BNA's

MEDICARE REPORT

Reproduced with permission from BNA's Medicare Report, Vol. 15, No. 01, 01/02/2004. Copyright © 2004 by The Bureau of National Affairs, Inc. (800-372-1033) http://www.bna.com

HHS OIG Targeting Organ Transplant Services in 2004

BY REBECCA L. BURKE

The Office of Inspector General (OIG), in its 2004 Work Plan, announced that it will begin auditing hospital cost reports to determine whether hospitals are accurately reporting their organ acquisition costs. [1] Although the OIG has previously investigated other issues related to organ transplantation[2], this is the first time it has focused on hospitals' reporting of organ acquisition costs. This development is hardly surprising in light of the government's recent success in the civil false claims lawsuit against Sharp Memorial Hospital and the San Diego Hospital Association related to Sharp's reporting of organ acquisition costs (discussed below).

This article will review the basic principles of Medicare reimbursement for organ transplants and will discuss some of the complex issues that arise in reporting of hospital organ acquisition costs. It will also review the recent settlement involving *Sharp Memorial Hospital* and will discuss other government initiatives in the area of organ transplantation. [3]

[1] HHS/OIG Fiscal year 2004 Work Plan – Centers for Medicare & Medicaid Services at 3.

[2] The OIG's 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.

[3] United States ex rel. Judith King v. San Diego Hospital Association, Civ. No. 00CV0848-BTM(RBB), (S.D. Cal.) Notice of Partial Intervention and Settlement filed March 4, 2003.

Burke is an attorney with Powers Pyles Sutter & Verville P.C. in Washington D.C. She can be reached at (202) 466-6550 or by e-mail at Rebecca.Burke@ppsv.com.

Introduction

Although organ transplantation is often viewed as benefiting relatively few individuals, it accounts for a large portion of U.S. and Medicare health care expenditures. The U.S. organ transplantation market totaled nearly $4.2 billion in 2002 and is projected to grow at an annual rate of 5 percent to reach $5.4 billion in 2007.[4] Last year, 24,833 solid organ transplants were performed at more than 250 transplant centers across the United States and, as of August 22, 2003, there were 88,305 registrations on the Organ Procurement and Transplantation Network (OPTN) patient waiting list for organ transplantation. [5] Kidney transplants account for approximately 59 percent of solid organ transplant procedures, most of which are paid for by Medicare under the End-Stage Renal Disease (ESRD) program.

Organ acquisition is one of the last areas of Medicare cost reimbursement, and consequently there is an incentive for a hospital to maximize its costs in this area. It is also an area where it is easy to make mistakes since the rules for classifying costs as organ acquisition are complicated and require special recordkeeping.

Only costs associated with activities that take place before a transplant are includible in organ acquisition costs, and hospitals must establish separate cost centers for each organ. The transplant itself, and any post-transplant services are generally paid for under the inpatient prospective payment (DRG) system. One of the things the OIG will be looking for is overpayments resulting from hospitals' improper inclusion, in the organ acquisition cost center, of post-transplant expenses which should be reimbursed under the DRG system.

[4] Business Communications Company, Inc. RB-103R, *The Market for Tissue and Organ Transplantation*, 2003.

[5] Smith S., *Quality Aspects of Transplantation*, Organ Transplant 2003. c. Medscape 2003.

Reporting of Organ Acquisition Costs

Medicare reimburses hospitals that are certified transplant centers (CTCs) for their reasonable costs associated with organ acquisition.[6] Thus, costs that qualify as organ acquisition are reimbursed outside of the Medicare prospective payment system and are in addition to the hospital's DRG payment for the transplant itself.

Medicare pays both direct and indirect costs of organ acquisition. Direct costs are those directly related to organ acquisition and are accumulated in the organ acquisition cost center on Worksheet A of the Medicare Cost Report. In contrast, indirect costs are transplant center overhead costs accumulated in the general service cost centers and allocated through the cost report ''stepdown'' process on Worksheet B.

