Review Board deny a transplant center's initial request or appealed request for an estimated value or a specific Lung Allocation Score, the transplant center has the option to override the decision of the LRB. If the transplant center elects to override the decision of the Lung Review Board, then the request or appeal will be automatically referred to the Thoracic Organ Transplantation Committee for review; this review by the Thoracic Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with *Appendix L: Reviews, Actions, and Due Process* of the OPTN Bylaws.

Estimated values will remain valid until an actual value is entered in the

system or a new estimated value is entered pursuant to the procedures described in this policy. A diagnosis that has been approved by the Lung Review Board or the Thoracic Organ Transplantation Committee will remain valid indefinitely or until an adjustment is requested and, if necessary, approved by the Lung Review Board. Lung Allocation Scores will remain valid for six (6) months from the entry date (or the candidate's twelfth birthday, whichever occurs later). If the candidate continues to be on the Waiting List six months after the entry date, then the candidate's Lung Allocation Score will be computed as described in Policy 3.7.6.1 and Policy 3.7.6.3 unless a new Lung Allocation Score request is entered pursuant to the procedures described in this policy or the center chooses to use the computed Lung Allocation Score instead.

The Thoracic Committee shall establish guidelines for special case review by the Lung Review Board.

3.7.7 **Allocation of Thoracic Organs to Heart-Lung Candidates.** When the candidate is eligible to receive a heart in accordance with Policy 3.7, or an approved variance to this policy, the lung shall be allocated to the heart-lung candidate from the same donor. When the candidate is eligible to receive a lung in accordance with Policy 3.7, or an approved variance to this policy, the heart shall be allocated to the heart-lung candidate from the same donor if no suitable Status 1A isolated heart candidates are eligible to receive the heart. Heart-lung candidates shall use the ABO matching requirements described in Policy 3.7.8 when they are included in the heart match run results. Heart-lung candidates shall use the ABO matching requirements described in policy 3.7.8.2 when they are included in the lung match run results.

3.7.8 **ABO Typing for Heart Allocation.** Within each heart status category, hearts will be allocated to patients according to the following ABO matching requirements:

(i) Blood type O donor hearts shall only be allocated to blood type O or blood type B patients;

(ii) Blood type A donor hearts shall only be allocated to blood type A or blood type AB patients;

(iii) Blood type B donor hearts shall only be allocated to blood type B or blood type AB patients;

(iv) Blood type AB donor hearts shall only be allocated to blood type AB patients.

(v) If there is no patient available who meets these matching requirements, donor hearts shall be allocated first to patients who have a blood type that is compatible with the donor's blood type.

(vi) Following allocation for all born transplant candidates who have blood types that are compatible with donors, hearts will be allocated locally first and then within zones in the sequence described in 3.7.10, by heart status category to born Status 1A or 1B pediatric heart candidates who are eligible to receive a heart from any blood type donor. Allocation to *in utero* candidates eligible for any blood type donors is initiated after all eligible born candidates have received offers.

A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if one of the following conditions is met:

(i) Candidate is *in utero*;

(ii) Candidate is less than 1 year of age, and meets all of the following:

a. Listed at Status 1A or 1B, and
b. Current isohemagglutinin titer information for A and/or B blood type antigens reported in UNet[SM].

(iii) Candidate is greater than or equal to 1 year of age, and meets all of the following:

a. Is listed prior to age 2;
b. Is listed at Status 1A or 1B;
c. Has current isohemagglutinin titer level(s) less than or equal to 1:4 for A and/or B blood type antigens reported in UNet[SM]; and,
d. Has *not* received treatments within the prior 30 days that may have reduced titer values to 1:4 or less.

3.7.8.1 **Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type.** A center may specify on the waiting list that a candidate is eligible to accept a heart from any blood type donor if the eligibility requirements set forth in Policy 3.7.8 are met.

Anti-A and/or Anti-B titers must be reported:

(i) At time of listing (except for *in utero* candidates);

(ii) Every 30 days after listing (**all** eligible born candidates);

(iii) At transplant; and

(iv) In the event of graft loss or death within one year after transplant (for all candidates transplanted with other than blood type identical or compatible donor hearts).

Listing and transplant outcomes for candidates determined to be eligible under this policy will be monitored on a quarterly basis by a subcommittee of the Pediatric Transplantation Committee, including at least two non-Committee members with analytical and/or other professional expertise in this area of medicine, and reported to the Pediatric Committee. Transplant programs that list candidates for receipt of donor hearts of any blood type shall be required to provide information requested for review by the subcommittee, including, for example, autopsy reports.

3.7.8.2 **ABO Typing for Lung Allocation**. Candidates who have the identical blood type as the donor and are awaiting an isolated lung transplant will be allocated thoracic organs before candidates who have a compatible (but not identical) blood type with that of the donor and are awaiting an isolated lung transplant

3.7.9 **Time Waiting for Thoracic Organ Candidates.** Calculation of the time a candidate has been waiting for a thoracic organ transplant begins with the date and time the candidate is first registered as active on the Waiting List. Waiting time will not be accrued by candidates awaiting a thoracic organ transplant while they are registered on the Waiting List as inactive, except as specified in Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age). When time waiting is used for thoracic organ allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same status/priority category. Where applicable, waiting time accrued by a candidate for a single thoracic organ transplant (heart or single lung) while

waiting on the Waiting List also may be accrued for a second thoracic organ, when it is determined that the candidate requires a multiple thoracic organ (heart-lung or double lung) transplant. In addition, where applicable, waiting time accrued by a candidate for a multiple thoracic organ transplant while waiting on the Waiting List may be transferred to the Waiting List for a single thoracic organ transplant.

3.7.9.1 **Waiting Time Accrual for Heart Candidates.** Candidates listed as a Status 1A, 1B, or 2 will accrue waiting time within each heart status; however, waiting time accrued while listed at a lower status will not be counted toward heart allocation if the candidate is upgraded to a higher status. For example, a candidate who is listed as a Status 2 for 3 months and then is upgraded to a Status 1A for one week will accrue one week of waiting time as a Status 1A. If the candidate is downgraded to a Status 2 for another 3 weeks, then the candidate will have 4 months of total accrued time. If the candidate subsequently is upgraded for another week as a Status 1A, then the candidate's Status 1A waiting time will be 2 weeks.

3.7.9.2 **Waiting Time Accrual for Lung Candidates liat Least 12 Years of Age Following Implementation of Lung Allocation Scores (LAS) System** ~~**Described in Policy 3.7.6** Waiting time accrued by lung candidates age 12 and older at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 **and thereafter** will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero. **In the event that multiple candidates receive identical Lung Allocation Scores greater than zero, whether computed Lung Allocation Scores or assigned Lung Allocation Scores that have been approved by the Lung Review Board pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by their total active waiting time accrued.~~

** **BOLD** *language that appears in Policy 3.7.9.2 was approved by the Executive Committee on March 11, 2005, and was implemented on May 4, 2005.*

In the event that multiple candidates receive identical computed Lung Allocation Scores greater than zero, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time of each candidate's most recent update in UNet^{SM} by the member, of variables used in calculation of the Lung Allocation Score. (For example, if Candidate A and Candidate B have an identical Lung Allocation Score and identical priority for a lung offer, and Candidate A's data variables were most recently updated by the transplant center on May 1, 2005, and Candidate B's data variables were most recently updated by the transplant center on June 1, 2005, then Candidate A would receive higher priority for the lung offer because his most recent data update by the transplant center occurred first and the same set of data variables has been used to calculate Candidate A's Lung Allocation Score for the longest amount of time.)

In the event that multiple candidates receive identical assigned Lung Allocation Scores pursuant to an exceptional case request, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time that each candidate's most recent approval of that Lung

Allocation Score by the Lung Review Board was entered in UNet[SM] (For example, if Candidate X and Candidate Y have identical Lung Allocation Scores assigned to them by the Lung Review Board and identical priority for a lung offer, and the approval for Candidate X's score was entered in UNet[SM] on June 1, 2005, and the approval for Candidate Y's score was entered in UNet[SM] on July 1, 2005, then Candidate X would receive higher priority for the lung offer because his most recent Lung Allocation Score was approved and entered in UNet[SM] first.)

~~Candidates that receive a Lung Allocation Score of zero due to missing or expired candidate variables as described in Policy 3.7.6.3 will be screened from the lung match following notification of the listing center, and will not receive isolated lung offers. Upon the entry or update of previously missing or expired candidate variables as described in Policy 3.7.6.3, those candidates will appear on the lung match.~~

Candidates awaiting a lung transplant on the Waiting List at inactive status will be subject to the same requirements for updating candidates' clinical data as indicated in Policy 3.7.6.3 and Policy 3.7.6.4 and will not accrue any waiting time while at inactive status.

NOTE: Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6) (BOLDED and as of the June 24, 2005 Board of Directors Meeting) shall be approved and implemented pending distribution of appropriate notice and programming on UNet[SM], if and as applicable.

3.7.9.3 Waiting Time Accrual for Lung Candidates Less than 12 Years of Age. Candidates listed as a Priority 1 or Priority 2 will accrue waiting time within each priority. Priority 1 and Priority 2 candidates will receive a preference over other candidates within a match run classification who have accumulated less waiting time. For Priority 1 candidates, UNet[SM] will only consider the most recent time spent as Priority 1, i.e., UNet[SM] will not tally the time waiting during multiple Priority 1 periods.

For Priority 2 candidates, and if there is ever a tie among Priority 1 candidates, UNet[SM] will use total waiting time. Total waiting time includes time spent waiting as Priority 1, Priority 2, and inactive.

3.7.10 Sequence of Adult Heart Allocation. Donor hearts recovered from donors age 18 and older shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

Local
1. Status 1A candidates
2. Status 1B candidates

Zone A
3. Status 1A candidates
4. Status 1B candidates

Local
5. Status 2 candidate s

Zone B
6. Status 1A candidates
7. Status 1B candidates

Zone A
8. Status 2 candidates

Zone B
9. Status 2 candidates

Zone C
10. Status 1A candidates
11. Status 1B candidates
12. Status 2 candidates

Zone D
13 Status 1A candidates
14. Status 1B candidates
15. Status 2 candidates

Zone E
16. Status 1A candidates
17. Status 1B candidates
18. Status 2 candidates

3.7.10.1 Sequence of Pediatric Heart Allocation. Hearts recovered from pediatric donors shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

1. Common OPO and Zone A Status 1A ABO Primary Ped Candidates for Pediatric Donor
2. Common OPO and Zone A Status 1A ABO Secondary Ped Candidates for Pediatric Donor
3. Common OPO Status 1A ABO Primary Candidates
4. Common OPO Status 1A ABO Secondary Candidates
5. Common OPO and Zone A Status 1B ABO Primary Ped Candidates for Pediatric Donor
6. Common OPO and Zone A Status 1B ABO Secondary Ped Candidates for Pediatric Donor
7. Common OPO Status 1B ABO Primary Candidates
8. Common OPO Status 1B ABO Secondary Candidates
9. Zone A Status 1A ABO Primary Candidates
10. Zone A Status 1A ABO Secondary Candidates
11. Zone A Status 1B ABO Primary Candidates
12. Zone A Status 1B ABO Secondary Candidates
13. Common OPO Status 2 ABO Primary Ped Candidates for Pediatric Donor
14. Common OPO Status 2 ABO Secondary Ped Candidates for Pediatric Donor
15. Common OPO Status 2 ABO Primary Candidates
16. Common OPO Status 2 ABO Secondary Candidates
17. Zone B Status 1A ABO Primary Ped Candidates for Pediatric Donor
18. Zone B Status 1A ABO Secondary Ped Candidates for Pediatric Donor
19. Zone B Status 1A ABO Primary Candidates
20. Zone B Status 1A ABO Secondary Candidates
21. Zone B Status 1B ABO Primary Ped Candidates for Pediatric Donor
22. Zone B Status 1B ABO Secondary Ped Candidates for Pediatric Donor
23. Zone B Status 1B ABO Primary Candidates
24. Zone B Status 1B ABO Secondary Candidates
25. Zone A Status 2 ABO Primary Ped Candidates for Pediatric Donor
26. Zone A Status 2 ABO Secondary Ped Candidates for Pediatric Donor
27. Zone A Status 2 ABO Primary Candidates
28. Zone A Status 2 ABO Secondary Candidates
29. Zone B Status 2 ABO Primary Ped Candidates for Pediatric Donor
30. Zone B Status 2 ABO Secondary Ped Candidates for Pediatric Donor
31. Zone B Status 2 ABO Primary Candidates
32. Zone B Status 2 ABO Secondary Candidates
33. Zone C Status 1A ABO Primary Ped Candidates for Pediatric Donor
34. Zone C Status 1A ABO Secondary Ped Candidates for Pediatric Donor

35. Zone C Status 1A ABO Primary Candidates
36. Zone C Status 1A ABO Secondary Candidates
37. Zone C Status 1B ABO Primary Ped Candidates for Pediatric Donor
38. Zone C Status 1B ABO Secondary Ped Candidates for Pediatric Donor
39. Zone C Status 1B ABO Primary Candidates
40. Zone C Status 1B ABO Secondary Candidates
41. Zone C Status 2 ABO Primary Ped Candidates for Pediatric Donor
42. Zone C Status 2 ABO Secondary Ped Candidates for Pediatric Donor
43. Zone C Status 2 ABO Primary Candidates
44. Zone C Status 2 ABO Secondary Candidates
45. Zone D Status 1A ABO Primary Ped Candidates for Pediatric Donor
46. Zone D Status 1A ABO Secondary Ped Candidates for Pediatric Donor
47. Zone D Status 1A ABO Primary Candidates
48. Zone D Status 1A ABO Secondary Candidates
49. Zone D Status 1B ABO Primary Ped Candidates for Pediatric Donor
50. Zone D Status 1B ABO Secondary Ped Candidates for Pediatric Donor
51. Zone D Status 1B ABO Primary Candidates
52. Zone D Status 1B ABO Secondary Candidates
53. Zone D Status 2 ABO Primary Ped Candidates for Pediatric Donor
54. Zone D Status 2 ABO Secondary Ped Candidates for Pediatric Donor
55. Zone D Status 2 ABO Primary Candidates
56. Zone D Status 2 ABO Secondary Candidates
57. Zone E Status 1A ABO Primary Ped Candidates for Pediatric Donor
58. Zone E Status 1A ABO Secondary Ped Candidates for Pediatric Donor
59. Zone E Status 1A ABO Primary Candidates
60. Zone E Status 1A ABO Secondary Candidates
61. Zone E Status 1B ABO Primary Ped Candidates for Pediatric Donor
62. Zone E Status 1B ABO Secondary Ped Candidates for Pediatric Donor
63. Zone E Status 1B ABO Primary Candidates
64. Zone E Status 1B ABO Secondary Candidates
65. Zone E Status 2 ABO Primary Ped Candidates for Pediatric Donor
66. Zone E Status 2 ABO Secondary Ped Candidates for Pediatric Donor
67. Zone E Status 2 ABO Primary Candidates
68. Zone E Status 2 ABO Secondary Candidates
69. Common OPO and Zone A Status 1A ABO Incompatible Ped Candidates for Pediatric Donor
70. Common OPO and Zone A Status 1B ABO Incompatible Ped Candidates for Pediatric Donor
71. Common OPO Status 2 ABO Incompatible Candidates
72. Zone B Status 1A ABO Incompatible Candidates
73. Zone B Status 1B ABO Incompatible Candidates
74. Zone C Status 1A ABO Incompatible Candidates
75. Zone C Status 1B ABO Incompatible Candidates
76. Zone D Status 1A ABO Incompatible Candidates
77. Zone D Status 1B ABO Incompatible Candidates
78. Zone E Status 1A ABO Incompatible Candidates
79. Zone E Status 1B ABO Incompatible Candidates
80. Common OPO and Zone A ABO Primary In Utero Candidates
81. Common OPO and Zone A ABO Secondary In Utero Candidates
82. Common OPO and Zone A ABO Incompatible In Utero Candidates
83. Zone B ABO Primary In Utero Candidates
84. Zone B ABO Secondary In Utero Candidates
85. Zone B ABO Incompatible In Utero Candidates
86. Zone C ABO Primary In Utero Candidates
87. Zone C ABO Secondary In Utero Candidates
88. Zone C ABO Incompatible In Utero Candidates
89. Zone D ABO Primary In Utero Candidates
90. Zone D ABO Secondary In Utero Candidates
91. Zone D ABO Incompatible In Utero Candidates
92. Zone E ABO Primary In Utero Candidates
93. Zone E ABO Secondary In Utero Candidates
94. Zone E ABO Incompatible In Utero Candidates

3.7.11 Sequence of Adult Donor Lung Allocation. Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung

allocation. If one lung is allocated to a candidate needing a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0 – 11 years old. Lungs from adult donors will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for adult donor lungs is as follows:

1. Local ABO identical candidates age 12 and older according to Lung Allocation Score in descending order;
2. Local ABO compatible candidates age 12 and older according to Lung Allocation Score in descending order;
3. Local ABO identical Priority 1 candidates 0 – 11 years old according to length of waiting time;
4. Local ABO compatible Priority 1 candidates 0 – 11 years old according to length of waiting time;
5. Local ABO identical Priority 2 candidates 0 – 11 years old according to length of waiting time;
6. Local ABO compatible Priority 2 candidates 0 – 11 years old according to length of waiting time;
7. ABO identical candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
8. ABO compatible candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
9. ABO identical Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
10. ABO compatible Priority 1 candidates 0 – 11 years old in Zone A according to length of waiting time;
11. ABO identical Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
12. ABO compatible Priority 2 candidates 0 – 11 years old in Zone A according to length of waiting time;
13. ABO identical candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
14. ABO compatible candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
15. ABO identical Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;
16. ABO compatible Priority 1 candidates 0 – 11 years old in Zone B according to length of waiting time;
17. ABO identical Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;
18. ABO compatible Priority 2 candidates 0 – 11 years old in Zone B according to length of waiting time;
19. ABO identical candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
20. ABO compatible candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
21. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;

22. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of waiting time;
23. ABO identical Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;
24. ABO compatible Priority 2 candidates 0 – 11 years old in Zone C according to length of waiting time;
25. ABO identical candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
26. ABO compatible candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
27. ABO identical Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;
28. ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;
29. ABO identical Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;
30. ABO compatible Priority 2 candidates 0 – 11 years old in Zone D according to length of waiting time;
31. ABO identical candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;
32. ABO compatible candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;
33. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time;
34. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of waiting time;
35. ABO identical Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time; and
36. ABO compatible Priority 2 candidates 0 – 11 years old in Zone E according to length of waiting time.

