CHAPTER 31

ORGAN DONATION AND TRANSPLANT REIMBURSEMENT

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3100. OVERVIEW

The Medicare program has established policies which support organ transplantation by providing an equitable means of payment for the variety of organ acquisition services required to support quality transplant programs. The following instructions explain how Medicare reimburses for organ acquisition costs of covered transplants provided to Medicare beneficiaries.

To participate in the Medicare program, a certified transplant center (CTC) or organ procurement organization (OPO) must be a member of the Organ Procurement and Transplantation Network (OPTN). An OPO can be a hospital-based OPO (HOPO) or an independent OPO (IOPO). (We refer to organ procurement organizations generally as "OPOs" throughout this chapter, unless differentiation of HOPO or IOPO is required for context.) Hospitals are required to notify the OPO designated for its service area of deaths or imminent deaths in its hospital. Organs may be procured by OPOs from CTCs, local community hospitals or other OPOs.

There are two payment components for organ transplantation. CTCs are paid a prospective payment system rate based on a Diagnostic Related Groups (DRG) for the actual organ transplant and they are also reimbursed for the reasonable and necessary costs associated with acquiring the organ (i.e., organ acquisition costs). Organ acquisition costs incurred by the CTC/HOPO are included on the appropriate organ acquisition cost center on its Medicare cost report (MCR), Form CMS-2552. Organ acquisition costs incurred by the IOPO are included on the appropriate organ acquisition cost center on its MCR, Form CMS-216.

3101. CERTIFIED TRANSPLANT CENTERS AND ORGAN ACQUISITION COSTS

CTCs must develop two standard acquisition charges (SACs) based on costs expected to be reasonably and necessarily incurred in the acquisition of an organ:

- The SAC for acquiring a living donor organ; and
- The SAC for acquiring a cadaveric donor organ.

The SAC does not represent the acquisition cost of an individual organ. Instead, it is a charge which reflects an average of the total actual costs associated with procuring either a cadaveric donor organs or a living donor organs, by type of organ (e.g., heart, kidney or lung). When a CTC/HOPO provides an organ to another CTC or OPO, it must bill its SAC or its standard departmental charges reduced to cost. When a CTC bills Medicare for the transplant, it must use its SAC for the procured organ and its DRG charge for the transplant.

The costs of procuring an organ cannot be billed directly to the Program because the procurement of an organ is not a covered service when performed independent of a Medicare covered transplant. However, the reasonable costs of procuring an organ are reimbursable when incurred in procuring the organ for a Medicare covered transplant. The costs are paid on an interim basis and reconciled through the MCR at the end of the CTC's cost reporting period.

A. Living Donor Standard Acquisition Charge.--The living donor SAC must be established before a CTC bills its first living donor transplant to the Program. This SAC is an average charge developed for each type of organ, by estimating the reasonable and necessary costs expected to be incurred for services furnished to living donors and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period. This estimated amount is divided by the projected number of living donor organs to be procured by the CTC for transplant within the hospital's cost reporting period. If there is no such data, use standard departmental charges reduced to cost. The actual incurred cost for organ procurement services is included in the CTC's organ acquisition cost center for eventual payment.

Expenses that may be used to develop the living donor SAC include, but are not limited to the following:

- costs of tissue typing services, including those furnished by independent laboratories;
- costs of physician pre-admission transplant evaluation services;
- organ recipient registration fees as assessed by the OPTN;
- costs for donor and recipient evaluation and workup furnished prior to admission for transplantation;
- other costs associated with procurement, e.g., general routine and special care services;
- costs of operating room and other inpatient ancillary services (related to the donor);
- preservation and perfusion costs; and
- costs of transportation of the organ.

For other costs relative to a living donor not included in the SAC, see §3105, Accounting for the Cost of Services Provided to Living Donors.

B. Cadaveric Donor Standard Acquisition Charge.--The cadaveric donor SAC is established by the CTC/HOPO for each type of organ. This charge is an average charge developed for each type of organ by estimating the reasonable and necessary costs expected to be incurred in procuring cadaveric organs, combined with the expected costs of acquiring cadaveric organs from other sources. This estimated amount is divided by the projected number of usable cadaveric organs to be transplanted within the hospital's cost reporting period. Where the CTC/HOPO provides the organ to an OPO, the CTC/HOPO uses its cadaveric donor SAC or its standard departmental charges, reduced to cost, to bill the OPO.

Expenses that may be used to develop the cadaveric donor SAC include, but are not limited to the following:

- costs of organs acquired from other providers;
- costs of transportation of the organs;
- surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys);
- costs of tissue typing services, including those services furnished by independent laboratories;
- preservation and perfusion costs;
- general routine and special care service costs; and
- operating room other inpatient ancillary service costs.

3102. ACCOUNTING FOR THE COST OF ORGAN ACQUISITION

A. Outpatient Costs.--Included in the CTC's organ acquisition costs are hospital services classified as outpatient and applicable to a potential organ transplant. These outpatient services include donor and recipient work-ups furnished prior to admission and costs of services rendered by interns and residents not in an approved teaching program. These costs would otherwise be paid under Part B of the Program. Because such costs are applicable to organ acquisitions which are predominantly cadaveric donor related and incurred without an identifiable beneficiary, the services are not billed to a beneficiary when the services are rendered but are included in the CTC's organ acquisition cost center.

