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IMPORTANT POLICY NOTICE

To: Transplant Professionals

From: James B. Alcorn
Director, Policy

RE: Summary of actions taken at June 10, 2013, OPTN/UNOS Executive Committee Meeting

Date: June 11, 2013

The attached report summarizes OPTN policy changes approved by the OPTN/UNOS Executive Committee at its June 10, 2013, meeting. This policy notice provides the specific policy language changes and the corresponding implementation dates. When reviewing the language changes, please note that underlined language is new and will be in effect upon implementation, and language that is ~~struck~~ will be deleted upon implementation. The policy language used to denote the changes approved at the June 10, 2013, Executive Committee meeting reflects the most recent version of policy that has been approved, but not necessarily what is currently implemented.

This policy notice, and those changes from previous Board of Directors meetings, can be found at optn.transplant.hrsa.gov (click on “News,” and then select “View all Policy Notices”).

For additional information on these policies, you should also review the relevant sections in the Evaluation Plan. The Evaluation Plan provides specific details regarding how members will be assessed for compliance with OPTN policies and bylaws. It can also be found at optn.transplant.hrsa.gov (click on “Policy Management,” and then select “Evaluation Plan”).

Thank you for your careful review of this policy notice. If you have any questions about a particular Executive Committee action, please contact your regional administrator at (804) 782-4800.

Lung Review Board Consideration of Pediatric Lung Candidate Classifications

Sponsoring Committee: Executive Committee

Policies Affected: 3.7.6.4 (Lung Candidates with Exceptional Cases)

Distributed for Public Comment: No

Effective Date: June 10, 2013 – July 1, 2014

Problem Statement

Sec. Kathleen Sebelius (HHS) requested that the OPTN “review the OPTN lung allocation policy as soon as possible.” As part of the review, Sec. Sebelius asked that the OPTN “pay particular attention to the age categories 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.”

The Lung Allocation Score (LAS) system does not apply to lung candidates less than 12 years old for deceased donor lungs offers. While there may be occasions where a lung candidate less than 12 years old would be more appropriately served by the LAS, policy does not provide a mechanism for the Lung Review Board (LRB) to consider (and act on) the validity of these cases.

Changes

Lung transplant programs may now submit a request to the LRB for lung candidates younger than 12 years old to have an additional listing, at the same hospital, ranking the candidate amongst adolescent lung candidates (12 to less than 18 years old) for offers from adult and adolescent donors based on the candidate’s LAS. The pediatric candidate would also retain his or her priority for pediatric donors younger than 12 years old.

The policy also clarifies the transplant program’s ability to override decision of the LRB in these cases.

Unless further action is taken by the Board of Directors, these policy changes will expire on July 1, 2014.

Action Required

Any lung transplant program caring for a lung candidate less than 12 years old may submit an exception application and a supporting narrative to the LRB to request to classify their candidate according to the new policy. If the application is approved, the candidate will receive a second registration in UNetSM. This second registration will contain a modified birth date that will allow the candidate to receive adult and adolescent donor lung offers as though the candidate were an adolescent.

Transplant programs should ensure that they have submitted all of the necessary information to

calculate the candidate's Lung Allocation Score (LAS). If the transplant program has not submitted the necessary information, the policy default values will be used to calculate the candidate's LAS. The candidate could then receive an LAS of zero, which would make the candidate ineligible to receive organ offers.

If the exception application is approved, the transplant program will need to maintain both waiting list records for the candidate.

Affected Policy Language:

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, and in the case of candidates aged 0-11 years old, transplant programs may request classification as an adolescent candidate for the purposes of Policy 3.7.11 (Sequence of Adult Lung Allocation) while maintaining their pediatric classification for the purposes of Policy 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation). 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, or adolescent classification, 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, adolescent classification, 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. If the MPSC agrees with the Thoracic Organ Transplantation Committee's decision, a member who has listed a candidate with an unapproved estimated value, adolescent classification, or Lung Allocation Score will be subject to 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 and adolescent classifications 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.

To read the complete policy language visit www.unos.org or optn.transplant.hrsa.gov. From the UNOS website, select "Policies" from the "I am looking for:" box in the upper left hand corner. From the OPTN website, select the "Policy Management" tab, then select "Policies."