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 **May 2025**

ANNOUNCEMENTS:

Trump Issues Most Favored Nation Drug Pricing Executive Order

In a May 12 executive order, President Trump directed federal agencies to implement policies to tie prescription drug prices to international price targets and to facilitate direct to consumer sales at the most favored nation (MFN) price. The executive order instructs the Secretary of the Department of Health and Human Services (HHS) to communicate MFN price targets to drug manufacturers within 30 days of the executive order. The executive order noted that if "significant progress" toward MFN pricing is not achieved, the HHS may take additional steps, including issuing a proposed rule and working with Congress to allow for drug importation for certain drugs. The executive order does not mention which drugs would be subject to MFN pricing. In 2020, the Trump administration issued a Most Favored Nation Moden interim final rule that would have set Medicare reimbursement rates for 50 Part B drugs at an international reference price through a payment model. The interim final rule was invalidated in court and later rescinded by the Biden administration [refer to *Washington Highlights*, Jan. 7, 2022].

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HHS Rescinds Guidance on Administration of Buprenorphine for Treating Opioid Use

The Department of Health and Human Services (HHS) on May 13 rescinded several informal guidance documents, effective immediately, including Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder. The practice guidelines, originally published in 2021, provided exemptions for eligible providers administering buprenorphine for the treatment of opioid use disorder from certain certification requirements related to training, counseling, and other ancillary services, such as psychosocial services. In addition to these guidelines, the HHS rescinded three other guidance documents, including:

- Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures; Extension of Effective Date with Modifications (2021).
- Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Repeal of Current Regulations and Issuance of New Regulations: Delay of Effective Date and Resultants Amendments to the Final Rule (2001).
- Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972 (2021).

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CMS Issues Proposed Rule on Medicaid Provider Tax Waivers

The Centers for Medicare & Medicaid Services (CMS) on May 12 issued a proposed rule, Preserving Medicaid Funding for Vulnerable Populations – Closing a Health Care-Related Tax Loophole Proposed Rule (PDF). The rule proposes to revise the Medicaid regulations related to health care-related taxes to ensure that these taxes are generally redistributive. Under the Medicaid statute, states may finance the nonfederal share of Medicaid costs by taxing health care providers, including hospitals and managed care organizations (MCOs). These taxes must be broad-based, uniform, and cannot hold providers harmless. States can request waivers of the broad-based and uniform requirements if they demonstrate, using a statistical formula, that the tax is generally redistributive, meaning it uses revenues from non-Medicaid services to fund the state's share of Medicaid payments. The CMS cited its concern with taxes imposed on MCOs in seven states, which the agency said are structured in a way that affects only Medicaid business within the MCOs and are therefore not generally redistributive. The rule would amend the regulations to prohibit states from imposing higher tax rates on entities with more Medicaid business than those with more non-Medicaid business. The CMS estimated the rule will result in $33 billion in federal savings over five years. Comments on the rule are due July 14.

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CMMI Releases New Strategy to Advance MAHA Agenda

The Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) on May 13 released its new CMS Innovation Center 2025 Strategy to Make America Health Again. The strategy is comprised of three pillars: (1) promote evidence-based prevention, (2) empower people to achieve their health goals, and (3) drive choice and

competition. Consistent with this strategy, stakeholders should anticipate that future CMMI model design will prioritize preventive care, access to health data, and engagement of new provider types who have not traditionally participated in CMMI models. In an accompanying presentation (PDF), CMMI noted their intent to "promote site neutral payment across settings" as part of an effort to promote choice in care. In the coming months, the CMMI plans to unveil new models in line with this strategic direction, as well as refinements to existing models to better align with this new strategy.
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CMS Requests Feedback on Health Technology Ecosystem