3.7.11.1 Sequence of Pediatric Donor Lung Allocation. Candidates 0 – 11 years old awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Candidates 12 – 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 – 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0 – 11 years old will first be offered to candidates age 0 – 11; then to candidates age 12 – 17; then to candidates 18 years and older. Candidates will be grouped so that those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

- Offers for 0-11 year-olds will first be made to combined local, Zone A and Zone B candidates by priority and waiting time. After adolescent and adult offers are completed through Zone B, offers will continue to these younger candidates in Zones C, D and E prior to adolescents and adults within in each zone.

- Offers for 12-17 year-olds will first be made to combined local and Zone A candidates according to lung allocation score in descending order after the completion of 0-11 year-old offers through Zone B. Once adult Zone A offers are completed, offers will continue to adolescent candidates in Zones B, C, D and E after the younger 0-11 candidates and before the adult candidates within each zone.

- Offers to adult candidates (18 years and older) will be made after the completion of 0-11 year old offers through Zone B and adolescent offers through Zone A. After local and Zone A adult offers are completed, offers will continue in Zones B, C, D and E after the completion of all pediatric offers within each zone.

In summary, the allocation sequence for lungs from donors 0-11 years old is as follows:

1. Combined local, Zone A and Zone B ABO identical Priority 1 candidates 0-11 years old according to length of waiting time;
2. Combined local, Zone A and Zone B ABO compatible Priority 1 candidates 0-11 years old according to length of waiting time;
3. Combined local, Zone A and Zone B ABO identical Priority 2 candidates 0-11 years old according to length of waiting time;
4. Combined local, Zone A and Zone B ABO compatible Priority 2 candidates 0-11 years old according to length of waiting time;
5. Combined local and Zone A ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
6. Combined Local and Zone A ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
7. Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
8. Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
9. ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
10. ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
11. ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
12. ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
13. ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
14. ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
15. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
16. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
17. ABO identical Status 2 candidates 0-11 years old in Zone C according to length of waiting time;
18. ABO compatible Priority 2 candidates 0-11 years old in Zone C according to length of waiting time;
19. ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
20. ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
21. ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;

22. ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
23. ABO identical Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
24. ABO compatible Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
25. ABO identical Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
26. ABO compatible Priority 2 candidates 0-11 years old in Zone D according to length of waiting time;
27. ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
28. ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
29. ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
30. ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
31. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
32. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
33. ABO identical Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
34. ABO compatible Priority 2 candidates 0-11 years old in Zone E according to length of waiting time;
35. ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
36. ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
37. ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
38. ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

Lungs from donors 12 – 17 years old will first be offered to candidates age 12 – 17 years old; then to candidates age 0 – 11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

In summary, the allocation sequence for lungs from donors 12 – 17 years old is as follows:

1. Local ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
2. Local ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
3. Local ABO identical Status 1 candidates 0 – 11 years old according to length of time waiting;
4. Local ABO compatible Status 1candidates 0 – 11 years old

according to length of time waiting;
5. Local ABO identical Status 2 candidates 0 – 11 years old according to length of time waiting;
6. Local ABO compatible Status 2 candidates 0 – 11 years old according to length of time waiting;
7. Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
8. Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
9. ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
10. ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
11. ABO identical Priority 1 candidates 0 – 11 years old in Zone A according to length of time waiting;
12. ABO compatible Priority 1candidates 0 – 11 years old in Zone A according to length of time waiting;
13. ABO identical Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
14. ABO compatible Priority 2 candidates 0 – 11 years old in Zone A according to length of time waiting;
15. ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
16. ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
17. ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
18. ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
19. ABO identical Priority 1candidates 0 – 11 years old in Zone B according to length of time waiting;
20. ABO compatible Priority 1 candidates 0 – 11 years old in Zone B according to length of time waiting;
21. ABO identical Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
22. ABO compatible Priority 2 candidates 0 – 11 years old in Zone B according to length of time waiting;
23. ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
24. ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
25. ABO identical candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
26. ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
27. ABO identical Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
28. ABO compatible Priority 1 candidates 0 – 11 years old in Zone C according to length of time waiting;
29. ABO identical Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
30. ABO compatible Priority 2 candidates 0 – 11 years old in Zone C according to length of time waiting;
31. ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
32. ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
33. ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
34. ABO compatible candidates 12 – 17 years old in zone D according

to Lung Allocation Score in descending order;
35. ABO identical Priority 1candidates 0 – 11 years old in Zone D according to length of time waiting;
36. ABO compatible Priority 1 candidates 0 – 11 years old in Zone D according to length of time waiting;
37. ABO identical Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
38. ABO compatible Priority 2 candidates 0 – 11 years old in Zone D according to length of time waiting;
39. ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
40. ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.
41. ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
42. ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;
43. ABO identical Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
44. ABO compatible Priority 1 candidates 0 – 11 years old in Zone E according to length of time waiting;
45. ABO identical Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
46. ABO compatible Priority 2 candidates 0 – 11 years old in Zone E according to length of time waiting;
47. ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and
48. ABO compatible candidates 18 years old and older in Zone E.

3.7.12 Minimum Information for Thoracic Organ Offers.

3.7.12.1 Essential Information. The Host OPO or donor center must provide the following donor information to the recipient center with each thoracic organ offer:

(i) The cause of brain death;
(ii) The details of any documented cardiac arrest or hypotensive episodes;
(iii) Vital signs including blood pressure, heart rate and temperature;
(iv) Cardiopulmonary, social, and drug activity histories;
(v) Serologies as indicated in 2.2.4.1 (qualified specimens preferred as noted in Policy 2.2.3.1);
(vi) Accurate height, weight, age and sex;
(vii) ABO type;
(viii) ABO subtype when used for allocation;
(ix) Interpreted electrocardiogram and chest radiograph;
(x) History of treatment in hospital including vasopressors and hydration;
(xi) Arterial blood gas results and ventilator settings;
(xii) Echocardiogram, if the donor hospital has the facilities; and
(xiii) Human leukocyte antigen (HLA) type if requested by the transplant center.

If a transplant center requires donor HLA type prior to submitting a final organ acceptance, it must communicate this request to the OPO; the transplant center must document this request. If a transplant center requests donor HLA type prior to submitting a final organ acceptance, the OPO must provide the following, identified splits before the organ's final acceptance:

HLA-A, HLA-B, HLA-Bw4, HLA-Bw6, HLA-Cw, HLA-DR, and HLA-DQ antigens. The transplant center may request HLA-DP type, but the OPO need only provide it if its affiliated laboratory performs related testing. The OPO must document provision of HLA type to the requesting transplant center.

The thoracic organ procurement team must have the opportunity to speak directly with responsible ICU personnel or the on-site donor coordinator in order to obtain current first-hand information about the donor physiology.

3.7.12.2 Desirable Information for Heart Offers. With each heart offer, the donor center is encouraged to provide the recipient center with the following information:

(i) Coronary angiography for male donors over the age of 40 and female donors over the age of 45;
(ii) CVP or Swan Ganz instrumentation;
(iii) Cardiology consult; and
(iv) Cardiac enzymes including CPK isoenzymes.

With each heart offer, it is reasonable for the transplanting center to request a heart catheterization of the donor where the donor history reveals one or more of the following:

(a) The donor is a male over the age of 40 or a female over the age of 45;
(b) Segmental wall motion abnormality;
(c) Troponin elevation;
(d) History of chest pain;
(e) Abnormal EKG consistent with ischemia or myocardial infarction; or
(f) Two or more of the following:

i. History of hypertension
ii. History of significant smoking
iii. Intra-cerebral bleed
iv. Strong family history of coronary artery disease
v. History of Hyperlipidemia
vi. History of diabetes
vii. History of cocaine or amphetamine use

3.7.12.3 Essential Information for Lung Offers. In addition to the essential information specified above for a thoracic organ offer, the Host OPO shall provide the following specific information with each lung offer:

(i) Arterial blood gases on 5 cm/H_20/PEEP including PO_2/FiO_2 ratio and preferably 100% FiO_2 within 2 hours prior to the offer;

(ii) Bronchoscopy results. Bronchoscopy of a lung donor is recognized as an important element of donor evaluation. The Host OPO must document if it is unable to provide bronchoscopy results. Confirmatory bronchoscopy may be performed by the lung retrieval team provided unreasonable delays are avoided. A lung transplant program may not insist upon performing its own bronchoscopy before being subject to the 60 minute response time limit as specified in Policy 3.4.2;

(iii) Chest radiograph interpreted by a radiologist or qualified physician within 3 hours prior to the offer;

(iv) Sputum gram stain with a description of the sputum character; and

(v) Smoking history.

3.7.12.4 Desirable Information for Lung Offers. With each lung offer, the Host OPO is encouraged to provide the transplant center with the following information:

(i) Mycology smear;
(ii) Measurement of chest circumference in inches or centimeters at the level of the nipples and x-ray measurement vertically from the apex of the chest to the apex of the diaphragm and transverse at the level of the diaphragm, if requested; and
(iii) Non-contrast computed tomography (CT) scan of the chest, if requested by the transplant center.

3.7.13 Removal of Thoracic Organ Transplant Candidates from Thoracic Organ Waiting Lists When Transplanted or Deceased. If a heart, lung, or heart-lung transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all Thoracic Organ Waiting Lists for that transplanted organ and shall notify the OPTN contractor within 24 hours of the event. If the thoracic organ recipient is again added to a Thoracic Organ Waiting List, waiting time shall begin as of the date and time the candidate is relisted.

3.7.14 Local Conflicts Involving Thoracic Organ Allocation. Regarding allocation of hearts, lungs and heart-lung combinations, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the Thoracic Organ Transplantation Committee and the Board of Directors.

3.7.15 Allocation of Domino Donor Hearts. A domino heart transplant occurs when the native heart of a combined heart-lung transplant recipient is procured and transplanted into a candidate who requires an isolated heart transplant. First consideration for donor hearts procured for this purpose will be given to the candidates of the participating transplant program from which the native heart was procured. If the program elects not to use the heart, then the heart will be allocated according to Policy 3.7, or an approved variance to this policy. For the purpose of Policy 3.7.16, the Local Unit of allocation for the domino heart shall be defined as the CMS-designated service area of the OPO where the domino heart is procured.

3.7.16 Crossmatching for Thoracic Organs. The transplant program and its histocompatibility laboratory must have a joint written policy that states when a crossmatch is necessary. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D of Policy 3.

Exhibit D

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Special Article

Lung and Heart Allocation in the United States

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Lung and heart allocation in the United States has evolved over the past 20–30 years to better serve transplant candidates and improve organ utilization. The current lung allocation policy, based on the Lung Allocation Score, attempts to take into account risk of death on the waiting list and chance of survival posttransplant. This policy is flexible and can be adjusted to improve the predictive ability of the score. Similarly, in response to the changing clinical phenotype of heart transplant candidates, heart allocation policies have evolved to a multitiered algorithm that attempts to prioritize organs to the most infirm, a designation that fluctuates with trends in therapy. The Organ Procurement and Transplantation Network and its committees have been responsive, as demonstrated by recent modifications to pediatric heart allocation and mechanical circulatory support policies and by ongoing efforts to ensure that heart allocation policies are equitable and current. Here we examine the development of US lung and heart allocation policy, evaluate the application of the current policy on clinical practice and explore future directions for lung and heart allocation.

Key words: Heart allograft, lung allograft, organ allocation, transplant waiting list, transplantation

Abbreviations: DSA, donation service area; ECMO, extracorporeal membrane oxygenation; HHS, Health and Human Services; HRSA, Health Resources and Services Administration; IABP, intraaortic balloon pump; ICU, intensive care unit; IPAH, idiopathic pulmonary arterial hypertension; IPF, idiopathic pulmonary fibrosis; LAS, lung allocation score; LVAD, left-ventricular assist device; MCS, mechanical circulatory support; NOTA, National Organ Transplant Act; OPO, organ procurement organization; OPTN, Organ Procurement and Transplantation Network; RRB, regional review board; RVAD, right-ventricular assist device; SRTR, Scientific Registry of Transplant Recipients; TAH, total artificial heart; UNOS, United Network for Organ Sharing; VAD, ventricular assist device.

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Introduction

The allocation of hearts and lungs for transplant in the United States involves distribution of a limited resource to a select few of the transplant candidates in need. The goals of lung allocation policies have evolved over the past three decades; the primary challenge now is to find methods that will allow equitable access to organs while maximizing the net benefit of transplant. Today, the Lung Allocation Score (LAS) is the primary determinant of candidate priority on the waiting list. Similarly, heart allocation has evolved over time. Since the first heart transplant was performed in 1967, the medical and surgical management of heart failure has changed dramatically, increasing survival among patients with heart failure and reducing morbidity and mortality among patients on the transplant waiting list. Concurrently, improved clinical management of heart transplant candidates has improved survival posttransplant. This overview does not discuss historical or current variances, but reviews the generally applied Organ Procurement and Transplantation Network (OPTN) national lung, then heart allocation policies.

Lung Allocation

History of lung allocation

The first lung transplant was performed by J.D. Hardy at the University of Mississippi in 1963; however, it would take 20 years before lung transplant was established as a treatment option for patients with end-stage pulmonary diseases (1). After the first transplant, refinement of the procedure proceeded slowly until the advent of cyclosporine in 1982; the emergence of this immunosuppressant

moved lung transplant beyond experimental medicine into mainstream therapy (2,3). After 1982, heart–lung and lung transplants were used to treat a growing number of pulmonary diseases and achieved substantially increased survival rates (4–6).

In 1984, Congress passed the National Organ Trensplant Act (NOTA), which mandated creation of a national organ transplant organization to act as a registry and organ matching entity to monitor allocation across the United States. This Act led to creation of the OPTN to organize allocation policies and, later, the Scientific Registry of Transplant Recipients (SRTR) to monitor outcomes (7). The OPTN contract for day-to-day organ donation and waiting list management operations is carried by the United Network for Organ Sharing (UNOS) (8).

After the passage of NOTA, OPTN began tracking solid organ transplants, but lung transplants were included with the thoracic organs and were not separately monitored. In 1990, OPTN amended the thoracic organ policies to monitor lung allocation. Until 1995, lungs were allocated to candidates purely on the basis of time spent on the waiting list, blood type and geographic proximity of the donor to the candidate (9). Because mortality rates vary for different pulmonary conditions, the waiting-time-only allocation policy tacitly discriminated against candidates who were most likely to die while waiting for an organ. In 1995, to remedy this discrepancy, OPTN amended the allocation process to include a special dispensation for patients with idiopathic pulmonary fibrosis (IPF). This change gave candidates with IPF credit for an extra 90 days on the waiting list, in hopes that the extra time credit would expedite their access to organs. Despite this modification, overall waiting times continued to increase (10). Before long, more than half the candidates for transplant waited more than 2 years after listing to gain access to lungs. The dramatically increased waiting times meant that many candidates died while on the waiting list, and a disproportionate number of lungs were allocated to candidates with more stable diagnoses.

In 1999, 599 of the 4868 candidates on the waiting list died; this is a wait-list mortality rate of 190 deaths per 1000 patient-years at risk. The wait-list mortality rate was highest for diseases such as IPF (with a rate 70% higher than average at 323 deaths per 1000 patient-years) and lowest for diseases such as emphysema (114 deaths per 1000 patient-years at risk) (10). In part to address high wait-list mortality across all organs, the US Department of Health and Human Services (HHS) issued the Final Rule, effective March 16, 2000, to mandate development of organ allocation policies based on medical necessity rather than waiting time (11). As a result of this rule, OPTN created the Lung Allocation Subcommittee and charged it with developing an allocation process that would decrease the wait-list mortality rate and give access to organs to candidates most in need (12).

In 2005, OPTN approved the implementation of the LAS for lung allocation (13). The revised allocation policies removed the emphasis on waiting time and replaced it with a combination of geographic priority and the LAS, a calculation of illness severity and projected posttransplant survival that was intended to place the sickest candidates with the best chance of survival at the top of the waiting list. This was the first time "utility" of the transplant was included as part of an organ allocation policy (14; OPTN Policy 3.7.6.1). Adoption of the LAS decreased the size of the waiting list by reducing the incentive for early listing, and improved access to lungs for candidates at greatest risk of dying while on the waiting list.

The LAS-based allocation policy had a dramatic effect on lung transplantation trends in the United States. By 2006, the size of the waiting list had decreased from 2163 to 1031 candidates. The LAS also affected which candidates were gaining access to transplants. Patients with IPF underwent 23% of lung transplants performed each year before the LAS and more than 33% after the LAS (10). From its inception, the LAS was designed to be an evolving calculation, changing in response to altered cohort composition, improved therapies and identified gaps in the process.

Current lung allocation policies

In addition to the LAS, national lung allocation policy is based on geography, age and blood type (ABO) compatibility; other criteria, such as thoracic cavity size match, are considered at the local level. The LAS is calculated for all candidates aged 12 years or older. Geographic distribution remains a central consideration in organ allocation as a means of minimizing ischemic times. With a limited exception, lungs are first offered locally and then to candidates outside the local area, in defined zones extending from the donor hospital. Local is defined as within the organ procurement organization's (OPO) donation service area (DSA). OPTN/UNOS defines the zones as: A (within 0–500 miles, nonlocal), B (within 501–1000 miles), C (within 1001–1500 miles), D (within 1501–2500 miles) and E (>2500 miles) (14; OPTN Policy 3.7.2.). The predefined borders of DSAs may allow organs to initially be offered to candidates hundreds of miles from the transplant center, well beyond the extent of zone A. For example, lungs available in Minneapolis are first offered to candidates in the local DSA including Minnesota, North Dakota and South Dakota, but will not be offered to candidates across the Wisconsin border until zone A offers are made. This remains true despite the fact that a candidate in Wisconsin may be hundreds of miles closer to the organ than a candidate in western North Dakota (Figure 1).