B. Multiple Organ Retrieval.--CTCs/HOPOs that participate in multiple organ retrieval must establish a formula for cost finding for these organs. They must separately identify the costs associated with the retrieval of all organs and appropriately apportion the acquisition costs by organ type.

When the CTC/HOPO procures multiple organs, it must allocate and record the direct costs associated with each organ type. Also, ancillary charges must be allocated among the types of organs procured. See §3111, Intent to Transplant. For example, if an operating room charge for procuring multiple organs is $1,000 and one kidney and one heart are procured, then the charge attributable to each organ is $500. However, if the CTC/HOPO has a more accurate basis for allocation that is verifiable by the Medicare Administrative Contractor, (hereinafter "contractor"), e.g., number of operating room minutes, this may be used.

The indirect costs associated with preservation technicians, transplant coordinators, and administrators, etc. must be allocated among the types of organs procured. The provider must establish a unit cost per organ by dividing the indirect cost by the total number of organs procured. The indirect costs are allocated using the unit cost per organ multiplied by each organ procured. For example, if the indirect cost equals $5,000 and five organs are procured (one heart, one liver, one pancreas, and two kidneys) then the cost for each organ is $1,000 ($2,000 must be allocated to kidney because two kidneys were procured). Organs procured and transplanted en bloc (two organs transplanted as one unit) must be counted as one organ for cost allocation purposes, see §3115, Counting of Organs.

C. Laboratory Services.--Pre-transplant evaluation services for recipients and donors, including laboratory services, are paid through the organ acquisition costs of the CTC. When laboratory tests are performed by the CTC, it uses the related costs in establishing the standard charge. The CTC also includes the reasonable charges paid for physician tissue typing services provided to living donors and recipients.

When the laboratory services are performed by a histocompatibility laboratory, interim rates established by the contractor are used by the laboratory in billing a CTC. Information on the interim rates are disseminated by the contractor to all CTCs, OPOs, and other contractors or can be found on the contractor's website. The CTC pays the laboratory the approved interim rate. When the laboratory bills an OPO for services, the OPO is responsible for paying the interim rate. The contractor determines the final payment to the histocompatibility laboratory by reconciling interim payments and reasonable costs during final settlement of the Medicare cost report.

D. Cost Adjustment.--Medicare cost reimburses a CTC for organ acquisition costs. The organ acquisition costs are accumulated on the MCR (Form CMS-2552) by specific organ type. CTCs/HOPOs that claim organ acquisition costs on the cost report must separate, from Medicare allowable costs, any costs associated with organs sent to foreign countries or transplanted in patients other than Medicare beneficiaries. The contractors will compute the ratio of the number of organs used for Medicare beneficiaries to the total number of organs used and adjust the costs for organs sent to foreign countries or transplanted in non-Medicare patients at cost report settlement. Services provided to patients other than Medicare beneficiaries are paid by those patients or their third party payers.

Kidneys sent to United States military renal transplant centers (MRTCs) by a HOPO are counted as Medicare organs for payment purposes on the CTC's cost report if the requirements are met within §3114, Military Renal Transplant Centers.

The Medicare program generally continues to pay for its proportionate share of costs incurred in procuring organs that are not transplanted. See §3116, Calculation of Medicare Costs.

3103. ACCOUNTING FOR THE COST OF SERVICES TO RECIPIENTS

A. Physician services.--A comprehensive payment is made under Part B for the services of a surgeon who performs an organ transplant and assumes primary responsibility for:

- the patient's postoperative surgical care for 60 days; or
- both the postoperative surgical care and the related course of immunosuppressant therapy for 60 days.

A comprehensive payment is also made under Part B when the surgeon performs other surgical procedures, e.g., splenectomy and/or nephrectomy at the time of the transplant. The payments, subject to the deductible and coinsurance requirements and the participating/nonparticipating physician rules, are revised annually by the contractor.

B. Backbench Preparation.--Physician backbench standard preparation work, as defined by the Current Procedure Terminology code, performed on organs transplanted into a recipient are billed under Part B of the Medicare program to the transplant recipient's health insurance number/account. Standard backbench preparation services are not included in organ acquisition costs on the cost report.

C. Recipient Laboratory Services.--Laboratory tests performed for the recipient after the recipient leaves the CTC following the transplant are Part B costs unless they occur while the beneficiary is an inpatient in a hospital. The beneficiary is responsible for the deductible and coinsurance.

3104. ACCOUNTING FOR THE COST OF MEDICARE SECONDARY PAYER

If a Medicare beneficiary has a primary health insurance coverage other than Medicare, determining whether an organ will be counted as a Medicare usable organ depends on the amount paid by the primary insurance. A provider must submit a bill to Medicare when payment from the primary payer is insufficient to cover the entire cost of a transplant including the DRG and the organ acquisition costs. However, when the primary insurance requires the acceptance of their payment in full, a bill is not required, because under the contractual agreement, Medicare has no liability because the primary payer has made the payment in full. Accordingly, the organ under the paid in full contractual agreement will not be counted as a Medicare usable organ.

