AMERICAN SOCIETY OF TRANSPLANTATION

Although the American Society of Transplantation (AST) supports the goals of the 12/21/23 "Expedited Placement Variance" policy, as outlined in AST's public comment response to that proposal, we have concerns that the proposed "Pre cross clamp placement of KDPI 75-100 Kidneys" protocol does not provide adequate specificity to ensure that the project will be implemented safely, transparently, and equitably and that sufficient and meaningful data will be obtained to drive further policy development.

Moreover, as comfort with this accelerated process is not uniform across our community, AST believes that it would be helpful for the OPTN to provide additional justification about why it believes that this (and future protocols) are sufficiently limited in scope and potential patient impact to allow moving them forward through the variance pathway rather than going through the full policy development cycle including the standard public comment process.

AST has the following specific concerns:

- The protocol alludes to "a number of OPOs have employed similar strategies for placement of kidneys from high-KDPI donors." It would be helpful for the OPTN to provide a catalog of these approaches as well as sufficient background information about how the pros/cons and outcomes of existing strategies to place high KDPI kidneys informed the development of this protocol. If data on existing strategies have not been collected, we suggest the OPTN acquire such data to guide and enhance the development of such new protocols.
- The protocol does not provide sufficient justification for using the 75% KDPI threshold rather than the 85% threshold (which would only impact one allocation sequence instead of both the 35-85% and >85% sequences). Does the number of extra kidneys in adding the 75-85% KDPI range to the protocol warrant the additional complexity? Because kidney candidates are required to provide written informed consent to accept KDPI >85% kidneys (OPTN Policy 5.3.C), it is not clear whether informed consent obtained from variance participants will be extended to cover KDPI > 75%.
- The term "high priority classifications" is not defined in OPTN Policy 8.4 as stated in the protocol. This ambiguity must be addressed prior to implementing this protocol.
- The protocol lacks sufficient details regarding data collection and analysis.
- Finally, the protocol does not provide sufficient operational details about how participating OPOs and transplant programs will be selected, how participating patients will be chosen by their programs and ordered in the expedited match sequence (including whether the protocol envisions two patients per center or two patients per blood type per center) and other implementation details.

Again, AST supports the strategies to increase utilization of difficult to place organs but cannot support this protocol without the OPTN addressing the above concerns. We would welcome the opportunity to discuss these concerns further with OPTN Executive Committee and Expeditious Task Force Leadership at a mutually agreeable time.