Graft

http://gft.sagepub.com

Regulatory and Fiscal Relationships between Transplant Centers and Transplant Surgeons/Physicians

Frank P. Stuart, Michael M. Abecassis and Dixon B. Kaufman

Graft 2001; 4; 398

The online version of this article can be found at:
http://gft.sagepub.com/cgi/content/abstract/4/6/398

Published by:

http://www.sagepublications.com

Additional services and information for *Graft* can be found at:

Email Alerts: http://gft.sagepub.com/cgi/alerts

Subscriptions: http://gft.sagepub.com/subscriptions

Reprints: http://www.sagepub.com/journalsReprints.nav

Permissions: http://www.sagepub.com/journalsPermissions.nav

Downloaded from http://gft.sagepub.com at LOCKSS on December 9, 2007

© 2001 SAGE Publications. All rights reserved. Not for commercial use or unauthorized distribution.

Regulatory and Fiscal Relationships between Transplant Centers and Transplant Surgeons/Physicians

Frank P. Stuart, Michael M. Abecassis, and Dixon B. Kaufman

Organ transplant centers are complex expensive enterprises that are highly regulated by federal and state government. The Code of Federal Regulation describes minimum requirements for transplant centers, the process for certification as a transplant center, obligations and responsibilities of transplant centers, acceptable accounting practices for costs of organ acquisition, and the rules for allocation of scarce transplantable organs into potential recipients on lengthy waiting lists. Transplant centers must appoint a medical director for each transplanted organ. Although a hospital "owns" the transplant center and is responsible for all fiscal matters, it is the medical director who plans, organizes, and leads the extensive staff in execution of the transplant center's activities. Functional integrity of the transplant center is best protected when transplant surgeons and physicians, as well as the hospital administrative officers, understand the regulatory and fiscal relationships established by law.

It is imperative that transplant centers and their medical directors understand the rules and accounting practices peculiar to transplantation if they are to be fully reimbursed for the cost of their services.

Frank P. Stuart, M.D.
Division of Organ Transplantation
675 North St. Clair, Street, Suite 17-200
Chicago, Illinois, USA 60611
Tel.: 312.695.0338
Fax: 312.695.9194
email: fstuart@nmh.org

Introduction

Organ transplantation is an unusually complex and expensive undertaking that is dependent on organ prostheses from either cadaveric or living donors, and it serves a long list of potential recipients whose health fails steadily as they await a transplant. During the past 30 years, Congress and the Health Care Financing Administration (HCFA) have written the rules that regulate organ transplantation in the United States. It is imperative that transplant centers and their medical directors understand the rules and accounting practices peculiar to transplantation if they are to be fully reimbursed for the cost of their services.

Chronic hemodialysis for end-stage renal disease and kidney transplantation was developed following World War II. Reimbursement by insurance was scarce until the mid-1960s. By 1972, approximately 3500 individuals in the United States survived because of regular hemodialysis maintenance treatments, yet insurance coverage was still haphazard. After a dramatic demonstration before a U.S. Senate committee in 1972, Congress amended the Social Security Act to include coverage for end-stage renal disease as a Medicare entitlement for any worker who had paid into the Social Security system for at least 14 quarters of 3 months each. The worker's spouse and children under the age of 26 are also entitled to the benefit.[1] Medicare became the primary insurer for kidney transplantation for more than 90% of the United States population.

Thus, Congress and the U.S. Department of Health and Human Services (DHHS), rather than the commercial health insurance industry, wrote the rules and accounting practices for kidney transplantation. As transplantation of heart, lung, liver, pancreas, and intestine evolved, the rules and accounting practices applicable to the kidney were extended to the other transplantable organs.[2] Medicare coverage of dialysis and kidney transplantation was made a co-insurer for the first 30 months of care; however, HCFA rules and accounting practices take precedence.

Downloaded from http://grt.sagepub.com at LOCKSS on December 9, 2007
© 2001 SAGE Publications. All rights reserved. Not for commercial use or unauthorized distribution.

Review

Organ transplantation in the United States is probably the most intensely regulated of medical disciplines. Congress creates relevant law and publishes the text in the *United States Code of Federal Regulations and the Federal Register*. The DHHS then develops and disseminates detailed rules for implementing transplant law via 3 government publications: *Commerce Clearinghouse Medicare and Medicaid Guide*, *Medicare Intermediary Manual*, and *Medicare Hospital Manual*. The HCFA contracts with intermediaries to manage its day-to-day business with hospitals, physicians, and other service providers. The intermediaries, usually large insurance companies, exercise considerable discretion as they interpret the *Medicare Intermediary Manual*. For example, specific regulations may be interpreted differently by intermediaries in various parts of the country. Successive intermediaries that contract for the same locale may also differ in their interpretation of the *Medicare Intermediary Manual*.