Allocation of adult donor lungs

Lung allocation is first determined based on the age of the lung donor; adult donors are defined as aged 18 years or older. An organ from an adult donor is first offered to local wait-list candidates (Figure 2). Within the local area,

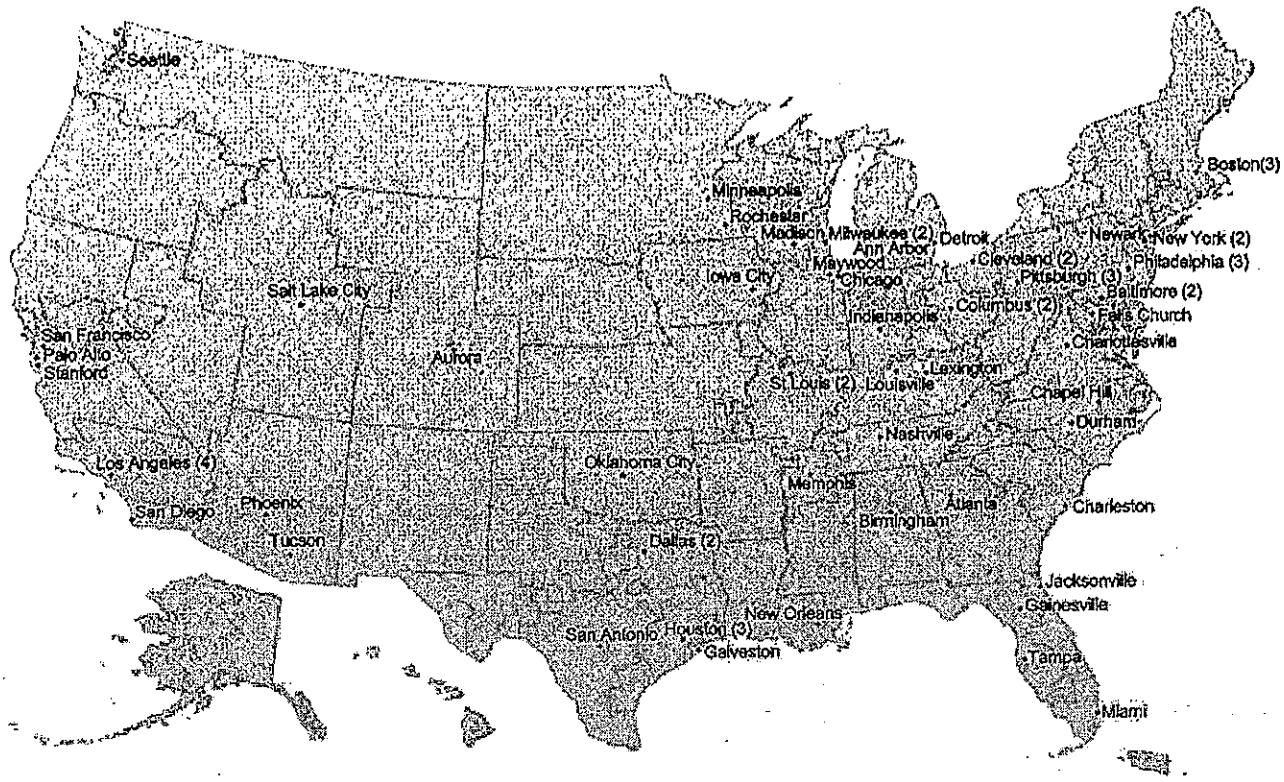

Figure 1: Lung transplant programs within each donor service area.

candidates aged 12 years and older have priority over children (aged 0–11 years), primarily because of thoracic size considerations. Of the local candidates aged 12 years or older, those who are ABO identical with the donor (Figure 2, bin 1) have priority over those who are nonidentical but ABO compatible (bin 2). The LAS is considered at this point, determining which of the local ABO identical candidates aged 12 years or older will be offered the lungs first. If none of those candidates accept the organ, it is offered to local ABO compatible candidates aged 12 years or older. If none of those candidates accept the organ, it is allocated to child candidates. Children are designated priority 1 or priority 2, based on severity of illness. Offers of adult lungs to children are made to priority 1 candidates first, then to priority 2 candidates. Offers are made to priority 1 local ABO identical children (bin 3), then to priority 1 local ABO compatible children (bin 4), priority 2 local ABO identical children (bin 5), and priority 2 local ABO compatible children (bin 6). If all offers within the local zone are turned down, the organ is offered in the same order to candidates in zone A, then sequentially to candidates in zones B, C, D and E. If the lungs are offered to a candidate who needs only one lung, the remaining lung is matched to another single-lung candidate (14; OPTN Policy 3.7.11).

Transplant centers are responsible for evaluating any determining factors not indicated or proscribed by the allocation policy. For example, considerations such as thoracic size, organ quality, and other factors are left up to the individual transplant center, surgeon and patient (14; OPTN Policy 3.7.1.1).

To ensure that LAS and illness severity are accurately assessed, lung transplant candidates must be up to date on all critical measures for predicting wait-list and posttransplant survival (Table 1). All noninvasive criteria are updated once in every 6-month interval following listing (14; OPTN Policies 3.7.6.3 and 3.7.6.3.2). If a measure that does not require clinical testing, such as functional status, is not updated during an interval, the candidate's LAS score reverts to zero until the measure is updated. Candidates with LAS of zero are screened from the organ matching process. Noninvasive clinical measures must also be updated during every 6-month interval or the measure will be replaced with the least beneficial value and the candidate's LAS will be recalculated using the substituted data. Ties between candidates are broken using accumulated active waiting time (14; OPTN Policy 3.7.9).

Allocation of adolescent donor lungs

Adolescent donors are defined as aged 12–17 years. Although the LAS is used to allocate organs to adolescent candidates much like adults, adolescent organs are

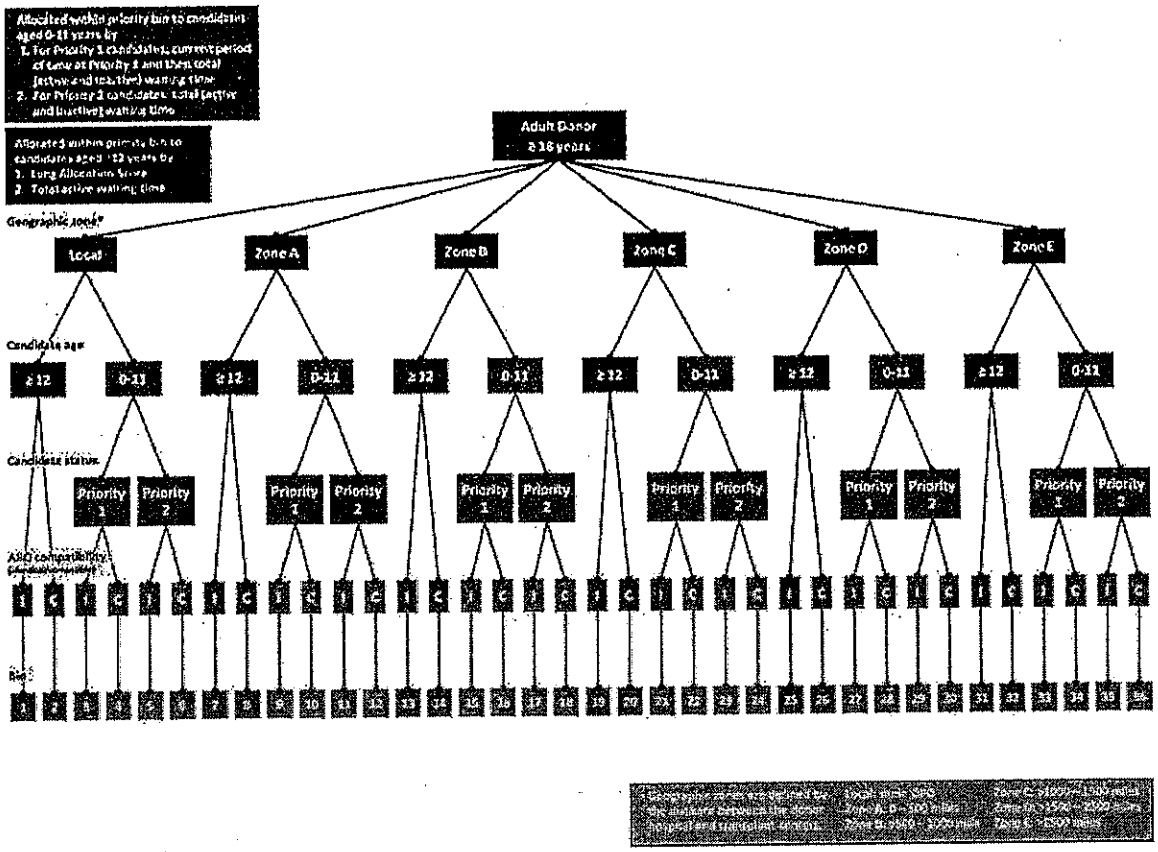

Figure 2: Allocation of adult donor lungs. This figure can be downloaded in color from www.srtr.org.

Table 1: Measures used to calculate the lung allocation score

Factors used to predict waiting list survival
Forced vital capacity (FVC)
Pulmonary artery systolic pressure (PA) for groups A, C and D[1]
O_2 required at rest for groups A, C and D
Age
Body mass index (BMI)
Diabetes
Functional status
6-min walk distance
Continuous mechanical ventilation
Diagnosis
PCO_2
Factors used to predict posttransplant survival
Forced vital capacity (FVC) for groups B and D
Pulmonary capillary wedge (PCW) pressure ≥ 20 for group D
Continuous mechanical ventilation
Age
Serum creatinine
Functional status
Diagnosis

[1]Group A, obstructive lung disease; Group B, pulmonary vascular disease; Group C, cystic fibrosis and immunodeficiency disorders; Group D, restrictive lung disease.

preferentially offered to adolescent candidates (Figure 3). When adolescent lungs become available, they are first offered to local candidates. The offer is first made to local ABO identical adolescent candidates, then to local ABO compatible adolescent candidates. If there are no suitable adolescent candidates in the local DSA, local child candidates are next in line. The lungs are offered to local adult candidates only if they have been turned down by all adolescent and child candidates in the local area. After the local candidate population has been exhausted, the lungs are offered in the same order to candidates in zones A, B, C, D and E (14; OPTN Policy 3.7.11.1).

Allocation of child donor lungs

For allocation purposes, child donors are defined as children aged 0–11 years. When the LAS-based allocation policy was implemented in 2005, children were excluded from the policy due to differences in diagnoses that made the LAS calculation inappropriate as a measure of medical urgency. Child candidates are ranked as priority 1 if they fulfill certain set criteria, or as priority 2 (Table 2; 14; OPTN Policy 3.7.6.2). Candidates who do not meat priority 1 criteria and are not inactive are designated priority 2. Qualified priority 1 candidates within a specific geographic zone are always

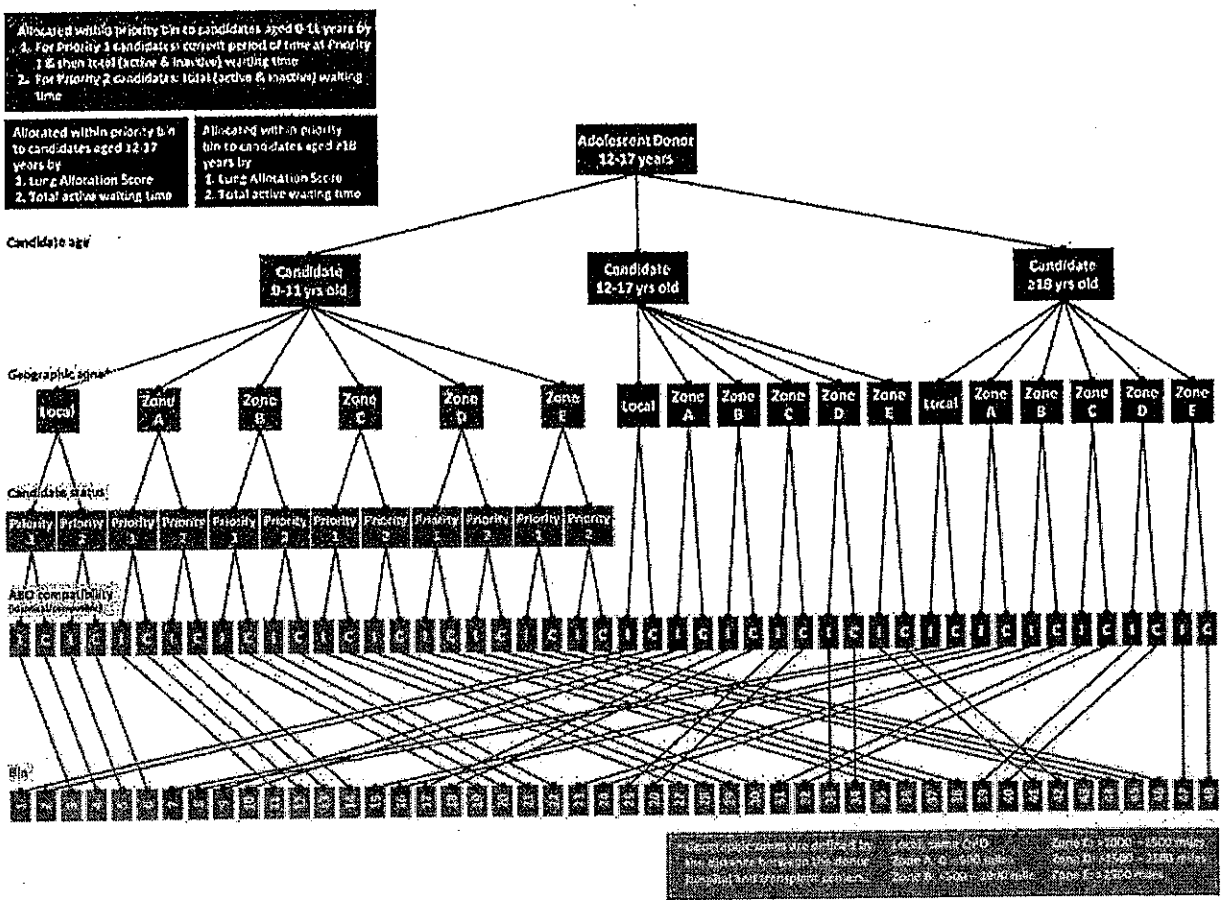

Figure 3: Allocation of adolescent donor lungs. This figure can be downloaded in color from www.srtr.org.

Table 2: Criteria for determining Priority 1 child candidates

Candidates must have one or more of the following:
Respiratory failure
Requiring continuous mechanical ventilation; OR
Requiring supplemental oxygen delivered by any means to achieve FiO_2 > 50% to maintain oxygen saturation levels > 90%; OR
Having an arterial or capillary PCO_2 > 50 mmHg or a venous PCO_2 > 56 mmHg
Pulmonary hypertension
Pulmonary vein stenosis involving three or more vessels; OR
Exhibiting any of the following, in spite of medical therapy:
Suprasystemic pulmonary artery pressure on cardiac catheterization or by echocardiogram estimate
Cardiac index < 2 L/min/m^2
Syncope or hemoptysis

ranked above priority 2 candidates. Within the priority rankings, candidates are ordered by ABO compatibility, then by waiting time. Waiting time for priority 1 candidates is defined as the time spent waiting as a priority 1 candidate since the most recent listing at priority 1. Priority 1 candidates cannot sum the total of all time spent waiting if they have multiple priority 1 periods. Total waiting time, defined as the sum of priority 1, priority 2 and inactive time, is used to break ties between priority 1 candidates (14; OPTN Policy 3.7.9.3). Priority 2 candidates are ranked by total waiting time. As always, the transplant center considers thoracic size, organ quality and other indicators when deciding if the organ is appropriate for transplant.

Just as with adult candidates, clinical data must be updated at least once in every 6-month interval (14; OPTN Policies 3.7.6.2 and 3.7.6.3). Failure to keep clinical data up to date will reduce a candidate's status from priority 1 to priority 2. Candidates remain at priority 2 as long as they are in need of an organ, unless they are removed from the list by the transplant center. The process of child donor lung allocation is illustrated in Figure 4.

When lungs become available from a child donor, they are preferentially offered to child candidates (ages 0–11 years). Due to the difficulty in finding a size match, this priority is

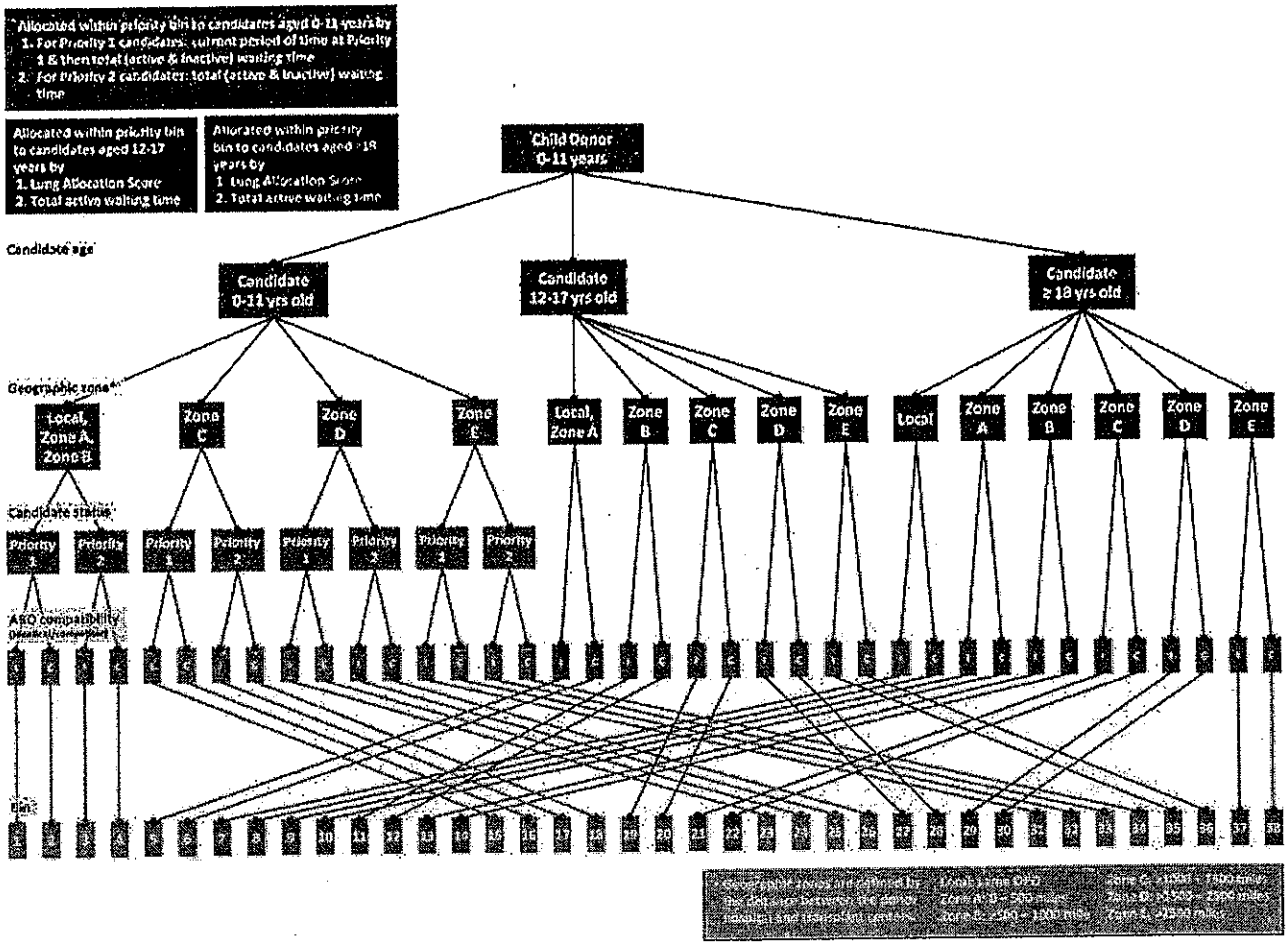

Figure 4: Allocation of child donor lungs. This figure can be downloaded in color from www.srtr.org.

critical to children on the waiting list. First, offers are made to child candidates from the local DSA, zone A, and zone B combined. Within that expanded geographic area, the first offer is made to a priority 1 ABO identical candidate (Figure 4, bin 1). If that offer is declined or there is no suitable candidate at that level, the next offer is made to a priority 1 ABO compatible candidate from the local area, zone A, or zone B (bin 2). Priority 2 candidates are offered the lungs if there are no suitable priority 1 candidates (bins 3 and 4). Successive offers are made to the following candidates in order: adolescent ABO identical candidates from the local area and zone A combined (bin 5), adolescent ABO compatible candidates from the local area and zone A (bin 6), adult ABO identical candidates from the local area (bin 7), adult ABO compatible candidates from the local area (bin 8), adult ABO identical candidates from zone A (bin 9) and adult ABO compatible candidates from zone A (bin 10). If there are no suitable candidates, the lungs are offered to adolescents in zone B (bins 11 and 12) and adults in zone B (bins 13 and 14) before being offered to child candidates in zone C (bins 15–18). If there are no acceptable child candidates in zone C, the organs will be offered to adolescents in zone C (bins 19 and 20), then to adults in zone C (bins 21 and 22). If no suitable candidates are identified, the order of offers in zone C is followed for zones D and E (bins 23–38) (14; OPTN Policy 3.7.11.1).

