



## Legislative and Regulatory Update

*May 2015*

### **ASTS Fly-In a Success**

Several members of the ASTS Legislative Committee, along with members at large, visited Congressional offices May 20 to advance a transplant-specific agenda. Drs. Sherilyn Gordon-Burroughs, David Reich, Mitch Henry, Mike Millis, and Sunil Geevarghese visited offices of their Congressional representatives and other lawmakers to discuss the [immunosuppressive drug bill](#), an [exemption for transplant in the hospital readmissions penalties](#), the [Living Donor Protection Act](#), and the Organ Donation Awareness and Promotion Act, which was introduced by Senator Casey (D-PA) on May 21 and would reauthorize and increase funding for several programs under Section 377 of the Public Health Service Act that support education and awareness of organ donation.



### **21st Century Cures Bill Goes to the House**

The House Energy and Commerce Committee unanimously passed the 21st Century Cures bill after reaching a bipartisan deal to pay for the legislation's \$13 billion price tag. The bill is intended to streamline the FDA's approval process for new drugs and includes more than \$10 billion over 5 years in increased NIH funding for medical research, as well as an additional \$550 million over 5 years for the FDA. A full House vote is anticipated in June.

Pay-fors included selling 8 million barrels of oil each year for 8 years from the Strategic Petroleum Reserve (estimated at \$5.2 billion); modifying the timing of government payments to insurance companies under the Medicare Advantage program so that the government can keep interest earned on the funds (\$5-7 billion); reducing Medicaid payments for certain medical equipment (\$2.8 billion); and limiting payments for X-rays on film (\$200 million).

The bill would accept broader evidence on a drug's effects and encourages the use of surrogate endpoints in drug testing. It also creates a priority review program for breakthrough medical devices.

### **SGR Repeal Is Law; Now What?**

Now that the SGR has been repealed, ASTS is analyzing the legislation. It replaces Medicare's multiple quality reporting programs with a new Merit-Based Incentive Payment System (MIPS) program, and it supports and rewards physicians for participating in new payment and delivery models to improve the efficiency of care while preserving fee-for-service as an option. ASTS is convening a task force to study its effect on transplant surgeons and determine how the Society can effectively respond to help members comply with the program and maintain the highest standards for patient care. ASTS is also analyzing whether and to what extent the new program will enable transplant surgeons to use the SRTR to get credit for quality reporting under MIPS.

### **Changes to Medicare Part D Rules for Subscribers**

The interim final rule will enable physicians and other professionals who are legally authorized to do so under state law to write prescriptions for Part D drugs, even though they are not eligible for Medicare enrollment, through December 2015. In addition, the interim final rule requires Part D sponsors to cover a provisional supply of a drug before they reject a claim based on a prescriber's Medicare enrollment status. These modifications will also require Part D sponsors to provide written notice to the beneficiary and take reasonable efforts to provide written notice to the prescriber that the drugs are provided on a provisional basis.

### **Looking for a Past Issue?**

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