For a hospital to bill Medicare for transplant services, it must first apply for HCFA certification for each organ it proposes to transplant.

For a hospital to bill Medicare for transplant services, it must first apply for HCFA certification for each organ it proposes to transplant. If approved, the hospital becomes a certified transplant center (CTC) for those organs. Certified transplant centers must apply for membership in the U.S. Organ Procurement and Transplant Network, which has been administered for the DHHS by the United Network for Organ Sharing (UNOS) since 1986. UNOS bylaws interpret federal code with respect to personnel, facilities, and other resources required to operate a certified transplant center. The transplant center must also establish working relationships with the HCFA-certified Organ Procurement Organization (OPO) in its area.[3] HCFA recognizes approximately 60 OPOs or organ banks throughout the country.

Clearly the hospital "owns" and is responsible for administration and operation of transplant programs. It is the hospital that is certified by Medicare; the hospital staff and the affiliated transplant physicians and surgeons constitute the hospital's transplant team and program. As the owner of its transplant programs, the hospital incurs obligations, many of which are executed by its surgeons and physicians. As most of these obligations are directly or indirectly related to organ acquisition, HCFA permits the hospital to compensate surgeons and physicians for their roles and recover these costs through charges against the acquisition cost of each organ.[4]

Surgeons and physicians who direct transplant programs play a major role in helping the certified centers meet the following obligations.[3]

- Participate in governance of UNOS and creation of organ allocation bylaws.
- Adhere to constantly evolving bylaws of UNOS, which control all aspects of cadaveric organ allocation through complex algorithms.
- Interface with UNOS national computerized waiting list via all HCFA-certified OPOs.
- Participate in governance and donor organ–related activities of the local OPO through organ-specific committee structures to maximize organ procurement and ensure equitable sharing of organs. Provide teams of surgeons and surgical technicians to procure cadaver organs.
- Ensure equal access of organs (a scarce national resource) as required under Title VI of the Civil Rights Act of 1964. Because organ transplant services are unique and concentrated in fewer than 300 hospitals nationwide, transplant centers must be proactive in educating the public and physicians about transplantation so that equal access is meaningful.
- Develop and maintain organ-specific lists of potential recipients who will wait for available cadaver organs. Evaluation of potential recipients is an ongoing, labor-intensive process that stretches from first contact through sequential reevaluation as the candidate's health and priority status change between listing and transplantation. Extensive data are maintained so that queries from UNOS, organ banks, and the Inspector General's office, with respect to equal access, can be answered.
- Transplant centers must evaluate potential living donors who might provide an intact organ or part of an organ. Evaluation of living donors is as complex as it is for recipients. Moreover, several potential donors are usually evaluated for each candidate who actually qualifies and proceeds to donation.

Downloaded from http://gft.sagepub.com at LOCKSS on December 9, 2007
© 2001 SAGE Publications. All rights reserved. Not for commercial use or unauthorized distribution.

- Provide complex, long-term posttransplant outpatient care. Management of immunosuppression and the array of problems associated with organ transplantation require that the transplant center be the primary provider of outpatient care for the first posttransplant year and secondary provider thereafter. Visits are frequent during the first few months, interspersed with laboratory tests performed at other hospitals and faxed to the transplant center. Recipients must be able to reach outpatient nurses by telepage at anytime. UNOS requires detailed reports from the recipient's medical record and the transplant center's databases as long as either the transplanted organ or the recipient survives. The reports required by UNOS include the candidate registration report (listing), the recipient registration report at the time of transplant (which includes data about the donor, the operative procedure, and the entire inpatient stay), and posttransplant follow-up reports at 6 months, the 1st year, and yearly thereafter.
- Appoint a medical director to supervise each specific organ transplant program. The physician or surgeon is responsible for planning, organizing, conducting, and directing the transplant center.[5]

Of the 6 organs transplanted (heart, lung, kidney, pancreas, liver, and intestine), only kidney transplantation is an entitlement under Medicare via the End Stage Renal Disease amendment of the Social Security Act in 1972.[1] As successful transplantation of other organs evolved, Congress did not amend the Social Security Act to specifically cover services for end-stage heart, lung, and liver disease or for diabetes and intestinal failure. Nevertheless, potential recipients of nonrenal organs may become eligible for Medicare via 2 separate provisions of the Social Security Act for the aged (over 65 years) and disabled (fully disabled for at least 24 months). In addition, insulin-dependent diabetes qualifies potential recipients for Medicare coverage of pancreas transplantation, if it occurs at the same time as or after kidney transplantation in a recipient who was eligible for Medicare at the time of kidney transplantation.

