CMS Rulings

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Ruling No.: CMS-1543-R

Date: December 21, 2006

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CMS Rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that the Social Security Administration adjudicates matters under the jurisdiction of CMS. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling sets forth our policy concerning the proper allocation of donor acquisition costs incurred by organ procurement organizations (OPOs) to the various types of acquisitions involved, in order to ensure that costs associated with the acquisitions are equitably distributed across all types of organs. Cost associated with a particular organ must be allocated to that organ's cost center if the OPO intended to procure it for transplant (regardless of whether that organ was ever actually procured). This Ruling is effective upon publication for all organs acquired on or after the publication date.

MEDICARE PROGRAM

CMS-1543-R Allocation of Donor Acquisition Costs Incurred by Organ Procurement Organizations (OPOs)

CITATIONS: Social Security Act (the Act) sections 1138(a)(1)(A)(iii), 1138(a)(3), 1138(b), 1861(v)(1)(A), 1881(d); Regulations 42 CFR 405.2102, 482.45, 486.302, 486.303, 486.322; Provider Reimbursement Manual, Part 1, CMS Pub.15-1, §2312,

§2313.2, §2770-2775; Provider Reimbursement Manual, Part II, CMS Pub. 15-2, sections 3300 and 3303.1.

BACKGROUND:

The 1972 amendments to the Act authorized Medicare coverage for End Stage Renal Disease (ESRD). One of the therapies for ESRD is kidney transplant. The regulations on kidney transplants appear at 42 CFR 405.2100. In 1987, we issued the first of several National Coverage Determinations for the purpose of providing for Medicare payment for other types of organs. At present, Medicare payment is available for transplantation of kidneys, heart, lung, liver, pancreas, and intestine on a cost, pass-through basis.

DISCUSSION:

OPOs are government-regulated entities that play a crucial role in ensuring that scarce transplantable human organs are provided to seriously ill patients suffering from end-stage organ failure. OPOs are responsible for identifying potential organ donors, informing families about their donation options, obtaining consent to donation, screening potential donors for infectious disease, clinically managing potential organ donors to maintain viability of their organs, placing the maximum number of organs possible with transplant centers, arranging for recovery, testing, tissue typing of organs, and packaging and transporting organs to transplant hospitals. OPO performance is one of the most critical elements of the nation's organ transplantation

system. An OPO that is effective in procuring organs and delivering them safely to transplant centers will save more lives than an ineffective OPO. Statutory requirements for OPOs appear at section 1138(b) of the Act.

In 1996, we developed performance standards to ensure that the optimal number of organs were being procured by each OPO. Regulations at 42 CFR 482.45 require each hospital to notify its designated OPO of imminent deaths in its facility, so that the OPO can procure the organs defined in §486.302. Thus, the intent of the Medicare program, through designation and certification of OPOs, is to procure the maximum number of organs possible. The intent has been and should be to recover every suitable organ as defined in regulation from each eligible donor.

The Medicare program reimburses the reasonable cost of allowable services furnished by an OPO on behalf of Medicare patients, 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 Organ Procurement and Transplantation Network. 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, excision, perfusion, preservation, packaging and transporting organs from deceased donors.

It has come to our attention that a number of OPOs have been allocating organ procurement costs in a manner that artificially inflates the costs of organ procurement to the Medicare program and that violates the Medicare cost-finding principles required by section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act requires that costs be properly allocated and apportioned in order to ensure that Medicare pays only for costs related to patient care and only its share of those costs. This means such costs must be allocated in a manner that accords with our cost-finding principles. To ensure these statutory and regulatory requirements are met, Medicare requires organs procured for transplants to share equally in certain costs involved in organ recovery (for example, operating room time, medications required to preserve organs, etc.), to the extent that these costs cannot be attributed to the recovery of any one type of organ.