When the provider submits a bill and the primary payer does not require the provider to accept the contractual payment in full, it is necessary to compare the total cost of the transplant, including the DRG and the organ acquisition costs, to the payment received from the primary payer. The provider's remittance advice may or may not show that Medicare has a liability because the bill is only submitted for the transplant portion of the payment. Thus, the provider will need to compare the total Medicare cost (DRG from the transplant and the organ acquisition costs) to the payment from the primary payer to determine whether Medicare has a liability for the organ acquisition costs. If the payment from the primary payer is greater than the cost of the DRG and the organ acquisition costs, there is no Medicare liability and the organ cannot be counted as a Medicare usable organ. If the payment from the primary payer is less than the DRG and the organ acquisition costs, there is a Medicare liability and the organ can be counted as a Medicare usable organ. The payment from the primary payer is pro-rated between the DRG payment and the organ acquisition payment. If the organ is counted as Medicare usable, the organ acquisition portion of the primary payment should be included on the appropriate line as a revenue offset on the MCR, Form CMS-2552. This is consistent with the Medicare Claims Processing Manual (CMS Pub. 100-04) and cost reporting instructions set forth in CMS Pub. 15, Part 2.

Example: A CTC transplants a patient that has private health insurance and Medicare. The private health insurance is primary and Medicare is secondary. The private health insurance pays the CTC $70,000 for the transplant and the organ acquisition costs; there is no requirement to accept this payment as payment in full. If Medicare was the primary payer, the combined payment to the CTC would have been $100,000 ($60,000 for the transplant and $40,000 for the organ acquisition costs). The CTC compares the primary payer payment to the total amount Medicare would have paid if it had been primary (transplant DRG and organ acquisition costs). The CTC prorates the primary payer's payment of $70,000 between a portion of the DRG and a portion of the organ acquisition costs. The CTC determines the primary payer amount for the DRG payment is $42,000 ($70,000 payment from the primary payer x [$60,000 for the transplant portion from Medicare/$100,000 combined Medicare payment]) and for organ acquisition costs is $28,000 ($70,000 payment from the primary payer x [$40,000 for the organ acquisition portion from Medicare/$100,000 combined Medicare payment]). The CTC counts this Medicare secondary payer organ as a Medicare usable organ on its MCR and offsets the primary payment amount ($28,000) as revenue received, thereby reducing Medicare's liability.

3105. ACCOUNTING FOR THE COST OF SERVICES PROVIDED TO LIVING DONORS

For costs associated with living donor organ acquisition costs, see §3101, Certified Transplant Centers and Organ Acquisition Costs.

Payment for physician services to a living donor provided in connection with an organ donation to a Medicare beneficiary is made at 100 percent of the Medicare Part B reasonable charge. These services include the donor's organ excision and inpatient stay.

The donor of an organ for a Medicare transplant beneficiary is covered for an unlimited number of days of care in connection with the organ removal operation. Days of inpatient hospital care used by the donor in connection with the organ removal operation shall not be charged against either party's utilization record. However, the Program's assumption of liability is limited to those donor expenses that are incurred directly in connection with the organ donation.

Coverage of organ donor services includes postoperative recovery services directly related to the organ donation. For routine follow-up care the period of postoperative recovery ceases when the donor no longer exhibits symptoms related to the organ donation. Claims for services rendered more than 3 months after donation surgery will be reviewed. However, follow-up examinations may be covered up to 6 months after the donation to monitor for possible complications. In all of these situations, the donor is not responsible for co-insurance or deductible.

A. Living donor follow-up.--

- Expenses incurred by the CTC for routine donor follow-up care are included in the transplant center's organ acquisition cost center.
- Follow-up services performed by the operating physician are included in the 90-day global payment for the surgery. Beyond the 90-day global payment period, follow-up services are billed using the recipient's health insurance claim number.
- Follow-up services billed by a physician other than the operating physician for up to 3 months following donation surgery should be billed under the recipient's health insurance claim number.
- Medicare does not consider the UNOS-required 6-month, 1-year and 2-year follow-up visits to be routine donor follow-up care. As such, the UNOS required follow-up visits are not allowable nor reported as organ acquisition costs on the MCR and cannot be billed to the recipient's health insurance claim number.

B. Living donor complications.--Expenses incurred for complications that arise with respect to the donor are covered only if they are directly attributable to the organ donation. Complications that arise after the date of the donor's discharge are billed under the recipient's health insurance claim number. This is true of both facility costs and physician services. Billing for donor complications will be reviewed by the contractor. For more information see the Medicare Claims Processing Manual, CMS Pub. 100-04, chapter 3, §90.1.3.

3106. KIDNEY PAIRED DONATIONS

Kidney paired donations (KPDs) are similar to directed living donations; however when the living donor and recipient do not match, they can consent to participate in a KPD matching program that matches living donor/recipient pairs with other living donor/recipient pairs. KPD exchanges can occur when two or more living donor/recipient pairs match each other; often, the living donor and matched recipient are at different CTCs.

