Medicare

Provider Reimbursement Manual Part 1, Chapter 27, Reimbursement for ESRD and Transplant Services

Department of Health & Human Services (DHHS)
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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
2770 – 2775.4	27-63 – 27-21 (11 pp.)	27-63 – 27-72 (11 pp.)

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NEW/REVISED MATERIAL--*EFFECTIVE 01- 05: January 1, 2005*

Section 2770, Payment for Renal Transplantation, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs. The requirement for CTCs to call the OPO on all deaths has been added to conform with regulations.

Section 2771, Certified Transplant Centers, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2771.1, Accounting For The Cost of Organ Acquisition, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2771.2, Accounting for the Cost of Physician Services to Recipients, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2771.3, Accounting for the Cost of Live Donor Physician Services, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2771.4, Accounting for the Cost of Recipient and Donor Follow-Up Services, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2772, Hospitals That Excise but not Transplant Organs, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs. The requirement for CTCs to call the OPO on all deaths has been added to conform with regulations.

Section 2773, Organ Procurement Organizations, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2773 B, Independent Organ Procurement Organizations, has been clarified to ensure that non-kidney standard acquisitions charges to be establish based on the OPOs cost of procuring those organs.

Section 2773.2, Pancreata Used for Pancreas Islet Cell Transplants, is being added to require pancreata procured for islet cell transplants to be assigned the full pancreas standard acquisition charge.

Section 2774, Organ Placement Efforts -- Docutmentation, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2775, Payment For Organs Sent to Foreign Countries or Transplanted in non-Medicare Beneficiaries, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2775.2, Military Renal Transplant Centers, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2775.3, Calculation of Medicare, is being revised to remove references to kidney procurement and transplant when applicability is to all types of organs. In these situations, the word kidney is being removed and replaced with the word organs.

Section 2775.4, Organs Sold at a Profit, obsolete address for the Office of the Inspector General Field Offices have been removed.

DISCLAIMER: The revision 01- 05 and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

CHAPTER 27

OUTPATIENT MAINTENANCE DIALYSIS SERVICES

Composite Rate Payment for In-Facility and Home Dialysis

2770. PAYMENT FOR RENAL TRANSPLANTATION.--

Renal transplantation is a principal form of treatment available to patients with end-stage renal disease. The Medicare program has established policies which contribute to the support of this method of treatment by providing an equitable means of payment for the variety of medical services that are required to support quality transplant programs.

The following instructions explain how Medicare pays for the covered services provided a Medicare patient who receives a living or cadaveric transplant. They also explain how a certified transplant center's (CTC) or organ procurement organization's (OPO) expenses in providing organs are paid and how a organ acquisition cost center and a living or cadaveric acquisition charge is constructed. To participate in the Medicare program, any CTC or OPO must be a member of the Organ Procurement and Transplantation Network (OPTN). The CTC is required to notify the OPO designated for its service area of deaths or imminent deaths in its hospital.

2771. CERTIFIED TRANSPLANT CENTERS.--

A. The Standard Organ Acquisition Charge.--Two basic standard charges must be developed by CTCs from costs expected to be incurred in the acquisition of organs.

- o The standard acquisition charge for acquiring a live donor organ; and
- o The standard acquisition charge for acquiring a cadaver organ.

The standard charge does not represent the acquisition cost of a specific organ. It is a charge which reflects the average cost associated with each particular type of organ acquisition, i.e., the actual cost of procuring all organs of each specific type (cadaveric or live donor) averaged over billable organs by type. When a facility provides an organ to another CTC or OPO, it must bill its standard charge by type of procurement. When a CTC bills the program for the transplant, it must use its standard acquisition charge for the procured organ and its diagnosis-related group (DRG) charge for the transplant.

