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MEMORANDUM

To: ASTS Council

From: Rebecca Burke and Diane Millman

Date: December 22, 2009

Re: Regulatory and Reimbursement Update

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1. Medicare 2010 Physician Fee Schedule. On October 30, the Centers for Medicare and Medicaid Services (CMS) posted the final 2010 Physician Fee Schedule Rule, which sets forth final payment rates for 2010. Under the Rule, Medicare payment for the physicians' services involved in transplantation will increase, assuming that Congress once again acts to block implementation of any conversion factor reduction. As of this date, both Houses of Congress have passed legislation which would maintain 2009 payment rates through the first two months of the year. This preserves the status quo while giving Congress more time to pass a flawed SGR payment formula.

There are a number of provisions in the final rule which are relevant to transplantation:

- **Implementation of AMA/RUC Physician Practice Expense Survey**: At CMS' direction, the American Medical Association, together with the medical specialties, funded and implemented a survey on physician practice expenses. This survey, undertaken in 2007-2008, was designed to replace the outdated SMS survey from 1995 that CMS had been using in its Physician Fee Schedule calculation. The survey yielded new practice expense per hour for each specialty as well as new data on direct to indirect cost ratios.

The Final Rule will phase in the new survey results over four years, to cushion the impact on specialties whose PE/hr decreased. This change will increase Medicare payment for all of the transplant codes in 2010 and each year throughout the transition (ending in 2013). We described this in more detail in our memo to ASTS of November 13 and accompanying spreadsheet.

- **Removal of Part B Drugs from SGR Update Formula:** CMS has finalized its proposal to remove Part B (i.e., physician-administered) drugs from the definition of "physician services" for purposes of computing the physician update formula. This change will reduce the number of years in which physicians are projected to experience a negative update.

- **Elimination of Consultation Codes:** CMS has finalized its proposal to eliminate all of the inpatient and outpatient consultations codes (except for certain telehealth consultation codes), and will do so in a budget neutral manner. The agency will redistribute the work RVUs for these services to other E and M services, including new and established office visits and initial hospital and initial nursing facility visits. Significantly, the Final Rule indicates that the redistribution will increase payment for visits included in the global surgical package, although the agency observed that the impact on payment was minimal. Several medical specialties have come together to lobby Congress to put a hold on the implementation of this new policy. However, we understand that this provision is not currently in either the House or Senate bills.

- **Recalculation of Malpractice RVUs:** CMS has adopted a new methodology designed to more accurately capture malpractice costs by specialty. CMS estimates the impact of this as a positive 1% for General Surgery and 2% for Cardiac/Thoracic Surgery. The malpractice changes appear to benefit transplant surgery.

- **Chronic Kidney Disease Education:** MIPPA included a new coverage provision for chronic kidney disease education (KDE) which provides for coverage of KDE for beneficiaries diagnosed with Stage IV CKD who will require dialysis or a kidney transplant.

  CMS is proposing to establish two G codes for KDE which would describe one sixty minute education session. There is one code for individual education sessions and another for education in a group setting. In the Final Rule, CMS adjusted the amounts payable for the service to reflect the one-hour time limit for each service.

CMS finalized its proposals with respect to beneficiary eligibility for this new benefit (Stage IV CKD as kidney damage with a severe decrease in GFR defined quantitatively as GFR of 15-29ml/min/1.73 m^2 using the Modification of Diet in Renal Disease Study formula). CMS also finalized its proposal to require KDE to be provided face-to-face and be given by a physician or other qualified person, which could include a PA or NP and, in rural areas, could be certain institutional providers such as hospitals, SNFs or home health agencies. Significantly, the KDE cannot be provided by a renal dialysis facility. CMS also finalized the content areas for education set forth in its proposed rule, and limited coverage to six sessions per beneficiary with a length of 60 minutes.

- **Physician Self Referral (Stark) law:**

  CMS has finalized two clarifications of the regulations implementing the physician self-referral law (Stark Law). The first provision clarifies that, even though the direct compensation exceptions will apply, it is not necessary for each physician owner of a practice to sign every agreement with an entity that provides services covered by the law. The second clarifies that, when applying the Stark prohibitions to a group medical practice, the parties must analyze whether the compensation payable to the practice takes into account referrals or other business generated by the practice as a whole, including all owners, employees, and independent contractors of the practice. It is not sufficient to look simply at the relationship of compensation from the DHS entity to referrals by the physician owners of the practice.

  These changes highlight that a physician who is part owner of a practice is now strictly liable under the Stark law for the arrangements of the practice, even those involving other physicians, and even though the physician may not have been in a position to control or influence the arrangement.

- **Immunosuppressive Drugs; Revision to Regulations to Conform to Statute:** CMS is revising its regulations to reflect amendments to the Medicare law from several years ago which extended coverage for immunosuppressive drugs post-transplant provided the individual is otherwise Medicare eligible. This is not a substantive change. It simply conforms the regulations to the governing statute.

