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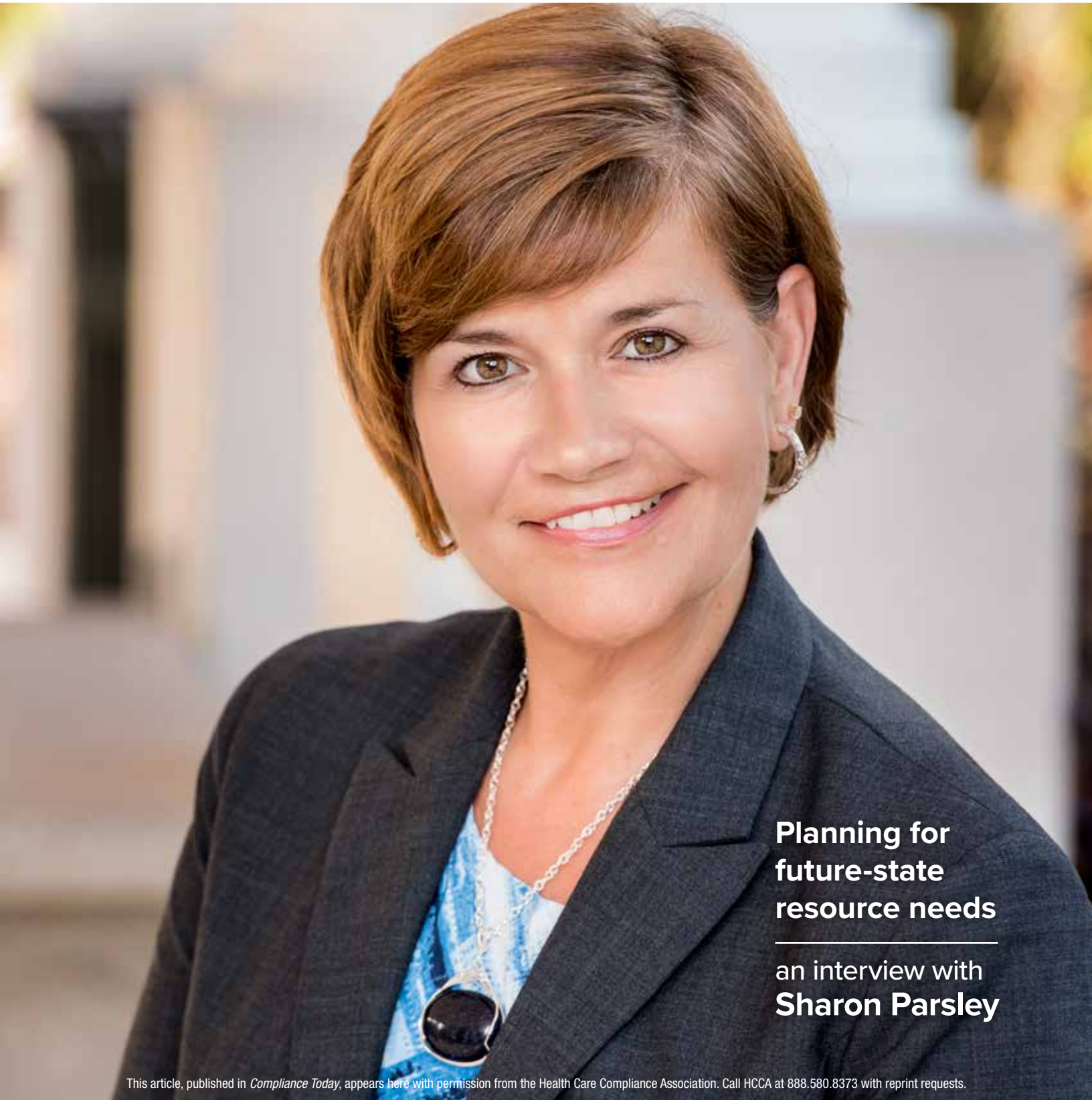

Planning for future-state resource needs

an interview with **Sharon Parsley**

ARTICLES

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by Lori Wink, Todd Selby, and Joseph Krause

Organ procurement and transplantation: From the basics to the issues

» To be paid by Medicare, Organ Procurement Organizations (OPOs) and transplant centers must be members of the United Network for Organ Sharing (UNOS), which manages the Organ Procurement and Transplantation Network (OPTN).

» Transplant centers and OPOs must comply with multiple oversight agencies and requirements, including OPTN policies and guidelines and the Medicare Conditions of Participation (CoPs).

» Medicare pays for organ procurement and transplants through various payment methodologies, including cost reimbursement.

» Because of the unique nature of these services, the government closely monitors this area, and organizations must be careful to avoid enforcement actions.

» Arrangements between transplant centers, OPOs, and physicians should comply with federal anti-kickback laws.

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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).