Direct Costs of Organ Acquisition

Hospital Services

Direct organ acquisition costs include

- Salaries of staff such as procurement coordinators, administrative and support staff, medical directors and social workers/financial coordinators;
- Operating room and other inpatient ancillary services for the donor, including anesthesia and post operative services;
- Hospital outpatient services for donors and recipients prior to admission for transplant (including lab tests and general medical evaluations);
- Registration fees paid to the United Network of Organ Sharing (UNOS);
- Tissue typing, including when done by an independent laboratory;
- Cadaver organs purchased from organ procurement organizations;
- Transportation and preservation of organs; and
- Medically necessary postoperative hospital services to live donors for complications from donation.[7]

Hospitals must maintain separate cost centers for each type of organ. Where an employee's time is split between services includible in organ acquisition and those that are not, documentation must be maintained to support time allocated to organ acquisition. Often an employee's job description involves services that are provided both before and after transplant. In such situations, the hospital is expected to keep accurate time records to support its decision to allocate a portion of the employee's salary to the organ acquisition cost center.

The situation becomes even more complicated if an employee is involved in transplant services for more than one type of organ. In that case, the hospital must support its allocations to more than one organ cost center. Cost center allocation issues can become especially complicated where a number of organs are procured at the same time from a single cadaver.

Proper allocation of staff time and associated costs was an issue in the OIG's recent audit of Tampa General Hospital in Florida and in the settlement with Sharp Memorial Hospital (discussed below) and will likely be a major focus of the OIG's upcoming 2004 Work Plan audits.

Physician Services

Special rules apply for physician services related to organ transplantation. A hospital can include in organ acquisition costs all donor and recipient preadmission physician transplant evaluation services; laboratory services, the surgeon's professional fees for excision of an organ from a cadaver, pre-admission laboratory and electroencephalography services, and services of residents and interns **not** in approved teaching programs. [8] There is a cap of $1,250 for kidney excisions;[9] however this cap does not apply to physician fees for excision of other cadaveric organs.

Physician services that may **not** be included in organ acquisition costs include transplant and post-transplant services for the recipient, medical evaluations occurring during the same inpatient stay as the transplant, excision of an organ from a **live donor** and postoperative physician services for the live donor. These services are payable under Medicare Part B through the Medicare physician fee schedule. [10]

Transplant centers can pay physicians as employees or under contractual arrangements. However, arrangements must be structured to comply with the Stark law and the federal anti-kickback law. In addition, physician fees charged to the organ acquisition cost centers for services such as excisions, tissue typing and the like must be reasonable in order to qualify for reimbursement.

Indirect Costs

In addition to the direct costs described above, Medicare will also reimburse reasonable indirect costs through the cost report ''stepdown'' process. Indirect costs include various transplant center overhead costs including staff fringe benefits based on salaries, space costs (depreciation, plant operations, utilities, etc) based on square feet, equipment depreciation (if not directly assigned), social services (if not directly assigned) general administration based on accumulated cost, data processing, insurance and other costs as appropriate and consistent with the overall allocation process.

Calculating Medicare's Share

Medicare will pay its fair share of organ acquisition costs as determined under a cost apportionment approach based on the ratio of Medicare usable organs to total usable organs. [11]

---

[6] 42 C.F.R. 412.2(e)(4). Organ acquisition costs include costs associated with transplantation of the following organs: kidney, liver, heart, lung, pancreas, and intestines (or multivisceral organs).

[7] 42 C.F.R. § 412.100; Provider Reimbursement Manual (PRM) Part I § 2771. Although these documents refer specifically to kidney acquisition costs, they apply equally to other organs.

[8] Id.

[9] PRM Part 1, § 2771B.

[10] CMS is currently reviewing the issue of whether surgeon fees for dissection of organs on the ''back table'' or ''back bench'' prior to transplant are includible in organ acquisition costs.

[11] 42 C.F.R. 413.203. Prior to 1997, the Medicare share of costs for organs other than kidney was based on a revenue off-

 COPYRIGHT © 2004 BY THE BUREAU OF NATIONAL AFFAIRS, INC., WASHINGTON, D.C. ISSN 1049-7986

Medicare Usable Organs

Medicare usable organs include the number of organs transplanted into Medicare recipients plus the number of organs excised at the transplant center and furnished to organ procurement organizations (OPOs).[12] Included in this are organs that had partial payments by a primary insurance payer in addition to Medicare. In most cases where Medicare is the secondary payer, the primary payer pays less than Medicare for organ acquisition. Therefore, transplant centers will be able to include in the count of Medicare-usable organs, those transplanted into patients who have Medicare as a secondary payer.

The denominator of the ratio – total usable organs – includes the total number of organs transplanted plus the number of organs excised at the transplant center and furnished to organ procurement organizations.

