MIDWEST TRANSPLANT
Give Hope. Share Life.

October 10, 2019

Attn: ACBTSA—RFI
U.S. Department of Health and Human Services
Mary E. Switzer Building
330 C Street SW, Room L001
Washington, DC 20024

Via Electronic Mail: ACBTSA@hhs.gov

Dear HHS Administrator,

Midwest Transplant Network (MTN) is pleased to provide information in response to revisions to the 2013 PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Organ Transplantation. MTN is a high performing, federally-funded Organ Procurement Organization (OPO) serving Western Missouri and the State of Kansas. MTN serves a population of 5.6 million individuals, about 78% of whom are registered donors. MTN is committed to expanding the number of organs recovered and transplanted by aggressively pursuing opportunities for donation and engaging in continuous quality review. MTN supports efforts to reduce the risk of disease transmission while saving lives through organ donation and transplantation; however, MTN maintains that the proposed revisions to the 2013 PHS Guideline, specifically, revisions related to additional sample collection 24 hours prior to organ recovery and the labeling of certain organs as "increased risk," will not result in a reduction in the transmission of infectious diseases.

I. MTN does not support revisions to the PHS Guideline which require additional donor sample collection and testing in the immediate 24 hours prior to organ recovery.

In more than 80% of cases, testing for infection disease markers is performed in the early stages of donor management when MTN staff members begin evaluating potential donors for organ allocation. This proposal will increase not only the frequency of testing but also increase costs related to the shipping of samples and testing of samples because the proposed revision will require duplicate testing on more than 80% of cases. Further, the proposed Guideline revision will create operational and logistical complications for OPOs related to obtaining qualified samples which may be scarce or non-existent. Typically, qualified samples are not stored by OPOs, rather, these samples are possessed by hospitals (or hospital labs) that may not be willing or able to share the samples which creates another logistical hurdle for OPOs to surmount. Another obstacle exists when donor hospitals are located far from the laboratory that performs donor testing. This geographical distance is likely to increase transportation costs and add logistical complexity to the delivery of additional donor material to the laboratory, especially within the immediate 24 hours prior to organ recovery. Sadly, these additional costs will ultimately be passed onto the recipients awaiting lifesaving transplants and their families.

Additionally, after an individual is exposed to HIV, HBV and or HCV which ultimately leads to infection, there is an eclipse period during which no existing diagnostic test can detect HIV. The current FDA approved donor screening assays can detect HIV RNA with an eclipse period of 7 days. For HCV RNA detection and HBV DNA

detection, the eclipse periods are approximately 25 and 14 days, respectively. Therefore, the proposed 24-hour re-testing timeframe does not increase the probability of viral DNA/RNA detection or antibody formation and would rarely add value to testing results performed within the 72-hour window.

Finally, conducting 72-hour and 24-hour testing can potentially result in contradicting testing results which complicate donor management, organ allocation and the transplantation process. Donor screening assays are prone to false positive rates of up three to five percent; therefore, this proposal to increase the frequency of testing may inadvertently increase the frequency of false positive results. For example, a positive HCV test result 72 hours prior to donation followed by a negative HCV test in the immediate 24 hours prior to recovery, or vice versa, might unnecessarily obfuscate test interpretation, increase the organ discard rate and complicate the course of patient management.

II. MTN supports revisions to the PHS Guideline pertaining to organ recipient testing protocols.

Infectious disease testing on organ donors is often performed using FDA-approved donor screening assays whereas testing on organ recipients is often performed using diagnostic testing. The limit of detection and sensitivity of the two different assays can differ based on the qualitative versus quantitate nature of these assays. Therefore, MTN supports the development of a clearer definition of requirements for recipient testing.

III. MTN supports the elimination of "increased risk terminology, or in the alternative, clarification regarding the process by which "increased risk" factors are communicated to potential organ recipients to ensure consistency in the organ allocation process.

Currently, a donor is designated as "increased risk" in Donor NET as a means of informing transplant programs of the donor's risk status. MTN supports the elimination of the "increased risk" terminology for multiple reasons stated in this proposal revision (the chilling effect on organ acceptance, perceptions that the risk is higher than the true risk for disease transmission, lack of association between "increased risk" designation criteria and significant risk of HIV, HBV and HCV infection/transmission, etc.), to avoid restricting the usage of organs from certain donors and to reduce the discard of otherwise healthy organs.

Alternatively, the PHS Guideline should be revised to ensure that communication regarding "increased risk" donors is communicated to transplant centers in a clear, consistent and systemic manner. Elimination of the "increased risk" terminology will require other means of communication to facilitate informed decision making by the transplant program and their recipients. One suggestion for facilitating this communication is the inclusion of electronic enhancements, such as individual radio buttons (predetermined checklists), in Donor NET which relate to the PHS guidelines that might apply to individual donors.

MTN appreciates the opportunity to comment on proposals related to the 2013 PHS Guidelines and is supportive of revisions which encourage efficiency, clarity and consistency in the donor testing and organ allocation process.

Sincerely,

Jan Finn, RN, MSN
President & CEO
Midwest Transplant Network