The costs of all hospital and physician services for pre-transplant living donor and recipient evaluations become acquisition costs and are included in the cost report of the recipient's CTC. Similarly, when a recipient and donor do not match and elect to participate in a KPD matching program, the costs of the initial living donor evaluations are incurred by the original intended recipient's CTC regardless of whether the living donor actually donates to their original intended recipient, a KPD matched recipient, or does not donate at all.

A. When a KPD Match is Determined.--In a KPD exchange, once the donor is matched with a recipient, any additional tests requested by the recipient's CTC, but performed by the donor's CTC are billed as charges reduced to cost to the recipient's CTC and included as acquisition costs on the cost report of the recipient CTC. This is true regardless of whether an actual donation occurs.

When a donor's CTC procures and sends a kidney to a recipient's CTC, the donor's CTC bills the recipient's CTC the donor CTC's charges reduced to cost for the reasonable costs associated with procuring, packaging and transporting the kidney. The donor's CTC records these costs on its MCR as kidney acquisition costs and offsets any payments received from the recipient's CTC against its kidney acquisition costs. The recipient's CTC records as part of its kidney acquisition costs, the amounts billed by the donor's CTC for the reasonable costs associated with procuring, packaging, and transporting the organ as well as any additional testing performed and billed by the donor's CTC. These costs must be reasonable and necessary.

When a donor's CTC does not procure a kidney, but the donor travels to the recipient's CTC for the procurement, the reasonable costs associated with the procurement are included on the MCR of the recipient's CTC. Travel expenses of the living donor are not allowable Medicare costs.

Example of Accounting for a KPD Exchange:

1. The Participants

There are four CTCs; each with a potential transplant recipient in need of a kidney and each recipient has a willing, but poorly matched, donor. Each recipient and donor pair has been evaluated at their respective CTC.

CTC A
Recipient A is at CTC A. CTC A evaluates three potential living donors for Recipient A before a donor, Donor A, is identified. The costs of these evaluations are reported as kidney acquisition costs on CTC A's cost report. Recipient A and Donor A do not match each other but both agree to participate in a KPD exchange.

CTC C
Recipient C is at CTC C. CTC C evaluates three potential living donors for Recipient C before a donor, Donor C, is identified. Recipient C and Donor C do not match each other but both agree to participate in a KPD exchange.

CTC D
Recipient D is at CTC D. CTC D evaluates three potential living donors for Recipient D before a donor, Donor D, is identified. Recipient D and Donor D do not match each other but both agree to participate in a KPD exchange.

2. The KPD Match

Through the KPD exchange it is determined that Recipient A matches Donor C; Recipient B matches Donor D; Recipient C matches Donor A; and Recipient D matches Donor B.

3. After the KPD Match

Recipient C's CTC requests Donor A's CTC perform an additional test that was not included in Donor A's initial evaluation. Donor A's CTC performs the additional test and bills Recipient's C's CTC, charges reduced to cost, for the additional tests of Donor A.

Donor B elects to travel to CTC D for the procurement and any additional testing[1].

Donor A, Donor C, and Donor D remain at their original intended recipients' CTCs (CTC A, CTC C and CTC D, respectively) where they were evaluated and where their organ procurement will occur.

4. Procuring, Packaging and Transporting the Kidneys

CTC A procures Donor A's kidney and packages and transports it to CTC C for Recipient C. CTC A bills CTC C, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by CTC C that was not included in the initial evaluation of Donor A. Donor A's CTC records these costs on its MCR as kidney acquisition costs and offsets any payments received from CTC C against its kidney acquisitions costs.

CTC B does not procure a kidney. Donor B elects to travel to CTC D for the procurement. CTC D procures Donor B's kidney and records these costs on its cost report as kidney acquisition costs.

CTC C procures Donor C's kidney and packages and transports it to CTC A for Recipient A. CTC C bills CTC A, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by CTC A that was not included in the initial evaluation of Donor C. Donor C's CTC records these costs on its MCR as kidney acquisition costs and offsets any payments received from CTC A against its kidney acquisitions costs.

CTC D procures Donor D's kidney and packages and transports it to CTC B for recipient B. CTC D bills CTC B, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by CTC B that was not included in the initial evaluation of Donor D. Donor D's CTC records these costs on its MCR as kidney acquisition costs and offsets any payments received from CTC B against its kidney acquisitions costs.

5. Counting Medicare Usable Organ[2]

CTC A counts two Medicare usable kidneys: 1) Donor A's kidney procured and sent to CTC C and 2) Donor C's kidney procured by CTC C and received and transplanted by CTC A.

CTC B counts one Medicare usable kidney: Donor D's kidney procured by CTC D and received and transplanted by CTC B (CTC B does not procure a kidney).

CTC C counts two Medicare usable kidneys. 1) Donor C's kidney procured and sent to CTC A and 2) Donor A's kidney procured by CTC A and received and transplanted by CTC C.

CTC D counts two Medicare usable kidneys: 1) Donor D's kidney procured and sent to CTC B and 2) Donor B's kidney procured by CTC D and transplanted.

The chart below summarizes the above KPD exchange.