Wink

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.


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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.

OPO Requirements for Certification

In addition to the CoPs for hospitals and transplant centers, CMS also has OPO Requirements for Certification (42 C.F.R. 486.301–486.348). OPOs cannot be paid for the cost of organs procured from OPOs unless it meets these requirements.

As mentioned above, hospitals are required to have an agreement with an OPO. Likewise, the OPO requirements state that an OPO must enter into an agreement with any hospital in the OPO's service area that requests an agreement, but, at a minimum, the OPO must have an agreement with 95% of Medicare-certified hospitals in its service area. If a hospital has an agreement with a tissue bank other than the OPO, it must cooperate with the tissue bank for potential tissue donors. A waiver process exists for hospitals that wish to have an agreement with an OPO in another service area, subject to approval from CMS.

It is important to note that CMS will only designate one OPO per service area, and the agreement is for four years. CMS will open up competition for a new OPO if the OPO has been decertified and all appeals have been exhausted, or if the OPO voluntarily withdraws from Medicare. OPOs undergoing a change of ownership must notify CMS in advance of the proposed change. CMS considers the merger or consolidation of one OPO with another as a change of ownership. An OPO must also notify CMS if it wishes to change its service area.

On August 10, 2018 CMS issued a new survey protocol for OPOs and made revisions to the OPO interpretive guidelines. The goal of the new survey protocol is to promote consistency in the survey process to ensure all OPO's are surveyed using standard survey protocol

The survey protocol instructs surveyors on what is required for pre-survey preparation. For example, surveyors will review any complaint information since the OPO's last survey as part of the pre-survey preparation.

The survey protocol sets forth activities and documentation requested during the entrance conference. Some of the entrance conference activities would include introducing

the survey team, provide a general timeframe for the length of the survey, and requesting a secure place to work. Information requested at the entrance conference would include a map of the OPO's designated service area, the OPOs organization chart, and the governing body bylaws.

The survey protocol also addresses the administrative review functions of the survey. Part of the administrative review includes a review of the OPO's agreements with the hospitals, tissue and eye banks, and transplant programs. A review will also be conducted of the OPO's advisory board and governing board, including governing board oversight of the OPO's QAPI committee.

The survey protocol also addresses donor record review. This includes a review of donor and evaluation management. Donor evaluation protocols would include chart review requirements, lab testing requirements, and timeframes for donor activities. Donor management protocols would include screening tests, ventilation management, and optimal vital signs. Surveyors will select a minimum of 10 records for review.

Personnel record review and interview is also addressed in the survey protocol. The surveyors will utilize the organizational chart and/or staff list to select a sample of personnel files to review and conduct interviews. This review should cover all staff positions, including contract employees. The personnel review will focus on licensure and credentialing of staff. The survey protocol sets forth very detailed staff interview guidelines for the organ procurement coordinator, organ recovery coordinator, and medical director.

The final task addressed by the survey protocol is a review of the OPO's QAPI program. This includes a review of the QAPI plan, minutes of the QAPI committee, and QAPI policies. Surveyors are also instructed to interview the QAPI staff utilizing interview guidelines, similar to the staff interview guidelines.

Payment and reimbursement

Medicare covers these organ transplants: kidney, heart, lung, heart/lung, liver, pancreas, pancreas/kidney, intestinal/multi-visceral, and stem cell transplants for certain conditions.[2] Services related to the acquisition and transplantation of organs may be covered by Medicare through various payment methods.

Medicare Part A reimburses organ acquisition costs as pass-through costs based on the ratio of Medicare transplants to total transplants. Under this system, Medicare makes interim payments based on reasonable costs. At the end of the year, each hospital or OPO files a cost report, and the Medicare Administrative Contractor (MAC) reconciles the interim payments with allowable costs as defined in Medicare regulations and policy.[3]

Medicare Part A reimburses centers for the costs of transplant surgeries and organ recipients' inpatient and post-transplant care through the Inpatient Prospective Payment System and diagnosis-related group (DRG) payments, which are set at a predetermined rate per discharge for groups of patients that demonstrate similar resource consumption and length-of-stay patterns.[4]

Medicare Part B pays for physician and other services furnished to live donors or recipients during and after transplants. Private payers also cover services related to organ acquisition and transplants that may be similar to the Medicare program.

Background and payment for OPOs

OPOs coordinate the procurement, preservation, and transport of organs and maintain a system for locating prospective recipients for available organs, and they are certified to cover specific geographic areas.[5] CMS recognizes two types of OPOs: independent OPOs (IOPOs) and hospital-based OPOs (HOPOs).[6]

IOPOs are freestanding organizations that have a distinct governing body separate from any transplant hospital and are not subject to the control of a hospital or considered a department of the hospital. HOPOs operate within an associated transplant hospital's administrative and financial structure.

