



Legislative and Regulatory Update

February 2014

ASTS Written Testimony Featured at Part D Hearing

The House of Representatives Energy and Commerce Committee's Subcommittee on Health held a hearing on Wednesday, February 26, 2014. The hearing, entitled, "Messing with Success: How CMS' Attack on the Part D Program Will Increase Costs and Reduce Choices for Seniors" focused on a recently released proposed rule by the Centers for Medicare and Medicaid Services (CMS) on the Part D Prescription Drug Program that contained a significant change in formulary rules for 6 protected classes of drugs, including immunosuppressants. ASTS submitted testimony for the record, introduced by Dr. Michael Burgess (R-TX), longtime champion of the transplant community. Dr. Burgess (R-TX) and Dr. Phil Gingrey (R-GA) spoke in strong opposition to the rule due to its negative impact on patients taking immunosuppressant drugs, with Dr. Burgess noting the rule's "penny wise and pound foolish approach" for immunosuppressants.

Members of Congress from both parties were strong in their opposition to this particular part of the rule. Dr. Donna Christenson (D-VI), another physician member of the committee, echoed her disappointment with this portion of the rule, noting that the panel that crafted this portion of the rule did not include any transplant physicians. Ranking Member of the Full Committee, Henry Waxman (D-CA), also raised concerns over changes to Six Protected Classes policy. He stated that while removing drugs from protected status will likely save money, "it's hard to ignore that these changes will make it more difficult for patients to access the drugs they need." Health Subcommittee Ranking Member Frank Pallone

(D-NJ) also said that his primary concern with the regulation is the rule's proposal regarding the Six Protected Classes. Many Members, patient groups, and medical specialty societies are calling for CMS to rescind this portion of the rule.

You can read the [ASTS testimony](#) online. Previously, Senators Richard Durbin and Thad Cochran and Congressmen Michael Burgess, MD, Ron Kind, and Tom Marino sent a letter to CMS Administrator Marilyn Tavenner stating that "transplant surgeons and physicians often need to have all FDA approved immunosuppressive drugs available in order to tailor combinations of drugs to meet the unique needs of individual transplant recipients. Not all patients respond in the same way to a particular regimen, therefore limiting access fails to account for the unique nature of the drug and needs of patients."

ASTS is also closely tracking the work of our allies in the mental health community on these efforts, as antidepressants are also at risk under the proposed CMS criteria. There is widespread agreement throughout the health care community that this provision should be rescinded. If you are interested in submitting comments on behalf of your institution prior to the deadline of March 7, 2014, you may do so at <http://regulations.gov>.

SGR Bills Introduced

On February 6, a bipartisan, bicameral agreement was reached by leaders of three key Congressional committees to repeal the Sustainable Growth Rate (SGR), the portion of the Medicare physician payment formula responsible for pending cuts, and create a new quality measurement system for physicians and others paid under the formula. Congress delayed the formula's required cuts over the past 12 years through short-term legislative patches, but this is the first time a permanent fix to the physician fee schedule has progressed this far. The legislation, [H.R. 4015 and S. 2000](#), was introduced in the House and Senate by the committee chairmen and ranking members of the Senate Finance, House Energy and Commerce, and House Ways and Means committees. A section-by-section [summary of the bill](#) is also available.

Congressional committee staffers must now identify "pay-fors" or "offsets" for the SGR repeal and quality program—Medicare policy proposals that save the government money over a 10-year period. These savings will be applied against the additional spending necessary to fix the fee schedule, resulting in a budget-neutral bill.

The agreement provides a 0.5 percent annual update for professionals

paid under the Medicare physician payment formula starting in 2014 through 2018, with 2018 rates maintained through 2023. The bill directs the Secretary of the Department of Health and Human Services (HHS) to develop a new methodology for assessing the annual performance of each professional within a new Merit-Based Incentive Payment System (MIPS).

The legislation consolidates under MIPS three existing incentive programs: the Physician Quality Reporting System (PQRS); the Value-Based Modifier; and the Meaningful Use of Electronic Health Records (EHR). Each program would sunset by the end of 2017, with planned PQRS and EHR penalties transferred to the physician payment pool.

To protect and encourage the use of physician clinical registries, the legislation creates a process by which HHS will certify "qualified clinical data registry measures." QCDR measures will not be subject to the additional MIPS requirements but instead will automatically be included in the Secretary's list of quality measures for the first year and can only be removed through a rulemaking process.

For a detailed analysis of the bill, please consult the SGR Memo on the [ASTS Legislative Issues webpage](#).

Missed an Issue?

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