

August 28, 2008

Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1390-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted via the CMS public comment website: <http://www.regulations.gov>

Re: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; CMS-1403-P; Organ Retrieval Costs

Dear Mr. Weems:

The American Society of Transplant Surgeons (ASTS), the American Urological Association (AUA) and the National Kidney Foundation (NKF) are pleased to have this opportunity to comment on the proposed physician fee schedule rule for 2009, as published in the July 7, 2008 Federal Register. ASTS is an organization comprised of over 1200 transplant surgeons, physicians and scientists dedicated to excellence in transplantation surgery through education and research with respect to all aspects of organ donation and transplantation so as to save lives and enhance the quality of life of patients with end stage organ failure. The AUA is the pre-eminent professional organization for urologists, with more than 16,000 members throughout the world with the mission of fostering the highest standards of urologic care by carrying out a wide variety of programs for members and their patients. The NKF represents transplant candidates, transplant recipients, and nephrologists and seeks to prevent kidney and urinary tract diseases, improve the health and well-being of individuals and families affected by these diseases, and increase the availability of all organs for transplantation.

1. Organ Retrieval Costs

A. Discussion

We appreciate the opportunity to respond to CMS' request for input on costs associated with cadaveric organ retrieval services. The agency notes that it has received requests for an increase in the kidney retrieval rates which have been capped at \$1,250 per donor since 1987 but that it does not currently have data upon which to base a change in payment. The Agency is soliciting comments and data that would assist in the determination of a reasonable cost for kidney retrieval services paid to transplant centers. CMS has also expressed interest in receiving comments and data on retrieval services for all types of organs and states that it may use such

information to determine whether a recalculation of payments for cadaveric organ retrieval is warranted in the context of future rulemaking.

We appreciate the efforts by CMS to solicit comments from the transplant community on this issue in advance of the issuance of any specific proposal. We fully agree with CMS that there is little or no data on actual costs of organ retrieval services and that any rulemaking without such data would be inappropriate. Determining the costs of cadaveric organ retrieval raises a number of problematic issues. In fact, it is not entirely clear what type of data could be assembled that would properly inform this process or how that data should be collected. We would be happy to work with CMS to develop a process for collection of appropriate cost data. In the meantime, however, we believe that the current cap of \$1250 per donor for kidney retrievals is inappropriately low and should be increased.

B. Specific Factors Impacting Cost of Organ Retrieval

We have serious concerns as to the feasibility of establishing an accurate cost or payment for organ retrieval given the extreme variability associated with these services and the impossibility of defining a “typical” service, particularly for extra-renal organs. Factors that contribute to this extreme variability include time and effort associated with evaluation of the donor organ for a particular recipient; travel and wait time; and additional complexities posed by ECD and DCD donor organs. Further, costs must take into consideration “dry runs” where no organ is retrieved. For this reason, an approach like that of the AMA’s Relative Value Update Committee (RUC), which is based on a typical “vignette” and physician surveys would not be feasible.

1. Donor Evaluation

The time and effort that goes into evaluating an organ before a decision has been made to accept it also varies significantly from case to case. When an organ is offered, the surgeon must evaluate the donor organ and determine whether it is appropriate for a particular recipient. This is especially true for extra-renal organs where the organ is typically allocated to a specific recipient. Donor evaluation may be less important for kidney retrievals where the surgeon is typically removing the kidney for another program and therefore would not have to verify compatibility and matching. In contrast, for extra-renal organs, the donor surgeon must review donor data in the context of the recipient to whom the organ is allocated.

This may take minutes to hours, and may require one or ten communications with OPO personnel, through Donor Net and/or in person until a decision is made once the final data are collected. After all these communications, the decision may be to decline the offer, and thus no opportunity to bill for time and effort spent by the surgical team. This lost time, which varies significantly from one case to the next, is difficult to capture through the use of “typical patient” as that used by the RUC. Any equitable determination of costs must take (lost) time and effort associated with donor evaluation into consideration.

2. Travel and Wait Time

Assuming an organ is accepted, the surgeon typically has to travel to the donor hospital which may be in the same city as the recipient hospital or may be several thousand miles away. Travel may vary from driving across town or driving to an airport, boarding a plane, and flying to the nearest airport, and then driving to the donor hospital finally arriving at the donor operating room. Thus, the travel time can be short or very long and there can be huge variability, including varying modes of transportation involved.

Once the surgeon reaches the donor hospital, the surgeon needs to evaluate the donor to make sure that all the data are correct. The surgical team may go directly to the operating room once the data have been confirmed, or instead, they may be forced to wait for several hours for the donor operating room. Frequently, donor hospitals will “bump” donor procedures for other cases, whether elective or emergency in nature. Once the donor is taken to the operating room, upon inspection of the organ and/or biopsy, the surgical team may decide that the organ is not usable and abandon the procedure, or alternatively decide that they do not wish to use the organ for their particular patient, in which case the OPO may request the surgeon to proceed with excision in the hopes that they can “place” the organ with another transplant program. The final outcome of these efforts is usually not known by the time the organs are removed, and therefore it is entirely possible that the surgeon will complete the procedure and the organs will not be used (discarded organs).