IOPOs are paid by the transplant hospital or other OPO that receives and purchases organs. IOPOs do not bill Medicare directly for organ procurement services, but they are paid for procuring organs by the transplant hospital or OPO, which pays the IOPOs its standard acquisition charge (SAC) for those organs. Medicare pays the IOPO for any unpaid costs or recovers any overpayments for kidneys at the end of the cost-reporting period. Medicare does not pay or recover payments for non-kidney organs procured at an IOPO; instead, this happens on the transplant hospital's cost report.

The costs incurred by a HOPO, on the other hand, are paid through the hospital cost report. Settlement for a HOPO's costs is included in the settlement of the transplant hospital's cost report. A HOPO is not separately reimbursed as an IOPO but is reimbursed through the transplant hospital's cost report. Medicare pays the cost of organ procurement for organs transplanted into Medicare beneficiaries and organs sold to other transplant centers or OPOs, less the revenue received.

Payment for transplant hospitals

There are two payment components to hospitals for organ transplantation services. The transplant hospital is reimbursed for the reasonable and necessary costs associated with acquiring the organ (i.e., organ acquisition costs) and is paid a prospective payment rate based on a DRG for the organ transplant. Services associated with organ acquisition are billed from the excising hospital (or other supplier/provider) to the OPO, which then bills the transplant hospital. The excising hospital or other supplier/provider that furnishes services in the excising of the organ does not submit a bill to Medicare.

Medicare pays only for organ acquisition costs related to transplants for Medicare beneficiaries.[7] Medicare's covered portion of organ acquisition costs is based on the ratio of the number of "Medicare usable organs" to the "total usable organs" (each as defined by Medicare).[8] The Medicare program reduces such costs by any revenue received for the organs, including payments that the transplant hospital received from OPOs and other transplant hospitals.[9]

Each transplant hospital must develop a SAC for acquiring an organ from costs it expects to incur in the acquisition of organs. The SAC reflects an average of the total actual costs associated with procuring either cadaveric donor organs or living donor organs by type of organ (e.g., tissue typing, pre-transplant evaluation services for recipients and donors, outpatient services prior to admission for donor and recipient work-ups, surgeon fees for excising organs, organ transport costs).

Hospitals must maintain separate cost centers for each type of organ to assist in developing the SAC and allocating costs appropriately (e.g., heart, kidney, or lung) and keep detailed records that identify the services furnished, the charges, the person receiving the service (donor/recipient), and the potential transplant donor.

Payment for other providers and suppliers

Physicians and other suppliers (e.g., laboratories) that furnish services as part of the excising and acquisition of organs are included in the cost-based reimbursement to the OPO or transplant hospital. These entities bill the OPO or transplant hospital for their services and do not directly bill the Medicare program.

When pre-transplant laboratory services are performed by a histocompatibility laboratory, interim rates established by the contractor are used by the laboratory in billing a transplant hospital or OPO. The MAC determines the final payment to the histocompatibility laboratory by reconciling interim payments and reasonable costs during final settlement of the Medicare cost report.

Medicare Part B separately covers payment for the services of the physician(s) who performs the organ transplant surgery, follow-up physician services, and the related course of immunosuppressive drugs. Laboratory tests performed for the organ recipient following the transplant are covered as Medicare Part B services unless the services are part of a hospital inpatient stay.

Compliance challenges

Organ procurement and transplant laws, regulations, and guidance create challenges for those providing services to patients. These challenges results from multiple agencies being involved in the oversite of the services, multiple providers being involved in the services, and the specific rules and requirements related to accounting for costs incurred and payments made for the services. The following describes some of the issues that OPOs, hospitals, and physicians should be aware of regarding organ procurement and transplant.

Enforcement related to organ acquisition costs

Over the years, the Office of Inspector General (OIG) has audited hospital and OPO cost reports to determine whether they are accurately reporting organ acquisition costs, including statistics and other issues related to organ transplantation. For example, OIG's FY 2003 Work Plan included a study of whether certified heart transplant centers were meeting Medicare certification criteria and a study of organ donation rates at transplant centers.

Because organ acquisitions are cost reimbursed by Medicare, enforcement agencies are concerned about the proper reporting of costs, statistics, and incentives to maximize costs. Also, because the rules related to determining organ acquisition costs are complicated and require maintaining specific records, hospitals or OPOs can easily make mistakes or misapply the rules. For example, a hospital must separate costs associated with services before a transplant (which are included in organ acquisition costs) from costs incurred during and after transplant (which are generally paid for under the Medicare DRG), and hospitals must maintain separate accounts and cost centers for each type of organ.

