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Organ Transplant Rates Remain Low: What Hospitals Need to Know to About Their Obligation to Help

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It may come as no surprise that, in the wake of the COVID-19 pandemic, the national organ transplantation rate has plummeted. Despite CMS's recently published guidance identifying transplants as Tier 3b procedures that should not be postponed, and even as elective surgeries resume, transplant rates remain abysmal.

Prior to the pandemic, efforts to increase the national organ transplantation rate were the subject of significant political and regulatory attention. Last summer, President Trump issued an [Executive Order](#) spotlighting the importance of organ donation and transplants. It required the establishment of new rules for evaluating organ procurement organization (OPO) performance. CMS subsequently proposed [a new rule](#) including a provision for measuring OPO success, not only by the number of organs procured, but by the number of organs which are "actually transplanted." More recently, there has been considerable Congressional pressure to investigate alleged failures in the organ donation and transplant system, including [inquiries](#) by the Senate Finance Committee to UNOS, the non-profit organization which manages the nation's organ transplant system.

Given the decline in transplant rates, which has been exacerbated by the pandemic, the entire organ procurement and transplant process will undoubtedly receive continued scrutiny. Therefore, hospitals should take steps now to ensure that they are in full compliance with their regulatory obligations to refer potential organ donors to OPOs.

Hospitals Should Understand and Comply with Their Duty to Notify OPOs of Potential Organ Donors

The first step in the organ donation and transplant process is the identification of potential organ donors. CMS's Conditions of Participation (COPs) squarely place this responsibility on hospitals by requiring that each hospital "[i]ncorporate an agreement with an OPO ... under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital." (42 CFR § 482.45). Hospitals retain the obligation to timely refer potential donors, even in the face of challenges related to, or derivative of, COVID-19, and in the absence of any CMS waivers. It is the responsibility of the OPO, not the hospital, to determine an individual's suitability for organ donation, and it is the responsibility of the transplant surgeon to determine the suitability of that organ for transplant. However, the hospital plays the critical initial role in ensuring timely access to potentially transplantable organs. Given this obligation and the scrutiny with which the process is expected to be analyzed, hospitals should ensure compliance with the COPs regarding organ procurement, including the following CMS guidelines:

- Hospitals should revisit and comply with the definition of "imminent death" as agreed to by and between the hospital and its designated OPO in its federally-mandated Memorandum of Understanding (MOU).
 - The MOU between Hospital and OPO should contain an agreed-upon definition of "imminent death" that honors the time constraints of the OPO and the need for the hospital to continue treatment until death is declared or until the patient's family has made the decision to withdraw supportive measures.

- CMS does not define "imminent death," but suggests that the definition could include:
 - a patient with severe, acute brain injury;
 - who requires mechanical ventilation;
 - is in an Intensive Care Unit or Emergency Department; AND
 - has clinical findings consistent with a Glasgow Coma Score (GCS) that is less than or equal to a mutually-agreed-upon threshold; OR
 - for whom physicians are evaluating a diagnosis of brain death; OR
 - for whom a physician has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.
 - The Hospital should also ensure that its staff understands and has a system in place for recognizing the clinical signs of a patient's "imminent death" which trigger OPO notification.
 - As the COVID-19 pandemic continues, hospitals should continue to timely refer all individuals who meet the criteria for "imminent death," regardless of whether that individual is a known or suspected COVID-19 positive patient, as it is the responsibility of the OPO to determine an individual's clinical suitability as a potential donor.
- Hospitals should ensure that they notify the OPO of a patient's imminent death in a "timely manner," as that term has been agreed to in its MOU so that the process of determining suitability for donation and transplantation can commence.
 - Timely notification is paramount as it increases the likelihood that the patient's organs will be viable for transplantation, assures that the family is approached only if the patient is medically suitable for organ donation, and assures that an OPO representative can be made available to collaborate with the hospital staff in discussing donation with the family.
 - CMS will consider a hospital to have made notification in a timely manner if such notification is made:
 - As soon as the hospital anticipates that a patient will meet or has met the criteria for "imminent death" as agreed to by the OPO and hospital (ideally within one hour), AND
 - Before withdrawal of any life sustaining therapies (*i.e.*, medical or pharmacological support, including ventilators).
 - Hospital staff should review the OPO notification process with its clinical staff to maximize the efficiency and timeliness of the process.

As transplant rates remain low and calls for Congressional investigations of the organ donation and transplant process continue, hospitals should confirm their compliance with the CMS COPs regarding organ procurement. Hospitals should also review the terms of their existing OPO MOUs with their health care givers to ensure practical compliance. If you have specific questions about OPO MOUs or would like more information regarding compliance with the CMS Conditions of Participation for Hospitals or Conditions for Coverage for OPOs, please contact [Melodie Hengerer](#).