B. Standard Live Donor Acquisition Charge.---The standard live donor organ acquisition charge must be established before a CTC bills its first live donor transplant to the program. This charge is an average charge constructed for each type of organ, by estimating the costs to be incurred for services furnished to live donors and pre-admission services furnished recipients of live donor organs during the hospital's cost reporting period. This estimated amount is divided by the projected number of live donor organs to be excised or otherwise acquired by that hospital for transplant. If there is no such data, the charge which is arrived at by a comparable hospital performing comparable services may be used, with appropriate adjustments where they appear necessary. The actual incurred cost for procurement services are included in the CTC's organ acquisition cost center for eventual payment.

Expenses that may be used to formulate the live donor organ acquisition charge include but are not limited to the following:

- o Tissue typing of donor and recipient;
- o Physician preadmission transplant evaluation services;
- o Organ recipient registration fees;

- Donor and recipient evaluation;
- Other costs associated with excising , e.g., general routine and special care services;
- Operating room and other inpatient ancillary services; and
- Preservation and perfusion costs.

C. Standard Cadaveric Donor Acquisition Charge.--The CTC's expected costs to be incurred in the excision of cadaver organs combined with the costs of cadaver organs to be acquired from other sources are divided by the expected number of usable cadaver organs to be transplanted. This amount is the standard cadaver organ charge and is to be developed for each type of organ. Where the CTC provides the organ to an OPO, the CTC uses its standard cadaver organ acquisition charge to bill them.

The costs of excising a cadaver organ cannot be billed directly to the program since excision of such a organ is not in itself a covered service. However, such costs are reimbursable when they are incurred in obtaining a organ for a Medicare covered transplant. They are recovered on an interim basis by the charging of the facility's standard acquisition charge and on a final basis through the filing of a Medicare cost report at the end of the facility's fiscal period. Usual provider costs related to the excision of a cadaver organ include:

- Costs of organs acquired from other providers;
- Transportation of the organs;
- Surgeons' fees for excising cadaver organs, currently limited to $1250 per kidney donor;
- Tissue typing services furnished by independent laboratories; and
- Preservation and perfusion costs.

2771.1 Accounting For The Cost of Organ Acquisition

A. Outpatient Costs.--Included in the cost of organ acquisition are hospital costs normally classified as outpatient cost applicable to organ excisions. Services include donor and donee work-up furnished prior to admission and cost of services rendered by residents and interns not in approved teaching programs. These costs would otherwise be paid under Part B of the program. Since such costs are applicable to organ acquisitions which are predominately cadaveric donor related and incurred without an identifiable beneficiary, the services are not billed to a beneficiary at the time the services are rendered.

B. Multiple Organ Retrieval.--CTCs and hospital-based OPOs (HOPO) 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 apportion to the Medicare program only the costs applicable to the acquisition of organs approved for Medicare transplants.

When the CTC procures multiple organs, it must allocate and record the direct costs associated with each specific organ. Also, ancillary charges must be allocated between the type of organs procured. For example, if an operating room procurement charge is $1000 and one kidney and one heart are

procured then the charge attributable to each is $500. However, if the CTC has a better basis for allocation, e.g., number of operating room minutes verifiable by the intermediary, this may be used.

Similarly, OPOs that procure organs at a local community hospital must prorate the various charges from that same hospital. This type of allocation must be done separately for organs procured from each donor. Total organs at the end of the cost reporting period is not an acceptable basis for allocation.

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 retrieved. This unit cost is multiplied by each organ obtained. The indirect costs cannot be allocated only to kidney acquisition, but must be allocated to all types of organs based on the number of each procured. For example, if the indirect cost equals $5000 and 5 organs are procured (one heart, one liver, one pancreas, and two kidneys) then the charge for each is $1000 ($2000 must be allocated to kidney acquisition).

C. Laboratory Services.--Pretransplant evaluation services, including laboratory services are paid through the organ acquisition charge 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 to live donors and recipients.

When the laboratory services are performed by an independent laboratory, interim rates established by the intermediary are used by the laboratory in billing CTCs. Information on the interim rates are disseminated by the intermediary to all CTCs, OPOs, and other intermediaries. 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. Payments made on the basis of the interim rate are reconciled directly with the independent laboratory after the close of its fiscal year.

