



Legislative and Regulatory Update

Bill to End Ban on Research on Organ Donation among HIV-Positive Patients Introduced in Senate

A bill introduced by Senators Barbara Boxer (D-CA) and Tom Coburn (R-OK) would end the ban on federal research into organ donations from HIV-positive donors to HIV-positive recipients. S. 330 would create a process for evaluating medical research in this area and, if the research demonstrates that such transplants can be performed safely and successfully, it would give the Secretary authority to direct OPTN to establish safe procedures for such transplants. The bill, which would give HIV-positive patients an increased pool of potential donors, is supported by ASTS as well as many others in the medical and patient community. There is a companion bill in the House (H.R. 698).

Senate Bill to Provide Lifetime Medicare Coverage of Immunosuppressive Drugs

Senators Durbin (D-IL) and Cochran (R-MS) have reintroduced a bill (S. 323) to provide for lifetime Medicare Part B coverage of immunosuppressive drugs for kidney transplant recipients. Currently, Medicare Part B coverage for immunosuppressive drugs critical to the survival of transplant recipients ends 36 months after transplantation and patients are often unable to obtain other insurance. This bill would allow kidney transplant recipients to enroll in Medicare Part B solely for coverage of immunosuppressive drugs. ASTS has long advocated an end to this coverage cliff for kidney transplant recipients and strongly supports this bill.

Physician Payment Sunshine Act Finalized Rule Announced

CMS has announced the [finalized regulations to implement the Physician Payment Sunshine Act—Section 6002 of the Affordable Care Act](#). As a result of input from the continuing medical education (CME) community, including ASTS, CMS created a new section, **42 CFR §403.904(g)**, that states payments or other transfers of value provided as compensation for **speaking at a continuing education** program are **not required** to be reported, if certain requirements are met. For more details, visit the [Policy and Medicine website](#) or [view the ASTS comments](#).

ASTS Comments on OPO Outcomes Standards Solicited by CMS

CMS has solicited comments from ASTS regarding how the outcomes standards for OPOs and Transplant Centers can be better harmonized. CMS regulations currently encourage OPOs to retrieve all organs without consideration of their suitability for transplantation, while requiring Transplant Centers to meet stringent transplant recipient outcomes requirements, regardless of donor organ quality. ASTS has submitted comments recommending that CMS apply OPO and TC outcomes

requirements separately for marginal and standard criteria organs and make certain other changes.

Medicare Coverage Advisory Committee to Review VAD Use

The Medicare Coverage Advisory Committee or MedCAC, an advisory group consulted by CMS on coverage issues, is planning to hold a meeting to review the use of Ventricular Assist Devices (VADs) for patients with heart failure, including a review of the facility and operator characteristics that predict improved outcomes for VAD patients.

ASTS Investigates Approval of SRTR as Qualified Registry for PQRS Purposes

The Taxpayer Relief Act of 2012 ("the fiscal cliff" bill) provided new authority for CMS to permit PQRS participation through reporting to clinical registries that do not track PQRS measures. In response to a CMS solicitation, ASTS plans to urge CMS to allow ASTS members to participate in PQRS through SRTR reporting.

ASTS Plans Response to CMS Proposed Rule to Eliminate Duplicative Transplant Certification Requirements

On February 4, 2013, CMS issued a Proposed Rule to eliminate or modify certain Transplant Center Conditions of Participation (CoPs) that were identified as administratively burdensome, confusing, or duplicative. For example, under the proposal, CMS would eliminate the requirement that a transplant center notify CMS of changes in its outcomes, which are reported to CMS by the SRTR; would eliminate the automatic 3-year re-approval cycle; and would clarify certain other provisions of the CoPs. ASTS is analyzing the Proposed Rule and intends to file comments.