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March 4, 2022

Mr. James Berger
Designated Federal Official
Office of Infectious Disease and HIV/AIDS Policy
U.S. Department of Health & Human Services
330 C Street, S.W., Suite L100
Washington, D.C. 20024

RE: Request for Information: Regarding a Revision to U.S. Public Health Service Guideline: Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection (4 Feb. 2022)

Dear Mr. Berger,

The Organ Procurement and Transplantation Network (OPTN) appreciates the opportunity to comment on the proposed change to the U.S. Public Health Service Guideline to exempt solid organ transplant candidates who are 10 years of age or younger and have received postnatal infectious disease testing from the recommendation for HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) testing during the hospital admission for transplant but prior to anastomosis of the first organ. This change is consistent with a proposed change to OPTN policy currently available for public comment which would exempt candidates 10 years of age or younger who have received HIV, HBV and HCV testing as transplant candidates from additional HIV, HBV and HCV during hospital admission for transplant but prior to anastomosis of the first organ.¹

Requiring additional HIV, HBV and HCV testing directly prior to transplant when the candidate has other testing and blood drawn simultaneously may lead the cumulative volume of blood drawn to be greater than what is recommended, especially for low-weight pediatric candidates. While the risk of adverse medical outcomes from overdrawing blood is greater for pediatric candidates, the risk of HIV, HBV, and HCV disease acquisition and transmission among the pediatric population is much lower than for other candidates.

The OPTN supports the proposed changes, which improve transplant recipient safety by removing an unnecessary timing recommendation that could incur the need for a blood

¹ "OPTN Public Comment Proposal: Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing." Organ Procurement and Transplantation Network. March 2022. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/pediatric-candidate-pre-transplant-hiv-hbv-and-hcv-testing/.

transfusion for certain pediatric candidates, while still ensuring all necessary testing is performed to avoid infectious disease transmission.

Please do not hesitate to contact me with any further questions.

Sincerely,

Matthew Cooper, MD

President, OPTN Board of Directors