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March 23, 2018

VIA E-MAIL

Kimberly Uccellini, MS, MPH
UNOS Policy Department
OPTN/UNOS Thoracic Organ Transplantation Committee

Re: OPTN/UNOS Thoracic Organ Transplantation Committee Proposals

Dear Ms. Uccellini,

On behalf of The Society of Thoracic Surgeons (STS), I am writing to provide comments on three OPTN/UNOS Thoracic Organ Transplantation Committee (Committee) proposals: "*Modifications to the Distribution of Deceased Donor Lungs,*" "*Modification of the Lung Transplant Recipient Follow-up Form (TRF) to Better Characterize Longitudinal Change in Lung Function following Transplantation,*" and "*Review Board Guidance for Hypertrophic and Restrictive Cardiomyopathy Exception Requests".* STS appreciates the opportunity to provide comments on these important proposals.

Founded in 1964, STS is an international not-for-profit organization representing more than 7,400 cardiothoracic surgeons, researchers, and allied health care professionals in 90 countries who are dedicated to ensuring the best surgical care for patients with diseases of the heart, lungs, and other organs in the chest. The mission of the Society is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

The Society offers the following comments regarding the Committee Proposals currently in the public comment phase.

Modifications to the Distribution of Deceased Donor Lungs

The overall role of organ allocation is to decrease waitlist mortality and improve posttransplant survival, while acting in accordance with the OPTN Final Rule. **Therefore, STS believes that that the 250-nautical mile radius is reasonable to promote the goal of the organ allocation process. However, we believe that going further and increasing the radius to a 500-nautical mile radius would improve organ allocation even more.**

STS recognizes the importance of this proposal and the need for additional data to make a more informed decision. **Therefore, STS believes that the transplant community, as well as the UNOS Thoracic Organ Transplant and Executive Committees, should be provided additional time and data in order to make an informed recommendation prior to making this proposal a permanent policy.** Importantly, the lung transplant community should take this opportunity to reevaluate and optimize lung allocations policies in the United States using data and simulated results for the betterment of all

patients and their families, while also considering the potential impact on our transplant providers and the cost-effective delivery of care. STS recommends that UNOS share the waitlist and post-transplant mortality data from before and after the radius change to allow for a more informed review of the policy prior to it being finalized.

Modification of the Lung Transplant Recipient Follow-up Form (TRF) to Better Characterize Longitudinal Change in Lung Function following Transplantation

STS appreciates that the Committee recognizes that the current Transplant Recipient Follow-up Form (TRF) is in need of updating, particularly because the current bronchiolitis obliterans syndrome (BOS) data is outdated, incomplete, or inaccurate and the Restrictive allograft syndrome (RAS) is not collected. Without the RAS data, the lung transplant community does not have data on the number of patients and the outcomes of patients with RAS, and transplant programs do not have a place to report on these patients.

The Committee's proposal to update the graft function section of the TRF to modify and update the data elements captured will allow reporting of RAF data and ensure a more complete data reporting of BOS data. **The STS believes that the proposed changes to the TRF are sorely needed and will allow for better outcomes evaluation moving forward.**

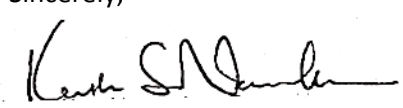
Review Board Guidance for Hypertrophic and Restrictive Cardiomyopathy Exception Requests

During their review to modify the adult heart allocation system in December 2016, the Committee received significant feedback that hypertrophic cardiomyopathy (HCM) and restrictive cardiomyopathy (RCM) candidates may be at a disadvantage in the policy due to the following factors: 1) HCM/RCM physiology may not benefit from mechanical circulatory support devices, but higher status on the list is device driven, 2) a lack of expertise in HCM/RCM physiology results will lend to a variability in Regional Review Board decisions nationwide, and 3) objectively quantifying the severity of the HCM/RCM illness is very difficult. Due to these challenges, the Committee has developed a guidance for review boards that seek to standardize the evaluation of HCM/RCM exception requests.

STS welcomes the Committee's recognition of the limitations on the HCM/RCM policy and believes that the proposed guidance is fair and represents a reasonable approach to patients with HCM/RCM.

We appreciate the Committee's efforts to ensure that the unique considerations for our patients awaiting transplants are recognized. We would welcome the opportunity to be a resource to the Committee as you continue your work on this important issue. Please contact Courtney Yohe, Director of Government Relations at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,



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