When Medicare introduced prospective global reimbursement to hospitals for inpatient care by diagnosis-related grouping (DRG), each DRG with its own dollar value, it instructed transplant centers to separate acquisition costs for both cadaveric and living donor organs from the cost of inpatient care. Organ acquisition cost centers (OACCs) were created outside the transplant DRG in each hospital for each transplanted organ. They were designed so as to compensate the hospital for reasonable expenses of organ acquisition, as well as evaluation, selection, maintenance, and reevaluation of recipient candidates on waiting lists until transplantation occurred.[6] Examples of appropriate charges against OACCs included in the Code of Federal Regulations are

- tissue typing,
- donor and recipient evaluation,
- other costs associated with excising organs such as general routine and special care services for the donor,
- operating room and other inpatient ancillary services applicable to the donor,
- preservation and perfusion costs,
- charges for registration of recipient with a transplant registry,
- surgeon's fees for excising cadaver organs,
- transportation,
- costs of organs acquired from other providers or organ procurement organizations,
- hospital costs normally classified as outpatient cost applicable to organ excisions (services include donor and donee tissue typing, work-up, and related services furnished prior to admission),
- costs of services applicable to organ excisions that are rendered by residents and interns not in approved teaching programs,
- all pre-admission physician services, such as laboratory, electroencephalography, and surgeon fees for cadaver excisions, applicable to organ excisions including the costs of physician's services.

For kidney transplantation, the cost of organ acquisition is approximately twice the cost of the in-

Downloaded from http://gft.sagepub.com at LOCKSS on December 9, 2007
© 2001 SAGE Publications. All rights reserved. Not for commercial use or unauthorized distribution.

patient transplant stay. When Medicare is the primary payor, the hospital is compensated for the inpatient stay through the Part A DRG case rate. Organ acquisition is treated as a full-cost "pass through." If a commercial payor is primary, both the inpatient charge and the standard acquisition charge are submitted to the carrier. Depending on the wording of the contract between the transplant center and the commercial payor, Medicare might become the secondary payor for any portion of the inpatient care or standard acquisition charge denied by the commercial payor (this assumes that the recipient is eligible for Medicare benefits). Through a process referred to as "coordination of benefits," HCFA intends that its allowable charges and allowable reimbursement will determine payments to hospitals and physicians when Medicare is the secondary payor.

For pancreas and liver transplantation, inpatient charges represent a larger fraction of total cost than is true for kidney transplantation; the inpatient liver transplant costs usually exceed the standard acquisition cost of a liver. Coordination of benefits with Medicare as a secondary payor is possible for the pancreas and liver as it is for kidney transplantation.

For pancreas and liver transplantation, inpatient charges represent a larger fraction of total cost than is true for kidney transplantation; the inpatient liver transplant costs usually exceed the standard acquisition cost of a liver.

Many commercial health insurers "exclude" organ transplantation from their general policies; the employer client must then contract separately with a reinsurance company that specializes in transplant insurance. Unfortunately for transplant centers, most transplant reinsurance networks sell global managed care contracts that fail to identify inpatient care and organ acquisition coverage as separate components of the benefit package in the same way that Medicare and HCFA accounting practices do. By disregarding HCFA accounting practices, transplant insurers compromise the transplant center's option to turn to Medicare for reimbursement via coordination of benefits for the full cost of organ acquisition.

Surgeons and physicians bill through part B Medicare for their services to transplant recipients during the inpatient stay and are paid 80% of the fee allowed by Medicare. When Medicare is the secondary payor to commercial insurance that pays less than 80% of Medicare allowable, Medicare may be billed for the difference if that possibility is not precluded by terms of the contract between the physician and the commercial payor.

When the organ is removed from a living donor, surgeons and physicians bill the recipient's part B Medicare for their services to the donor and are paid 100% of allowable Medicare fees. If a commercial payor is primary, it should be contacted prior to transplantation to determine whether it will accept separate charges from physicians and surgeons for care of the living donor. Some commercial insurers require that physician's bills be submitted with the hospital's standard acquisition charge. If the recipients' commercial payor refuses altogether to pay for physician's services to the living donor, the transplant hospital becomes payor of last resort by charging those services to its organ acquisition cost center.