Further, there are often times when the various teams that appear on-site may have differing schedules. It is not unusual for example, for one team to have to wait for another team to complete retrieval of organs. Another variable affecting wait time is whether the donor is a standard DBD donor or a DCD donor. In the case of the latter, the donor has not progressed to brain death. Therefore, once the surgical team arrives at the donor hospital, the donor is extubated. However, this can occur shortly after the arrival of the team at the donor hospital or many hours later depending on availability of hospital staff, hospital operating rooms and the like. This variability is amplified many fold by the fact that a donor may “progress” in a manner of minutes, may take up to 90 minutes to progress to brain death, or may not progress at all after 90 minutes, at which time the surgical team returns to their home base (“dry run”).

Because kidney retrieval is often performed by the team that is procuring the liver or pancreas (assuming those organs are being retrieved), some of the travel and wait time could be included in the costs of retrieving the extra-renal organs. Thus, this variable may not be as significant for kidney acquisition at least when harvested by the same team that is retrieving other organs.

3. Dry Runs

Because of efforts to increase both the number of donors and the number of organs procured per donor, surgical teams are often dispatched to a donor hospital with the intent of procuring organs but, despite this intent, organs are either not removed, or they are removed but not utilized (discarded). These expeditions result in “dry runs” for the surgical team, not only in terms of organs procured, but also in the inability to bill for their time and effort. In neither case can the

donor surgeon bill for organ retrieval since there is no recipient and therefore no acquisition cost center or recipient insurance/payor to bill. With the recent increase in use of ECD and DCD donors (partly as a result of federal policy) dry runs are becoming increasingly common, especially for extra-renal organs. Although donor hospital costs can be included in the calculation of the OPO's SAC for the particular organs for which there was "intent" and these costs can be used in adjusting the average SAC for transplant organs, the surgical fee cannot be recovered, and therefore the surgical team is unpaid in most instances.

Therefore, any attempt to accurately price organ retrieval costs must factor in those cases in which the organ is not removed or discarded. This would require ongoing tracking of discarded organs as well as extremely complex calculations of surgeon time and effort, including travel times, waiting times, and the like.

C. Other Risks/Costs Associated with Organ Retrieval Costs

It is also important to remember that organ retrieval is performed by highly trained specialists with extensive post-graduate surgical training. Further, organ retrieval is not without risk to the surgical team as illustrated by two recent tragedies in which donor teams perished as a result of airplane mishaps. Organs have to be retrieved when they become available; this requires the surgical team to drop everything (including cancelling or postponing other scheduled surgeries) and often requires trips in the middle of the night, in bad weather, and to remote locations. These risks must be taken into consideration in evaluating appropriate payment for organ retrievals. If surgical teams cannot be adequately compensated for these risks, they may be unwilling to procure organs, further aggravating the already existing shortage of organs.

D. Recommendation

We agree with CMS that there is insufficient data on which to calculate costs of organ retrieval services. We appreciate the fact that CMS is soliciting data from the public. However, we caution that we do not believe any accurate or useful data currently exists. For the reasons explained above, there is no "typical" organ retrieval service, especially for extra-renal organs. Thus, establishing costs for such services is a complex undertaking which, to the extent it is even possible, must take into consideration the variables described above.

1. Kidney Retrieval Cap

We do not know how the \$1250 cap for kidney retrieval was established, but given the many changes in organ donation and transplantation that have taken place over the last twenty years, this amount is no longer appropriate or equitable. In particular, the increased use of ECD and DCD organs has added significantly to the complexity of the organ retrieval process. These complexities were not present in 1987 when CMS established the cap.

Given the changes that have taken place since 1987 and the extreme variability of organ retrieval procedures generally, data is needed to determine an accurate and equitable payment. We would be pleased to assist CMS in establishing a process to collect such data. In the meantime, we do

not believe a cap on kidney donor retrievals is appropriate and recommend that, pending development of an accurate cost assessment taking into all relevant factors, the cap be removed.

Alternatively, as a matter of fairness given the very high percentage of kidney transplants that are paid for by Medicare, we recommend that the cap be updated to reflect current economic realities. We suggest that the Medicare Economic Index might be an appropriate index for such an update.

Conclusion

We appreciate the opportunity to submit comments on this important issue. As described above, there is enormous variability in organ retrieval services and any cost setting initiative would require consideration of a number of complex factors. We would be pleased to assist in any efforts to develop data on such costs. If you have any questions, please contact Katrina Crist, ASTS Executive Director, at 703-414-7870 or katrina.crist@asts.org.

Sincerely,



John P. Roberts, MD
President
American Society of Transplant Surgeons



John M. Barry, MD
President
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John Davis
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