Allocation exceptions

The current allocation policy allows for special review of exceptional cases when the treating transplant team believes that the assigned LAS or priority level does not appropriately reflect the severity of the case, or when essential clinical values must be estimated to assign a score (14; OPTN Policy 3.7.6.4). Requests for exceptions to the standard scoring criteria are sent to the Lung Review Board through OPTN/UNOS. The Lung Review Board, a seven-member board selected from separate lung transplant centers, reviews all exception requests nationwide (15). The Board has 7 days to reach a decision about each case. If the exception is granted, the requested score or value applies for 6 months. If the candidate remains on the waiting list

6 months after being granted an exception, the request for exception must be renewed or the candidate's score will be recalculated according to the standard formulae (14; OPTN Policies 3.7.6.4, 3.7.6.1 and 3.7.6.3).

If the Lung Review Board denies the request for exception, the transplant center may appeal the decision. If the request is denied a second time, the transplant center has the option of overriding the decision of the Board. If the transplant center chooses to override the decision, the action will be reviewed by the OPTN/UNOS Thoracic Organ Transplantation Committee to determine if the center abused the override provision. If abuse is determined, the action may be referred to the Membership and Professional Standards Committee of OPTN/UNOS for evaluation (14; OPTN Policy 3.7.6.4).

The evolution of the LAS and future directions

The current LAS calculation was designed to be re-evaluated and refined as frequently as every 6 months. The first change to the LAS formula occurred in late 2008, when PCO_2 level was added to the LAS calculation (14,16; OPTN Policy 3.7.6.1 (b)). This parameter was added after analysis indicated that including PCO_2 values would increase the accuracy of the LAS in predicting wait-list mortality and posttransplant survival.

In 2008, OPTN approved the addition of bilirubin to the LAS calculation, although determining how bilirubin could be most effectively integrated into the calculation has taken some time (14,17; OPTN Policy 3.7.6.1 (c)). The proposed methodology for including bilirubin is expected to be factored in to LAS calculations sometime in 2012–2013. Although the bilirubin modification to the LAS will have little effect on most current transplant candidates, it will make a substantial difference for some candidates with idiopathic pulmonary arterial hypertension (iPAH), whose scores currently understate risk of death while on the waiting list.

The Lung Subcommittee of the OPTN/UNOS Thoracic Committee is in the process of developing and approving a revision to the LAS to improve the score's overall ability to predict wait-list mortality and posttransplant survival. This modification will include the already approved and developed bilirubin addition, and more comprehensive adjustments to the formula (18). The approval process to implement the fully revised LAS model has not been completed and the full effects of the final adjustments are not known. Modifications to the LAS calculation will continue as additional measures and criteria are determined to be predictors of waiting list and posttransplant outcomes. The required reviews of the formula have imparted flexibility that will allow the calculation to change with new criteria and changing candidate populations. Though the LAS assigned to an individual candidate may change based on evolving models, the mandate to decrease wait-list mortality and increase posttransplant survival will ensure that the candidates most in need will continue be prioritized on the waiting list.

Heart Allocation

History of heart allocation

We provide an overview of heart allocation policy evolution (Table 3) in response to changing trends in treatment and outcomes (including use of mechanical circulatory support [MCS] to stabilize critically ill patients awaiting transplant), historically, at present, and into the future. In the 1980s, OPTN assembled a policy review committee of heart surgeons and cardiologists, which became the Heart Transplant Committee. The Heart Transplant Committee expanded to include all thoracic organs in 1988, and in 1991 it became known as the Thoracic Organ Transplantation Committee. This committee primarily develops and monitors heart and lung organ allocation policies and reviews issues related to procurement and transplant, including the scientific, medical and ethical aspects. The committee is composed of regional representatives including physicians, surgeons or transplant coordinators; transplant hospital and OPO representatives; and at least one public or patient representative (e.g. a transplant candidata or recipient or a family member). Additional monitoring oversight is provided by the regional review boards (RRBs), which evaluate regional requests to list candidates as Status 1A or 1B by exception. Generally composed of transplant surgeons, physicians and coordinators, RRBs evaluate the appropriateness of exceptions on the basis of clinical information and compliance with OPTN policies.

To initially list a heart transplant candidate as Status 1A or 1B or to extend Status 1A or 1B justification form. OPTN is responsible for "the development, monitoring, enforcement and modification of the policies that govern the allocation, procurement and the transportation of deceased organs" (19). Policies under OPTN jurisdiction are outlined in detail in the Code of Federal Regulations (Final Rule) Part 42, section 121.4, and in the OPTN bylaws (20). Policy development is a collaborative process between OPTN, the transplant community, and the public. Any interestad party may forward proposals for policies directly to the Committee Chair or via other representatives. Although time-limited variances may be established for experimental policies that test methods of improving allocation, most policy changes undergo lengthy evaluation and comment before implementation (20). When heart allocation policy changes are required or requested, the Thoracic Committee develops a proposal using data provided by UNOS and/or SRTR. Performance indicators and additional analyses may also be requested to measure the effect of the proposed changes. Required analyses may include the effect on various transplant programs due to transplant volume, risk-adjusted total life-years pre- and posttransplant, risk-adjusted waiting time and OPO performance. If the

Table 3: Summary of major changes to heart allocation policy

Date	Policy change
1988	Approved primary allocation criteria for hearts: medical urgency status; waiting time; distance of donor to recipient hospital and identical blood groups unless medical urgency dictated otherwise.
	Approved 2 medical urgency categories: Status 1 (candidates implanted with MCS device or admitted to ICU and requiring inotropic support) and Status 2 (all other candidates).
	Approved geographic zones A, B and C, comprising concentric circles with the donor hospital at the center (zone A, within 500 miles of the donor hospital; zone B within 1000 miles; zone C beyond 1000 miles).
	Permitted local OPOs to allocate hearts to potential recipients at local transplant programs on the basis of the primary allocation criteria.
	Permitted the Heart Transplant Committee, Organ Procurement and Distribution Committee, and Board of Directors to resolve local-level inequities or conflicts regarding donor heart distribution arising from prevailing OPO boundaries or policies.
	Established essential and desirable data needed for each heart offer.
1989	Required OPOs to apply to the Heart Transplant Committee to establish a variance.
	Prohibited inter-OPO sharing of hearts.
	Included allocation of lungs in the existing heart allocation criteria.
	Prohibited heart or heart–lung candidates from accruing waiting time while inactive on the waiting list.
1990	Enabled candidates aged < 6 months to be categorized Status I.
	Changed "heart" to "thoracic organ" in the policy dictating the minimum data requirements for thoracic organ offers.
	Removed requirement to confirm blood typing of thoracic organs in the policy dictating the minimum data requirements for thoracic organ offers because rerunning the test is redundant.
1991	Required that heart and lung be recovered from a deceased donor if these organs could be transplanted.
	Made the host OPO responsible for appropriate donor management to assure recovery of multiple thoracic organs when possible.
1992	Permitted registration of *in utero* candidates on the waiting list.
1993	Permitted candidates to receive the waiting time accrued for 1 thoracic organ when listed for a second thoracic organ.
	Permitted a candidate to transfer waiting time for multiple thoracic organ transplant to a single thoracic organ.
	Required transplant programs to list candidates needing heart and liver transplants as two separate waiting list registrations.
	Created a joint heart–liver allocation policy that: (1) required the OPO to offer a heart and liver from a deceased donor to a joint heart–liver candidate if the donor and candidate were in the same local area and (2) recommended that OPOs voluntarily share the second required organ (heart or liver) if the candidate and the deceased donor were not in the same local area.
	Restricted accrual of Status 1 time to the period when the candidate was listed as Status 1.
	Allowed a candidate to carry over time accrued at Status 1 to Status 2.
1994	Required reporting of hepatitis B and C data for all thoracic organs offered.
	Stratified heart–lung match runs by acceptable donor height instead of donor weight.
	Required reporting of echocardiogram data, if the donor hospital has the facility to perform it, for all thoracic organs offered.
	Required all thoracic organ transplant centers within an OPO and the OPO to agree to prioritize a sensitized thoracic candidate for an organ offer.
1999	Prioritized pediatric candidates for receiving adolescent deceased donor heart offers.
	Prohibited use of an adult or pediatric candidate's level of sensitization as a reason for listing that candidate as Status 1A by exception.
	Permitted an adult or pediatric candidate's transplant center to determine the candidate's sensitization level.
	Implemented heart medical urgency Statuses 1A, 1B and 2 for adult and pediatric candidates.
	Assigned Status 1A to candidates with uncomplicated VADs for ≤ 30 days and admitted to the listing transplant center.
	Assigned Status 1A to candidates with complicated MCS for > 30 days.
	Required submission of a heart Status 1A justification form to the OPTN contractor within 24 h of listing or recertification as Status 1A.
	Created the primary blood group matching system still in use.
	Allocated deceased donor hearts to local Status 1A, 1B and 2 candidates before offering them to Status 1A and 1B candidates in zones A and B (Status 2 candidates in zones A and B received deceased donor heart offers after Status 1A and 1B candidates in zones A and B).
	Dissolved variances that existed until this time, but participants in the dissolved variances could reapply in cases of need for alternative local allocation systems.
	Allowed adult and pediatric candidates to be listed as Status 1B by exception.
	Enabled adult and pediatric candidates in need of both a heart and lung to appear on lung match runs.
	Allowed for allocation of domino donor hearts.
2000	Required that RRBs approve extensions of Status 1A by exception listings, beyond an extra 7 days for adult and an extra 14 days for pediatric candidates.

Continued

Table 3: Continued

Date	Policy change
2001	Allowed submission of heart status justification forms via UNet.
	Lowered status to 1B automatically upon conclusion of a candidate's permitted time at a Status 1A criterion, unless the candidate's physician recertified Status 1A listing.
2002	Allowed candidates implanted with VADs to receive 30 days of time at Status 1A, regardless of admission to the listing center.
	Classified as blood type "Z" candidates listed *in utero* or able to accept an ABO-incompatible deceased donor heart offer.
	Allowed candidates aged < 1 year to receive ABO-incompatible deceased donor heart offers but only after these hearts were offered to ABO-compatible candidates.
	Allowed candidates *in utero* to receive deceased donor hearts after all born candidates.
2003	Created the geographic zone D for thoracic organ allocation.
2005	Removed inpatient requirement for adult candidates listed as Status 1A by criterion (b).
2006	Modified the heart allocation sequence so adult local and zone A Status 1A and 1B candidates receive heart offers from deceased donors aged 0–11 years and adult deceased donors before local Status 2 candidates; zone B Status 1A and 1B candidates receive these heart offers before zone A and B Status 2 candidates.
	Dissolved all programmed heart variances.
2007	Defined zone D as the geographic area 1500–2500 miles, inclusive, from the donor hospital.
	Created the geographic zone E, > 2500 miles from the donor hospital.
2009	Prioritized pediatric candidates to receive pediatric (ages 0–17 years, inclusive) deceased donor hearts.
	Combined local and zone A geographical areas for broader geographic sharing of pediatric donor hearts.
2010	Increased the maximum age for listing pediatric candidates for ABO-incompatible hearts from 1 to 2 years.
	Required isohemagglutinin titer data entry for all born candidates eligible to receive an ABO-incompatible heart offer, and set isohemagglutinin titer and treatment-based eligibility restrictions for ABO-incompatible transplants.
	Created an interim policy for adult, outpatient candidates implanted with TAHs allowing these candidates to be listed as Status 1A for 30 days.
2011	Required OPOs to provide human leukocyte typing of thoracic organs offered if requested to do so by the transplant programs receiving the organs offered.
	Codified the process whereby RRBs examine and approve requests to list candidates as Status 1A for device-related infection or complications not detailed in policy.
	Dissolved the Status 1 listing verification policy, as it was no longer current.
	Extended for 1 year the interim policy for outpatient candidates implanted with TAHs.
	Removed identification of specific inotropic agents from the adult heart policy, because the OPTN contractor maintains an updated list of these medicines in UNet.

ICU = intensive care unit; MCS = mechanical circulatory support; OPO = organ procurement organization; OPTN = Organ Procurement and Transplantation Network; RRB = Regional Review Board; TAH = total artificial heart; VAD = ventricular assist device.

proposal involves a substantive change in policy, the Committee distributes the proposal for public comment for a maximum of 45 days. Policy proposals that require immediate action due to patient health and safety concerns, that clarify or correct existing policy rather than substantively change it, or are administrative in nature do not require public comment (19). When the public comment period ends, the Committee submits a briefing document, including its responses to public comments and its final recommendations, to the Board of Directors, which then votes on the policy. Policies approved by the Board and recommended for enforcement as mandatory are forwarded to the Secretary of HHS for review and comment a minimum of 60 days before implementation, in accordance with OPTN Final Rule Section 121.4(b) (19). Mandatory policies cannot be enforced without the Secretary's approval. The Secretary may solicit guidance from the Advisory Committee on Organ Transplantation and elect to publish proposed policies in the Federal Register for public comment before approval (20). OPTN provides the Secretary and the membership with copies of its policies as they are adopted and publishes current and pending policies on the Internet for public access. OPTN heart allocation policies are re-evaluated periodically by the Thoracic Committee to determine whether they achieve their stated objectives and remain relevant in light of scientific and technological advances (19).

The overarching goal of heart allocation policy is to prioritize organ allocation to the most critically ill heart transplant candidates, as evidenced by the current urgency-based algorithm and ongoing policy deliberations. Over the past two decades, as the clinical profile of end-stage heart failure patients has evolved, heart allocation policies have similarly evolved. The original heart allocation system approved in 1988 was a two-tiered policy using medical urgency codes that applied to adult and pediatric candidates. Regional variances were allowed but required approval by the Heart Transplant Committee (Report of the Heart Transplant Committee to the Board of Directors, February 28, 1989). Hearts were allocated based on medical urgency code and time, first within the DSA, then within the OPO region and subsequently to the rest of the United States (20).

In 1989, the Heart Transplant Committee implemented the new allocation algorithm using only two tiers for medical urgency, Status 1 and Status 2. This policy, in effect until 1999, applied to adult and to pediatric candidates. Status I defined patients who required MCS, including total artificial heart (TAH), ventricular assist device (VAD), intraaortic balloon pump (IABP) or ventilator support; candidates in an intensive care unit (ICU) and requiring inotropes; and, in the one pediatric-specific consideration, candidates aged <6 months. All other actively listed heart transplant candidates were designated Status 2. Although this policy was an improvement over the prior system, it did not include in the highest urgency category other critically ill adult patients, such as those with untreatable, life-threatening arrhythmias or those in whom MCS or inotropes were contraindicated (20).

In 1999, OPTN implemented a major policy change that assigned higher priority to sicker Status I patients whose short-term survival was compromised. Medical urgency was expanded to three tiers (Status 1A, 1B, and 2). The highest urgency category (1A) required that candidates be admitted to the transplant center. Candidates whose life expectancy was <7 days could be listed and recertified as Status 1A after review by the RRB and Thoracic Organ Transplantation Committee. Candidates with VADs (and no VAD complications) for more than 30 days and candidates on continuous inotropes qualified for Status 1B. This new allocation scheme decreased median waiting times for Status 1A and 1B patients compared with prepolicy Status I patients, and decreased wait-list mortality (21).

The 1999 heart allocation policy change also established criteria for pediatric candidates (aged 0–17 years at the time of listing) and mandated that within each status category, adolescent donor hearts (ages 11–17 years) would be offered preferentially to pediatric candidates in an effort to improve wait-list survival (14,20,22). The preferential allocation to pediatric candidates resulted in more adolescent donor hearts being transplanted into pediatric recipients (23). Young donor hearts (ages 0–10 years), however, continued to be allocated according to the algorithm for adult donor hearts. As part of the broader geographic sharing initiative, the pediatric policy was revised in 2008 and implemented in 2009. This revision preferentially allocated *all* pediatric donor hearts (ages 0–17 years) to pediatric candidates and used the pediatric distribution sequence for all pediatric donor hearts rather than the adult distribution scheme for younger hearts as in the previous policy.

Monitoring oversight of Status 1A listings increased with the establishment of RRBs in 1999 and the requirement that Status 1A justification forms be completed by the transplanting center to justify a candidate's listing as 1A, which replaced random ICU audits under the previous policy. Increased oversight improved compliance with Status 1A listing policies (23). Table 4 lists the major adult and pediatric heart allocation policy changes, 1988 through 2011.