The Centers for Medicare & Medicaid Services (CMS), together with the assistant secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC), on May 16 published a new request for information (RFI) seeking stakeholder feedback to build off the existing health information technology policy framework "to drive large-scale adoption of health management and care navigation applications, reduce barriers to data access and exchange, realize the potential of recent innovations in healthcare that promote better health outcomes, and accelerate progress toward a patient centric learning health system." The RFI is broken out into four sections to focus questions for specific constituencies: patients and caregivers; providers; technology vendors, data vendors, and networks; and value-based care organizations.
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HHS Requests Feedback on Deregulatory Agenda
The Department of Health and Human Services (HHS) on May 14 issued a new request for information (RFI), entitled, "Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again." The RFI is an effort by the department to implement recent executive orders focused on deregulation. Specifically, the HHS seeks public input to assist in identifying "any opportunities to produce cost savings, increase efficiency, and stoke health and economic innovation through deregulation." Questions seek stakeholders' feedback regarding regulations that: are unlawful, should be reconsidered to focus on reversing chronic disease, are confusing or unnecessarily complicated, could be replaced with less burdensome approaches, are based on outdated technology, or are inconsistent with executive orders.
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AAMC Urges HHS to Forgo Implementing 340B Rebate Models
The AAMC sent a letter to Department of Health and Human Services (HHS) Secretary Robert F. Kennedy Jr. outlining the association's concerns with 340B rebate models (PDF) proposed by five drug manufacturers and cautioning the department against adopting rebate models in upcoming guidance. In a May 2 notice filed with the U.S. District Court for the District of Columbia the HHS announced it would be issuing guidance related to 340B rebate models by June 2 (PDF). In anticipation of the upcoming guidance, the AAMC submitted this letter to Kennedy, which stressed that the proposed rebate models are unlawful under the 340B statute, usurp the Health Resources and Services Administration's oversight responsibilities, and are financially and operationally disruptive to 340B hospitals. Beginning last August, five drug manufacturers announced their intention to provide 340B pricing as retrospective rebates instead of upfront discounts. But the HHS prohibited the manufacturers from implementing their rebate models without prior HHS approval, which led to the five manufacturers suing the department in federal court [refer to *Washington Highlights*, Nov. 22, 2024]. Earlier this year, the AAMC joined other hospital associations in submitting an amicus brief in support of the HHS and urging the court to block 340B rebate models [refer to *Washington Highlights*, March 7]. The court ultimately ruled (PDF) that the manufacturers could not unilaterally implement rebate models without prior HHS approval, placing the onus on HHS to decide whether to allow 340B rebate models.
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Departments Issue Guidance, RFI on Price Transparency
The departments of Health and Human Services (HHS), Labor, and the Treasury on May 22 issued updated guidance and requests for information (RFIs) seeking to amend hospital and health plan requirements to publish prices for items and services. Since 2021, the Centers for Medicare & Medicaid Services (CMS) has required hospitals to publish a machine-readable file (MRF) listing all standard charges for all items and services and a consumer-friendly list of standard charges for 300 "shoppable services." The updated hospital transparency guidance (PDF) requires hospitals to publish actual dollar amounts of estimated charges in the MRF instead of using a value of 999999999 as the estimated allowed amount where no

dollar amount is available, citing the CMS' findings that hospitals have been underreporting actual dollar amounts. The hospital transparency RFI seeks input on improving compliance with hospital price transparency requirements. Comments are due July 21. Separately, the departments issued an RFI (PDF) and guidance pertaining to health plan transparency requirements (PDF) under the Transparency in Coverage (TiC) rules. The departments request comments on implementing the prescription drug machine MRF disclosure requirements under the TiC rules. This would require health plans to report net prices for covered prescription drugs in their MRFs. Comments on the TiC RFI are due 30 days from when the RFI is published in the *Federal Register*.
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AAMC COMMENT LETTERS:

AAMC Responds to RFI on Deregulation
The AAMC submitted a May 12 response (PDF) to the Office of Management and Budget's (OMB's) Request for Information on deregulation (PDF), which sought feedback on proposals to rescind or revise regulations deemed "unnecessary, unlawful, unduly burdensome, or unsound." Acknowledging the complex regulatory landscape that academic medical institutions navigate, the AAMC emphasized the need to modernize outdated requirements, harmonize duplicative regulations, and streamline compliance without compromising critical protections. The letter urged the OMB to take a balanced, evidence-informed approach grounded in meaningful dialogue with the regulated community and adherence to the Administrative Procedure Act's notice and comment requirements. The AAMC's recommendations included: harmonizing conflict of interest rules across agencies, establishing a research policy board to improve cross-agency coordination, and aligning single institutional review board mandates [refer to *Washington Highlights*, Feb. 8, 2018, Aug. 9, 2024]. The AAMC also called for permanent regulatory flexibilities in telehealth and virtual supervision, reforms to the Quality Payment Program and hospital quality reporting, and withdrawal of certain rules with unclear statutory authority or disproportionate burden. These proposals reflect the AAMC's commitment to ensuring the ability of medical schools and academic health systems to advance scientific progress and deliver high-quality patient care.
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AAMC Submits Comments on Proposed Removal of Civil Service Protections
The AAMC submitted a May 23 letter (PDF) in response to the U.S. Office of Personnel Management's (OPM) proposed rule, "Improving Performance, Accountability and Responsiveness in the Civil Service." The proposed rule would permit the reclassification of policy-influencing positions into a new "Schedule Policy/Career" category, rendering them as at-will positions exempted from civil service protections and appeals processes. While the OPM stated that this rule is intended to allow agencies to expeditiously address misconduct and poor performance, the AAMC raised concerns that the changes could negatively impact the stability, impartiality, and institutional knowledge of the federal workforce, particularly within agencies essential to academic medicine. The association urged the OPM to withdraw the rule and undertake a comprehensive impact assessment before proceeding with such sweeping changes.
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COMMENT DEADLINES:
Due Date: June 10, 2025: FY 2026 Medicare Inpatient Prospective Payment System (IPPS) Proposed Rule
Due Date: June 10, 2025: FY 2026 Inpatient Psychiatric Facility (IPF) Prospective Payment System Proposed Rule
Due Date: June 10, 2025: Medicare Regulatory Relief RFI
Due Date: June 16, 2025: Health Information Ecosystem RFI
Due Date; July 14, 2025: Ensuring Lawful Regulation and Unleashing Innovation to Make America Health Again RFI
Due Date: July 14, 2025: Preserving Medicaid Funding for Vulnerable Populations-Closing a Health Care-Related Tax Loophole Proposed Rule
Due Date: July 21, 2025: CMS Hospital Price Transparency Accuracy and Completeness RFI

WEBINAR RECORDING:
May 12, 2025: Fiscal Year (FY) 2026 Inpatient Prospective Payment System Proposed Rule-May 12