



The Society of Thoracic Surgeons

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September 28, 2017

VIA E-MAIL

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

**Re: Regional Review Board Guidance for Adult Congenital Heart Disease
Exception Requests**

Dear Ms. Uccellini:

On behalf of The Society of Thoracic Surgeons (STS), I am writing to provide comments on the proposal titled, "Regional Review Board Guidance for Adult Congenital Heart Disease Exception Requests." STS appreciates the opportunity to provide comments on this important document that recognizes the significant limitations in the new adult heart allocation system with respect to adult patients with congenital heart disease (ACHD). With the current heart allocation model, exceptions are useful in accommodating clinical circumstances for patients with ACHD that may not benefit from or are at high risk regarding mechanical circulatory support (MCS), limiting their options while awaiting a heart transplant. Therefore, The Society supports the OPTN/UNOS document that provides guidance on these ACHD exception requests.

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 appreciates that the Committee has identified certain limitations within the ACHD population. These limitations include: 1) that higher urgency statuses are currently device-driven and not based upon heart anatomy and that adult patients with congenital heart disease generally have fewer device options or face higher risks from device therapy; 2) there is documented variability in review board decision-making for ACHD exception requests, based, in part on differing levels of congenital heart disease expertise across regions; and 3) there are challenges to objectively quantify severity of illness, in part, due to the heterogeneity of the anatomy of the ACHD population. The document identifies subtypes of anatomy and applies guidance for regional review boards to permit exceptions to higher urgency listing by providing more objective criteria that identify increased risk of certain types of congenital anatomy.

While The Society supports the document, we do have concerns regarding the limitations to this proposal, including the need for more specificity and identification of subgroups with higher risk. Additionally, we fear that this

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resource will be interpreted as guidelines rather than a guidance leading Regional Review Boards to default to the exceptions outlined in this document rather than evaluate each exception request for a specific ACHD patient. Therefore, we believe robust data must be collected to determine the frequency of the exception requests and acceptances in addition to the waitlist mortality in the ACHD population.

We appreciate the Committee's efforts to ensure that the unique considerations for this patient population is considered. 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,

A handwritten signature in black ink, appearing to read "Richard L. Prager". The signature is written in a cursive, flowing style.

Richard L. Prager, MD
President