2. Hospital Outpatient Prospective Payment Rule. Most hospitals will receive an inflation update of 2.1 percent in their payment rates for services furnished to Medicare beneficiaries in outpatient departments, under the final Hospital Outpatient Prospective Payment Rule, issued earlier this year. As required by Medicare law, CMS will reduce the update by 2.0 percentage points for hospitals that did not participate in quality data reporting for outpatient services or did not report the quality data successfully, resulting in a 0.1 percent update for those hospitals.

The final rule also includes a number of provisions of particular interest to transplant centers. First, the Final Rule provides payments to rural hospitals for kidney disease education services furnished in outpatient departments to Medicare beneficiaries with Stage IV chronic kidney disease. More specifically, Section 152(b) of Public Law 110–275 (MIPPA) amended the Medicare Act by adding a new subsection to provide for coverage of kidney disease education (KDE) services as a Medicare Part B benefit for Medicare beneficiaries diagnosed with stage IV chronic kidney disease (CKD) who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant, effective for services furnished on or after January 1, 2010. The Act defines ‘‘kidney disease education services’’ and specifies that those services must be furnished by a ‘‘qualified person.’’ The term “qualified person” is defined as a physician, physician assistant, nurse practitioner, or clinical nurse specialist, or as a provider of services (e.g., a hospital) located in a rural area.

Also of interest to transplant centers, the Final Rule incorporates a payment adjustment for the hospital pharmacy overhead costs of separately payable drugs and biologicals, some of which may include drugs administered to post-transplant patients. This adjustment better recognizes the overhead costs for these drugs and biologicals. The new policy will result in payment for most separately payable drugs and biologicals administered in hospital outpatient departments at the manufacturer's average sales price (ASP) plus four percent.

In order to maintain beneficiary access to safe, cost-effective health care, the Final Rule with comment period also modifies CMS's requirements for physician supervision to ensure that hospital outpatient services are appropriately supervised by physicians or other qualified practitioners.

While the Final Rule addresses only hospital outpatient services and Medicare payment to hospitals for most transplant services, therefore will not be affected. The rule does address two transplant services that may be performed in whole or in part in outpatient settings. Specifically, the Rule addresses Medicare payment for backbench preparation of corneal endothelial allograft prior to transplantation (CPT Code 65757), which is currently “packaged” into the underlying Medicare payment for the transplantation itself. CMS denied the request to provide separate Medicare payment for the preparation process for corneal transplants, finding that it is an intraoperative service that is ancillary and supportive to the transplant itself; however, CMS did

indicate that it would consider the costs of preparing the tissue for transplantation in establishing the payment rate for the transplantation.

CMS also addressed Medicare payment for stem cell transplantation, backing away from its proposal to provide Medicare payment for certain stem cell transplantation related services in the inpatient setting only. Specifically, CMS stated in the hospital outpatient prospective payment proposed rule that it believes that allogeneic stem cell transplants performed on Medicare beneficiaries are provided on an inpatient basis only, and all services related to acquiring the stem cells from a donor (whether performed on an inpatient or outpatient basis) are billed and are payable under Medicare Part A through the inpatient prospective payment system only. In addition to payment for the stem cell transplant procedure itself, the inpatient prospective payment system includes payment for stem cell acquisition services, which include, but are not limited to, National Marrow Donor Program fees for stem cells from an unrelated donor (if applicable); tissue typing of a donor and a recipient; donor evaluation; physician pre-admission/pre-procedure donor evaluation services; costs associated with the harvesting procedure; post-operative/post-procedure evaluation of a donor; and preparation and processing of stem cells. While certain acquisition services, such as donor harvesting procedures, may be performed in the hospital outpatient setting, hospitals are instructed to include the charges for these services in the recipient's inpatient transplant bill as acquisition services and not to bill them under the outpatient payment system. Accordingly, CMS proposed to change the status indicator for certain harvesting and related procedure CPT codes to make them non-payable in the hospital outpatient setting.

In response to comments indicating that reduced intensity conditioning (RIC) regimens have made outpatient allogeneic stem cell transplants feasible for some Medicare beneficiaries, CMS modified its position to retain outpatient payment for a number of these CPT codes; however, CMS did not agree to allow separate payment under the hospital outpatient payment system for stem cell harvesting services. Instead, CMS indicated that it continues to believe that it continues to be appropriate to pay for these services through payment for the associated stem cell transplant procedure.

3. **Regulatory Issues Relevant to Kidney Swaps.** We have been participating, on behalf of ASTS, in discussions with a number of transplant centers around the country related to development of uniform and Medicare compliant payment policies related to costs associated with kidney swaps. Currently, there are divergent policies on treatment of living donor costs with Medicare intermediaries apparently providing inconsistent advice. It appears that there are some Medicare payment policies,

particularly those related to treatment of living donor costs that are presenting obstacles to multi-center kidney swaps. We will be working with ASTS to identify Medicare policy or regulatory modifications that address these obstacles and advocating with CMS for those changes.