Offsets Against Medicare's Share

The Medicare share is determined by multiplying organ acquisition costs for each organ cost center times the Medicare percentage and then deducting or offsetting any revenue obtained from the provision of organs to OPOs and any revenues received from other primary payers for Medicare patients. In this regard, CMS recently clarified that transplant centers may charge an OPO either a standard acquisition charge or the departmental charges actually incurred for the organ retrieval services provided to the OPO.[13]

Recent Government Initiatives in Organ Transplantation

Sharp Memorial Hospital and San Diego Hospital Association

The 2004 OIG Work Plan is the most recent manifestation of the government's growing interest in organ transplant reimbursement but it is by no means the only one. In March of this year the Department of Justice announced that Sharp Memorial Hospital and the San Diego Hospital Association had agreed to pay $6.2 million to settle Civil False Claims Act allegations.[14] The Complaint, originally brought by a qui tam relator, alleged that Sharp Memorial Hospital had knowingly claimed non-organ acquisition costs as organ acquisition costs on its Medicare cost report in connection with the operations of its kidney and heart transplant centers.

Perhaps the most serious aspects of the case were the allegations of excessive medical director fees paid to physicians. The government asserted that Sharp had created several medical directorships with few substantive duties. Among them was a contract with a referring physician for $350,000 per year for administrative services in which the physician performed little or no services. The government also alleged that the Hospital had entered into several similar, though less lucrative, arrangements with a number of other surgeons, all of whom were in a position to refer to the hospital. Also at issue were below market rate leases with referring physicians.

In addition, the government alleged that the Hospital had knowingly allocated to the organ acquisition cost center, salary costs of employees whose services were not part of organ acquisition. In one case, for example, the government maintained that although one hundred percent of a nurse's time had been classified by the hospital to organ acquisition, none of it was allowable because all the services she provided were post-transplant. In several other cases, the hospital had allegedly classified costs as organ acquisition when the employee's services were rendered to other hospital departments.

Audit of Tampa General Hospital

Even before it specifically identified organ acquisition costs in its 2004 Work Plan, the OIG had audited at least one transplant center. Specifically, it recently completed an audit of Tampa General Hospital's organ acquisition cost center in which it found that the Hospital had been overpaid $1.4 million for fiscal year 1999.[15] The audit focused largely on allegedly improper allocations of salaries paid to provider-based physicians. The OIG maintained that the hospital had not adequately documented the hours the physician devoted to organ acquisition services.

Investigation of Medicare Certified Heart Transplant Centers

The OIG's interest in the area of organ transplantation is not confined to Medicare cost reimbursement. In addition to its intent to audit hospital organ acquisition costs, the OIG's Office of Inspections and Evaluations is currently investigating whether CMS is properly enforcing its certification requirements for heart transplant centers. Heart transplant centers are expected to perform at least 12 transplants per year and maintain a one and two-year actuarial survival rate of 73% and 65% respectively. Although transplant centers are expected to report to CMS any deviation from this standard, CMS has not been zealous in its enforcement of this requirement. Nor has the agency been actively enforcing its other certification criteria.

However, possibly in response to the OIG's review of its enforcement activities, CMS recently sent letters to many transplant centers around the country reminding them of their obligation to report to the agency any failure to meet certification standards.

Audit of Illinois Hospitals for Medical Necessity of Liver Transplants

Another recent area of government scrutiny is the medical necessity of organ transplantation procedures. In a recent investigation in the Chicago area, the U.S. Department of Justice together with the State of Illinois intervened in a whistleblower lawsuit brought by a liver transplant surgeon and professor at the University of Il-

---

set approach. However, effective September 15, 1997, the cost allocation approach applies to all organs.

[12] This clarification was announced in an August 31, 1995 letter from Michael Powell, HCFA Insurance specialist to William P. Vaughn. Although that letter refers to kidneys the clarification should be equally applicable to other organs.

[13] CMS Program Memorandum A-03-081, September 26, 2003.

[14] United States ex rel. Judith King v. San Diego Hospital Association, Civ. No. 00CV0848-BTM(RBB), (S.D. Cal.) United States' Notice of Partial Intervention and Settlement filed March 4, 2003.

[15] Audit of Organ Acquisition Costs at Tampa General Hospital, OIG Report No. A-04-02-02017, April 17, 2003.

linois College of Medicine. [16] The government alleged that patients at three Chicago area hospitals had received medically unnecessary liver transplants in part to permit the hospitals to meet their volume requirements for Medicare certification. Two of the Hospitals (Northwestern Memorial Hospital and the University of Chicago) settled for relatively low amounts. The case against the University of Illinois has not settled and the government is seeking treble damages of $3 million.