In its review of transplant centers, OIG identified overpayments to hospitals, because hospitals improperly included post-transplant expenses in the organ acquisition cost center and claimed unallowable and unsupported salaries, medical director fees, laboratory costs, and floor space.[10] To the extent that costs were part of post-transplant activities, but were included in organ acquisition costs, the hospital would have been paid twice: once through the DRG as part of the transplant surgery and again as an organ acquisition cost. In response, hospitals claimed that they lacked awareness and understanding of Medicare requirements for claiming organ acquisition costs or stated that they had inadvertently claimed costs that were not allowable as organ acquisition costs. Additionally, some hospitals did not have all the necessary systems in place to identify, allocate, document, and claim organ acquisition costs consistent with Medicare requirements.

In reviews of OPOs, OIG found that OPOs have incorrectly reported organ statistics, such as underreporting organs, that resulted in Medicare overpaying its share of organ procurement costs,[11] and that OPOs were incorrectly reporting lung statistics (i.e., reporting double lungs as one organ).[12]

The government has pursued a civil false claims lawsuit against at least one hospital that was initiated by a whistleblower.[13] In this case, it was alleged that the hospital reported costs for work unrelated to organ acquisition costs, including employee salaries, medical director fees, laboratory charges, and square footage that were not incurred or used for organ acquisition activities and, thus, did not qualify for reimbursement. The hospital reportedly paid more than $6 million to settle the allegations and entered into a corporate integrity agreement.

Compliance with privacy laws

OPOs require access to medical record information in order to provide services. OPOs' functions are addressed in two exemptions in the federal privacy regulations. First, a healthcare provider may use or disclose information if and as required by law. The Medicare regulations specifically require the sharing of information for organ and tissue donation. For example, the Medicare CoPs require hospitals to refer all potential organ and tissue donors to the OPO and require OPOs to conduct medical record reviews. Second, a healthcare provider can release information without an authorization to an OPO or other entities "involved in the procurement, banking or transplantation of cadaveric organs, eyes or tissue, for the purposes of facilitating organ, eye or tissue donation and transplantation."[14]

These exemptions allow hospitals to release information related to organ donation without patient consent by, and to, donor hospitals, transplant centers, OPOs, OPTN/UNOS, tissue banks, and laboratories.

Federal fraud and abuse laws

The Stark Law and Anti-Kickback Statute are federal laws that prohibit making payments to physicians who incentivize their referral of services paid for by federal healthcare programs. Multiple providers and physicians are part of the continuum of services that relate to an organ donation, beginning with the coordination of the donor's donation and the harvesting of the organ, to the OPO procurement and allocation of the organ, to the transplant of the organ, to follow-up services after the transplantation of the organ. The donor hospitals and physicians involved in the harvesting of the organs are typically compensated by the OPO for their services, and then the OPO is subsequently reimbursed by Medicare, other insurers, and the transplant center. Hospitals, physicians, and other providers should consider these federal laws when evaluating and entering into arrangements that involve making payments to physicians related to their organ procurement services. The payment arrangements may need to be structured to conform to the requirements of a Stark Law exception or Anti-Kickback Statute safe harbor.

Conclusion

Organ donation, procurement, and transplantation involve a coordinated effort among numerous organizations and individuals. These stakeholders must understand the applicable Medicare and OPTN regulations and policies to, properly report costs and statistics related to organ procurement, comply with fraud and abuse laws, and avoid enforcement from CoP violations.

1. Organ Procurement and Transplant Network, Charter, November 19, 2004. Available at https://bit.ly/2MtoUt4
2. CMS: *Medicare Claims Processing Manual*, Chapter 3, Section 90.
3. CMS: *Medicare Provider Reimbursement Manual*, Part 1, Chapter 31.
4. Ibid, Ref #2
5. 42 CFR 486.302 (Definitions)
6. Ibid, Ref #3
7. Social Security Act §1861(v)(1)(A) (Reasonable cost)
8. 42 CFR § 413.203(c) (Transplant center costs for organs … transplanted in patients other than Medicare beneficiaries)
9. Ibid, Ref #3
10. HHS Office of Inspector General: Review of Organ Acquisition Costs Claimed by Certified Transplant Centers (A-09-05-0034). September 2006. Available at https://bit.ly/2o23cgW
11. HHS OIG: Audit A-09-11-02039: "LifeCenter Northwest Did Not Fully Comply With Medicare Requirements for Reporting Organ Statistics In Its Fiscal Year 2009 Medicare Cost Report" November 2012. Available at https://bit.ly/2BCYznk
12. HHS OIG: "Medicare Could Have Saved Millions If Organ Procurement Organizations Had Correctly Reported Procurement" December 2013, A-09-12-02085. Available at https://bit.ly/2w32FQk
13. *United States ex rel. Judith A. King v. San Diego Hospital Association (Sharp Memorial Hospital)*, Case No. 00CV00848-BTM(RBB), (S.D. Cal.)
14. 45 CFR § 164.512 (Uses and disclosures for which an authorization is not required)