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 **January 2025**

ANNOUNCEMENTS:

CMS Opens Applications for New Medicare-Funded GME Positions

The Centers for Medicare & Medicaid Services (CMS) on Jan. 7 opened the application for slot distributions under Section 126 of the Consolidated Appropriations Act, 2021 and Section 4122 of the Consolidated Appropriations Act, 2023. Each program can award up to 200 full-time equivalent (FTE) Medicare-funded positions to qualifying hospitals. This will be the fourth round for distributions through Section 126, and the first for Section 4122. For both distribution programs, qualifying hospitals are rural hospitals, hospitals over the Medicare FTE cap, hospitals in states with new medical schools or branch campuses, and hospitals that serve a geographic Health Professional Shortage Area (HPSA). Hospitals may apply for distributions from both programs, but there are some differences between the distribution programs for Section 126 and Section 4122. For instance, Section 126 Rounds 4 and 5 hospitals in geographic HPSAs will receive awards first, then if slots remain, the CMS will distribute based on the same HPSA score prioritization used in the first three rounds. Under Section 4122, the agency will distribute up to 1.0 FTE to all qualifying hospitals that apply and submit timely applications to comply with a "pro rata" distribution requirement found in the authorizing legislation. More information and the application for both programs are available on the CMS direct graduate medical education website under the Section 126 and Section 4122 tabs. Applications are due by March 31, and any slots awarded will be effective July 1, 2026.

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VA Provides Enhanced Background Check Resources for Academic Affiliates

The Department of Veterans Affairs (VA) on Jan. 1 implemented an enhanced background check policy for health professions trainees (HPTs), which includes resident physicians and medical students on clinical rotations at the VA. Previously, HPTs were exempt from the background check policy required for all other VA appointments. To ensure that all individuals with VA credentials are properly vetted, the VA removed the waiver for HPTs, and now all HPTs must undergo the same background check that all other VA appointments are required to complete. This means that United States citizens and most individuals who have been in the United States for at least three years will need to complete a Tier 1 background check. Noncitizens will need to complete a different background check. Those individuals with current VA credentials should be able to continue rotations at VA sites while the background checks are completed. The VA Office of Academic Affiliations (OAA) provided updates on the new policy at an AAMC webinar in September 2024, and at the end of December, the OAA provided updated resource information for academic affiliates. The resources and webinar can be found on the AAMC Group on Resident Affairs website.

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Departments Withdraw 2023 Proposed Rule on Coverage of Contraceptive Services

The departments of Health and Human Services, Treasury, and Labor on Dec. 23, 2024, withdrew a February 2023 proposed rule that would have expanded access to contraceptive services under the Affordable Care Act. The rule would have expanded access to contraceptives by eliminating the exemption for objections based on nonreligious grounds and would have created a workaround (termed the individual contraceptive arrangement) to provide coverage for individuals covered by plans subject to a religious exemption. The agencies cited a need to focus time and resources on alternative matters and a need to further consider the proposals made due to the volume and depth of comments received as the reasons for withdrawing the proposals. The AAMC had previously commented in support of the proposed rule.

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HHS OCR Proposes New Cybersecurity Requirements for Health Care Organizations

The Department of Health and Human Services (HHS) Office for Civil Rights (OCR) Jan. 6 published a proposed rule intended to strengthen the Security Rule under the Health Insurance Portability and Accountability Act (HIPAA) to improve cybersecurity protections in the health care sector in response to high profile cyberattacks in 2024. The proposals include requiring HIPAA-covered entities and business associates to encrypt electronic protected health information with limited exception, implement multifactor authentication with limited exception, and establish written procedures to restore certain

electronic information systems and data within 72 hours of cyberattack, among other updates to the Security Rule. OCR issued a fact sheet with the proposed rule. Comments are due March 7.
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CMS Releases CY26 MA and Part D Advance Notice