While this cost allocation methodology comports favorably with Medicare’s long-standing cost allocation policies dating back to the mid 1980s, OPOs may use other cost finding methodologies. The requirements of PRM §2312 and §2313.2.E.1 must be strictly followed for any request to change the cost finding methodology. Should an OPO desire to change the cost finding methodology, it must request a change from the fiscal intermediary, in writing, 90 days before the end of the cost reporting period to which the plan is to apply.

The Medicare prescribed cost allocation methodology for organ acquisition costs is used, in part, to establish a standard acquisition charge for each type of organ. Costs that are specific to one type of organ (for example, a specific laboratory test for liver function) are also factored into the standard acquisition charge, and are allocated to the cost center for the specific type of organ first, before shared costs are allocated among the various organs that were intended for recovery. Reasonable and necessary costs that are organ-specific on a hospital bill must be allocated to that organ's cost center, even if the organ is designated for research, and regardless of whether the organ is ruled out as a viable organ for transplant.

For example, if the OPO rules out a liver transplant based on a medically necessary liver function test, the cost of the test is nevertheless incurred and must be allocated to the liver cost center. Also, costs must be allocated to tissue donation for any donor who was a tissue donor.

The Medicare program pays for the majority of renal transplants, but is not the main payer for other, non-renal transplants. Approximately 62 percent of kidneys are transplanted into Medicare patients, but only 24 percent of non-renal organs are transplanted into Medicare patients. For this reason, if costs (including both organ-specific costs as well as shared direct and overhead costs) are not allocated properly among renal and non-renal organs, the standard acquisition charge

for renal organs will reflect costs that should reasonably have been assigned to non-renal organs. As a result, the standard acquisition charge for renal organs will be inflated, and, because the majority of renal organs are transplanted into Medicare patients, Medicare will pay more than its fair share of all organ acquisition costs, thus improperly subsidizing the standard acquisition charges for non-renal organs transplanted into non-Medicare patients. In effect, this improper allocation of costs not only shifts more costs than are appropriate to the Medicare program, but also misrepresents organ acquisition costs for all third-party payers.

In order to avoid the cross-subsidization discussed above, and in keeping with the Medicare cost-finding principles required by section 1861(v)(1)(A) of the Act, Medicare cost reporting instructions at sections 3300 and 3303.1 of the Provider Reimbursement Manual, Part II require that when an OPO has acquired organs other than kidneys, it must go through cost finding "to ensure that overhead is allocated to all types of acquisitions." PRM §3300. Furthermore, to ensure proper allocation of overhead costs, if procurement is attempted, but no organ actually retrieved, the organ must still be counted for purposes of proper cost-finding.

Medicare regulations require OPOs to have agreements with 95 percent of the hospitals and critical access hospitals in its service area that have both a ventilator and an operating room in

order to acquire all usable organs from potential donors (42 CFR 486.322). Further, hospitals are required to notify OPOs of every death in their facilities (42 CFR 482.45). Thus, CMS will presume that an OPO intends to procure all transplantable organs from a donor, and that, regardless of whether such organs are actually procured, the OPO still 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, for an operating room in which the excisions would take place, and for medications required to maintain the organs in a viable state. If the surgeons determine, upon initial inspection, or upon removal, that one or more of the organs are 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. Because, as stated above, 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 section 486.302 of the regulations.
- The organ has been ruled out by basic 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 agree 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 fiscal intermediary may nevertheless, 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 should not lead to an absolute conclusion that intent to procure did not exist, without any ability for the fiscal intermediary to question such conclusion. For example, an OPO may claim that a family did not agree 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 situations, the intermediary would not be precluded from overriding an OPO's contention that intent to procure did not exist.

The following represents an example of how costs should 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 excise the organs, for an operating room for the excisions to take place, and for medications required 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 the medications is allocated to the liver cost center, or to the lungs cost center. The costs for the operating room fees and the medication 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.

EFFECTIVE DATE

This Ruling is effective December 21, 2006.

Date: December 21, 2006

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Leslie V. Norwalk,

Acting Administrator Centers for Medicare & Medicaid Services