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Organ procurement and transplantation: From the basics to the issues

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The process of donating, procuring, and transplanting organs, tissues, and eyes involves a significant coordinated effort among individuals and organizations. This process includes the donor hospital, organ procurement organization, transplant hospital, and physicians and staff involved in each step. Each of these individuals and organizations must comply with laws and policies of the Centers for Medicare & Medicaid Services (CMS) and the requirements of the Organ Procurement and Transplantation Network (OPTN).

Because of the number of organizations and individuals involved, and because organ donation is cost reimbursed by Medicare, these services present unique challenges. This article discusses regulatory oversight by OPTN and CMS, the payment methodology for organ transplants, and compliance issues. It is important for providers to understand these points to avoid enforcement from violations of Medicare and OPTN regulations and policies, properly report costs and statistics related to organ procurement, and comply with fraud and abuse laws.

Regulatory oversight

With several different agencies overseeing organ procurement and transplantation, it is important for transplant centers and federally designated Organ Procurement Organizations (OPOs) to understand the roles of each agency and the requirements related to its services.

Organ Procurement and Transplantation Network

The OPTN was created by federal law, but it is a private, not-for-profit entity with expertise in organ procurement and transplantation. The OPTN standardized the process for organ donation and allocation across the country. The OPTN includes all OPOs and transplant centers and is managed under contract by the United Network for Organ Sharing (UNOS). The OPTN's primary purpose is to operate and monitor an:

> equitable system for allocating organs donated for transplantation; maintain a waiting list of potential recipients; match potential recipients with organ donors according to established medical criteria for allocation of organs and, to the extent feasible, for listing and de-listing transplant patients; facilitate the efficient, effective placement of organs for transplantation; and increase organ donation. [1]

As a result, the focus and enforcement of the OPTN is different and narrower than CMS enforcement under its regulations.

Conditions of Participation

The Medicare program has different requirements under the CoPs for OPOs and transplant centers.

Organ, tissue, and eye procurement CoP

The hospital CoP for organ, tissue, and eye procurement (42 C.F.R. 482.45) is intended to promote organ donation and transplantation. The CoP applies to all hospitals participating in Medicare regardless of whether the hospital is accredited. With regard to accreditation, The Joint Commission standards also address organ, tissue, and eye procurement, which are very similar to those contained in the CoP but should not be overlooked. Hospitals are required to have an agreement with an OPO to provide the OPO, or a third party designated by the OPO, with routine referrals of all deaths that occur in the hospital or for individuals whose deaths are imminent. This notification must be provided regardless of medical suitability for organ donation and occur prior to approaching the family regarding organ donation.

Hospitals also must have an agreement with at least one tissue bank and one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes. The CoP allows hospitals to enter into tissue and eye arrangements that do not involve the OPO. This provision addressed concerns that serving as a focal point for both organ and tissue donation would place too great of a burden on the OPO.

The interpretive guidelines to the CoP require hospitals to develop protocols that define "imminent death" and "timely notification." Many states have laws in place that define death, so relying on those laws would be a means of determining "imminent death" for the purpose of developing these protocols.

The CoP allows only representatives or individuals trained by the OPO (designated requestors) to approach families to explain their donation options and make the actual request for donation. Although the OPO has the responsibility of approaching the family regarding organ donation, it is recommended that a hospital representative be included when approaching the family. Studies have shown that when a representative of the hospital and the OPO approach the family together, consent for organ donation is higher.

With regard to education, the CoP requires the hospital to work cooperatively with the OPO, tissue bank, and eye bank with staff education. This education would include explaining donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissue, and eyes take place.

Transplant Centers/Programs CoP

The CoPs regarding transplant centers are located at 42 C.F.R. 482.68 — 482.104. An advance copy of the State Operations Manual (SOM) interpretive guidelines for organ transplants was issued by CMS on March 11, 2016 and revised on May 3, 2016, but the guidelines have yet to be published in the SOM.

Transplant centers must be located in a Medicare-certified hospital and be in compliance with the general hospital CoPs. They must also be a member of OPTN and comply with those requirements.

The CoPs require notices to CMS and patients. For example, transplant centers are required to notify CMS and patients when there are changes relative to the transplant center's program. The CoPs also require notification of:

- changes in transplant team key staff,
- termination of the OPO agreement,
- inactivation of the transplant program,

- when the transplant surgeon is unavailable (if the transplant center is staffed by a single surgeon or physician), and
- at least 30 days before termination of participation in Medicare.

In the event of a Medicare termination, the transplant center must provide assistance to patients who wish to transfer to the waiting list of another Medicare-certified transplant center.

Transplant centers must have written criteria to determine a patient's suitability for placement on a transplant waiting list that include a fair and non-discriminatory distribution of organs. The same holds true if the transplant center performs living donor transplants. If requested, the transplant center must provide its patient selection criteria to the patient or dialysis facility. Living donors must be given a psychosocial evaluation and provide informed consent for the potential organ donation.

Lists of potential organ donation recipients must be current and updated on an ongoing basis. This includes updating clinical information as necessary, removing patients from the waiting list as necessary (e.g., the patient dies or receives the transplant), and notifying the OPTN within 24 hours after a patient is removed from the waiting list.

Transplant centers must maintain accurate and current patient management records for any patient who receives an evaluation for placement on the transplant center's waiting list and patients admitted for an organ transplant, including for living donor transplants. The transplant center must also have written patient management protocols for the transplant and discharge phase of the organ transplant. Documentation required in the patient management record includes whether the patient has been placed on the transplant center's waiting list, a decision not to place a patient on the waiting list, and the inability to place the patient on the waiting list due to the need for additional clinical testing. If the patient is receiving a kidney transplant, the patient's dialysis facility must be notified. If a patient is removed from the waiting list, the patient must be notified no later than 10 days after the date the patient was removed.

Transplant centers must develop, implement, and maintain a written, comprehensive, and data-driven Quality Assessment and Performance Improvement program. This program must monitor and evaluate the performance of the transplant center's services, including services provided under arrangement.

Transplant centers must ensure all individuals providing or supervising services at the transplant center are qualified to provide or supervise transplant services. The transplant center must be supervised by a qualified transplant director and have a clinical coordinator to ensure continuity of care throughout the transplant process.

Transplant centers that perform living donations must identify an independent living donor advocate or living donor team to protect the rights of living or prospective living donors. The independent living donor advocate or team must have knowledge of organ donation, transplantation medical ethics, and informed consent, and also understand the impact organ donation may have on the donor's family. The advocate or team must also represent and advise the donors, protect and promote the interests of the donors, respect the donors' decisions, and ensure they are free from coercion.

The CoPs require transplant centers to implement written patient informed consent policies. These policies should inform the patient of the evaluation process and surgical procedures, alternative treatments, potential risks, and the patient's right to refuse the transplant. The informed consent process is similar for living donors but includes additional requirements, such as:

- national and transplant center-specific outcomes for beneficiaries and living donors,

- the potential that future health problems associated with the donation may not be covered by insurance, and
- the donor's right to opt out of the decision to donate at any time.