CMS released the Calendar Year (CY) 2026 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. The advance notice, issued annually, proposes updates to MA payment rates and technical updates to keep MA payments up to date and accurate. The proposals would result in a net increase of 4.33% in MA payments to plans on average, resulting in over $21 billion in additional payments for CY 2026. Most notable for CY 2026, the agency is proposing to complete the phase-in of two technical changes. The first is the completion of the three-year phase-in of the 2024 CMS-Hierarchical Condition Category updated risk adjustment model. The second is completion of the introduction of technical adjustment to the per capita cost calculations used for determining the effective growth rate. Specifically, the technical adjustment is related to how indirect medical education and direct graduate medical education costs are included in that calculation. CMS points out that if they were to pause the phase-in of these policies, it would result in an additional $10.4 billion in payments to MA plans that are not necessary to support stability in the program. However, the agency warns that it is critical to ensure accurate payments in MA as the program continues to grow. Lastly, the agency stated it will have the ability to phase-in an encounter data-based risk adjustment model beginning in 2027 and may explore doing so in future rulemaking. Comments are due Feb. 10, and the final rate announcement for CY 2026 must be announced by April 7.
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CMS Finalizes 2026 Notice of Benefit and Payment Parameters Rule

CMS issued the Notice of Benefit and Payment Parameters final rule for 2026, relating to issuers offering qualified health plans (QHPs) through federally facilitated Marketplaces and state-based Exchanges on the federal platform (SBE-FPs). Exchanges are entities, established under the Patient Protection and Affordable Care Act, through which qualified individuals and qualified employers can purchase health insurance coverage in QHPs. Highlights of the final rule include strengthening review and enforcement of unscrupulous broker and agent practices; refining the risk adjustment program to phase out a market pricing adjustment for hepatitis C drugs and to include an HIV pre-exposure prophylaxis affiliated cost factor; increasing user fees in anticipation of the expiration of enhanced premium subsidies under the Inflation Reduction Act of 2022; and improving transparency and public reporting of data on SBEs and SBE-FPs. The provisions of the final rule went into effect Jan. 15 and apply to plan year 2026.
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DEA Plans Special Registration for Telehealth Prescription of Controlled Substances

The Drug Enforcement Administration (DEA) jointly with the Department of Justice (DOJ) released a notice of proposed rule rulemaking (NPRM) that would create a special registration system to allow a patient to receive prescribed controlled substances through telemedicine visits without having an in-person medical evaluation from a medical provider. Comments are due March 18. Specifically, the DEA and DOJ propose three types of Special Registrations for Telemedicine: (1) a Telemedicine Prescribing Registration for authorizing qualified clinician practitioners to prescribe Schedule III-V controlled substances via telemedicine, (2) an Advanced Telemedicine Prescribing Registration for authorizing qualified, specialized clinician practitioners (e.g., psychiatrists, hospice care physicians) to prescribe Schedule II-V controlled substances via telemedicine, and (3) a Telemedicine Platform Registration for authorizing covered online telemedicine platforms, in their capacity as platform practitioners, to dispense Schedule II-V controlled substances. The agencies also propose to maintain a State Telemedicine Registry that requires practitioners who are participating in the Special Registration to document the state where the patient is located. Practitioners who see patients for in-person medical evaluations do not need to register to a telemedicine registry even if providing a prescription through telemedicine for those patients previously seen in person.
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DEA Allows Practitioners to Prescribe Buprenorphine via Telemedicine

The DEA, the DOJ, the Substance Abuse and Mental Health Services Administration (SAMHSA), and HHS released a final rule in which the administration responded to comments submitted on the 2023 Expansion of Buprenorphine Treatment via Telemedicine Encounter proposed rule. Beginning February 18, DEA-registered practitioners may prescribe an initial six-month supply of buprenorphine via audio-visual or audio-only telemedicine encounter. After the initial six-month supply, additional prescriptions of buprenorphine can be issued by the practitioner though a Special Registry or other approved telemedicine encounter. This final rule does not apply to patients who have received an in-person medical evaluation. Additionally, prior to prescribing buprenorphine, practitioners must review the prescription drug monitoring program data in the state where the patient lives and document the date and time of the review or note if the data was unavailable or inaccessible. The pharmacist must then verify the identity of the patient before filling the prescription.

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DEA Allows VA Practitioners to Prescribe Controlled Substances via Telemedicine

The DEA, DOJ, SAMHSA, and HHS Jan. 15 jointly released the Continuity of Care via Telemedicine for Veterans Affairs Patients final rule (PDF), effective Feb.18, that exempts VA practitioners from Special Registrations requirements. Under this final rule, a VA practitioner who is acting within their scope of employment with the VA is permitted to prescribe controlled substances via telemedicine to a VA patient without an in-person medical evaluation if another VA practitioner has previously rendered an in-person visit with the patient. Prior to issuing a prescription via telemedicine for a schedule II-V controlled substance, the VA prescribing practitioner must review and update the patient's VA electronic health record (EHR) and review the prescription drug monitoring program data for the state in which the VA patient is located at the time of the telemedicine visit. The policies in the final rule do not apply to contracted practitioners located outside a VA facility or clinic providing care via the community care network or conducting disability compensation evaluations.