CMS Rulemaking on Transplant Center Certification Criteria

CMS is actively engaged in a major rulemaking that will establish new certification standards for transplant centers and OPOs. Current certification requirements have never been established through regulation and are in the form of notices published in the Federal Register or CMS Manuals.[17] A probable focus of this rulemaking will be to establish procedures for suspending or terminating facilities that are out of compliance with CMS standards. A proposed rule is expected in January 2004.

Compliance Pointers for Transplant Centers

As described above, the government has been taking a keen interest in Medicare payments to organ transplant centers. The most recent initiative, announced in the 2004 Work Plan, indicates an intent by the OIG to greatly expand its activities in this area. Since there are only 257 certified transplant centers in the United States, the chances of being audited by the OIG are quite high. [18] Set forth below are some suggestions for actions transplant centers may want to initiate to prepare for a possible OIG audit:

1. Review relationships with physicians: As a result of the *Sharp* investigation, it seems evident that physician contracts or other physician arrangements, including leases, will be a primary focus of an OIG audit. Transplant Centers should have contracts with physicians reviewed by legal counsel for compliance with the Stark and federal anti-kickback laws. Stipends for medical directorships, in particular, should be carefully reviewed to ensure that they reflect fair market value. If compensation seems excessive, transplant centers should consider having the compensation reviewed by an outside third party such as an independent auditing firm. Payments to physicians for organ donor excision must be reasonable. Although there is a cap of $1250 for kidney excision, no cap applies to other organs. Nevertheless the amount paid the physician and the amount charged to organ acquisition must be reasonable.

2. Review classifications of employee salaries to organ acquisition: Another issue in *Sharp* and the Tampa General audit was improper classification of employee salary costs to the organ acquisition cost center. Transplant centers should review documentation to determine whether it adequately supports such classification. Although ongoing time reports are preferable, CMS does permit time studies if they meet certain criteria.[19] Among other things, the time studies must encompass at least one week per month of the cost reporting period and represent a full work week. If time studies are used, they must also support allocation of time among organ-specific cost centers at institutions that have more than one transplant program. If time is divided among more than one transplant center (e.g. kidney, heart) then the salary costs allocated to each center must be based on reasonable criteria. In addition, time studies must distinguish between pre-transplant services which are classifiable as organ acquisition and post transplant services which are not. Finally, the transplant center should do a ''reality check'' on the time reports or time studies to make sure they do not contain errors or are internally inconsistent.

3. Review Volume and Survival Rates for Compliance with Certification Criteria: Transplant Centers should determine their compliance with volume and survival rate requirements in accordance with CMS instructions. If the numbers show that the CTC is below the requisite volume and survival rates, it should notify CMS and provide an explanation for the problem and, if appropriate, describe corrective action the institution is taking to correct the problem.

4. Review Medical Necessity: Review patient records to ensure that the chart adequately documents that the patient met medical necessity criteria for the transplant and that patients status levels were accurate based on United Network for Organ Sharing (UNOS) criteria.

Conclusion

Transplant centers figure largely on the OIG's radar screen and are likely to remain there for the foreseeable future. Hospital reporting of organ acquisition costs is likely to prove a fruitful area for OIG audit activities.

Transplant centers can minimize their exposure, in the event of an audit, by performing their own internal review and ensuring that organ acquisition costs are correctly classified and adequately documented and that the center is otherwise in compliance with federal requirements related to organ transplantation.

---

[16] *United States of American and State of Illinois ex rel. Raymond Pollak, M.D., v. Board of Trustees of the University of Illinois and the University of Chicago,* 99 C 710 (N.D. Ill.) (complaint filed Feb. 4, 1999.)

[17] See CMS Ruling 87-1, ''Criteria for Medicare Coverage of Heart Transplants''(April 6, 1987 Federal Register); Program Memorandum AB-02-040 ''Intestinal and Multi-Visceral Transplantation (March 27, 2002); Criteria for Medicare Coverage of Lung Transplants (Feb. 2, 1995 Federal Register); Criteria for Medicare Coverage of Liver Transplants (April 12, 1991 Federal Register);

[18] See http://www.unos.org/whoweare/transplantcenters.asp (Nov. 11, 2003). There are 257 transplant centers in the United States with a total of 876 certified programs.

[19] Provider Reimbursement Manual § 2313.2.

COPYRIGHT © 2004 BY THE BUREAU OF NATIONAL AFFAIRS, INC., WASHINGTON, D.C.
MCR ISSN 1049-7986