Adult candidates implanted with VADs

Early MCS devices improved survival over medical therapy, but were associated with significant device- and procedure-related complications and lacked durability (24). Newer devices have substantially fewer complications and improved durability compared with their predecessors. Heart allocation policies have kept pace with changes in VAD development and have been adjusted accordingly.

Under the 1989 policies, transplant candidates with VADs were categorized as Status I due to lack of durability of the devices and high complication rates. Beginning in 1999, candidates with VADs could be listed as Status 1A only if the device had been implanted for ≤30 days or for >30 days if a device-related complication occurred, such as thromboembolism, infection or mechanical failure. Candidates with TAH, IABP, extracorporeal membrane oxygenator (ECMO), mechanical ventilation or high dose inotropes also qualified for Status 1A. To minimize VAD-associated complications, candidates with left and/or right VADs (LVAD/RVAD) were upgraded to Status 1A for 30 days immediately after implantation regardless of medical stability or appropriateness for a second surgery.

In June 2002, OPTN discontinued the policy requiring Status 1A time to be accrued immediately after VAD implantation. As a result, candidates with VADs can be listed as Status 1A for 30 days any time after VAD implantation. The 2002 policy did not require that VAD patients be hospitalized to be listed as Status 1A, allowing VAD patients to stabilize before listing to minimize perioperative and post-transplant complications.

Pediatric candidates implanted with VADs

The 1999 changes to the pediatric heart allocation policy allowed pediatric candidates implanted with VADs or other MCS devices, including ECMO, to qualify for listing as Status 1A. Admission to the listing transplant center was not and is not required. No major policy change has occurred in this category since 1999.

Geographic sequence for organ distribution

Under early policies, heart allocation first occurred locally within the DSA or an approved alternative local unit. DSAs are geographic units served by an OPO. If no local recipient was identified, the donor heart was allocated to one of three zones defined by concentric circles of 500 nautical miles with the donor hospital at the center; zone A is within 500 miles of the donor hospital, zone B > 500–1000 miles, and zone C > 1000 miles. The zones were established to facilitate coordination and to minimize ischemic time.

The sequence of allocation has undergone revision to prioritize organs to the most critically ill heart transplant candidates (Table 5). In the 1999 revision, organs were offered to local Status 1A, 1B and 2 candidates before being offered to candidates in zones A, B or C. A consequence

Table 4: Comparison of historical and current heart allocation policies[1]

Component	Policies		
	1989–1999	1999	Current
Medical urgency	2-tiered, Status 1 and 2	3-tiered, Status 1A, 1B and 2	Status 1A, 1B and 2
Geographic sequence	Local, zone A, zone B, zone C	Local, zone A, zone B, zone C	Adult donors: OPO Status 1A, 1B; zone A Status 1A, 1B; local Status 2 (Figure 5). Pediatric donors: combined OPO and zone A Status 1A pediatric; OPO Status 1A adult; OPO + zone A Status 1B pediatric; OPO Status 1B adult; zone A Status 1A, zone A Status 1B (Figure 6).
ABO blood type	Identical/compatible not differentiated for Status 1; differentiated for Status 2, identical prioritized for Status 2	Primary ABO prioritized before secondary ABO within each Status category	Primary ABO prioritized before secondary ABO within each status category; allocation to candidates eligible to receive a heart from any blood type donor after allocation to all compatible blood types
Time waiting	Status 1 time = Status 1 time; Status 2 time = Status 1 + Status 2 time	Status 1A time = Status 1A time; Status 1B time = Status 1A + 1B time; Status 2 time = Status 1A + 1B + 2 time	Status 1A time = Status 1A time; Status 1B time = Status 1A + 1B time; Status 2 time = Status 1A + 1B + 2 time
Heart–lung	Separate category, allocated after Status 1 heart	May be on both heart and lung lists; lungs go with heart or heart goes with lungs if no Status 1A heart candidate	May be on both heart and lung lists; lungs go with heart or heart goes with lungs if no Status 1A heart candidate
Pediatric considerations	Age < 6 months may be Status 1	Separate urgency criteria, preference to pediatric recipient for adolescent donor	Separate urgency criteria, preference to pediatric candidate for pediatric donor
Sensitized patients	Local agreement	Local agreement	Local agreement
Monitoring issues	Status 1 random audits of ICU location	Regional review boards for assignment of status; random audits of justification forms	Regional review boards for exceptions to Status 1A and 1B; random audits for Status 1A and Status 1B justification forms

OPO = organ procurement organization.
Status 1, candidates requiring total artificial heart, left or right ventricular assist device, intraaortic balloon pump, ventilator, or in intensive care unit requiring inotrope therapy; Status 2, all other actively listed candidates. Geographic zones: Local, donation service area; zone A, < 500 nautical mile radius of donor hospital; zone B, 500-< 1000 miles; zone C, 1000–1500 miles; zone D, 1501–2500 miles; zone E > 2500 miles. Pediatric heart donor is defined as age < 18 years; pediatric heart candidate is defined as age < 18 years at the time of listing. Primary ABO compatibility includes all four identical combinations (O donor/O candidate, A donor/A candidate, B donor/B candidate, AB donor/AB candidate) and O donor/B candidate, A donor/AB candidate, and B donor/AB candidate; secondary ABO compatibility includes O donor/A candidate and O donor/AB candidate; ABO identical includes O donor/O candidate, A donor/A candidate; B donor/B candidate, AB donor/AB candidate; ABO compatible includes O donor/A, B, or AB candidate and A donor/O candidate, B donor/O candidate.
[1]Adapted from Renlund et al. (20).

of this allocation sequence was that local Status 2 candidates would be offered a compatible donor heart ahead of Status 1A or 1B candidates in zone A or B. The sequence was revised in 2006; under the new policy, hearts could be offered to Status 1A and 1B candidates in zone A before being offered to Status 2 local candidates. This policy change affected adult and young pediatric (ages 0–10 years) donor hearts.

In 2008, the Pediatric Transplantation Committee proposed a new allocation sequence to reduce wait-list mortality in younger patients and to expedite allocation of young donor hearts (ages 0–10 years) to pediatric patients. The new sequence, implemented in 2009, mandated that all pediatric donor offers be allocated first to combined local and zone A pediatric Status 1A candidates, then to local adult Status 1A candidates, then to combined local and zone A pediatric Status 1B candidates, before being offered to adult and pediatric candidates according to the prior algorithm (Table 5).

Blood group considerations

In the 1989 system, ABO identical and ABO compatible were considered equal for Status 1 patients. A Status 1 candidate whose blood group was identical to a donor's received the same consideration as a candidate whose blood group was compatible. For Status 2 candidates within a specified geographic zone, ABO identical received priority over ABO compatible. Consequently, waiting times for blood group O candidates increased substantially

Table 5: Evolution of the heart allocation sequence

January 1999–June 2006	Current Adult Heart Sequence[1]	Current Pediatric Heart Sequence
	1. OPO Status 1A ABO primary candidates	1. Combined OPO and zone A Status 1A ABO primary pediatric candidates for pediatric donor
1. Local Status 1A	2. OPO Status 1A ABO secondary candidates	2. Combined OPO and zone A Status 1A ABO secondary pediatric candidates for pediatric donor
2. Local Status 1B	3. OPO Status 1B ABO primary candidates	3. OPO Status 1A ABO primary candidates
3. Local Status 2	4. OPO Status 1B ABO secondary candidates	4. OPO Status 1A ABO secondary candidates
		5. OPO + zone A Status 1B ABO primary pediatric candidates for pediatric donor
	5. Zone A Status 1A ABO primary candidates	6. OPO + zone A Status 1B ABO secondary pediatric candidates for pediatric donor
	6. Zone A Status 1A ABO secondary candidates	7. OPO Status 1B ABO primary candidates
4. Zone A Status 1A	7. Zone A Status 1B ABO primary candidates	8. OPO Status 1B ABO secondary candidates
5. Zone A Status 1B	8. Zone A Status 1B ABO secondary candidates	9. Zone A Status 1A ABO primary candidates
	9. OPO Status 2 ABO primary candidates	10. Zone A Status 1A ABO secondary candidates
6. Zone B Status 1A	10. OPO Status 2 ABO secondary candidates	11. Zone A Status 1B ABO primary candidates
7. Zone B Status 1B	11. Zone B Status 1A ABO primary candidates	12. Zone A Status 1B ABO secondary candidates
	12. Zone B Status 1A ABO secondary candidates	13. OPO Status 2 ABO primary pediatric candidates for pediatric donor
8. Zone A Status 2	13. Zone B Status 1B ABO primary candidates	14. OPO Status 2 ABO secondary pediatric candidates for pediatric donor
	14. Zone B Status 1B ABO secondary candidates	15. OPO Status 2 ABO primary candidates
	15. Zone A Status 2 ABO primary candidates	16. OPO Status 2 ABO secondary candidates
	16. Zone A Status 2 ABO secondary candidates	17. Zone B Status 1A ABO primary pediatric candidates for pediatric donor
	17. Zone B Status 2 ABO primary candidates	18. Zone B Status 1A ABO secondary pediatric candidates for pediatric donor
9. Zone B Status 2	18. Zone B Status 2 ABO secondary candidates	19. Zone B Status 1A ABO primary candidates
	19. Zone C Status 1A ABO primary candidates	20. Zone B Status 1A ABO secondary candidates
	20. Zone C Status 1A ABO secondary candidates	21. Zone B Status 1B ABO primary pediatric candidates for pediatric donor
10. Zone C Status 1A	21. Zone C Status 1B ABO primary candidates	22. Zone B Status 1B ABO secondary pediatric candidates for pediatric donor
11. Zone C Status 1B	22. Zone C Status 1B ABO secondary candidates	23. Zone B Status 1B ABO primary candidates
12. Zone C Status 2	23. Zone C Status 2 ABO primary candidates	24. Zone B Status 1B ABO secondary candidates
	24. Zone C Status 2 ABO secondary candidates	25. Zone A Status 2 ABO primary pediatric candidates for pediatric donor
		26. Zone A Status 2 ABO secondary pediatric candidates for pediatric donor
		27. Zone A Status 2 ABO primary candidates
		28. Zone A Status 2 ABO secondary candidates
		29. Zone B Status 2 ABO primary pediatric candidates for pediatric donor
		30. Zone B Status 2 ABO secondary pediatric candidates for pediatric donor
		31. Zone B Status 2 ABO primary candidates
		32. Zone B Status 2 ABO secondary candidates
		33. Zone C Status 1A ABO primary pediatric candidates for pediatric donor
		34. Zone C Status 1A ABO secondary pediatric candidates for pediatric donor
		35. Zone C Status 1A ABO primary candidates
		36. Zone C Status 1A ABO secondary candidates
		37. Zone C Status 1B ABO primary pediatric candidates for pediatric donor
		38. Zone C Status 1B ABO secondary pediatric candidates for pediatric donor
		39. Zone C Status 1B ABO primary candidates
		40. Zone C Status 1B ABO secondary candidates
		41. Zone C Status 2 ABO primary pediatric candidates for pediatric donor
		42. Zone C Status 2 ABO secondary pediatric candidates for pediatric donor
		43. Zone C Status 2 ABO primary candidates
		44. Zone C Status 2 ABO secondary candidates

OPO = organ procurement organization.
Zone D was added in 2003 and zone E in 2007.
[1]At implementation, this policy applied to adult donors and young pediatric donors but not to adolescent donors. In May 2009, when the pediatric donor policy was modified, this policy applied only to adult donors.

between 1988 and 1995 (20). The 1999 revisions attempted to rectify this by prioritizing blood group O hearts first to blood group O or B recipients (primary ABO matching), irrespective of waiting time for other potentially compatible blood groups. Other primary ABO matching categories included the following: blood type A donors were prioritized to blood type A or AB recipients; blood type B donors to type B or AB recipients and blood type AB donors to type AB recipients. Other compatible pairs, O donor/A candidate or O donor/AB candidate, were considered secondary ABO matching pairs. This prioritization scheme applied to each urgency category and geographic zone. Policy for ABO-incompatible (ABO-I) heart transplant was established by OPTN in 2001 (25,26); hearts were allocated to infants aged <1 year listed for ABO-I heart transplant only if no ABO compatible candidate nationwide accepted the donor heart.

Current heart allocation policies

Current heart allocation policy reflects an effort to prioritize hearts to the sickest heart transplant candidates on the waiting list, while taking into account technological advances that have changed the clinical profile and prognosis. This is supported by recent revisions to the policy and ongoing proceedings attempting to provide more granularity to the current medical urgency criteria. US heart allocation policy is based on medical urgency, waiting time, blood group compatibility and geography. The most important recent revision to heart allocation policy occurred in 2006, when the geographic sequence was modified, prioritizing the most critically ill patients while taking into account optimal maximal ischemia time. Changing VAD technology and effective heart failure therapies have introduced a new level of medical and ethical complexity to the discussion of allocation policies, and the current policy is being reviewed and revisions considered that would reflect emerging technology and changing wait-list survival and posttransplant outcomes.

Medical urgency status (OPTN Policies 3.7.3 and 3.7.4)

Adult criteria: Adult heart transplant candidates qualify for a status code corresponding to medical urgency. Status 1A, the highest medical urgency code, has 4 subcategories (Table 6). Status 1A candidates must be admitted to the listing transplant center, except for LVAD/RVAD candidates, who qualify for 30 days as Status 1A (subcategory a (i)), and candidates with device complications (subcategory b). Status 1A candidates must meet one of the four criteria outlined in Table 6 (Policy 3.7.3).

Qualification for Status 1A under subcategories a–c (with the exception of a (i)) is valid for 14 days and must be recertified every 14 days from the time of initial listing. Qualification for Status 1A under subcategory d is valid for 7 days and must be recertified every 7 days. Centers are notified of the need for recertification and unless the criteria are recertified, candidates are automatically reclassified to Status 1B (9).

LVAD/RVAD candidates and candidates on continuous intravenous inotrope infusion who do not meet Status 1A criteria qualify for Status 1B. These candidates are not required to be admitted to the transplant center or to be using high-dose inotrope infusion. Candidates who do not meet criteria for Status 1A or 1B may be listed as Status 2. Those who are temporarily unsuitable for receiving an organ are listed as Status 7 (inactive) and will not receive organ offers.

Pediatric criteria: Pediatric candidates (aged <18 years) qualify for listing as Status 1A for 14 days under five criteria (Table 7). After 14 days from the initial listing, the candidate is automatically downgraded to Status 1B, unless the attending physician recertifies the 1A listing. A heart Status 1A justification form must be submitted to UNet^{SM} for new Status 1A candidates, and for extension of current Status 1A candidates. The pediatric policy is similar to the adult policy but provides two additional criteria: 1A (d) addresses candidates who qualify for Status 1A if they are infants aged <6 months with acquired or congenital heart disease and reactive pulmonary hypertension (>50% of systemic level); 1A (f) addresses candidates who qualify for Status 1A if the life expectancy is <14 days without heart transplant (e.g. refractory arrhythmia) and do not meet criteria for Status 1A (a), (b), (c), (d) or (e). Pediatric candidates who are receiving a single inotrope (dopamine or dobutamine) in low dosage, are aged <6 months and do not fulfill the criteria of Status 1A, or have growth failure (defined as <1.5 standard deviations of expected growth or greater than fifth percentile for height and/or weight) qualify as Status 1B. Candidates who do not meet criteria for Status 1A or 1B are listed as Status 2, and candidates who are temporarily unsuitable to receive a thoracic organ transplant are listed as Status 7. Pediatric heart transplant candidates who remain on the waiting list at the time of their eighteenth birthdays without having undergone heart transplant continue to qualify for medical urgency status based on the pediatric criteria. There is no policy requirement that pediatric candidates be hospitalized or receiving hemodynamic monitoring to qualify for Status 1A.

Status exceptions (OPTN Policy 3.7.3)

Candidates who do not meet criteria for Status 1A or 1B but have documented need for urgent listing may qualify for an exception. Transplant physicians must submit a status justification form to the RRB describing the rationale for the exception. Candidates may be listed as Status 1A or 1B by exception whereas the RRB reviews the status justification. If the RRB does not approve the exception, the physician may list the candidate as Status 1A or 1B while awaiting an appeal to the Thoracic Organ Transplantation Committee. Adult candidates considered for Status 1A

Table 6: Adult candidate status 1A and 1B (OPTN Policy 3.7.3)

Status	Subcategory	Qualifications	Comments
1A		Candidate should be admitted to the hospital where the heart transplant is to be performed and should be managed with one of the following therapies or devices:	
	(a)	MCS for acute hemodynamic decompensation and at least one of:	
		(i) LVAD/RVAD	Candidates may be listed for 30 days as 1A at any point, hospitalization not required.
		(ii) TAH	
		(iii) IABP	
		(iv) ECMO	Qualification under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified to extend 1A Status.
	(b)	MCS with objective medical evidence of significant device-related complications (infection, thromboembolism, ventricular arrhythmias, mechanical failure, other related complications) approved by heart RRB.	Admission to listing center not required.
	(c)	Continuous mechanical ventilation.	Qualification under criterion 1A(b) or (c) is valid for 14 days and must be recertified every 14 days to extend 1A Status.
	(d)	Continuous infusion of single or multiple inotropes in addition to hemodynamic monitoring.	Qualification under 1A(d) is valid for 7 days and must be recertified every 7 days to extend 1A Status.
1A exception		Candidates who do not meet the above criteria	Initial listing requires approval by the RRB and is valid for 14 days. Further extension requires review and approval by the RRB.
1B		At least one of the following devices or therapies:	
	(aa)	LVAD/RVAD	
	(bb)	Continuous infusion of intravenous inotropes	
1B exception		Does not meet the above criteria for 1B	Requires provision of justification and review by the RRB.

ECMO = extracorporeal membrane oxygenation; IABP = intraaortic balloon pump; LVAD/RVAD = left or right ventricular assist device; MCS = mechanical circulatory support; OPTN = Organ Procurement and Transplantation Network; RRB = Regional Review Board; TAH = total artificial heart.

exception must be admitted to the listing transplant hospital. The pediatric allocation policy incorporates language for exceptions to Status 1A under criterion (f). Listing under this criterion is valid for 14 days and does not require admission to the listing transplant center hospital. Further extension requires a conference with the RRB. If a pediatric candidate does not meet Status 1B criteria but is considered a 1B candidate, the transplant physicians can apply for and justify Status 1B listing to the RRB.