	CTC A	CTC B	CTC C	CTC D
Recipient	Recipient A	Recipient B	Recipient C	Recipient D
Number of evaluations	Evaluates 3 potential donors before Donor A is identified.	Evaluates 2 potential donors before Donor B is identified.	Evaluates 3 potential donors before Donor C is identified.	Evaluates 3 potential donors before Donor D is identified.
Donor	Donor A	Donor B	Donor C	Donor D
	Recipient A and Donor A do not match each other but agree to a KPD exchange.	Recipient B and Donor B do not match each other but agree to a KPD exchange.	Recipient C and Donor C do not match each other but agree to a KPD exchange.	Recipient D and Donor D do not match each other but agree to a KPD exchange.
KPD match	Recipient A matches with Donor C.	Recipient B matches with Donor D.	Recipient C matches with Donor A.	Recipient D matches with Donor B.
After the match	CTC A performs additional tests and procures kidney from Donor A for CTC C.	CTC B does not procure kidney from Donor B for CTC D. Donor B travels to CTC D.	CTC C procures kidney from Donor C for CTC A.	CTC D procures kidney from Donor D for CTC B. Donor B travels to CTC D for the kidney procurment[1].

Accounting				
Cost of evaluations	$12,000 incurred by CTC A	$9,000 incurred by CTC B	$15,000 incurred by CTC C	$20,000 incurred by CTC D
Counting Medicare usable kidneys[2]	2 Medicare usable kidneys: 1 kidney procured/ sent and 1 kidney received/ transplanted.	1 Medicare usable kidney: 1 kidney received/ transplanted.	2 Medicare usable kidneys: 1 organ procured/sent and 1 kidney received/ transplanted.	2 Medicare usable kidneys: 1 kidney procured/sent and 1 kidney procured/ transplanted.
Donor costs associated with procuring, packaging and transporting the kidney to the recipient CTCs	CTC A bills CTC C $18,000 for costs incurred to procure Donor A's kidney.	No bills sent to CTC D.	CTC C bills CTC A $10,000 for costs incurred to procure Donor C's kidney.	CTC D bills CTC B $14,000 for costs incurred to procure Donor D's kidney.
Recipient costs associated with procuring, packaging and transporting the kidney bill by Donor CTCs	CTC A receives a bill from CTC C for $10,000 for costs incurred to procure Donor C's kidney.	CTC B receives a bill from CTC D for $14,000 for costs incurred to procure Donor D's kidney.	CTC C receives a bill from CTC A for $18,000 for costs incurred to procure Donor A's kidney.	No bills received from CTC B. CTC D claims all costs after initial evaluation for Donor B.
Kidney acquisition costs recorded on MCR	$12,000 evaluation costs of CTC A $18,000 for costs billed to CTC C $10,000 billed from CTC C	$9,000 evaluation costs of CTC B $14,000 billed from CTC D	$15,000 evaluation costs of CTC C $10,000 for costs billed to CTC A $18,000 billed from CTC A	$20,000 evaluation costs of CTC D $14,000 for costs billed to CTC B $8,000 for costs incurred to procure Donor B's kidney at CTC D.
Subtotal	$40,000	$23,000	$43,000	$42,000
Offset on MCR amounts received from recipient CTC	($18,000) received from CTC C	No payment received from CTC D	($10,000) received from CTC A	($14,000) received from CTC B
Net cost recorded on MCR	**$22,000**	**$23,000**	**$33,000**	**$28,000**

[1]The cost of travel for a living donor is not an allowable organ acquisition cost.

[2] For this example, all organs are transplanted into Medicare beneficiaries. For more information on how to count organs, see cost reporting instructions, Form CMS-2552 and also §3115, Counting Organs, of this chapter.

B. Donor Follow-up and Complications.--In KPD exchanges, post-donation follow-up or donor complications are handled in the same manner as described in §3105, Accounting for the Cost of Services Provided to Living Donors.

3107. HOSPITALS THAT PROCURE BUT DO NOT TRANSPLANT ORGANS

Medicare does not require that donor hospitals belong to the OPTN. However, a donor hospital must always notify, in a timely manner, the designated OPO of any deaths or imminent deaths in its hospital. The contacted OPO will implement its donation protocol and, when appropriate, will procure any available organs. When the donor hospital incurs expenses for services authorized by the OPO, the donor hospital bills its customary charges for the services furnished to the OPO to receive payment. Negotiated rates between the OPO and the donor hospital are an acceptable payment methodology but must be reasonable.

3108. ORGAN PROCUREMENT ORGANIZATIONS

An organ procurement organization performs or coordinates the procurement, preservation and transportation of organs from deceased donors, and maintains a system for locating prospective recipients for organ transplantation. An OPO must have agreements with hospitals or critical access hospitals in its service area, to identify potential organ donors.

OPO's provide both administrative and medical services that include, but are not limited to, arranging for tissue typing of donated organs, removal of the cadaveric organs (where the physicians are employed by the OPO or are under contract or agreement with the OPO); and perfusion, preservation, and transportation of the procured organ.

