



Legislative and Regulatory Update

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Welcome to the inaugural issue of ASTS' newest e-newsletter, designed to keep you up to date on the work ASTS does on your behalf both on Capitol Hill and with the federal agencies involved in regulations and reimbursement for the field of transplantation. Instead of waiting for the next issue of *Chimera*, you will now receive a brief monthly recap of the issues and challenges in our field. Future editions will focus on topics such as immunosuppressive drug coverage, National Living Donor Assistance Center (NLDAC) and OPTN funding, PHS guidelines, the Social Security Master Death File, Essential Health Benefits (EHB), Medicare and Medicaid reform, non-transplant legislation relevant to surgeons, and legislative committee projects.

Legislative Issues

What the Election Means for ASTS Members

The results of this election will have far-reaching implications for America's health care system. Congress will undoubtedly continue to debate entitlement reform to find ways to reduce federal expenditures for these programs. Significantly, momentum will be curtailed to convert the Medicare entitlement into a partially private system (commonly referred to as a "voucher" program) and to block grant Medicaid. However, both programs will continue to be at risk of additional spending cuts in the context of solving the "fiscal cliff."

In addition, the programs and spending cuts outlined in the Affordable Care Act (ACA) will continue to be implemented. Over the next few years, the small group and individual insurance markets will see dramatic reforms and restructuring. Since the administration has given much leeway to states on the pace and scope of these reforms, the election results for gubernatorial and state legislative races will also impact the fate of healthcare reform on a state-by-state basis. It can also be expected that any politically sensitive ACA regulations that may have been delayed for the election will be released over the coming weeks and months.

Implementation of the state insurance exchanges and federal subsidies to purchase insurance may be delayed as Congress debates ways to trim federal spending in the coming months. The work of the Center for Medicare and Medicaid Innovation (CMMI) will likely continue at its current pace, unless a lack of funding impacts these programs. For example, stakeholders can expect to continue to see movement on the Independence at Home Program and Care Transition program under Medicare; Medicaid medical homes and dual eligible demonstrations; and continued work on the bundling, accountable care organizations and pay for performance efforts.

While it is extremely unlikely that the ACA will be repealed in the next two years, Republican leadership has pledged publicly to try to eliminate or delay funding for measures they do not support while allowing others to go into effect. The Obama Administration has indicated that it plans to implement as many of the reform measures as possible as quickly as possible on the assumption that the public will support health reform once the key provisions begin to take effect.

This likely means that the next two years will see a struggle over funding measures and a series of hearings conducted particularly in the House on the potential adverse effects of health reform. At the same time, there may be some compromise on these issues to reach overarching consensus on deficit reduction. The net result is that health reform measures which can be implemented without additional funding or which reduce costs will likely proceed unopposed while more controversial measures that add costs, even in the near term, will face continued opposition.

Fiscal Cliff

The lame duck session of the 112th Congress, which began November 13, is being very closely watched. The Continuing Resolution passed in September will keep the government functioning until March 27 or until final appropriations legislation can be passed. In addition, across-the-board reductions in funding (sequestration) for FY 2013 will go into effect on January 1 unless Congress passes, and the President signs, an alternative spending deal that achieves the same amount of savings but in a manner other than through across-the-board cuts.

For the rest of this year and into 2013, Congress will attempt to address a number of significant issues commonly referred to as the “fiscal cliff,” including:

- Automatic cuts to spending (i.e., sequestration) included in the Budget Control Act of 2011, scheduled to begin on January 1, 2013;
- The pending 27 percent cut to Medicare physician fees scheduled for January 1st;
- The expiration of favorable tax provisions including the payroll tax, the Bush-era income tax rates, and the current treatment of the Alternative Minimum Tax (AMT);
- Expiration of the existing unemployment insurance provisions; and
- The need to again increase the federal debt limit in early 2013.

If implemented, sequestration would include cuts of:

- **2 percent to Medicare provider reimbursement rates,**
- **7.6 percent to other non-exempt nondefense mandatory programs,** and
- **10 percent to non-exempt defense mandatory programs.**

Medicaid and Social Security, by statute, are held harmless under sequestration and not impacted by it.

Until Congress acts, there will continue to be a great deal of uncertainty, though many observers think Congress will prevent or quickly reverse many of the most painful provisions. ASTS is closely monitoring the lame duck session and will continue advocating on several fronts regarding issues that affect transplantation.

Regulatory and Reimbursement Issues

OPTN Living Donor Policy

Last month, the UNOS Board of Directors voted to approve new requirements for living donor follow-up. ASTS supports the best possible care for living donors, including follow-up that is as complete and meaningful as possible, and is working to determine how best to help our members comply with this new policy.

Food and Drug Administration

A group including ASTS President Kim M. Olthoff, MD, Immediate Past President Mitchell L. Henry, MD, and Past Presidents Arthur Matas, MD, and Goran Klintmalm, MD, visited the FDA in October to discuss generic equivalency issues. They provided the clinician's viewpoint and concerns related to how the FDA should address generic drugs in the field of transplantation. Specifically, ASTS requested that generics be tested on relevant patient population and that criteria for approval be narrowed as is required in Europe and Canada. ASTS appreciates the opportunity for candid dialogue with the FDA and looks forward to our continued discussions on this and other topics.

Public Health Service Disease Transmission Guidelines

ASTS has vigorously protested the draft PHS Guideline for Reducing Transmission of HIV, HBV, and HCV Through Organ Transplantation. The most recent draft available to ASTS failed to address many of the concerns raised by ASTS and the broader transplant community when the initial draft was published last year. The most recent draft continues to overstate the risk of transmission and to cite outdated data and data that includes transmissions of diseases other than HIV, HBV, and HCV. Moreover, the draft Guideline- continues to exaggerate the potential risk of unintended disease transmission by including cases that were, in fact, caught by existing screening mechanisms and by including transmissions of infectious diseases other than HBV, HCV, and HIV.

ASTS understands that the draft Guideline is currently under agency review at HHS and is anticipated to be published in final form in early 2013.

RVUs for Renal Transplant

The Centers for Medicare and Medicaid Services (CMS) has identified CPT code 50360 (renal transplant) as one of a large list of potentially misvalued services through a screen of procedures that have not been reviewed in 20 years and have Medicare allowed charges over \$10 million. CMS has requested that the AMA Specialty Society Relative Update Committee (RUC) review the physician work for all the codes on this list, including 50360. The ASTS Reimbursement Committee and Michael M. Abecassis, MD, MBA, are working on this issue. Over the next few months, the ASTS will send out a standardized RUC survey that requests information about physician time and visits related to this procedure. If you receive a survey, ASTS hopes you will take the time to complete it to ensure relative values will be accurately and fairly presented to CMS during the review process. This is important to you and other physicians because these values determine the rate at which Medicare and other payers reimburse for procedures.