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HRSA Publishes New RRPD Grant Opportunity for Rural GME Startup Costs

The Health Resources and Services Administration (HRSA) published on Jan. 13 a notice of funding opportunity regarding the next round of Rural Residency Planning and Development (RRPD) grants for new rural residency and new rural track programs. The RRPD grant provides awardees up to $750,000 over a three-year period that can be used for the startup costs associated with new residency programs, such as accreditation costs, faculty development, and resident recruitment. Programs in family medicine, internal medicine, preventative medicine, psychiatry, general surgery, and obstetrics and gynecology are eligible for grants. To be considered a rural program, residents must spend greater than 50% of training in an area designated rural by the Centers for Medicare & Medicaid Services or the Federal Office of Rural Health Policy. Applications are due to HRSA by April 10. Additional information about RRPD grants can be found on the HRSA RRPD website.

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HHS Releases Strategic Plan for Use of AI in Health Care

HHS Assistant Secretary for Technology Policy Jan. 10 released a new artificial intelligence (AI) strategic plan (PDF). The plan provides a road map for the use of AI in health care delivery; medical research and discovery; medical product development, safety, and effectiveness; human services; and public health. The strategic plan highlights the agency's goal to be a global leader in advancing health care using AI by prioritizing innovation while emphasizing the importance of quality of care, safety, equity, and patient privacy. Overall, HHS intends to use the strategic plan to prioritize resources, coordinate efforts across agencies, benchmark progress, and signal its priorities to industry, academia, and the public.

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CMS Seeks Feedback on Research Data Request, Access Policy Changes

CMS is seeking feedback from the research community regarding changes to its research data request and access policies, processes, and tools, to ensure it maximizes protections for beneficiary information while also enabling important research using CMS data. In February 2024, CMS announced changes to these policies, including discontinuing the delivery of physical data in support of external research projects and instead requiring researchers to use the Chronic Conditions Warehouse Virtual Research Data Center (VRDC), as well as changes to the fees charged for data. Based on feedback from close to 300 commenters about the detrimental impact of this policy on ongoing and future research, the agency announced these changes would not go into effect until at least 2026. Commenters, including the AAMC (PDF), raised significant concerns with VRDC technical challenges, costs of accessing data, and the timeline for moving projects to the VRDC. To determine the next steps, CMS is seeking input from the research community through specific questions and has stated that it will provide guidance on any policy changes at a later date, ensuring researchers have adequate time to plan.

Comments are due April 14.

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MedPAC Votes on Recommendations for Updates to Physician and Hospital Payment

The Medicare Payment Advisory Commission (MedPAC) met on Jan. 16 and 17 to review a number of status updates and vote on recommendations for payment updates and payment adequacy for physician services and hospital inpatient and outpatient services, in addition to other care settings. Commissioners unanimously voted to approve a two-part recommendation for calendar year 2026 to update the 2025 Medicare base payment for physicians and other health care professionals by the Medicare Economic Index (projected to be 2.3% in 2026) minus one percentage point and establish safety-net add-on payments for services provided to low-income Medicare beneficiaries. The safety-net add-on payment is projected to increase payments by an estimated 1.7%. The combined effect of these two policies would result in an estimated average increase of 3%, or a 5.7% increase for primary care clinicians and a 2.5% increase for all other clinicians.

Commissioners voted to approve the recommendation for fiscal year 2026 to update the 2025 Medicare base payment rates for general acute care hospitals for inpatient and outpatient settings by the amount specified in current law plus 1%. As part of the hospital payment update, MedPAC also approved a recommendation that Congress redistribute existing disproportionate share hospitals and uncompensated care payments through the Medicare Safety-Net Index (MSNI) and add $4 billion to the MSNI pool, as described in MedPAC's March 2024 report.