The Medicare program reimburses the reasonable cost of allowable services furnished by an OPO provided it has been certified and is designated for a particular service area by the Secretary. An OPO must be a member of and have a written agreement with the OPTN. Organ acquisition costs are not paid directly by Medicare to an OPO. The OPO is reimbursed for its services by the CTC, subject to later adjustment by Medicare. See 42 CFR §413.200(c)(1)(iv) and §413.200(d)(3).

An OPO can be a hospital-based OPO (HOPO) or an independent OPO (IOPO). (We refer to organ procurement organizations generally as "OPOs" throughout this chapter, unless differentiation of HOPO or IOPO is required for context.) Both OPO types are reimbursed on the basis of reasonable cost. In determining the reasonable cost of these services and cost reporting requirements, the policies set forth in regulations and in the Provider Reimbursement Manual (CMS Pub. 15) must be followed.

A. Hospital-Based Organ Procurement Organizations.--Some hospitals contribute to the basic financial support of an in-house OPO, called a HOPO, or provide supervision over the operations of a HOPO to the extent that it represents control over their operations. In such cases, the contractor applies the provisions of CMS Pub. 15-1, Chapter 10 to determine the allowable costs of the HOPO.

A HOPO is not separately reimbursed as an IOPO but is reimbursed through the CTC on the MCR, Form CMS-2552. The CTC/HOPO is expected to acquire the organ at a reasonable cost-related charge. Such reasonable charge payment to the CTC/HOPO is included as an organ acquisition cost of the CTC and is recorded in the hospital's organ acquisition cost center of its MCR. Cost adjustments are made for the CTC/HOPO when the hospital's cost report is settled.

A HOPO that is not designated by the Secretary receives payment for organs procured within the CTC when they are used for its CTC's in-house transplants (when the organ is not transported to another hospital following procurement). When the CTC cannot use the organ in-house and the organ is instead furnished to a designated OPO, the CTC will receive payment from that OPO and the costs are reported on the CTC's cost report.

B. Independent Organ Procurement Organizations.--An independent OPO (IOPO) is not subject to the control of a hospital and is not considered a department of the hospital. An IOPO provides services to a number of hospitals. The initial kidney SAC for an IOPO is developed by the contractor based on the IOPO's budget information. The kidney SAC for subsequent years is based on the IOPO's cost report, i.e., costs of operating during its prior cost reporting year. These standard charges are the basis for the interim payments by the CTC to the IOPO. An IOPO's non-kidney SAC are established by the IOPO based on its costs of procuring organs, similar to procedures set forth in §3101, Certified Transplant Centers and Organ Acquisition Costs.

The kidney SAC, established by the contractor for an IOPO, consists of an estimate of the reasonable and necessary costs expected to be incurred procuring cadaveric kidneys. The estimated amount is divided by the projected number of usable cadaveric kidneys procured. The kidney SAC may be adjusted during the year, if necessary, for anticipated cost changes. The IOPO cannot charge or change its kidney SAC without the contractor's approval.

When an IOPO acquires an organ from another IOPO each IOPO is responsible for paying that that IOPO's SAC. The IOPO uses its SAC and not the SAC paid to another IOPO when billing a CTC receiving the organ.

Example: IOPO A has a SAC of $35,000 and IOPO B has a SAC of $50,000. IOPO A acquires an organ from IOPO B and pays IOPO B their SAC of $50,000. IOPO A provides the organ to the CTC and bills its SAC of $35,000.

The IOPO must file a cost report (Form CMS-216) with the contractor at the end of its cost reporting period. The IOPO must separate from Medicare allowable costs all costs associated with organs that are sent to foreign countries or transplanted in patients other than Medicare beneficiaries. The IOPO's cost report is used to reconcile kidney acquisition costs. The contractor will compute the ratio of kidneys used for Medicare beneficiaries to the total number of kidneys used, and adjust the Medicare allowable costs for kidneys sent to foreign countries or transplanted in non-Medicare beneficiaries. For kidneys sent to MRTCs, see §3114, Military Renal Transplant Centers.

C. OPO Costs Not Covered by Medicare.--Certain costs incurred by OPOs are not covered under the Program. These activities or services include but are not limited to:

- burial and funeral expenses for the cadaveric donor;
- costs incurred in furnishing an organ to a hospital outside the United States;
- costs associated with the transportation of a donor;
- costs incurred prior to a potential donor being declared brain dead;
- fees or in-center payments for donor referrals;
- costs associated with OPO sponsored seminars where continuing education credits are given (When no continuing education credits are given, direct seminar expenses may be paid by the Program. See CMS Pub. 15-1, chapter 4 for more information regarding the cost of educational activities.); and
- certain costs incurred for administrator's duties associated with professional organizations.