Waiting time (OPTN Policy 3.7.9)

Within each status category, allocation is based on waiting time. Waiting time is accrued while the candidate is listed as Status 1A, 1B and 2; however, time accrued at a lower status does not accrue toward time at a higher status. Specifically, all accrued time is applied while awaiting heart transplant as Status 2, but time accrued as Status 1A is applied only to 1A time, and time accrued as Status 1B is combined with 1A time for total 1B time. Therefore, a candidate on the waiting list for 3 weeks as Status 1A and never listed as Status 2 receives priority over a candidate who has waited for 2 weeks as Status 1A and has combined Status 1A and Status 2 time of 3 months. When applicable, time accrued on the waiting list for a single thoracic organ (heart or single lung) may also accrue for a second thoracic organ when the candidate requires a multiple thoracic organ transplant (heart–lung or double lung). Alternatively, time accrued for a multiple thoracic organ transplant (heart–lung) may be transferred to time for a single thoracic organ (heart only) (14).

Mechanical circulatory support

Adult candidates with MCS devices: Ventricular assist devices

Current OPTN thoracic organ allocation policy allows LVAD and/or RVAD patients to be listed as Status 1A for 30 days at any point after implantation once they are deemed clinically stable by the treating physician, without being admitted to the transplant facility (14; Policy 3.7.3). Candidates with objective evidence of MCS device-related complications can be listed as Status 1A, subcategory (b), without being admitted to the hospital. Centers may request exceptions for other complications (except sensitization) not described in the policy statement as justification for listing

Table 7: Pediatrics candidate status 1A and 1B (OPTN Policy 3.7.4)

Status	Subcategory	Qualification	Comments
1A		Candidates aged < 18 years at the time of listing qualify for Status 1A if one of the following criteria is met:	
	(a)	Ventilator	
	(b)	Mechanical assist device	
	(c)	IABP	
	(d)	Infant aged < 6 months with acquired or congenital heart disease and reactive pulmonary hypertension > 50% of systemic level	May be treated with prostaglandin E.
	(e)	High dose inotropes (e.g. dobutamine ≥ 7.5 mcg/kg/mn or milrinone ≥ 0.5 mcg/kg/mn) or multiple inotropes (e.g. addition of dopamine ≥ 5 mcg/kg/mn).	Qualification for 1A(a), (b), (c), (d) and (e) is valid for 14 days and requires recertification.
	(f) Exception	Does not meet above criteria but has a life expectancy without heart transplant of < 14 days (e.g. refractory arrhythmias)	Qualification for 1A(f) is valid for 14 days and may be recertified for one additional 14-day period; extensions beyond this require conference with the RRB.
1B		Candidate must meet at least one of the following criteria:	
	(a)	Infusion of low dose single inotropes	
	(b)	Aged < 6 months and does not meet criteria for Status 1A	Growth failure is defined as defined as loss of 1.5 standard deviations of expected growth (height or weight) or < 5th percentile for height and/or weight.
	(c)	Growth failure	
1B exception		Does not meet above criteria for Status 1B	Requires provision of justification and review by the RRB.

IABP = intra-aortic balloon pump; OPTN = Organ Procurement and Transplantation Network; RRB = regional review board.

as Status 1A. These requests are subject to review by the respective RRB (14; Policy 3.7.3).

Total artificial heart. The policy implemented in 1999 classified inpatient heart transplant candidates with TAHs as Status 1A. Once discharged, however, these candidates no longer qualified as Status 1A but could be listed as Status 1B. This policy did not address outpatient TAH candidates, as this patient population did not exist until recently. The Thoracic Organ Transplantation Committee thus proposed an interim policy that allows for the accrual of 30 days of Status 1A time at any point after discharge for a TAH candidate, similar to the VAD policy. This policy was approved by the OPTN Board of Directors and implemented in November 2010. Candidates with TAHs can qualify for an unlimited amount of Status 1A time, a provision that remains contentious because the total Status 1A time that can be accrued by an LVAD and/or RVAD candidate without complications is 30 days. As of this writing, the current revision to the TAH policy will expire in December 2012 (14).

Pediatric candidates with MCS devices: Pediatric candidates with MCS, including ECMO, VADs and TAHs, are eligible to be listed as Status 1A indefinitely with recertification every 14 days under criteria (b) (Table 7). Because all pediatric candidates with MCS are eligible under this criteria, the pediatric heart policy does not specifically address VAD-related complications or infections.

Geographic Sequence (OPTN Policy 3.7.2)

Adult donors: In 2006, OPTN began prioritizing zone A Status 1A and 1B candidates ahead of local Status 2 candidates (Table 5). This revision was intended to reduce the death rate on the waiting list. Despite an increase in wait-list mortality between 2007 and 2008, wait-list mortality decreased overall from 199 deaths per 100 patient-years at risk in 1999 to 170 in 2008 (27). Thus, the policy change appeared, in part, to have favorably influenced wait-list mortality.

The policy change also resulted in a higher proportion of candidates undergoing transplant as Status 1A and 1B. The wider geographic sharing promoted by this policy raised concerns regarding decreased posttransplant survival, due to potentially longer ischemia times and more procedures in more urgent recipients; however, 1-year survival after this policy was implemented was not adversely affected, based on OPTN/SRTR data as of October 2010.

Heart allocation accounts for medical urgency while optimizing geographic distribution to reduce ischemia time. Allocation begins within the DSA and expands according

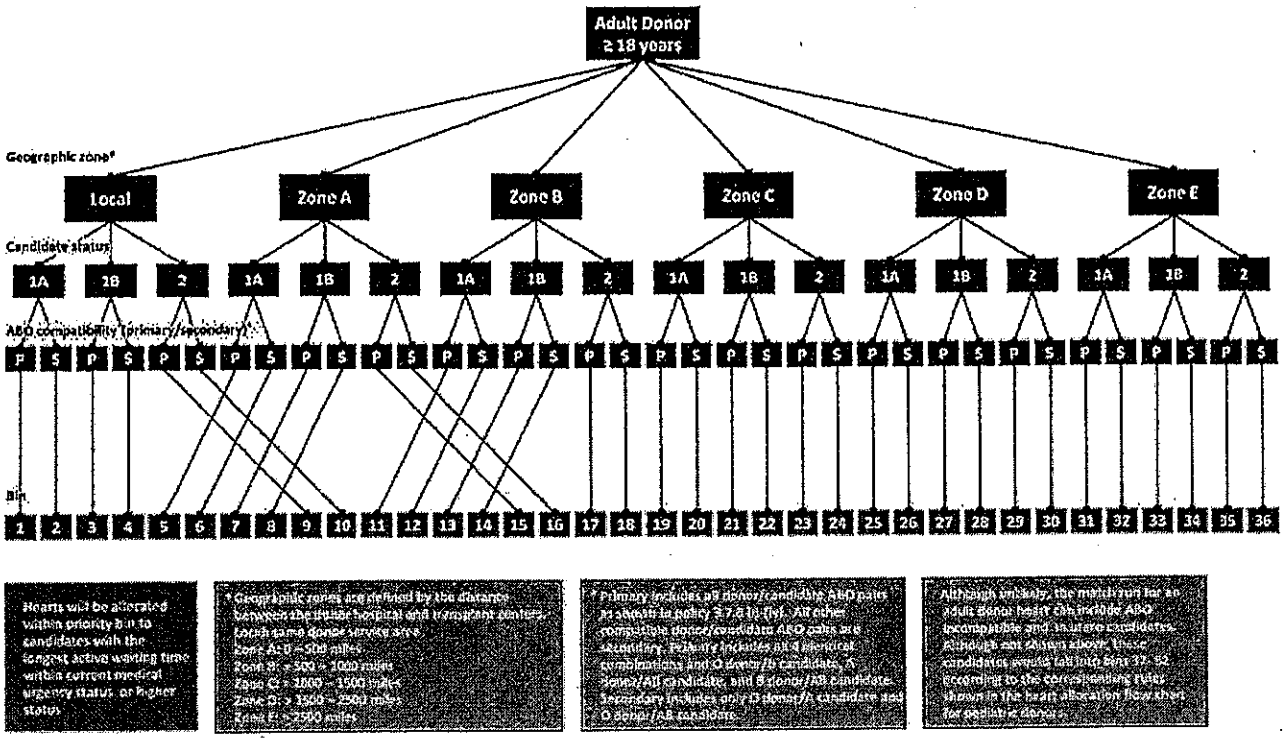

Figure 5: Allocation of hearts from adult (ages ≥ 18 years) donors. This figure can be downloaded in color from www.srtr.org.

to geographic zones defined by concentric circles of 500 nautical mile radii from the donor recovery hospital as follows: zone A, 0–500 miles; zone B, >500–1000 miles; zone C, >1000–1500 miles; zone D, >1500–2500 miles; zone E, >2500 miles. A donor heart is first offered locally to Status 1A (Figure 5, bins 1 and 2) or 1B (bins 3 and 4) candidates. Within each status category, hearts are allocated first to candidates with primary ABO matches and subsequently to secondary blood types. If the organ is not accepted for a compatible recipient, it is offered to zone A Status 1A (bins 5 and 6) or 1B (bins 7 and 8) candidates. If there is no zone A recipient, the offer reverts to the DSA for local Status 2 candidates (bins 9 and 10). If there is no compatible recipient, the organ is offered to zone B Status 1A (bins 11 and 12) or 1B (bins 13 and 14) candidates. If there is no compatible recipient, the organ is offered to zone A Status 2 (bins 15 and 16) candidates. If there is no compatible recipient, allocation proceeds as follows: zone B, Status 2 (bins 17 and 18); zone C, Status 1A, 1B or 2 (bins 19–24); zone D, Status 1A, 1B or 2 (bins 25–30); zone E, Status 1A, 1B or 2 (bins 31–36). Thus, in this sequence, Status 1A or 1B candidates in the subsequent region precede Status 2 candidates in the preceding region up to zone B (OPTN Policy 3.7.8; Figure 5).

Pediatric donors: Current pediatric heart allocation policy preferentially allocates pediatric donor hearts to pediatric candidates. Consistent with the broader sharing policy, offers for pediatric donor hearts are initially made to pediatric candidates within the combined local DSA and zone A region for Status 1A candidates with preference for primary ABO matching (Figure 6A, bins 1 and 2). If the heart is not accepted for a pediatric candidate, it is offered to local Status 1A adults (bins 3 and 4). If there is no compatible Status 1A recipient, the organ is offered to Status 1B pediatric candidates within the combined DSA and zone A region (bins 5 and 6), and subsequently to Status 1B adults within the OPO (bins 7 and 8). If there is no compatible recipient, the heart is offered to Status 1A and 1B adult candidates within zone A (bins 9–12). Allocation then proceeds to candidates as follows: OPO Status 2 pediatric and adult (bins 13–16), zone B Status 1A pediatric then adult (bins 17–20), zone B Status 1B pediatric then adult (bins 21–24); zone A Status 2 pediatric then adult (bins 25–28); zone B Status 2 pediatric then adult (bins 29–32). Allocation to candidates in zones C–E proceeds in order of medical urgency with pediatric candidates first within each Status category and preference to primary ABO compatibility (bins 33–68).

ABO considerations (Policy 3.7.8)

Very young pediatric candidates (aged ≤14 months) are unique in their potential to accept an ABO-I donor heart because isohemagglutinins (anti-A and anti-B antibodies) develop late in infancy (28,29). In 2006, OPTN approved

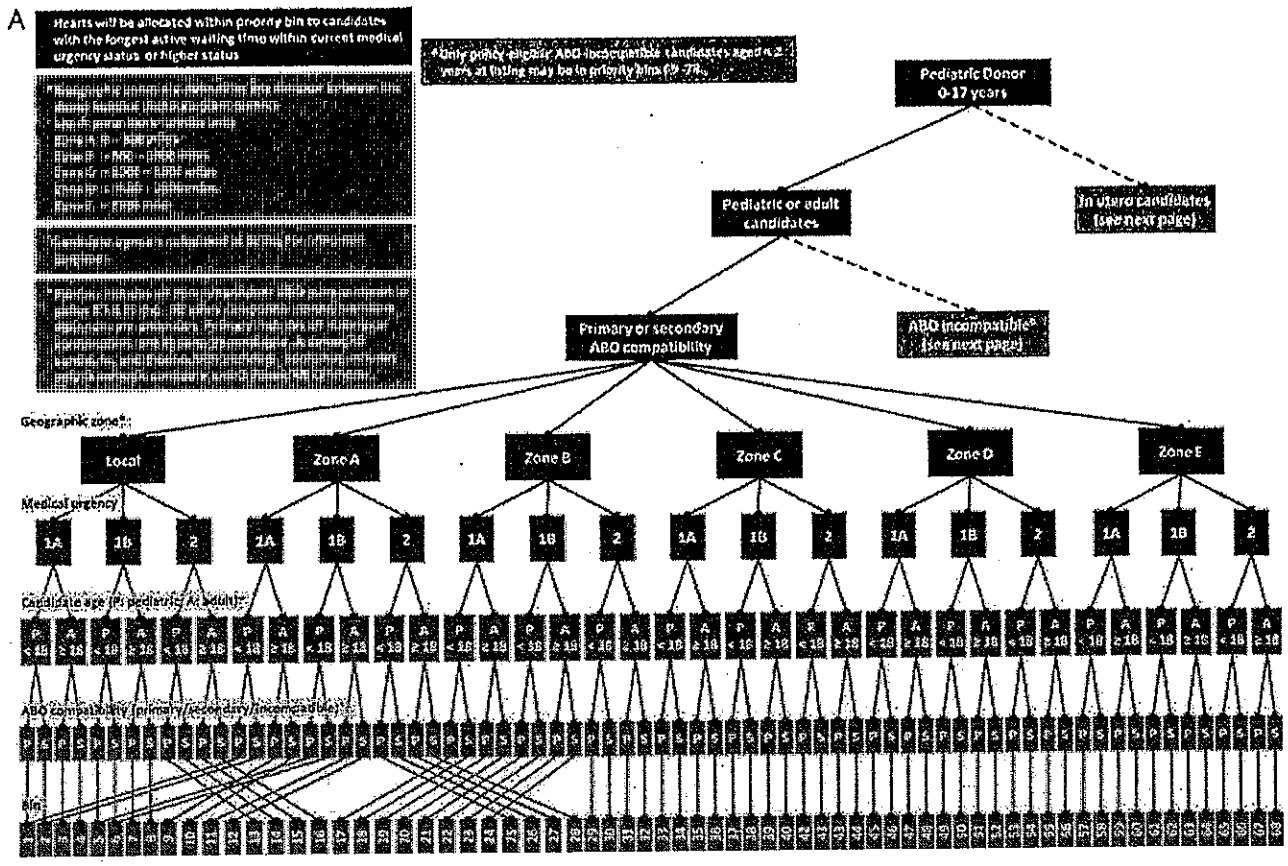

Figure 6: Allocation of hearts from pediatric (ages 0–17 years) donors, (A) bins 1–68 and (B) bins 69–93. This figure can be downloaded in color from www.srtr.org.

ABO-I heart transplant in children added to the waiting list before their second birthdays and meeting certain conditions (30). This policy was implemented in 2010. As a result, in 2007 the proportion of eligible infants aged <6 months listed for ABO-I heart transplant was 53% (31). Before a donor heart is allocated to an ABO-I candidate, the list of born (postnatal) ABO-compatible recipients must be exhausted (Figure 6A, bins 1–69). The donor heart is allocated first to Status 1A and 1B ABO-I pediatric candidates in the combined OPO and zone A region (Figure 6B, bins 69 and 70), then to local Status 2 pediatric ABO-I candidates (bin 71), then to Status 1A and 1B pediatric ABO-I candidates in zones B–E (bin 72–79). If no compatible candidates are eligible for ABO-I transplant, the heart is allocated to *in utero* candidates. Under current policies, to qualify for an ABO-I donor heart, a candidate must be (1) *in utero*; (2) aged <1 year and listed as Status 1A or 1B or (3) aged ≥1 year but listed before age 2 years and currently listed as Status 1A or 1B. For candidates aged ≥1 year, current isohemagglutinin titer must be ≤1:4 for A or B blood type antigens and the candidate must not have received treatments within the prior 30 days that may have reduced titer values to ≤1:4 (Policy 3.7.8).

Heart–lung allocation (Policy 3.7.7)

Between 2000 and 2011, 399 simultaneous heart–lung transplants were performed. In January 2011, the Thoracic Organ Transplantation Committee encouraged thoracic transplant programs to list candidates who require simultaneous heart–lung transplant for both organs according to listing policies governing each organ individually, and to list them on the heart–lung waiting list. Priority for a heart–lung transplant candidate on the lung transplant waiting list is determined by the LAS (for candidates aged ≥12 years), and on the heart waiting list by medical urgency status code as described earlier. When a donor heart becomes available to an eligible candidate, the lung is allocated from the same donor. When the candidate is eligible to receive a lung, the heart is allocated from the same donor only if no suitable Status 1A isolated heart candidates are eligible to receive the heart.

ABO matching requirements are determined by which organ match run the candidate is included in; ABO matching policy for heart allocation is used if the candidate is included in the heart match run, and for lung allocation if in the lung match run.