In most transplant centers, physicians and surgeons most directly involved in evaluating potential donors and recipients, maintaining ready tests, organ procurement, and overall direction of transplant centers, are largely unaware if compensation for their daily activities is appropriately charged to the hospital's OACCs. Transplant hospitals rarely solicit charges from transplant surgeons and physicians; it is incumbent on physicians to understand the Medicare rules concerning charges against OACCs and to initiate the process of billing the hospital for their services in organ acquisitions.

Physicians and surgeons should be aware that OACCs have 4 distinct components:

1. Normal operating costs associated with program operations:
   a. space, phone, supplies, pagers, answering services, utilities, computers, maintenance, pre-transplant patient records, storage;
   b. personnel costs of clerical and professional staff, financial and insurance counselors, social service, nurse coordinators. (salary and benefits such as travel reimbursement for relevant meetings, continuing education, seminars, memberships, dues, and subscriptions);
   c. program direction and administration;
   d. UNOS recipient registration charges;
   e. medical center overhead;
   f. educational materials, presentations.

Downloaded from http://gft.sagepub.com at LOCKSS on December 9, 2007
© 2001 SAGE Publications. All rights reserved. Not for commercial use or unauthorized distribution.

2. Medical consultation/evaluation and testing service costs associated with pretransplant evaluation of both potential recipients and potential living donors:
   a. dental evaluation,
   b. psychological evaluation,
   c. multidisciplinary assessment conferences,
   d. tissue typing and other assessment of immunological activity, cross-matches,
   e. outpatient services related to living donor after donation.
3. Costs associated with maintaining the evaluated patient/potential recipient on the waiting list such as monitoring to determine whether he or she remains suitable for transplant:
   a. exchange of information with potential recipient's physicians,
   b. laboratory tests and X rays,
   c. interval history and physical examination,
   d. specialty consultations.
4. Costs associated with acquiring organs for transplant (cadaver donor and living donor):
   a. charges by OPOs,
   b. educational materials concerning transplantation for use with potential recipients and living donors,
   c. preservation, perfusion, and organ preparation laboratory.

Federal code permits compensating transplant centers for all reasonable expenses of organ acquisition.[6] Aggregate acquisition expenses are fully reimbursed as a pass through outside the DRG prospective payment system. Hospital administrators should be receptive to compensating well-articulated, reasonable costs of physicians and surgeons as allowed by law. In return, transplant physicians should work closely with the hospital's chief financial officer and staff to keep the overall transplant program's full cost and reimbursement in balance.

Complex transplant centers cannot remain fiscally sound without rigorous participation by the physicians as listed below:

- Practice efficient and exemplary care based on sound medical decisions.
- Develop critical care pathways for patients and efficient protocols and systems for pre- and posttransplant care.
- Determine the full cost of critical care pathways and reassess their cost-effectiveness regularly.
- Maintain extensive outcome data and assist hospital in negotiating payor contracts that will cover full costs of care.

Analysis of full costs and expected reimbursement on a quarterly basis should include pretransplant care, transplant hospitalization, and postoperative outpatient care for each type of organ transplanted. Data on the payor should also be analyzed to identify those commercial insurers that reimburse an unreasonably low fraction of full costs.

Transplant centers in which the hospital and its physicians/surgeons are equally concerned about the other's fiscal integrity will thrive and maintain the privilege of providing high-quality organ transplant services.

References

1. United States Code of Federal Regulations. Title 42, Chapter IV, Subchapter B:**42 C.F.R. 405.**
2. United States Code of Federal Regulations. Title 42, Chapter IV, Subchapter B:**42 C.F.R. 486.302.**
3. United States Code of Federal Regulations. Title 42, Chapter IV, Subchapter B:**42 C.F.R. 405.2171.**
4. United States Code of Federal Regulations. Title 42, Chapter IV, Subchapter B:**42 C.F.R. 412.100.**
5. United States Code of Federal Regulations. Title 42, Chapter IV, Subchapter B:**42 C.F.R. 405.2170.**
6. United States Code of Federal Regulations. Title 42, Chapter IV, Subchapter B:**42 C.F.R. 412.113.**

Downloaded from http://gft.sagepub.com at LOCKSS on December 9, 2007
© 2001 SAGE Publications. All rights reserved. Not for commercial use or unauthorized distribution.