

# AAMC Policy and Regulatory Roundup

## Policy and regulatory updates from the Regulatory Team

December 2019

### Announcements

#### AAMC, Hospital Groups Lawsuit Regarding CMS Hospital Price Disclosure Final Rule

On December 4, the AAMC along with the American Hospital Association, Children's Hospital Association, Federation of American Hospitals, along with a group of hospital plaintiffs, filed suit challenging the price disclosure rule recently finalized by CMS. The rule is effective January 1, 2021. The [complaint](#) filed by the AAMC and others states that the Department of Health and Human Services lacks the statutory authority to require hospitals to make public payer-specific negotiated rates. Furthermore, the final rule violates the First Amendment because it compels hospitals' speech in a manner than will confuse patients and unduly burden hospitals.

Staff contact: Ivy Baer, [ibaer@aamc.org](mailto:ibaer@aamc.org)

#### Comment Period Extensions for CMS Payer Price Transparency and Medicaid Rules

CMS has delayed the comment periods for two proposed rules; [Transparency in Coverage proposed rule](#) comments are now due January 29, and the [Medicaid Financial Accountability Regulation](#) comments are due February 1, 2020. The AAMC will be submitting comments on both rules.

Staff contacts: Ivy Baer, [ibaer@aamc.org](mailto:ibaer@aamc.org), Mary Mullaney, [mullaney@aamc.org](mailto:mullaney@aamc.org)

### Proposed Rules

#### FDA Prescription Drug Importation Proposed Rule

On December 20, the FDA released a [proposed rule](#) and [draft guidance](#) addressing the importation of prescription drugs. This proposed rule would allow the importation of certain prescription drugs from Canada, and the draft guidance specifically addresses the importation of FDA-approved drugs that were also authorized for sale in a foreign country in which the drugs were originally intended to be marketed. Comments on the proposed rule are due March 9, 2020, and comments on the draft guidance are due March 5, 2020.

Staff contact: Mary Mullaney, [mmullaney@aamc.org](mailto:mmullaney@aamc.org)

### Letters Submitted

#### Comments on "Cures 2.0"

On December 16, Chief Public Policy Officer Karen Fisher submitted [comments](#) in response to an announcement from Reps. Diana DeGette and Fred Upton on "[Cures 2.0](#)." Cures 2.0 is a bipartisan effort intending to build upon the 21<sup>st</sup> Century Cures Act, focusing on exploring digital health technologies; reforming Medicare coding, coverage and payment to better support patients' access to innovative therapies; harnessing data to empower patients and improve health; and improving the ability of families and caregivers to support their loved ones. Members of the Regulatory team participated in composing these comments as part of a cross-cluster effort, focusing on electronic health record usability, patient and provider access to data, Medicare coverage of technology-based communication services, advanced APM thresholds and participation, and high-cost technologies and drugs (such as CAR-T).

Staff contacts: Kate Ogden, [kogden@aamc.org](mailto:kogden@aamc.org), Andrew Amari, [aamari@aamc.org](mailto:aamari@aamc.org)

#### CMS Proposed Changes to Stark Law Exceptions, HHS OIG Proposed Changes to Safe Harbors Under the Anti-Kickback Statute

On December 31, the AAMC submitted comments to [CMS](#) and [HHS OIG](#) in response to proposed changes to Stark Law exceptions and safe harbors under the Anti-Kickback Statute, expressing general support for CMS' efforts to address the challenges hospitals and physicians face when attempting to structure innovative arrangements to transform patient care, while also offering refinements to reduce burden and encourage broad use of these new exceptions and safe harbors.

Staff contacts: Gayle Lee, [galee@aamc.org](mailto:galee@aamc.org), Phoebe Ramsey, [pramsey@aamc.org](mailto:pramsey@aamc.org)

### **Reports**

#### **GAO Report on Expanding Medicare GME Funding to Nurse Practitioner and Physician Assistant Training**

On December 18, the GAO released a [report](#) that discusses providing Medicare GME funding for NP and PA graduate training, which was requested as part of the Departments of Labor, Health and Human Services, Education and Related Agencies Appropriations Bill in 2018. The report examined the possibility of diverting Medicare GME funding for medical residents to NPs and PAs, however, provided limited estimates of NP and PA graduate training costs. GAO noted that some members of Congress suggested that expanding the scope of the Medicare GME program to include NPs and PAs could help to mitigate the effects of physician shortages.

Staff contact: Andrew Amari, [aamari@aamc.org](mailto:aamari@aamc.org)

### **Meetings**

#### **MedPAC December 5-6**

The Medicare Payment Advisory Commission (MedPAC) [met](#) December 5-6 to discuss the Commissioners' draft recommendations related to payment adequacy and payment updates for physician services and inpatient and outpatient hospital services.

Staff contacts: Kate Ogden, [kogden@aamc.org](mailto:kogden@aamc.org), Mary Mullaney, [mmullaney@aamc.org](mailto:mmullaney@aamc.org)

#### **MACPAC December 12-13**

The Medicaid and CHIP Payment and Access Commission (MACPAC) [met](#) December 12-13 to discuss the [proposed rule on Medicaid supplemental payments](#), an expert roundtable on Medicaid prescription drugs, and updates on MACPACs draft chapter analyzing disproportionate share hospital (DSH) allotments.

Staff contacts: Mary Mullaney, [mmullaney@aamc.org](mailto:mmullaney@aamc.org), Andrew Amari, [aamari@aamc.org](mailto:aamari@aamc.org)