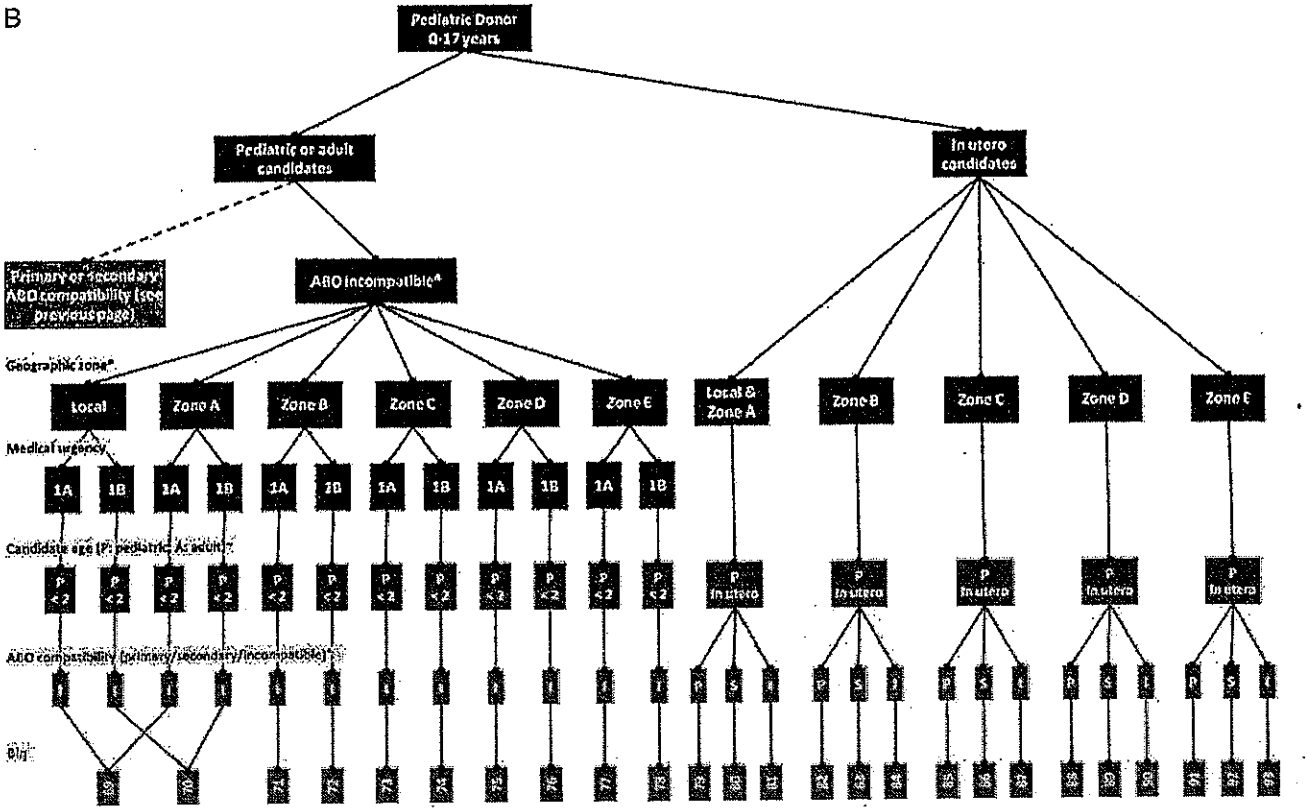

Figure 6: Continued.

Allocation of domino donor hearts (Policy 3.7.15)

Domino heart transplant refers to procurement and transplant of the native heart of a combined heart–lung transplant recipient. When a domino heart is available, it is first offered to candidates at the transplant center from which the native heart was procured. If the program does not use the heart, it is allocated based on the general heart policy or an approved variance. Only one domino heart transplant procedure has been performed in the United States since 1997.

Comparison to international heart allocation policies

Most heart allocation policies throughout the international transplant community are based on medical urgency with waiting time being a secondary feature (Table 8). Similar to the US allocation policies, algorithms are based on geography, which in some countries may extend to neighboring countries. For instance, if no country within the Scandiatransplant community has a suitable donor, a donor heart may be allocated to a recipient in another European country through an international exchange program. In general, heart transplant candidates appear to be grouped into urgent and nonurgent categories in several international allocation schemes. Similar to trends in the United States, a growing proportion of candidates are listed in the high-urgency category, similar to UNOS Status 1A, following revision of the Eurotransplant allocation policy in 2000 and 2005, which provided for a high urgency category in addition to an urgent category (32–34). Furthermore, candidates who receive VADs (excluding nondurable mechanical support such as ECMO or IABP) are removed from the urgent category unless they develop VAD-related complications, a policy similar to that in the United Kingdom and countries in the Scandiatransplant program (35,36). Scandiatransplant policy will consider candidates aged less than 16 years and with an LVAD for more than 1 year as high-urgent status (Priority 0) (37). The Canadian Cardiac Transplant Network allocation system promotes nationwide allocation. The allocation algorithm has six categories, with Status 4 being the highest urgency category. (Table 8) Hearts are allocated using a nationwide list, although priority is given to the region where the donor heart becomes available. When there are competing potential recipients, the recipient with the longest current listing as Status 4 is given priority. Similar to other international policies, candidates with VADs are listed in the highest urgency category when complications occur. Otherwise, candidates with VADs are listed as Status 3 (38). These international allocation policies could help inform discussions about future heart allocation policy in the United States.

Table 8: Examples of international heart allocation policies

Country	Policies
Canadian Cardiac Transplant Network (38)	Status 4: (1) Mechanically ventilated patient on high-dose single or multiple inotropes ± mechanical support (e.g. IABP, ECMO, abiomed BVS5000 or biomedicus), excluding VAD. (2) Patient with VAD malfunction or complication, such as thromboembolism, systemic device-related infection, mechanical failure or life-threatening arrhythmia. (3) Patient should be reconfirmed every 7 days as a Status 4 by a qualified physician if still medically appropriate. Status 4S: (1) High PRA (> 80%), or PRA > 20% with three prior positive crossmatches (in the setting of negative virtual or actual donor/recipient-specific crossmatch and appropriate size and blood type of the prospective donor). Status 3.5: (1) High-dose or multiple inotropes in hospital, and patients not candidates for VAD therapy or no VAD available. (2) Acute refractory ventricular arrhythmias. Status 3: (1) VAD not meeting Status 4 criteria. (2) Patients on inotropes in hospital, not meeting above criteria. (3) Heart/lung recipient candidates. (4) Cyanotic congenital heart disease with resting saturation < 65%. (5) Congenital heart disease, arterial-shunt dependent. (6) Adult-sized complex congenital heart disease with increasing dysrhythmic or systemic ventricular decline. Status 2: (1) In-hospital patient, or patient on outpatient inotropic therapy not meeting the above criteria. (2) Adult with cyanotic CHD: resting 02 saturation 65%-75% or prolonged desaturation to <60% with modest activity (i.e. walking). (3) Adult with Fontan palliation with protein-losing enteropathy or plastic bronchitis. (4) Patients listed for multiple organ transplantation (other than heart–lung). Status 1: All other out-of-hospital patients
Eurotransplant community[1] (32–34)	Each EU country has a unique algorithm. Heart allocation policy generally based on medical urgency. Major difference from US policy is that candidates with VAD are not automatically considered candidates for urgent heart transplant. Once a VAD is implanted, patient loses urgent status. If a patient with a VAD (irrespective of medical urgency for heart transplant) develops VAD-related complications, status for heart allocation is changed to urgent. Criteria for urgency status include: 1. Continuous IV inotropic therapy. 2. Assist device complications. 3. Documented intractable recurrent ventricular rhythm disorders. 4. End-stage transplant vasculopathy. 5. Persisting angina pectoris.
Scandiatransplant[2] (37) countries	Donor hearts used locally among patients labeled priority 0 (high urgent). If a member country lacks a priority (0/1) patient, a donor heart is provided to a patient labeled priority 2 in the region. If all member countries lack a suitable recipient, the donor heart is provided to other European countries through European organ-exchange organizations. Priority classifications: 0: ECMO, centrifugal pumps, blood pumps (implantable) with uncontrollable infection or device failure; patients aged < 16 years on LVADs for more than 1 year or on inotropes. Patient status renewed weekly. 1: This classification not used for heart transplant. 2: Patients who are transplantable. 3: Patients who are not transplantable.
United Kingdom Transplant Services Authority (36)[3]	Heart-allocation policies in the United Kingdom and Ireland are based on principles of biological matching, clinical priority, logistical factors such as ischemia time, prior sternotomies, adult congenital heart disease (ACHD), prior VADs etc. and fairness (time on waiting list) (19). Uses urgent heart allocation scheme. Candidates on the nonurgent waiting list are allocated hearts when there are no suitable candidates on the urgent list. Urgent status includes use of high-dose continuous inotropes, IABPs (with or without inotropes), short-term MCS (e.g. venoarterial ECMO), long-term VADs and device-related complications.

CHD = coronary heart disease; ECMO = extracorporeal membrane oxygenation; IABP = intraaortic balloon pump; LVAD = left-ventricular assist device; MCS = mechanical circulatory support; PRA = panel reactive antibody; VAD = ventricular assist device.

[1]Netherlands, Germany, Austria, Belgium, Croatia, Germany, Slovenia.

[2]Denmark, Finland, Norway, Sweden.

[3]United Kingdom and Ireland.

Future directions

Adult heart allocation policy: Current heart allocation policy attempts to prioritize allocation to the sickest candidates. As evidenced by recent revisions to the TAH policy, the policy is dynamic, allowing for adaptation in response to the latest technological and medical innovations, and the changing transplant candidate population. There is controversy over whether candidates with VADs, who are now stabilized, should continue to receive 30 days of Status 1A time and a potential listing advantage over sicker patients (39). Compared with older VADs, newer-generation VADS produce fewer complications and can effectively treat heart failure for extended periods; thus this policy may no longer be necessary. In its effort to revise the adult heart Status 1A policy, the OPTN/UNOS Thoracic Organ Transplantation Committee is considering changing the length of time a VAD candidate would receive Status 1A time. Thirty days is arbitrary, and how long a VAD candidate should receive Status 1A time may depend on factors such as the type of VAD. These data are being evaluated and will inform planned future policy change. The OPTN/UNOS Thoracic Organ Transplantation Committee is revising criterion (b), which allows clinicians to classify adult heart transplant candidates experiencing MCS device complications as Status 1A. The goal of this revision is to more clearly define what constitutes VAD complications to prioritize the sickest VAD patients.

Policy revisions may also consider candidates who are disadvantaged by the current listing process due to cardiomyopathies for which VADs or inotropes are contraindicated. As VAD survival improves, it may be prudent to consider prioritizing patients who are unable to benefit from VADs. Finally, many heart transplant professionals question the continued appropriateness of the Status 2 category. One-year survival of Status 2 candidates approaches that of heart transplant recipients, suggesting that early listing of adults may no longer be justified (27). Furthermore, waiting times for Status 2 candidates have risen dramatically in recent years. The median time to transplant for a Status 2 candidate on the waiting list in 2010–2011 was 17.6 months, compared with 1.7 months for Status 1A and 5.5 months for Status 1B (based on SRTR data as of March 15, 2012). In some regions, wait-list survival of Status 2 candidates may exceed the projected survival benefit of heart transplant (40).

A new allocation scheme predicated on evidence-based markers of disease severity and outcomes is being considered. The Heart Subcommittee of the OPTN Thoracic Organ Transplantation Committee is currently considering revising the entire policy (Policy 3.7.3) to better address medical urgency and disease severity in candidates with MCS devices. These revisions are expected to specify definitions of MCS-related infections and complications to provide more guidance and consistency in assigning medical urgency subcategories.

In January 2011, OPTN began collecting data on MCS devices at the time a candidate is removed from the waiting list. These and other analyses are being reviewed to more accurately address the clinical heterogeneity among candidates with MCS devices. The revised allocation system may account for posttransplant survival and wait-list mortality as indicators of disease severity (41).

Pediatric heart allocation policy

The Heart Subcommittee, the Thoracic Working Group of the Pediatric Committee and investigators from the Pediatric Heart Transplant Study, an international registry of pediatric heart transplant candidates and recipients, have evaluated revisions to current heart allocation policies that will address medical urgency categories, *in utero* listings, and ABO-I transplant. *In utero* listings are rare, and at its April 2011 meeting the Pediatric Transplantation Committee voted unanimously to submit for public comment a proposal to eliminate all policies allowing *in utero* listings (42). Also, in light of data demonstrating that ABO-I transplants may be performed safely at isohemagglutinin titers higher than 1:4, proposals for a new titer threshold for ABO-I transplant are being considered. Finally, a proposal for revising medical urgency categories for pediatric candidates is in development, with a goal of reducing wait-list mortality in the highest risk groups. Under the current system, most pediatric heart candidates, particularly infants, are listed as Status 1A at the time of transplant, in effect changing the allocation process to one based on time rather than medical urgency. Current policy may disadvantage certain patients, such as infants with restrictive cardiomyopathy and hypertrophic cardiomyopathy. A revised pediatric heart policy is anticipated for public comment distribution in 2012. Proposed revisions will specifically address listing criteria for candidates with congenital heart disease (41).

Heart–lung policy

The current heart–lung allocation policy does not address the potential occurrence of a tie, in which 2 heart–lung candidates are eligible to receive the same heart–lung bloc in the same geographic area. Further, the current policy does not address geography, Status 1B candidates, or sick lung transplant candidates also in need of heart transplants. The Policy Oversight Committee is currently developing principles for multiorgan allocation that will be considered by the Thoracic Organ Transplantation Committee in the development of modifications for this policy.

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Disclosure

The authors of this manuscript have conflicts of interest to disclose as described by the *American Journal of Transplantation*: By virtue of employment at or affiliation with a transplant program or an organization with an interest in transplant program performance, any author of this manuscript could be perceived to have a conflict of interest. Beyond that, no author has any conflict of interest to disclose as described by the *American Journal of Transplantation*.

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Exhibit E

DECLARATION OF SHARON RUDDOCK

I, Sharon Ruddock, hereby declare and state as follows:

1. Sarah Murnaghan is a 10-year-old girl who was diagnosed with Cystic Fibrosis when she was 18 months old. She is now in the intensive care unit at Children's Hospital of Philadelphia ("CHOP").

2. I am Sarah Murnaghan's aunt. Her mother Janet is my sister. I am a business executive with an engineering degree from Cornell University and an MBA from Duke University.

3. Janet and her husband Francis have been very busy dealing with Sarah and her doctors. They also have been busy dealing with requests from the press about Sarah's case. As a result, they asked me to work with the lawyers who represent them to prepare this declaration. I have been communicating closely with Janet and Fran as well as Sarah's doctors for many months about Sarah's condition and the effort to obtain a donated set of lungs for Sarah.

4. Sarah has been in and out of hospitals since she was first diagnosed, with multiple trips to the hospital each year for 3 to 4 days at a time. She has also needed additional medical care at home. Despite her condition, until about 18 months ago she attended school and had a relatively normal life.

5. Sarah's condition grew worse about 18 months ago as her lung capacity diminished to about 30% of its normal capacity. She has required supplemental oxygen 24 hours a day since then. On December 7, 2011, Sarah was put on the pediatric lung transplant list, which means that she was then eligible to receive donated lungs preferentially from a child donor under 12 years of age.

6. Organ donation in the United States is controlled by the United Network for Organ Sharing ("UNOS"), a private entity that has a contract with the Department of Health and Human Services ("HHS") to operate the Organ Procurement Transplantation Network ("OPTN"), which was created by Congress. The OPTN has developed and published organ transplant policies which can be found on the OPTN's website. The specific policy at issue in Sarah's case is Policy 3.7 entitled "Allocation of Thoracic Organs."

7. Under Policy 3.7, Sarah is eligible for lungs donated from children under 12 based on time on the waiting list and severity (children are categorized as priority 1 or 2 based on severity) assuming the lung is compatible in size and blood type, lungs donated from adolescents aged 12 to 17 based on time on the waiting list and severity again assuming the lung is compatible in size and blood type but only after the lung is declined by all adolescents in the zone, and for lungs donated by adults based on time on the waiting list and severity again assuming the lung is compatible in size and blood type but only after the lung is declined by all adults and adolescents in the zone (the "Under 12 Rule"). As a practical matter, the Under 12 Rule prevents children like Sarah from being considered for a donation of a lung from the much larger pool of adult donated lungs or if children are offered adults lungs after they have been declined by all adults and adolescents in the zone the lungs are damaged or otherwise medically unsuitable.

8. In November of 2012 in order to increase the size of the donor pool Sarah's doctors increased the height range for Sarah's listing thus allowing her to receive organs from larger donors. If Sarah were to receive an offer from a larger donor then her surgeons would downsize the donor lungs to fit Sarah's smaller body.

9. For lung transplants, the size of the donated lung has to fit the thoracic cavity of the candidate for donation, but we have been advised that an adult lung can be downsized by the doctors and that, although this may be a complicating factor, the likely outcome is the same or nearly the same as with a lung that did not need to be downsized. I am aware of an Australian medical study that also validated that medical outcomes are the same or nearly the same with downsized lungs.

10. My understanding is that adults lungs are allocated based on several factors, including lung compatibility (based on size and blood type), geography (i.e., consideration of how far the donated organ has to be transported), and something called the lung allocation score ("LAS"), which is a formula that UNOS/OPTN uses to weigh severity and posttransplant survivability. I understand that the LAS system was meant to allocate lungs with preference to the most severe cases.

11. Sarah has received a LAS since the date she was listed for a lung transplant. The LAS system is not used for organ allocation but the data is required by UNOS. Sarah is categorized as priority 1 for child lungs. I read in the May 30, 2013 letter from John P. Roberts, M.D. of OPTN to Secretary Sebelius the suggestion that the LAS system is not used with children. This is contrary to our experience at CHOP. The doctors at CHOP have been responsible for providing the results of medical tests which are then used to calculate Sarah's LAS. The calculation is done by UNOS. UNOS has been tracking Sarah's LAS since she was added to the lung transplant organ listing. Further, I have had recent communications with many hospitals about possible lung donors and have discussed Sarah's LAS as a measure of severity of her condition with all of them. When she first went on the adult list it was 40. Over time, we watched that number grow into the 50s, then 60s, as Sarah's condition grew worse.

12. Sarah has been in CHOP for the past 103 days as of today. About two weeks ago, she took a turn for the worse and was admitted into the ICU. At that time, she had a significant and permanent loss of hearing because of the side effects of the antibiotics she must take. At the same time, her LAS went to 60. Since then, her LAS has climbed to 66, where it is today.

