

The American Society of Transplantation (AST) provided the following comment on January 11, 2024, in response to the proposal “Expedited Placement Variance” that the OPTN posted for comment during a special public comment period. The special public comment period was originally slated for December 21, 2023- January 21, 2024, and on January 8th, the OPTN announced the special public comment period would be extended through February 4, 2024.

The American Society of Transplantation (AST) supports the goals of the proposed variance policy changes to facilitate more rapid exploration and implementation of system improvements; however, the proposed open variance for expedited placement (5.4.G) is missing key operational details. The AST offers the following comments in response to this proposal:

The proposal as written fails to provide sufficient justification for the special, shortened public comment period (it is stated explicitly that the proposal does not meet criteria for “Emergency Action” or “Expedited Action”). Although the proposed policy language changes are reasonable, the open variance for expedited placement proposal needs more specificity to ensure that protocols can be implemented safely, transparently, and equitably, meaningful data will be collected to evaluate the protocols, and that concurrent protocols can be operated effectively. The AST recommends that the OPTN update this proposal with additional operational details and extend the comment period through the upcoming winter 2024 regional meeting cycle to allow time for additional community discussion on this important topic.

Although alluded to in the policy proposal, it should be made clear in the variance operational guidelines that the Executive Committee’s role is to review and approve protocols that have been proposed by those with appropriate content expertise within the Expeditions Task Force or OPTN committees. The operational guidelines should also clarify the analysis of results will include committees with appropriate content expertise.

Lastly, the proposed policy language references the “Executive Transplantation Committee” in line 41. It is assumed that line 41 is referring to the OPTN Executive Committee. If this assumption is correct, the AST recommends editing this reference to align with the nomenclature found elsewhere in the OPTN Bylaws and the proposed policy to avoid possible confusion.