



March 17, 2020

Honorable Michael R. Pence
Vice President of the United States
The White House
Office of the Vice President
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Vice President Pence and Secretary Azar,

As you confront the challenges brought on by the spread of COVID-19 we want to bring to your attention some of the critical issues that this pandemic is creating in the organ recovery process, as well as the impact that it may have on organ transplantation.

As background, the Association of Organ Procurement Organizations (AOPO) represents the fifty-eight federally designated organ procurement organizations (OPOs) across the country serving more than 320 million Americans. The professionals working in OPOs are dedicated to one goal, saving lives. In 2019, more than 39,700 individuals received life-saving organ transplants due to the efforts of OPOs nationwide.

The spread of COVID-19 has created the following critical issues for which we seek your guidance:

1. **Access to Hospitals and Donor Families** – In an effort to reduce exposure to the virus, hospitals are instituting broad policies barring visitors including family members from visiting any patient in an ICU. In addition, varying restrictive policies are being implemented regarding all other visitors to the hospitals. In some cases, OPO clinicians are not being allowed to do their normal donor evaluation work in the ICU. Clarification that OPO personnel are trained healthcare workers who have a critical need to access the ICU would be helpful in informing hospital policy during the crisis. Inconsistency is rampant currently which is leading to lost opportunities for donation.
2. **Lack of standards testing of potential donors** - Currently, there are no standards or guidelines for the testing of potential organ donors for COVID-19. The current protocols as of this date range from every potential donor must be tested to no testing required at all. This variability is due to the severity of the outbreak in individual geographic locations but has raised a variety of concerns. As an example, if a potential donor is admitted to the hospital with a gunshot wound and previously had no symptoms of COVID-19 is testing required? It is vital that HHS provide

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clear and consistent guidance to ensure continuation of safe and effective organ recovery and transplantation nationwide.

3. **Variability of access to COVID testing** – Currently, OPOs are using enhanced screening criteria to protect recipients from potential COVID transmission. OPOs are also working to obtain access to testing for their organ donors but are running into resistance in areas where testing is not widely available. Testing will significantly enhance our ability to properly evaluate the risks associated with an individual donor. Given the relatively small number of tests required (there are roughly 40 consents obtained daily for donation) prioritizing organ donors for COVID testing would make sense. We would like to request that CMS and HHS provide such clarification for health departments, hospitals and testing laboratories. Strong guidance would ensure that life-saving organs that would be available for transplantation are not wasted. Every organ recovered is critical now more than ever.
4. **Ensure organ recovery and transplantation are not classified as “elective” surgery** – As hospitals seek to preserve capacity to treat COVID-19 infected patients, they have begun cancelling or postponing elective surgery. In order to ensure continued organ recovery and transplantation HHS guidance should clarify these activities are not defined as elective surgery. In addition, the guidance should stress the importance of maintaining as much recovery and transplantation activity as possible, recognizing local conditions. This would ensure as many life-saving organs are recovered and transplanted as possible during these extraordinary times.
5. **Request for waiver from outcome measures and metrics** – Unfortunately, during this time of emergency, it is inevitable donation and transplant rates will decrease across the country. For example, as COVID-19 spreads hospitals will need more and more ventilators and other life-saving equipment in order to treat those infected. Because organ recovery requires a ventilator, this shift will invariably impact the ability of organ recovery to proceed. OPOs will continue to strive for the highest possible outcomes and continue to work with all of our partners to continue to receive much needed donated organs for those who are in need of transplants. However, we ask that while we are under this state of national emergency all entities within the donation and transplantation spectrum be granted a waiver from any outcome measures and metrics so that no one is unduly penalized for the ongoing pandemic. Our top priority is always the to ensure organ recovery and transplantation be maintained in a safe and effective manner, however we also recognize the incredible strain being placed on hospital staff.

We appreciate the monumental challenge that we are confronting as a country and stand ready to help. If you have any questions, please contact Steve Miller at smiller@aopo.org or 202-725-6353.

Sincerely,



Kelly Ranum
President
AOPO