AAMC Policy and Regulatory Roundup

Issues that impact clinical care provided by hospitals, physicians, and other providers

Policy and Regulatory Updates from the Health Care Affairs Regulatory Team **October 2025**

GOVERNMENT SHUTDOWN:

Congress failed to pass a stopgap spending bill before Oct. 1, triggering a government shutdown. Following the Oct. 1 deadline to fund the government, the Senate attempted and failed to advance a House-passed spending bill and a Senate Democratic-led spending bill [refer to *Washington Highlights*, Sept. 19]. Lawmakers remain at an impasse over a spending bill and health care policy provisions, leaving no clear timeline for when government operations will resume. The House of Representatives is slated to return to session on Oct. 7.

The AAMC has issued a resource that provides information on the effects of the government shutdown on HHS operations and key Medicare/Medicaid policies.

ANNOUNCEMENTS:

HRSA Approves Eight Drug Manufacturers' 340B Rebate Models

The U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) on Oct. 30 announced its approval of eight drug manufacturers' applications to participate in a voluntary 340B Rebate Model Pilot Program (PDF). In August, HRSA unveiled a voluntary rebate model pilot, limited to the 10 drugs eligible for negotiation through the Medicare Drug Price Negotiation Program in 2026. [refer to Washington Highlights, Aug. 1, 2025]. HRSA's approval covers nine of the ten Medicare negotiation-eligible drugs in 2026. Implementation of the rebate models for these drugs begins on Jan. 1, 2026. Manufacturers must provide notice to covered entities on the specifics of their rebate models 60 days prior to implementation. Under the pilot program, covered entities will purchase the affected drugs at wholesale price and manufacturers must pay covered entities rebates within 10 days of claims submission. Covered entities will submit claims through the Beacon system, a third-party platform chosen by manufacturers for their rebate models. In its announcement approving the eight rebate models, HRSA expanded the data fields covered entities must report to manufacturers to include medical claims data fields. The AAMC had submitted comments opposing the use of 340B rebate models, noting the insufficient implementation timeline, the absence of information on how HRSA will enforce 340B compliance under a rebate model, the lack of a clear process for disputing improperly rejected rebate requests, and the substantial administrative burden these models would impose on 340B hospitals [refer to Washington Highlights, Sept. 12].

CONTACT: Shahid Zaman, szaman@aamc.org

CMS Issues Guidance on Payment and Coverage of Emergency Medicaid Services

The Centers for Medicare & Medicaid Services (CMS) issued guidance on managed care payment and coverage of emergency Medicaid services (PDF). Under the Medicaid statute, the federal government provides federal financial participation (FFP) to cover emergency services for noncitizens ineligible for full Medicaid by virtue of their immigration status. The agency now interprets that only payments made for care and services actually furnished to treat an emergency medical condition are eligible for FFP, and that managed care payments — including risk-based capitation and state directed payments — do not qualify. The CMS asserts this change is intended to safeguard program and fiscal integrity by preventing Medicaid cross-subsidization of nonemergency services or state-only benefits.

Under this updated interpretation, states have two paths for covering emergency care for this population. First, they can use fee-for-service models and claim FFP solely for the actual rendered emergency care. Second, states may contract with prepaid inpatient or ambulatory health plans on a non-risk basis but only reimburse for actual

emergency services — not administrative or prospective payments. States must also ensure these individuals are excluded from their regular managed care rate-setting, state directed payments, and capitation calculations.

To comply, states must maintain documentation to support any claim for FFP, revise their managed care contracts and state directed payment preprints, and update reporting practices and rate certification processes. States seeking FFP should segregate any state-funded benefits and ensure transparent claims on the CMS-64 form. While states have a year before enforcement begins (e.g., starting with the first rating period after publication), the CMS expects them to act promptly to align with this new policy.
CONTACT: Shahid Zaman, szaman@aamc.org

COMMENTS:

AAMC Comments on DHS Proposed Repeal of Duration of Status for Visa Holders
The AAMC submitted a Sept. 29 comment letter (PDF) strongly opposing the Department of Homeland Security's (DHS's) proposed rule to eliminate Duration of Status (D/S) for most F, J, and I visa holders. Under the longstanding D/S policy, these visa holders, primarily international students including PhD researchers, resident physicians, and postdoctoral scholars, are permitted to remain in the United States for the full length of their academic or training program. The DHS proposal would replace this system with a fixed-term visa, capped at four years, tied to the length of the individual's program. Visa holders needing additional time would be required to file for an extension of status through U.S. Citizenship and Immigration Services, creating new layers of cost, delay, and uncertainty.
In its letter, the AAMC emphasized the significant drawbacks of this proposed shift, particularly the administrative and financial burden it would impose on international learners, the institutions that train them, and American taxpayers. The strength of the current D/S policy is the flexibility it provides, which allows medical trainees and research scholars to complete their programs without interruption, while maintaining exceptionally low rates of misuse. In addition to these comments, the AAMC joined several groups in various sign-on letters expressing concerns with the proposal [refer to related story].
CONTACT: Brad Cunningham, bcunningham@aamc.org

AAMC Comments on Section 232 Investigation on Imports of Medical Goods
The AAMC submitted an Oct. 17 letter (PDF) in response to a Department of Commerce request for comments on the initiation of a Section 232 investigation into the national security implications of imports of personal protective equipment, medical consumables, and medical equipment, including medical devices. Under the Trade Expansion Act of 1962 (P.L. 87-794, PDF), the Secretary of Commerce may initiate an investigation to determine if the importation of goods implicates national security concerns. Depending on the findings of the Section 232 investigation, the president may impose tariffs on goods in a sector.

In its comments, the AAMC agreed with the need for a robust and resilient supply chain with diversified sources of production, but urged against the imposition of tariffs on these broad categories of supplies and devices. The association emphasized that tariffs could result in supply shortages and price increases, which would affect patient access and safety. Finally, the AAMC recommended that if the administration were to decide to impose tariffs, they should be limited in scope and duration and include an exceptions process for critical medical devices and supplies. The department has 270 days from the Sept. 2 initiation of the investigation to submit a report to the president.
CONTACT: Shahid Zaman, szaman@aamc.org