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 **March 2025**

ANNOUNCEMENTS:

AAMC Joins Amicus Briefs Urging Court to Block 340B Rebate Models

The AAMC joined the American Hospital Association, Children's Hospital Association, and America's Essential Hospitals to file amicus briefs (PDF) in several lawsuits in the U.S. District Court for the District of Columbia urging the court to uphold the Health Resource and Services Administration's (HRSA's) decision to prevent drug manufacturers from replacing upfront 340B discounts with back-end rebates. Johnson & Johnson was the first drug company to propose a 340B rebate model, and HRSA warned the company that it would be subject to steep fines and loss of Medicaid and Medicare Part B coverage for its drugs if it proceeded with its model [refer to *Washington Highlights*, Sept. 20, 2024]. Johnson & Johnson suspended its rebate model plans and filed a lawsuit over the dispute [refer to *Washington Highlights*, Oct. 4, 2024, Nov. 14, 2024]. Subsequently, four additional companies (Bristol Myers Squibb, Eli Lilly, Novartis, and Sanofi) also sued HRSA in the same court seeking to impose rebate models. The briefs explain that "the rebate policy will require hospitals and other covered entities to float significant sums to J&J and other drug companies," highlighting the negative impacts of these policies on 340B-covered entities and the patients they serve.

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CMS Rescinds Guidance on Addressing Health-Related Social Needs in Medicaid

The Centers for Medicare & Medicaid Services (CMS) published a Center for Medicaid and CHIP informational bulletin rescinding guidance from the Biden administration that outlined and encouraged the use of Medicaid authorities, including section 1115 demonstrations, to address Medicaid enrollees' health-related social needs (HRSN). The March 4 bulletin specifically rescinds a 2023 bulletin (PDF) and a 2024 bulletin (PDF), as well as an HRSN framework (PDF) published by the CMS in 2023. These now-rescinded documents discussed opportunities under Medicaid and the Children's Health Insurance Program (CHIP) to cover services and supports, such as housing and nutrition supports, that address HRSN. Eighteen states have approved section 1115 waivers to address HRSN under the HRSN framework. In the new guidance, the CMS states that it will evaluate states' applications to cover HRSN-related services on a case-by-case basis, without reference to the November 2023 and December 2024 bulletins or the HRSN framework.

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CMS Issues Proposed Rule on ACA Marketplace Enrollment and Eligibility

CMS on March 19 issued the Marketplace Integrity and Affordability proposed rule (PDF), which revises standards for issuers offering qualified health plans (QHPs) through federally facilitated Exchanges and state-based Exchanges on the federal platform.

The CMS proposes to reverse many of the changes to Exchange coverage made during the Biden administration, including ending eligibility for QHP and Basic Health Program coverage for individuals with Deferred Action for Childhood Arrivals status. The rule also proposes to prohibit individual and small group health plans from offering gender-affirming care as an essential health benefit.

Other provisions of the proposed rule would:

- Shorten the open enrollment period by one month, to run from Nov. 1 to Dec. 15, instead of Jan. 15.
- Impose pre-verification procedures before an individual can enroll during special enrollment periods.
- Require additional income verification checks for premium tax credits.
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Certain provisions of the proposed rule would go into effect in the 2026 plan year, with the remaining proposals taking effect in the 2027 plan year. Comments are due April 11.

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MedPAC Reviews Medicare Payments for Physicians and Insurance Agents

The Medicare Payment Advisory Commission (MedPAC) met on March 6 and 7 to discuss reforming Physician Fee Schedule (PFS) updates, Medicare insurance agents, and other topics.

MedPAC reviewed and discussed two draft recommendations for updating payments to physicians and other health care providers under the Medicare PFS. The first recommendation, if adopted, would encourage Congress to replace current-law updates with an annual update based on a portion of the growth in the Medicare Economic Index (MEI), such as MEI minus 1 percentage point. The second recommendation, if adopted, would urge Congress to direct CMS to improve the accuracy of relative payment rates for clinician services by regularly updating cost data and ensuring that the methodology used to determine payment rates for different services reflects the setting in which clinicians practice medicine. Commissioners expressed substantial and broad support for these draft recommendations, and the commission will likely vote on final recommendations in the April meeting to include in their June 2025 report to Congress.

Additionally, commissioners reviewed background and preliminary work related to the use of Medicare insurance agents and Medigap plans, specifically looking at how these factors impact beneficiary choice. Commissioners voiced concerns related to plan bias from agents potentially misleading beneficiaries and concerns that beneficiaries may be priced out of Medigap plans if they need to switch from Medicare Advantage to Medicare Fee-for-Service after their initial enrollment period. While MedPAC does not plan to include a chapter on these topics in their report to Congress this cycle, the commission does plan to continue their work on these topics in future cycles.

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MedPAC Releases March 2025 Report to Congress on Medicare Payment Policy

MedPAC released its March 2025 Report to Congress, which evaluates payment adequacy and issues payment recommendations across seven Medicare fee-for-service payment systems, including hospital and physician payments. MedPAC released its March 2025 Report to Congress, which evaluates payment adequacy and issues payment recommendations across seven Medicare fee-for-service payment systems, including hospital and physician payments. In its report, MedPAC recommended that Congress increase hospital inpatient and outpatient services by the statutorily required update plus 1% for 2026. The commission also recommended that Congress transition to redistributing disproportionate share hospital and uncompensated care payments as an add-on payment to both inpatient and outpatient payments using the Medicare Safety-Net Index (MSNI) as described in the commission's March 2023 report and add $4 billion to the MSNI pool [refer to *Washington Highlights*, Jan. 13, 2023].