D. Cost Adjustment.--All OPOs and CTCs that claim organ acquisition costs on supplemental worksheet D-6 of the Hospital Cost Report (HCFA -2552,) must separate costs associated with organs that are sent to foreign countries or transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the intermediary. The intermediary 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. Services provided to patients other than Medicare beneficiaries are paid by those patients or their third party payers.

Organs sent to United States military renal transplant centers (MRTC) by a certified OPO are counted as Medicare organs for payment purposes on the OPO's cost report. The Medicare program continues to pay for its proportionate share of costs incurred in procuring organs that are not transplanted. See section 2775.2 for more detailed requirements.

2771.2 Accounting for the Cost of Physician Services to Recipients.--

A comprehensive payment is made for the services of a surgeon who performs an organ transplant and assumes primary responsibility for:

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

A comprehensive payment is also made 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 Medicare Part B carrier.

2771.3 Accounting for the Cost of Live Donor Physician Services.--Payment for physician services to a live donor provided in connection with a organ donation to an entitled beneficiary is made at 100 percent of the Part B reasonable charge. These services include the donor's organ excision inpatient stay and any subsequent related postoperative period. There is no deductible or coinsurance charged for services furnished to live donors, but in determining the reasonable charge, the participating/nonparticipating physician rules apply. The Part B claim includes the name, address, and health insurance number of the recipient as well as the name and address of the live donor.

2771.4 Accounting for the Cost of Recipient and Donor Follow-Up Services.--

A. Recipient Laboratory Services.--Laboratory tests performed for the recipient after he 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.

B. Donor Postoperative Services.--Medically necessary postoperative inpatient services furnished to a live donor for complications resulting from the organ donation are organ acquisition services paid on a Part A basis.

The hospital that treats the organ donor, bills its customary charges to the CTC where the transplant occurred. It includes on the bill the statement, "services for organ donor" with the name and address of the donor. The bill also shows the name, address, and health insurance number of the organ recipient. There are no deductibles or coinsurance charged for hospital services furnished to organ donors.

C. Donor Postoperative Physician Services.--Postoperative physician services furnished to live organ donors are billed to the Medicare carriers and paid on a Part B reasonable charge basis. There is no deductible or coinsurance charged for services furnished to donors, but in determining the reasonable charge, the participating/nonparticipating physician rules apply. The Part B claim includes the name, address, and health insurance number of the organ recipient as well as the name and address of the donor.

2772. HOSPITALS THAT EXCISE BUT DO NOT TRANSPLANT ORGANS.--

There is no requirement 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 retrieve any available organs. When the donor hospital incurs expenses for services they perform which were authorized by the OPO, the donor hospital bills the OPO to receive payment and uses its customary charges for the services furnished. The OPO bills the CTC its (OPO) standard acquisition charge for the retrieved organ. When the organ is unusable, payment for the organ is dependent on when and where the determination of non-viability is made.

2773. ORGAN PROCUREMENT ORGANIZATIONS.--

Organ procurement organizations provide services designed to coordinate the acquisition of usable organs for transplantation. The Medicare program reimburses the reasonable cost of allowable

services furnished by an OPO provided it has been designated as an OPO by the Secretary of Health and Human Services. An OPO must be a member of and have a written agreement with the OPTN. An OPO that has not been designated by the Secretary for its service area will not receive payment for procurement services.

Services may include, but are not limited to, arranging for tissue typing of donated organs, excision of the cadaver organs (where the physicians are employed by the OPO or are under contract or agreement with the OPO), perfusion, preservation, and shipping of the excised organ.

Hospital-based and independent OPOs are reimbursed on the basis of reasonable cost. In determining the reasonable cost of these services and cost reporting requirements, the policies contained in the Provider Reimbursement Manual (PRM) are to be used.

