



Legislative and Regulatory Update

Physician Payments Sunshine Act Effective August 1

As of August 1, manufacturers are required to start tracking meals, faculty payments, certain educational events, grants and other transfers of value provided to physicians and teaching hospitals under the Physician Payments Sunshine Act (PPSA) and the [regulations](#) issued by the Centers for Medicare and Medicaid Services (CMS). Manufacturers and Group Purchasing Organizations (GPOs) will also separately report physicians' and immediate family members' ownership and investment interests. CMS will publish these reports on the public [OPEN PAYMENTS website](#).

CMS recently issued the OPEN PAYMENTS Apps for iPhone and Android to facilitate internal tracking by physicians and manufacturers. Through these Apps, physicians will track and retain transfers of value in real-time and share information with manufacturers directly. These Apps will ease some of the burdens associated with the new rule and minimize disputes. Proactive tracking of manufacturer and GPO relationships will enable physicians to respond quickly to erroneous reports that could implicate their professional reputation and livelihood.

Additionally, CMS recently issued a request for comments on the burden estimates associated with the PPSA. While this solicitation of comments is directed at the administrative impact of the PPSA, rather than the substantive rule itself, physicians may want to submit comments that highlight the significant burdens physicians face under the new rule. Comments are due September 20.

Immunosuppressive Drug Coverage Bill

The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2013 (H.R. 1428/S. 323) was the subject of a June 28 hearing in the House Energy and Commerce Health Subcommittee in response to a request from Representative Burgess (R-TX), co-author of the legislation with Representative Kind (D-WI). ASTS

submitted testimony for the record stating that current Medicare policy ending coverage after 36 months is unfair to patients, living donors, donor families, and the federal government.

The Immuno bill would indefinitely extend Part B coverage of immunosuppressive drugs only to these Medicare beneficiaries in exchange for payment of a Part B premium. The Congressional Research Services (CRS) released a report in July on Medicare Part B coverage of immunosuppressive drugs for kidney transplant recipients that favorably detailed the legislation and included important data regarding the utilization and Medicare expenditures of these life-saving medications, a key component of Congress' ability to advance the legislation.

ASTS has been fighting for passage of this bipartisan legislation for many years. With significant movement in the last few months, including more than 70 co-sponsors in the House and 15 in the Senate, and specific mention by Rep. Burgess in committee markup that he remains committed to moving the bill, we are getting closer to passage.

To support this legislation, please contact your Members of Congress in both the House and Senate today, asking them to co-sponsor H.R. 1428/S. 323, the "Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2013." The easiest way to do this is to contact the Capitol switchboard at 202-225-3121, ask for your elected official, and then ask the office staff for the health legislative assistant.

The "HOPE" Act

The Senate passed the "HIV Organ Policy Equity Act," (the "HOPE" Act), S. 330, on June 17. The House Energy and Commerce committee passed its version of the bill (H.R. 698) in July, and the legislation now stands ready for House floor action. Assuming there are no differences between the House and Senate bills, passage by the House will be the last step before the President signs the legislation into law.

The HOPE Act would amend the Public Health Service Act to remove the current legal ban on the use of HIV-positive organs for HIV-positive individuals in need of a donor organ. The current federal restriction, originally enacted in 1988, has been eclipsed by advances in HIV treatment and is simply not supportable in contemporary medicine. Furthermore, passage of this legislation will not only increase access to life-saving transplants; it will also allow the scientific and transplant community to conduct much needed research in this area.

To support this bill, please contact members of the House of Representatives and ask that they co-sponsor and support final passage of H.R. 698, the HOPE Act. The easiest way to do this is

to contact the Capitol switchboard at 202-225-3121, ask for your representative, and then ask the office staff for the health legislative assistant.

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