3109. CHARGES FOR EYE AND TISSUE DONATIONS AND SERVICES

OPOs must establish a schedule of charges for eye and tissue services and ensure that the charges are offset against the costs of all procurement services. This is necessary because eye and tissue retrievals are not usually separated on the cost report. If the OPO performs an eye or tissue service, the established charge representing the estimated cost incurred for the service is offset against its cost. Where the costs for the eye or tissue services is significant the OPO must establish a non-reimbursable cost center to capture the direct and indirect costs; these costs are not offset. See CMS Pub. 15-1 §2328, Distribution of General Service Costs to Nonallowable Cost Areas. However, where cost centers are not maintained for these functions, the income derived from them must be used to reduce total costs of all procurement services. For example, when an OPO procures an eye or tissue, the OPO must ensure the charge approximates the cost of the service. If the OPO performs only a minor service in which the cost is insignificant that a charge cannot be reasonably determined (e.g., calling an eye or tissue bank and informing it that a donor is available without approaching the family about donation), the OPO does not establish a charge.

3110. PANCREATA USED FOR PANCREATIC ISLET CELL TRANSPLANTS

The Medicare Modernization Act of 2003 requires Medicare to pay for islet cell transplants for Medicare patients included in the National Institutes of Health clinical trial on islet cell transplants. The pancreata procured for islet cell transplants require the same quality and care to procure as pancreata procured for solid organ transplants. Accordingly, pancreata procured for islet cell transplants must be assigned a full charge and treated as solid organs for procurement purposes.

3111. ALLOCATION OF DONOR ACQUISITION COSTS INCURRED BY ORGAN PROCUREMENT ORGANIZATIONS (INTENT TO TRANSPLANT)

An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. (42 CFR §486.322). Each hospital is required to notify its designated OPO of every death or imminent death in its facility (42 CFR §482.45). It is presumed that an OPO intends to procure all transplantable organs from a donor, and regardless of whether organs are actually procured, the OPO incurs costs in attempting to recover such organs.

For example, when an OPO learns of a deceased donor, it attempts to recover as many organs as possible from the donor. The OPO must arrange for surgeons to excise the organs, an operating room in which the procurement will take place, and services necessary to maintain the organs in a viable state. If the excising surgeons determine, upon initial inspection, or after removal, that one or more of the organs is not viable, the aforementioned costs, nevertheless have been incurred by the OPO. These costs must be allocated to the cost centers of both the recovered and unrecovered organs. Thus, all general costs must be allocated to all organs the OPO intends to procure, regardless of whether the OPO actually recovers the organ for transplant (i.e., when an OPO cannot recover the organ because of its non-viability upon inspection). Because CMS presumes an OPO intends to procure all transplantable organs, CMS will allocate the general costs across all organs (whether or not actually recovered), unless an OPO can demonstrate that it did not intend to procure a particular organ.

An OPO can demonstrate that it did not intend to procure a particular organ if one of the following occurs:

- The donor does not meet the criteria for "eligible donor" in 42 CFR §486.302 of the regulations.
- The organ has been eliminated for eligibility because of donor information.
- The organ has been ruled out by laboratory data prior to the donor entering the operating room for excision of organs.
- The family does not provide consent to donate the organ.
- The search for a recipient for that particular organ has ended unsuccessfully prior to the donor's entrance into the operating room.

While the above situations will ordinarily allow an OPO to demonstrate that it did not intend to procure a particular organ, a contractor may, upon an evaluation of the totality of the circumstances, conclude that the OPO intended to procure an organ. Thus, the existence of one of the above situations does not lead to an absolute conclusion that intent to procure did not exist; in fact, the contractor has the flexibility to further examine such conclusion. For example, an OPO may claim that a family did not provide consent to donate an organ, yet the facts may demonstrate that the OPO arranged for a surgeon to procure the organ, or located a potential recipient for that particular organ. In these instances, the contractor could override an OPO's contention that intent to procure did not exist.

The following represents an example of how costs must be allocated to the various organ cost centers.

Example: Hospital A notifies OPO B that a death is imminent in its facility and that the individual is listed as a potential organ donor. OPO B arranges for surgeons to procure the organs, an operating room for the excisions to take place, and services necessary to maintain the organs in a viable state. Prior to calling the liver transplant surgeon, the OPO arranges for a liver function test, which shows that the liver is not viable. Surgeons remove all of the remaining organs, but the heart surgeon determines, upon inspection of the heart, that it is not suitable for transplant. The lungs were designated for non-transplant research activities prior to the time the donor entered the operating room. Costs are allocated as follows: The cost of the liver function test is allocated to the liver cost center. No portion of the operating room fees or other services is allocated to the liver cost center, or to the lungs cost center. The costs for the operating room fees and the other services are allocated equally to the other organ cost centers, including the heart cost center. Surgeon's fees that are specific to a particular organ are allocated directly to that organ.

3112. ORGAN PLACEMENT EFFORTS, DOCUMENTATION REQUIREMENTS

OPOs and CTCs furnishing organ procurement services for organ transplants under the Medicare program must maintain adequate and verifiable records for each organ retrieved and furnished to a Medicare patient. Because it is not possible to determine at the time of retrieval whether an individual organ will be placed with a Medicare beneficiary, a placement effort record must be maintained for every organ. The record should contain the following:

- organ(s) and/or tissue recovered;
- recovery date;
- donor's name/number;
- hospital recovered from;
- name of transplant center;
- recipient's name or dispensation;
- indication of research intent; and
- indication of en bloc transplants.