Related to Medicare Part D, commissioners discussed the implications of the Inflation Reduction Act of 2022 and the interplay between standalone Part D plans and Medicare Advantage (MA). In the MA status update, commissioners discussed enrollment trends, market structure including vertical integration, the quality bonus program, an analysis of coding intensity and favorable selection, and a comparison of MA and fee-for-service spending. MedPAC plans to include chapters in their March 2025 report on the Part D and MA status reports.
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MACPAC Votes on Recommendations and Discusses MOUD and Managed Care Oversight

The Medicaid and CHIP Payment and Access Commission (MACPAC) met on Jan. 23 and 24 to discuss a variety of topics including the utilization of Medications for Opioid Use Disorder (MOUD) in Medicaid and the role of external quality review (EQR) in managed care oversight and accountability. As next steps on its MOUD-related work, the commission will include findings on utilization of MOUD in June 2025 report to Congress, present additional findings from stakeholder interviews, and consider examining the use of prior authorization for MOUD in Medicaid.

Further, commissioners reviewed and approved three recommendations related to the role of external quality review in managed care oversight and accountability, which will appear in their March 2025 report to Congress. The first would direct the Centers for Medicare & Medicaid Services (CMS) to require EQR annual technical reports to include outcomes data and results from quantitative assessments. The second recommendation would direct the CMS to update EQR protocols to reduce areas of duplication with other federal quality and oversight reporting requirements, standardize structure in the annual technical report, and identify key takeaways on plan performance. Lastly, the third recommendation would direct the CMS to require states to publish EQR annual technical reports in a central repository on the CMS website. MACPAC also voted on and approved two recommendations related to home and community-based services (HCBS), including recommending CMS issue guidance on states' use of provisional plans of care and Congress amend the Medicaid statute to increase the renewal period for HCBS programs to 10 years. **STAFF CONTACTS: Shahid Zaman, szaman@aamc.org ; Katie Gaynor, kgaynor@aamc.org**

AAMC COMMENT LETTERS:

AAMC Comments on Contract Year 2026 MA, Part D Proposed Rule

The AAMC submitted Jan. 27 comments (PDF) to CMS in response to the Contract Year 2026 Medicare Advantage (MA) and Part D Policy and Technical Changes proposed. The proposed rule covered various policy topics related to MA and Part D plans, including prior authorization, network adequacy, supplemental benefits and marketing, the use of Artificial Intelligence (AI), Medical Loss Ratio (MLR) reporting, dual special needs plans, Part D plans, and additional policies. The AAMC's comments focused on supporting improvements to transparency and access in MA plans by adopting policies to address narrow provider networks, increased use of utilization management tools such as prior authorization and denials, and lack of transparency in supplemental benefits. Comments also touched on affordability by asking the agency to finalize a proposal to align cost sharing to behavioral health services with Medicare Fee-for-Service. Additionally, the association asked CMS to finalize proposed guardrails for safe and equitable use of AI by MA plans and changes to improve MLR reporting and calculations to improve accuracy. In response to an included request for information on vertical integration, the AAMC urged the agency to monitor the impact of consolidation in the insurer market, including pharmacy benefit managers, and how it may affect the availability of services and providers and quality of care. Related to Part D plans, the AAMC requested that CMS prohibit utilization management practices that are more stringent than corresponding clinical guidelines and increase access to prescription drugs by limiting cost sharing and adopting policies that improve beneficiary affordability. Lastly, the AAMC continued to urge CMS to finalize proposals to streamline enrollment and encourage integration of dual special needs plans.
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RECORDED WEBINAR:
Jan. 28, 2025: Overview: The Increasing Organ Transplant Access Model (IOTA)

UPCOMING WEBINAR:

Webinar Covering Section 126 and 4122 Applications February 12, 2:00 PM EST

The Association of American Medical Colleges (AAMC) will host a webinar to review two opportunities for new Medicare-funded graduate medical education (GME) positions. These slots, available under Section 126 of the Consolidated Appropriations Act, 2021 (CAA) and Section 4122 of the CAA, 2023, will award up to 200 FTEs each to qualifying hospitals, but there are differences between the distribution programs that stakeholders should know prior to submitting applications. This webinar will cover background information for the Section 126 and Section 4122 programs, updates to the distribution methodology for Section 126 rounds four and five, and key differences between Section 126 and Section 4122. Applications are due to CMS by March 31, 2025, and awarded positions will be available starting July 1, 2026.

Registration for the webinar is here. Please reach out to Brad Cunningham (bcunningham@aamc.org) with questions about the webinar.

UPCOMING COMMENT DEADLINES:

Feb. 10, 2025: Advance Notice of Methodological Changes for CY 2026 for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies

Mar. 7, 2025: OCR HIPAA Security Rule to Strengthen the Cybersecurity of ePHI

Mar. 18, 2025: DEA Special Registrations for Telemedicine and Limited State Telemedicine Registrations