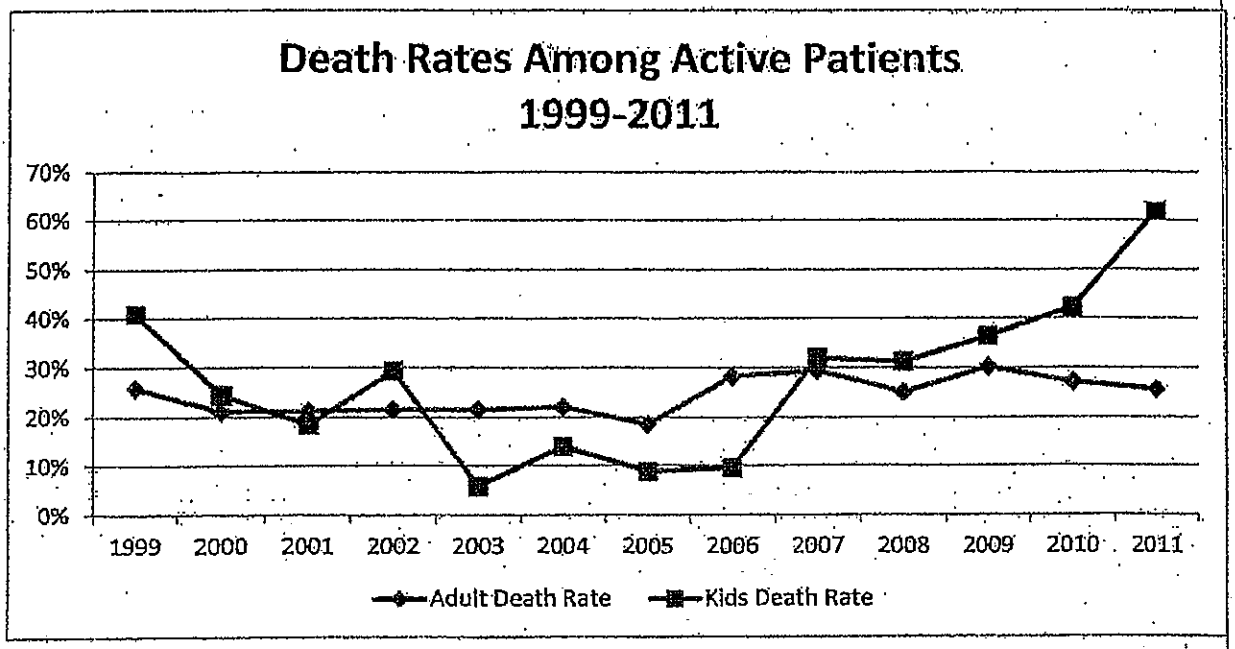
13. With a LAS of 66, if Sarah were an adult she would be very likely to receive a donated lung. Again, looking at the data available on the UNOS website, for 2011 (the last full year for which data is available) a LAS of 50 would put her in the top 6% of organ donor candidates. Assuming those numbers are similar for 2013, Sarah would be very near the top of the list, based on the severity of her condition.

14. Unfortunately, Sarah is not at the top of the list, she is instead at the very back of the list, because OPTN Policy 3.7 discriminates against children under 12.

15. I have reviewed the information on the UNOS website and the website of the Scientific Registry of Transplant Recipient ("SRTR"), a national database of transplantation statistics based on data from the OPTN. The SRTR works closely with UNOS and is responsible for ongoing data analyses designed to provide policy makers with information needed to make decisions. The data shows that children active on the lung transplant waiting list die at more than twice the rate as adults active on the lung transplant waiting list.[1] Attached hereto as Exhibit B is a table based on SRTR data that shows that the death rate for children is 62% vs 26% for adults in 2011. Also, the 2009-11 three-year average death rate is 46% for children versus 28% for adults. These conclusions are statistically significant. This same data for the

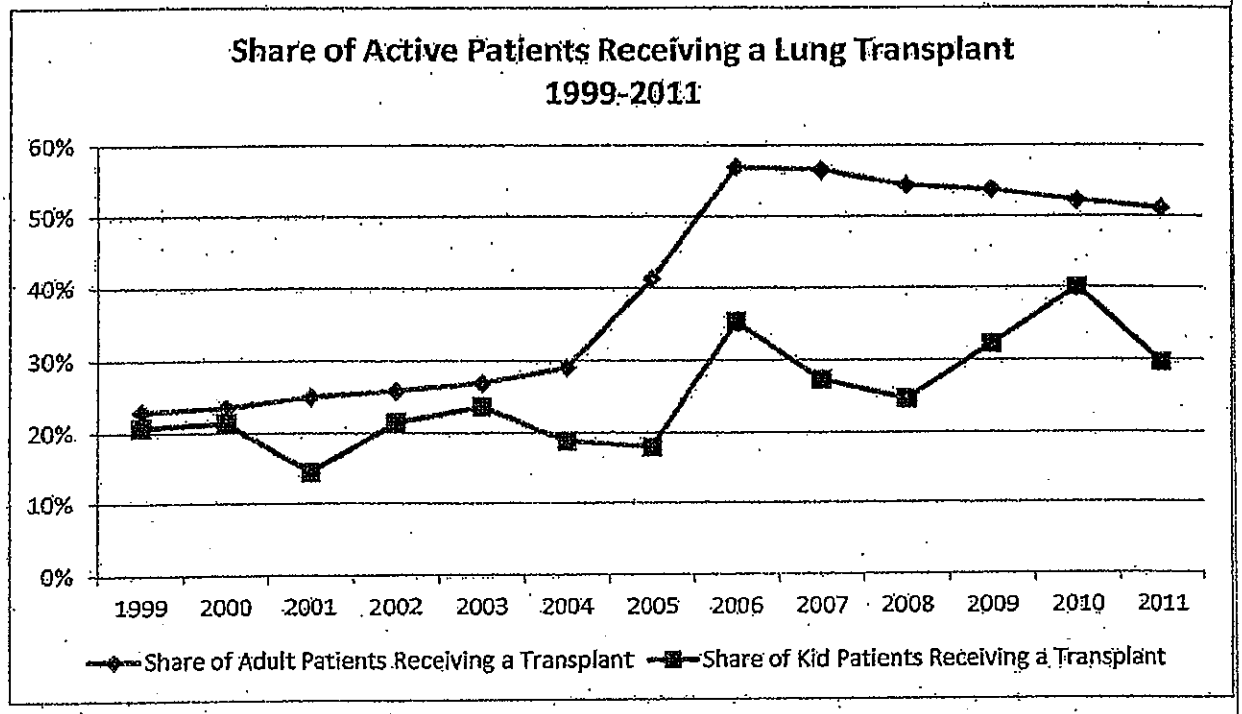
[1]Exhibit A attached hereto explains the use of active vs inactive patients in analyzing death rates.

years 1999 – 2011 shows a marked increase in the death rate for children since the OPTN implemented the Under 12 Rule in 2005. This can also be represented graphically, as follows;



16. As can be seen from UNOS data, attached hereto as Exhibit C, the success rate for children on the lung transplant list was 32%, while the success rate for the adults was 50%. Success rate is the percentage of people who get a lung transplant as compared to the total number who were on the transplant list at any time during the year. Since the Under 12 Rule was instituted in 2005, adults have experienced a substantial increase in success in receiving a

transplant from 29% in 2004 to 50% in 2011, while children are left behind with a success rate of 30%. This is represented graphically below:



17. The total number of lungs available for children in need of transplant is very small. I do not have access to current data but available UNOS data shows that there were only 23 lungs available in 2011 in the entire country. Given the limitations of blood type, size, and geographic range, a total pool of only 23 lungs is likely to result in few lung donations for a child on the lung transplant waiting list. In comparison, the adult transplant pool had 1,573 lungs available in 2011.

18. We are concerned that the segmentation by age can lead to significant statistical disparities between age groups. UNOS data for 2011 shows that if lungs were allocated within age segments of the 12 and over population, there would be significant statistical disparities.[2]

[2]UNOS data for children under 12 is not available to me.

Age Group	Percentage of Lungs Donated by Group	Percentage of Lung Transplants Received by Group
18-34 Yr Old	50%	12%
35-49 Yr Old	30%	13%
50-64 Yrs Old	19%	48%
65+ Yrs Old	1%	27%

19. To date, Sarah has not had any suitable offers of donated adult lungs through OPTN.

20. Through Sarah's doctors at CHOP, we have twice asked the Thoracic Committee of UNOS/OPTN if an appeal could be made to the OPTN Lung Review Board. UNOS/OPTN rejected both requests on the grounds that the OPTN Lung review Board has no discretion to set aside the Under 12 Rule.

21. On Thursday, May 16, 2013, Sarah's parents and I decided to fight this inequity and started a media campaign. We began actively looking for counsel shortly thereafter and on May 31 engaged the law firm of Pepper Hamilton.

22. We are asking the Department of Health and Human Services (HHS) to direct UNOS and the OPTN to set aside the Under 12 Rule on an emergency basis so that Sarah and other children can be considered for a lung donation on the same basis as persons over 12. We are not seeking preferential treatment, we only want her and the other children to be treated equally with persons over 12. This should not cause any significant disruption to the OPTN because there are very few children under 12 seeking donations of adult lungs. The UNOS data does not show the number of children under 12 seeking donation of adult lungs, but it does show the number of children aged 6-10 seeking lungs from any age donor, which is currently 16. In 2011, that number was 18. What this shows is that there are not many children seeking lung

donations overall, and the number seeking adult lungs would be even less. There may be a few more such children between 10 and 12, but in any event, it is a very small number in relation to the number of adults seeking lung transplants which is currently 1,637.

23. Sarah's doctors have told us that if Sarah could be considered as a candidate for an adult lung, without regard to her age, all other factors remaining equal, the chance of her receiving a compatible and medically appropriate adult lung would be greatly increased. They have also advised us that at this time Sarah's chances for successful lung transplant surgery are good.

24. Sarah has now been in Children's Hospital of Philadelphia for the last 103 days. Sarah's parents have been advised by her doctors that the medical outcome is uncertain and it's possible that she only has weeks to live.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

Sharon Ruddock 6/2/13

Sharon Ruddock

EXHIBIT A

Active Wait List vs Inactive

Because the pediatric waiting list system uses the amount of time a patient has accrued on the list is an important factor in determining when a patient will be eligible to receive an available donor organ, pediatric patients are incentivized to get on the waiting list as early as possible in order to accrue time and increase their standing on the list. As a result, there are many "inactive" patients on the pediatric list. "Inactive" patients are those who are on the waiting list accruing time though they are not currently seeking a donor organ. They may change their status to "active" when and if they are sick enough to need a transplant without losing their "place" on the list. Sixty-five percent of the children on the official waiting list today are "inactive."

Prior to 2005, the adult list was handled the same way as the pediatric list -- on a first come, first served basis. But in 2005, the approach used for the adult waiting list was changed to one that determines a patient's position on the list based on the severity of illness. Patients are assigned a LAS. This score is then used to determine who should receive donor lungs that become available. As a result, most adult transplant patients are not placed on the wait list until they are actually sick enough to need a transplant. The result of this is that there are now far fewer patients on the adult wait list who are "inactive" at any given time. In 2005, sixty-five percent of patients on the adult list were "inactive"; today, that number has dropped to twenty-two percent.

This causes a problem in determining if pediatric patients fare as well as adult patients under the current system. UNOS includes statistics from both "active" and "inactive"

patients on each wait list to calculate death rates. As a result, the percentage of pediatric patients who die each year while awaiting transplant *appears* to be lower than it actually is. Examining statistical data from two systems that operate under such different rules without making an adjustment to accommodate for those differences leads to inaccurate and misleading results. To obtain an accurate comparison of the death rates of patients on the adult list with those on the pediatric list I used *only* the data of "active" patients from each list.

EXHIBIT B

Death Rates for Children and Adults Active on the Lung Transplant Waiting List

Adult Active Patients

	Total Active Patients (beginning of year)	Total Deaths	Death Rate
1999	[redacted]	[redacted]	26%
2000	[redacted]	[redacted]	21%
2001	[redacted]	[redacted]	21%
2002	[redacted]	[redacted]	22%
2003	[redacted]	[redacted]	22%
2004	[redacted]	[redacted]	22%
2005	[redacted]	[redacted]	19%
2006	[redacted]	[redacted]	28%
2007	[redacted]	[redacted]	29%
2008	[redacted]	[redacted]	25%
2009	[redacted]	[redacted]	30%
2010	[redacted]	[redacted]	27%
2011	[redacted]	[redacted]	26%

Pediatric Active Patients

	Total Active Patients (beginning of year)	Total Deaths	Death Rate
1999	[redacted]	[redacted]	41%
2000	[redacted]	[redacted]	25%
2001	[redacted]	[redacted]	18%
2002	[redacted]	[redacted]	29%
2003	[redacted]	[redacted]	6%
2004	[redacted]	[redacted]	14%
2005	[redacted]	[redacted]	9%
2006	[redacted]	[redacted]	10%
2007	[redacted]	[redacted]	32%
2008	[redacted]	[redacted]	31%
2009	[redacted]	[redacted]	36%
2010	[redacted]	[redacted]	42%
2011	[redacted]	[redacted]	62%

EXHIBIT C

Success Rates for Children and Adults Active on the Lung Transplant Waiting List

	Adult Total Patients (Active)	Adults Getting Lungs	Adult Transplant Rate	Kids Total Patients (Active)	Kids Getting Lungs	Kid Transplant Rate
1999	4,013	919	23%	130	27	21%
2000	4,193	984	23%	112	24	21%
2001	4,284	1,070	25%	118	17	14%
2002	4,092	1,055	26%	98	21	21%
2003	4,080	1,095	27%	89	21	24%
2004	4,102	1,193	29%	101	19	19%
2005	3,446	1,422	41%	106	19	18%
2006	2,470	1,407	57%	82	29	35%
2007	2,618	1,481	57%	66	18	27%
2008	2,739	1,490	54%	61	15	25%
2009	3,107	1,670	54%	62	20	32%
2010	3,418	1,785	52%	65	26	40%
2011	3,580	1,830	51%	64	19	30%

[3] Total Adult Patients equals the count of active adult patients at the beginning of the year plus new active adult patients during the course of the year.

[4] Total Kid Patients equals the count of active kid patients at the beginning of the year plus new active kid patients during the course of the year.

Exhibit F

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

May 29, 2013

John Roberts, M.D.
President, OPTN Board of Directors
UCSF Medical Center
Room M-896, Room 0780
505 Parnassus Avenue
San Francisco, CA 94143-0780

Dear Dr. Roberts:

As I believe you are aware, there has been intense interest by the national media, Congress, and others in the case of a ten-year-old girl who is a lung transplant candidate in Pennsylvania. When 118,145 patients are on a transplant waiting list, including 1005 children ten and under, we must all be concerned that the Nation's organ and transplantation system is as fair and equitable as possible.

While I have been asked to begin the process of convening the Committee and potentially revising the protocol around lung transplants for children, I know that process can be lengthy and involves public input. Knowing the urgency of this situation, I am writing to you to request more information about the Organ Procurement and Transplantation Network (OPTN) policies and the process used by the OPTN to develop the policy relevant to this case. I would appreciate a response by 5:00pm on Thursday, May 30, 2013.

1. What is the current OPTN lung allocation policy for deceased donor lungs from both adult and pediatric donors? Please provide a summary of these policies.
2. What criteria were used by the OPTN in developing the current lung allocation policy? Please describe the process used to develop the OPTN lung allocation policy.
3. When was the current OPTN lung allocation policy approved and implemented by the OPTN?
4. How frequently does the OPTN consider changes to its lung allocation policy?
5. What are the medical risks inherent in transplanting adult donor lungs into a pediatric lung transplant candidate? How are these risks reflected in the OPTN lung allocation policy?

Thank you for your service to the Nation through your work with the OPTN. I look forward to your responses to these important questions as I seek to gain a greater understanding of the circumstances impacting this case. I appreciate your service and that of your colleagues dealing with this critical life-saving process.

Sincerely,

Kathleen Sebelius

Exhibit G

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

May 31, 2013

John Roberts, M.D.
President, OPTN Board of Directors
UCSF Medical Center
Room M-896, Room 0780
505 Parnassus Avenue
San Francisco, CA 94143-0780

Dear Dr. Roberts:

Thank you for your detailed response to my May 29, 2013 letter regarding lung transplant policy, particularly as it impacts children in need of these vital organs. I appreciate your timely attention to this serious matter.

I recognize that there is a significant disparity in the number of transplantable organs to the number of people in need of an organ. While more than 28,000 transplants occurred in 2012, over 118,000 people are currently waiting for an organ, and nearly 1,700 of them are waiting for a life-saving lung transplant. I am concerned that this disparity is especially stark for pediatric lung candidates as defined by the OPTN Lung Allocation Policy. In 2012, only 20 lung transplants occurred as a result of organs donated from pediatric organ donors age 0-11.

As Secretary, my role is one of oversight. I am tasked with ensuring that OPTN's policies are consistent with the National Organ Transplant Act and our regulations. As we stated in the preamble to our final regulations on the OPTN, "decisions about who should receive a particular organ in a particular situation involve levels of detail, subtlety and urgency that must be judged by transplant professionals." 64 Fed. Reg. 56650, 56652 (Oct. 20, 1999). Therefore, I am asking that the OPTN initiate a process to review the OPTN lung allocation policy as soon as possible. I ask that you pay particular attention to the age categories currently used in lung allocation; and review the policy with the intent of identifying any potential improvements to this policy that would make more transplants available to children, consistent with the requirements of the OPTN final rule to ensure equity in organ allocation while balancing best use of donor organs. I expect that this review will be a transparent, deliberative process, also consistent with the requirements of the OPTN final rule and that the OPTN membership and other interested parties will have an opportunity to provide comments.

With 1,819 pediatric patients on organ transplant waitlists and only 852 pediatric organ transplant donors each year, it is especially clear that we can and should, if possible, do more to encourage the public to become registered organ donors. It is important to encourage families to consider organ donation as a family issue, and think about how they would respond under tragic circumstances if their child were in a situation to become an organ donor. As challenging as this focus area is, I have asked the Health Resources and Services Administration (HRSA) Division of Transplantation to consider new approaches for promoting pediatric and adolescent organ donation.

I am also asking the HRSA Division of Transplantation to continue to work directly with you to address these issues. If you have any questions, please contact Bob Walsh, Director of the HRSA Division of Transplantation.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Exhibit H

DECLARATION OF ARTHUR P. BAINES

I, Arthur P. Baines, hereby declare and state as follows:

1. I am an economist with more than 20 years of business, economic and quantitative analysis experience. I am currently Vice President, at Charles River Associates, a global consulting firm offering business, economic, and management expertise. My credentials and experience are set forth in the curriculum vitae attached as Exhibit A to my Declaration.

2. I have been retained by the law firm Pepper Hamilton to assist it in its representation of the family of Sarah Murnaghan, a 10-year-old girl in the intensive care unit at Children's Hospital of Philadelphia ("CHOP"), who requires a lung transplant. Pepper has asked me to interpret statistical information relating to organ transplants available on the UNOS website and the website of the Scientific Registry of Transplant Recipient ("SRTR"). I have the expertise and experience to evaluate the data on these websites.

3. I have reviewed and evaluated the information set forth in paragraphs 15-18 of the Sharon Ruddock declaration and the exhibits to the Ruddock declaration, all of which are attached as Exhibit B to my Declaration, and incorporate by reference those paragraphs into my Declaration, with the exception of the first sentence of paragraph 16 which contains a slight error – it should refer to a success rate in 2011 for children of 30% versus 51% for adults. If called as a witness in a lawsuit on behalf of Sarah Murnaghan and her family, I am prepared to testify consistent with the statements in those paragraphs.

I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct, and that this declaration is executed this 4th day of June, 2013.

Arthur P. Baines