A. Hospital-Based Organ Procurement Organizations.--Some hospitals contribute to the basic financial support of an OPO or provide supervision over the operations of an OPO to the extent that it represents control over their operations. In such cases, the intermediary applies the provisions of Chapter 10 to determine the allowable costs of the hospital-based OPO (HOPO).

In developing its first standard organ acquisition charge, live donor or cadaveric, procedures similar to those found in 2771A and B are used.

The CTC is expected to acquire the organ at a reasonable cost-related charge. Such reasonable charge payment to the HOPO is included as a cost of the CTC. The costs of organ procurement activities of HOPOs are recorded in the hospital's organ acquisition cost center. Cost adjustments are made for the 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 in-house transplants. It will receive payment for organs furnished to a designated OPO when the CTC cannot use it in-house. These costs are reported on the CTC's cost report.

B. Independent Organ Procurement Organizations.--An independent OPO's (IOPO) organ acquisition charge is developed by the intermediary based on the IOPO's cost report, i.e., costs of operating during its prior fiscal year. These standard charges are the basis for the interim payment for the IOPO. Non-kidney acquisition charges are established by the OPO based on its costs of procuring organs.

The initial interim rate for an IOPO is obtained from budget information submitted by the IOPO. The budget is based on costs of the latest fiscal period adjusted to reflect Medicare reasonable cost requirements.

The interim rate established by the intermediary for an IOPO consists of a single amount representing the average cost per service associated with procuring a cadaver organ for transplantation. The interim rate may be adjusted during the year, if necessary, for anticipated cost changes. The IOPO cannot charge a standard kidney acquisition fee nor can changes be made to the rate without the intermediary's approval.

Each IOPO is responsible when it acquires an organ from another IOPO for paying that IOPO's approved standard acquisition charge. Such charges are also used by the IOPO when billing a CTC receiving the organ. The CTC pays the IOPO the approved charge.

The IOPO must file a cost report with the intermediary at the end of its fiscal period. The IOPO must separate costs associated with organs that are sent to foreign countries or transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare fiscal intermediary. The intermediary 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. Organs sent to Military Renal Transplant Centers are counted as Medicare organs for payment purposes on the OPO's cost report if the requirements of Section 2775.2 are met.

Certain costs incurred by IOPOs are not covered under the program. These activities or services include but are not limited to:

- o Burial expenses for the cadaveric donor;
- o Costs incurred in furnishing a organ to a hospital outside the United States;
- o Costs associated with the transportation of a donor;
- o Costs incurred prior to when a potential donor is declared braindead;
- o Fees or in-center payments for donor referrals;
- o Costs associated with OPO sponsored seminars where continuing education credits are given. (When no continuing education credits are given, direct seminar expenses are paid by the program); and
- o Certain costs incurred for administrator's duties associated with professional organizations.

2773.1 Charges for Eye and Tissue Donations and Services.--Establish a schedule of charges for eye and tissue services and ensure that the charges are offset against the cost of all procurement services. This is necessary since eye and tissue retrievals are not usually separately costed on the cost reports. If you perform an eye or tissue service, the established charge representing the estimated cost incurred for the service is offset against your cost. If you approach the family regarding donation and procure the eye or tissue, ensure the charge approximates the cost of the service. If you perform only a minor service in which the cost is so 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), do not establish a charge.

2773.2 Pancreata Used for Pancreas 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 study on islet cell transplants. The pancreata procured for islet cell transplants require the same quality and care as pancrea 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.

2774. ORGAN PLACEMENT EFFORTS--DOCUMENTATION REQUIREMENTS.

To ensure proper utilization and distribution of organs, 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. Since 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.

o For each organ retrieved independent and hospital-based OPOs and CTCs must maintain a record (e.g., a log) showing the attempts to place the organ with Medicare transplant patients and the final disposition of the organ. Include the following information:

- Name of individual making calls;

- Name of donor;

- Time (01- 05, hour, minute, e.g., 11/18/86, 9:45 p.m.) of retrieval;

- Name of donor center;

- Name and telephone number of each OPO/CTC contacted as a potential user, including name of the person talked to at the OPO/CTC and the time (01- 05, hour and minute) of contact;

- Name of OPO or CTC that accepts the organ and time and 01- 05 sent;

- Disposition of the organ if not placed, i.e., non-viable; and

- Age of organ when shipped.