3113. PAYMENT FOR ORGANS SENT TO FOREIGN COUNTRIES OR TRANSPLANTED IN NON-MEDICARE BENEFICIARIES

Medicare does not pay for organ acquisition costs for organs sent to foreign countries or organs transplanted into non-Medicare recipients. These costs are reported on the MCR (Form CMS-2552) and on the OPO/Histocompatibility Laboratory cost report (Form CMS-216) but are excluded from Medicare allowable costs and Medicare payment. Cost reports will be reviewed by the contractor to ensure that all costs are properly accounted for.

3114. MILITARY RENAL TRANSPLANT CENTERS

Some OPOs have a long-standing arrangement with MRTCs formalized by a Memorandum of Understanding between the OPO and the MRTC, specifying a reciprocal kidney sharing system. Such arrangements that were in effect before March 3, 1988 are accepted after the contractor reviews and approves the arrangement. See 53 Fed. Reg. 6672 (March 2, 1988). For these cases, a kidney procured by an OPO at a MRTC and retained for transplant at that hospital is deemed to be a Medicare organ for cost reporting statistical purposes. While we know of no other special arrangements, if any existed before March 3, 1988, the OPO must submit a request to the contractor for review and approval of the arrangement. Absent an approved special arrangement that existed before March 3, 1988, a kidney sent to a non-Medicare institution is treated as a non-Medicare organ.

3115. COUNTING ORGANS

OPOs and CTCs are responsible for accurately counting both Medicare and non-Medicare organs to ensure that costs are properly allocated on the MCR. The OPO and CTC should count organs procured and transplanted en bloc (two organs transplanted as one unit) as one organ. This can include but is not limited to en bloc kidneys and en bloc lungs.

A. Counting Medicare Usable Organs at CTCs/HOPOs.--Medicare usable organs include organs transplanted into Medicare beneficiaries (excluding Medicare Advantage beneficiaries), organs that had partial payments by a primary insurance payer in addition to Medicare, organs sent to other CTCs, organs sent to OPOs and kidneys sent to MRTCs (that have a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988 and approved by the contractor). Medicare usable organs do not include organs used for research, organs sent to veterans' hospitals, organs sent outside the United States, organs transplanted into non-Medicare beneficiaries, organs that were totally paid by primary insurance other than Medicare, organs that were paid by a Medicare Advantage plan, organs procured from a non-certified OPO and kidneys sent to MRTCs (without a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988 and approved by the contractor).

B. Counting Medicare Kidneys at IOPOs.--Medicare kidneys include kidneys sent to CTCs, certified OPOs, or MRTCs (with a reciprocal sharing agreement with the OPO in effect prior to March 3, 1988 and approved by the contractor). It does not include kidneys sent to foreign countries, VA hospitals, or MRTCs (without a reciprocal sharing agreement with the OPO in effect prior to March, 3 1988 and approved by the contractor), or those used for research.

3116. CALCULATION OF MEDICARE COSTS

Total organ acquisition costs are accumulated by organ type on the applicable cost report. A ratio of Medicare usable organs to total usable organs is applied to the total organ acquisition costs in determining Medicare's share of expenses. This ratio includes only usable organs, but total organ acquisition costs include the cost of organs that are determined to be unusable as Medicare continues to share in these costs.

The following is an example of the method of determining proper reimbursement for Medicare's share of organ acquisition costs at an OPO or CTC.

Total Organs	130
Total Unusable Organs	10
Total Usable Organs	120
Total Foreign Organs	20
Total Military Organs	10
Total VA Organs	10

Total Costs	$1,200,000[1]
Foreign Revenue	$25,000
Military Revenue	$100,000
VA Revenue	$100,000
Payments from Other OPOs or Transplant Centers	$850,000

[1]Included in the $1,200,000 total cost are costs associated with nonviable (unusable) organs.

An OPO's or CTC's total cost for all organs is reduced by the costs associated with organs transplanted in patients other than Medicare beneficiaries or organs sent to foreign countries regardless of income received from these sources. Using the above data the amount the OPO or CTC pays the Medicare program at the end of the cost reporting period is $50,000, as computed below.

Step 1 - Compute the Medicare Ratio

(Medicare Usable Organs)	=	(Total Usable Organs)	-	(Total Foreign & VA Organs)
90	=	120	-	30[2]

Medicare Ratio	=	Medicare Usable Organs /Total Usable Organs
.75	=	90/120

Step 2 - Compute Medicare Allowable Costs

Total Cost (Net of transportation costs for exported organs)	$1,200,000
Multiplied by Medicare Ratio (.75)	X .75
Medicare Costs	900,000
Less Payment from OPOs, Military Hospitals, and CTCs for Medicare Organs	-950,000
Balance due Medicare program from OPO or CTC	$ (50,000)

[2]The example does not include organs procured at a MRTC because our example assumes the institutions have an approved agreement with the OPO.

3117. ORGANS SOLD AT A PROFIT

Any CTC or OPO that sells an organ to any other organization at an amount in excess of its cost, is in violation of 42 U.S.C. §274e. If a contractor becomes aware that organs are sold significantly in excess of the reasonable costs, they will refer the matter to the Department's Office of the Inspector General providing the identity of the facility and the specifics of the organs sold for their review.