

Notice of OPTN Board of Directors Action

Termination of Select Variances

Sponsoring Committee: Executive Committee
Board Approved: December 3,, 2019
Effective Date: March 1, 2020

Purpose of Policy Changes

The Board terminated four variances that were outdated.

Proposal History

UNOS staff reviewed all active variances and gathered supporting documentation regarding previous Board actions, resolutions, and minutes. UNOS staff identified variances that were active (meaning that there was no evidence of BOD termination) and had been in place for many years, but were potentially not being used by members. They reached out to applicable members to confirm that the variances needing renewal or termination are no longer in use. Research data corroborated none of the variances being recommended for termination herein are currently being used. The UNOS Legal Department reviewed the variances and agreed that recommending them for termination was appropriate.

Summary of Changes

Four variances were terminated by the OPTN Board of Directors (Board). All of them were originally implemented prior to the passage of the OPTN's current variance policy requirements. As such, these variances were not codified in policy, nor did they comply with the OPTN's standards for variances - specifically the Final Rule requirement that variances must be time limited. Because the variances were no longer in use (or in the case of Region 2 AAS and OneLegacy AAS, duplicative with existing variance policy), these variances were approved for termination by the Board. Doing so makes active OPTN variances current and relevant. The authority provided in OPTN Policy 1.3.A: *Acceptable Variances*, gives the Board explicit power to terminate a variance at any time.

Implementation

No programming changes will be required to terminate the variances. There is no effect on members, as these variances were no longer in use.

Affected Variances

Region 2 AAS (Split Liver)

This variance allowed participating transplant hospitals within the region to accept a liver offer for an adult candidate (the index candidate) and transplant the right lobe into the index patient and the left lateral segment in a pediatric candidate at that center or an affiliated pediatric center. The variance was approved at the November, 2010 BOD meeting, along with the OneLegacy AAS (see below). The variance did not include an evaluation period or expiration date. Also at the November, 2010 BOD meeting, the BOD encouraged the OPTN Liver and Intestinal Transplantation Committee (the Liver Committee) to consider a committee-sponsored split liver variance. At the November, 2011 BOD

meeting, the BOD approved an open variance for split liver transplantation identical to the previously-approved Region 2 AAS. The open variance remains in OPTN Policy.1 As such, the Region 2 AAS variance is redundant, and its termination does not preclude Region 2 members from participating in the policy based split liver variance.

OneLegacy (CAOP) AAS (Split Liver)

This variance allowed for the same allocation of split liver segments as the Region 2 AAS. It was also passed at the November, 2010 BOD meeting, but the board report did contain a set timeframe of one year. However, there is no subsequent record of the BOD terminating the variance. Similar to the Region 2 AAS, the allocation of split liver segments in this variance is identical to the allocation included in the open variance approved November, 2011. OneLegacy leadership concurred with terminating this variance.

LifeGift of Houston (TXGC) AAS (Split Liver)

This variance allowed participating transplant programs in the donation service area (DSA) TXCG to transplant either lobe into the index patient and the other lobe into any other candidate on their waiting list. The variance was only applicable when the index patient was an adult. The variance was approved in 2005 and extended in 2008. There is no further evidence of BOD consideration after 2008. TXGC leadership concurred with terminating this variance.

University of California (CAUC) AAS (Heart)

This variance established an alternate recipient list for heart patients whereby patients with relative contraindications who were otherwise excluded from the primary heart transplant list could elect to accept expanded criteria donor hearts that go unplaced. The variance was approved by the BOD in June, 2002 and is no longer in use, per the medical center. Additionally, current heart allocation policy does not differentiate between standard and expanded criteria donors, making this variance futile

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