



COVID-19: Effect on Organ Donation and Transplantation

April 20, 2020

The [U.S. domestic response to Coronavirus Disease 2019 \(COVID-19\)](#) poses both short- and long-term concerns for the U.S. organ transplant system. [Organs are a limited resource](#), and their allocation is strictly regulated to try to ensure that no donated organs go unused. A number of [transplant centers have suspended their transplant programs](#) due to COVID-19. In addition, individuals are [inactivating from organ waitlists](#) in large numbers due to COVID-19 precautions. Disruptions in the system may create long-term effects for both the allocation of organs and the viability of organizations involved in the process, which are subject to federal outcome measures.

This Insight provides background information on the organ donation and transplantation system, summarizes action taken to respond to COVID-19 by the organ transplant community, and identifies potential issues for Congress.

Background

Organ donations and transplantations are coordinated through the [Organ Procurement and Transplantation Network \(OPTN\)](#), a nationwide network of all organizations involved in the process (e.g., [transplant centers](#), [organ procurement organizations \[OPO's\]](#), [laboratories](#)). OPTN is administered by the [United Network for Organ Sharing \(UNOS\)](#), a private organization under contract with the Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA). UNOS has held the contract to administer OPTN since it was established by the [National Organ Transplant Act of 1984](#) (P.L. 98-507).

OPTN administers a [series of policies](#) designed to [allocate organs with consideration of both the limited number of organs and their short shelf-life](#), among other considerations. OPTN is also responsible for [monitoring performance of OPTN members](#). OPTN is able to take [emergency action](#) in the event that a policy proposal is required due to an emergent public health issue or patient safety factors. Policy proposals under emergency action must be [submitted through the normal policy proposal process](#), but they are subject to a truncated comment period and carry an expiration date.

In addition, the Centers for Medicare & Medicaid Services (CMS) plays a role in oversight of OPOs by requiring conditions for coverage in order to receive payment for activities under Medicare and Medicaid.

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(42 C.F.R. §§486.301-486.360). Those conditions include outcome metrics, such as donor recovery rates and donor yield, which OPOs must meet in order to be recertified.

COVID-19 Response

UNOS first responded on March 18, 2020, by implementing specific codes to indicate if a transplant candidate inactivates from an organ waitlist due to COVID-19 precautions, allowing transplant programs to inactivate their entire waitlist if the program closes, and issuing organ retrieval guidance to OPOs. Since that date, UNOS has issued guidance periodically to all affected individuals and organizations.

Actions to respond to COVID-19 can be placed in three categories (1) affecting transplant programs, (2) affecting OPOs, and (3) affecting transplant patient safety.

Transplant Programs

UNOS is allowing transplant programs to inactivate their entire waitlist while associated health systems are responding to the COVID-19 pandemic. Ultimately, reducing transplant capacity is a decision made by the transplant center or the associated health system. This may become necessary as many hospital resources are stretched thin responding to the COVID-19 pandemic, to protect transplant patients from contracting COVID-19, and as fewer donor organs become available. On March 23, 2020, a team of transplant surgeons published guidelines for a phased approach to reducing transplant activity during the pandemic that begins with a 25% reduction (e.g., no living donors) and progresses to a complete stop of all new transplant activity in the event that a health system is overwhelmed.

Organ Procurement Organizations

OPOs are being encouraged to recover organs locally whenever possible. Under normal circumstances, the transplant team may travel to a hospital where a donor is located in order to perform surgery to recover organs. The UNOS guidance, with support from the donation and transplant community, is recommending that surgeons within the donor hospital conduct the recovery surgery whenever possible. This guidance is intended to prevent infection among transplant teams, thereby facilitating the continuation of organ transplants.

Transplant Patient Safety

Transplant recipients are generally considered high risk for developing illnesses due to a suppressed immune response. After transplantation, patients are prescribed anti-rejection medications that suppress the immune system for the remainder of their lives.

OPTN amended a number of policies to help protect patient safety by minimizing exposure risk to the COVID-19 virus:

- Allowing transplant programs to maintain waitlist priority for patients who cannot undergo routine testing due to the COVID-19 pandemic. This allows individuals to prioritize safety by forgoing entering a medical facility (OPTN Policy 1.4.F).
- Allowing waitlist priority to apply retroactively to certain patients who cannot obtain required routine pre-transplant testing (OPTN Policy 3.7.D).
- Relaxing transplant follow-up data requirements to prevent unnecessary exposure to the COVID-19 virus (OPTN Policies 18.1, 18.2, 18.5.A, and 18.5.B).

In addition, OPTN is implementing COVID-19 testing reporting criteria for deceased donors. Transplant centers are to be able to see whether a donor was tested for COVID-19 and the results of the test. UNOS

anticipates that the [additional reporting criteria will be added the week of April 20](#). The criteria are intended to limit the possibility of transmission of the COVID-19 virus to a transplant recipient through transplantation.

Issues for Congress

Current disruptions in the organ transplant system may have long-lasting effects as individuals and transplant centers postpone lifesaving surgeries in order to mitigate exposure to the COVID-19 virus. The number of [transplants performed per week](#) and the number of [deceased donors recovered per week](#) have decreased considerably since the start of the COVID-19 pandemic.

This activity decrease may affect performance reviews for some transplant centers and OPOs. OPTN has indicated that it is working to make changes to its outcomes metrics. CMS has not yet indicated whether any changes would be made to the outcome measures that are required for recertification of OPOs. On March 17, 2020, the [Association of Organ Procurement Organizations](#) issued a [letter to the Trump Administration requesting a change to the outcome measures](#). Without action to amend outcome measures, it is possible that some OPOs will not meet metrics required to be recertified.

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