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New HHS Guidance on Solid Organ Transplantation: Reducing Risk and Increasing Availability

Authors: Melodie Hengerer
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Organ procurement organizations (OPOs) and transplant centers should take note: as expected, and as outlined in our recent organ procurement and transplant alert, the U.S. Department of Health and Human Services (HHS) continues to prioritize reduction of the organ transplant waitlist by increasing access to transplantable organs. On June 26, 2020, the U.S. Public Health Service (PHS) published new guidelines meant to encourage the safe transplantation of organs, particularly where donors may have been at risk for HIV, hepatitis B virus (HBV), or hepatitis C virus (HCV). Advances in testing for these infections have made results highly accurate, and accordingly, have drastically reduced the risk of transmission during transplant. These guidelines are also significant because they are meant to address the potential underuse of organs which were previously classified as being at an "increased risk" due to the national opioid epidemic.

Previous PHS guidelines required that certain donors be classified as "increased risk donors" (IRDs). OPOs were charged with assessing donor risks in 14 categories relating to certain medical and social behavioral risks of the donor for the 12 months prior to the donor's death. If that donor information were unavailable, or if the donor's blood sample for HIV, HBV or HCV was unusable, the donor was designated IRD. The previous guidelines then required additional HIV testing and specific informed consent from the potential transplant recipient regarding risk of potential disease transmission. The transplant recipient was also required to undergo pre- and post-transplant monitoring for HIV, HBV and HCV infection.

Not surprisingly, and as reported by the Centers for Disease Control (CDC), organs designated "IRD" were underused. The transplant community expressed concerns that the "increased risk donor" terminology could play a role in deterring organ acceptance. Despite IRDs typically being younger candidates, often with higher quality organs than standard donors, the rate of IRD acceptance was low. Per the CDC, this rate remained low, even though studies show that candidates on the organ transplant waitlist who decline IRD organs have higher rates of death than patients who accept IRD organs.

In 2018 and 2019, the transplant community and several federal agencies, including the CDC and Health Resources and Services Administration, conferred on possible improvement to the PHS guidance. They concluded that the then-existing criteria for IRD designation were not clinically significant factors for determining risk for HIV, HBV or HCV. OPOs had universally been screening for these infections since 2017 and proffered that the 12-month timeframe should be shortened. Because the number of donors with risk factors has increased, due in large part to the opioid crisis, the group also concluded that all recipients should be screened after transplantation due to the inability to comprehensively and accurately assess risk factors. Finally, the development of effective HIV and HBV suppression therapies and a cure for HCV were significant considerations for amending the guidance.

As a result of this and other significant reviews, including consideration of public comments, PSH has now issued new recommendations for solid organ procurement and transplant practices that encourage an increase in organ acceptance and a reduction in transplantation risk. These recommendations fall into five categories:

- Donor Risk Assessment
  - OPOs must now determine whether any of 10 risk criteria were present in potential organ donors during the 30 days before organ procurement
  - OPOs should discontinue labeling HIV, HBV or HCV at-risk donors as "IRD"
- Solid Organ Donor Testing
  - All potential organ donors (living and deceased) should be tested for HIV, HBV and HCV
  - Deceased donor specimens should be collected within 96 hours before organ procurement and OPOs should ensure results of testing are available at the time of procurement
  - Living donor testing should be performed as close as possible to the surgery, but at most, 28 days before organ procurement
- Transplant Candidate Informed Consent
  - OPOs should report the existence of one or more risk criteria to transplant centers
  - Transplant centers should include this information in informed consent discussions with potential recipients, but specific informed consent is no longer required
  - Transplant centers should, however, relay that the risk for undetected transmission of HIV, HBV and HCV is very low (but not zero) and explain that effective therapies exist for these infections
  - Transplant centers should convey to the recipient that accepting an organ from a donor with risk factors may increase the chance for the patient's survival
- Recipient Testing and Vaccination
  - Pre- and post-transplant testing for HIV, HBV, and HCV should be conducted for all recipients, regardless of donor risk criteria
  - Pre-transplant testing should be conducted during the hospital admission, prior to transplant
  - Post-transplant testing should be conducted 4-6 weeks post-transplant
  - Recipients who develop signs and symptoms of liver injury after transplantation should be retested for hepatitis
  - All transplant candidates should be vaccinated against HBV
- Collection and Storage of Donor and Recipient Specimens
  - OPOs and living donor recovery centers should retain donor blood specimens for at least 10 years
  - Specimens should be collected within 24 hours before organ procurement

We continue to monitor developments in organ procurement and transplantation and will provide further guidance as it becomes available. If you have any questions regarding this alert or the impact of these guidelines on your organization, please contact Melodie Hengerer or a member of Baker Donelson's Health Law Team.