For physicians, MedPAC recommended that for 2026, Congress should replace the existing bifurcated update based on participation in alternative payment models with a single update equal to the Medicare Economic Index minus 1 percentage point. Additionally, like the recommendations for payments for hospital services, there is a second recommendation referencing the commission's March 2023 report that Congress should establish safety-net add-on payments in the Medicare Physician Fee Schedule for services delivered to low-income Medicare patients.
The report also included three status report chapters covering ambulatory surgical center services, Medicare Advantage, and the Medicare prescription drug program (Part D). In the report's final chapter, the commission reviewed eliminating Medicare's coverage limits on stays in freestanding inpatient psychiatric facilities**.**
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MACPAC Releases March 2025 Report to Congress on Medicaid and CHIP

The Medicaid and CHIP Payment and Access Commission **(MACPAC) released its March 2025 Report to Congress (PDF)**. This report contains three chapters that review hospital payment policies for safety-net hospitals and focus on improving the managed care external quality review process, improving timely access to Home and Community Based Services (HCBS), and reducing the administrative burden for states and the federal government for HCBS programs.

The first chapter focuses on improving the managed care external quality review process, in which MACPAC issued three recommendations intended to improve transparency and usability of findings included in the external quality review annual technical reports. The second chapter focuses on eligibility and enrollment processes for HCBS programs and makes a recommendation for guidance on provisional plans of care. Lastly, the third chapter includes an analysis of federal administrative requirements for HCBS programs and recommends that the secretary of the U.S. Department of Health and Human Services increase the renewal period for HCBS programs operating under Section 1915(c) waivers and Section 1915(i) state plan amendments from five years to 10 years.

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VA Implements Enhanced HPT Background Check Policy

The Department of Veterans Affairs (VA) notified AAMC-member institutions and other stakeholders that as of April 1, a new enhanced security background check policy applies to all entering Health Professions Trainees (HPTs), which should be addressed in initial onboarding activity to ensure they will be able to enter VA facilities and access associated systems. The policy requires U.S. citizens and most permanent residents to undergo a Tier-1 background check, which takes longer to complete than the previous background check requirement. Affected HPTs include resident physicians and medical students. Initially, the VA communicated that the new background check requirement would be implemented as of March 21.

The VA Office of Academic Affiliations (VA-OAA) is urging external academic affiliates to expedite the onboarding process for HPTs. Ideally, that process should begin when an HPT is accepted into a program that includes VA site rotations. Initially, the policy will apply to HPTs who have not previously completed VA onboarding. Enhanced vetting through a separate background check process for non-U.S. citizens has been in place since Nov. 1, 2024. Also, some current HPTs whose VA credentials have lapsed may be required to complete a Tier-1 background check.

In September 2024, the AAMC hosted a **webinar to explain the new background check policy (video)**. The Group on Resident Affairs webpage provides access to the webinar recording and additional informational documentation from the VA under the **VA Health Enhanced Security Process** section. The VA-OAA has provided a **Journey Map (PDF)**, which delineates essential onboarding milestones and several learning aids, including fact sheets for both U.S. and non-U.S. HPTs.

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DEA Delays Final Buprenorphine and VA Rules

The Drug Enforcement Administration (DEA) **delayed until Dec. 31 the effective dates for two prior rules**: the Expansion of Buprenorphine Treatment via Telemedicine Encounter and Continuity of Care via Telemedicine for Veterans Affairs Patients. These rules provide a limited exception to special registration requirements for the prescription of controlled substances via telemedicine without an in-person visit for an initial six-month prescription of buprenorphine and treatment of Department of Veterans Affairs (VA) patients by VA practitioners, respectively [refer to *Washington Highlights*, **Jan. 17 (Buprenorphine)**; **Jan. 17 (Controlled Substances)**].

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AAMC COMMENT LETTERS:

AAMC Comments on Proposed Cybersecurity Updates to HIPAA Security Rule

The AAMC **submitted March 7 comments** in response to proposals from the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) to strengthen the Security Rule under the Health Insurance Portability and Accountability Act (HIPAA) [refer to ***Washington Highlights*, Jan. 10**]. The HIPAA Security Rule, last updated in 2013, establishes policies and procedures that HIPAA-covered entities and business associates must have in place to protect electronic protected health information (ePHI).

The OCR proposed these new updates, citing the need to improve cybersecurity protections in the health care sector in response to the increase in high-profile cyberattacks. Emphasizing the inordinate burden and costs associated with the proposals, the AAMC urged the OCR to withdraw the proposed rule and convene a broad group of stakeholders to provide input on updating the Security Rule in a less burdensome manner. The AAMC provided detailed comments on provisions of the proposed rule, including allowing for increased compliance timelines and providing flexibility for regulated entities to adopt security practices in line with their risk analyses. The provisions of the rule, if finalized, would take effect 240 days from the publication of a final rule.

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AAMC Submits Comments to DEA on Proposed Telemedicine Prescribing Registrations

The AAMC submitted March 17 comments to the Drug Enforcement Administration (DEA) in response to proposals to create a special registration system to allow physicians to prescribe controlled substances to patients through telemedicine visits without having a prior in-person medical evaluation [refer to *Washington Highlights*, Jan. 17].

In its letter, the AAMC urged the DEA to work collaboratively with policymakers and provider stakeholders to break down barriers to medically necessary care while limiting drug diversion. In general, the association recommended that the DEA revise its proposed policies to ensure patient access to clinically appropriate medications through virtual care and support the continuity of care. The AAMC encouraged the DEA to build off the experience from the existing COVID-19 public health emergency flexibilities and waivers that enabled providers to safely prescribe controlled substances via telemedicine encounters.

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UPCOMING COMMENT DEADLINES:

Due Date: April 11, 2025: Marketplace Integrity and Affordability Proposed