Attach a copy of the computer printout on the organ to the log.

o Independent and hospital-based OPOs and CTCs that are offered organs must maintain records (e.g., a log) containing the following information:

- Name and telephone number of OPO or CTC offering the organ;

- Name of donor;

- Time (01- 05, hour, minute) of retrieval of age of the organ at time of offering;

- If accepted, indicate time accepted, name of recipient and social security number (or health insurance number), or other identifying information; and

- Reason organ not accepted (if applicable).

Furnish the above information to the intermediary upon request.

2775. PAYMENT FOR ORGANS SENT TO FOREIGN COUNTRIES OR TRANSPLANTED IN NON-MEDICARE BENEFICIARIES.

Organs sent to foreign countries or transplanted in non-Medicare beneficiaries are excluded from Medicare payment. The costs associated with non-Medicare organs are excluded from Medicare payment on the hospital cost report (HCFA 2552 supplemental D-6) and the IOPO cost report (HCFA 216). These cost reports will be revised to properly separate the non-Medicare costs.

A. Organ Procurement Organizations.--An organ sent to a CTC is deemed for cost reporting purposes a Medicare organ. An organ sent to a transplant center that is not Medicare certified, a VA hospital, or sent to a foreign country is considered a non-Medicare organ.

B. Certified Transplant Centers.--A CTC is paid based on the number of Medicare organ transplants that it performs.

2775.1 Primary Payer.--If a Medicare beneficiary has some group health insurance coverage, determining Medicare transplant status depends on the amount paid by the primary insurance. Specifically, if a beneficiary has primary insurance coverage and payment by the primary payer satisfies the liability of the Medicare program, the transplant is considered a non-Medicare transplant for cost reporting purposes. This is consistent with Medicare billing and cost reporting instructions.

2775.2 Military Renal Transplant Centers.--Some OPOs have a long-standing arrangement with Military Renal Transplant Centers. These arrangements which were formalized by a Memorandum of Understanding between the OPO and the Military Renal Transplant Center specify a reciprocal organ sharing system. Any special arrangement, such as the one mentioned above, that was in effect before March 3, 1988 (the publication 01- 05 of the proposed rule on foreign organs in the Federal Register) should be accepted after intermediary review and approval. For these cases, an organ procured by an OPO at a Military Renal Transplant Center 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 fiscal intermediary for review and approval. Absent a special arrangement that existed before March 3, 1988, a organ sent to a non-Medicare institution is treated as a non-Medicare organ.

2775.3 Calculation of Medicare Costs.--Total organ costs are accumulated on the applicable cost report. By type of organ, a ratio of Medicare organs to total organs applied to total organ costs is used to determine Medicare's share of expenses. This ratio includes only usable organs, but total organ costs includes the cost of organs that are determined to be unusable. Therefore, Medicare continues to share in the cost of organs that are unusable.

This is an example of the method of paying OPOs and CTCs for organ acquisition costs.

Total Organs	- 130	
Total Usable Organs	- 120	
Total Nonviable Organs	- 10	
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.

Under this methodology, an OPO's total cost for all organs is reduced by the costs associated with organs transplanted in patients other than Medicare beneficiaries or sent to foreign countries regardless of income received from these sources. Using the above data in the computation below, the amount the OPO pays the Medicare program at the end of the OPO's fiscal year is $50,000.

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 Transplant centers for Medicare Organs	-950,000
Balance due Medicare Program from OPO	$ (50,000)

[2]The example does not include organs procured at a military renal transplant center since our example assumes the institutions have an approved agreement with the OPO.

2775.4 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 Pub.L. No. 98-507 section 301. If an intermediary becomes aware that organs are sold significantly in excess of the reasonable costs, they should 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.