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 **August 2025**

ANNOUNCEMENTS:

HRSA Announces Application Process for 340B Rebate Model Pilot Program

The U.S. Department of Health and Human Services (HHS) Health Resources and Services Administration (HRSA) on Aug. 1 announced an application process for a voluntary 340B Rebate Model Pilot Program (PDF). The announcement comes as a response to litigation from drug manufacturers pursuing 340B rebate models in 2024 without prior HHS approval [refer to Washington Highlights, Nov. 22, 2024]. The voluntary program would run for a minimum of one year, be open to applications only from manufacturers with Medicare Drug Price Negotiation Program Agreements for 2026 and apply to a limited set of drugs that are subject to the Medicare Drug Price Negotiation Program. Manufacturers must submit plans by Sept. 15 for approval by Oct. 15 and implementation by Jan. 1, 2026. Under the pilot program, approved manufacturers would be required to pay covered entities rebates within 10 days of claims submission and would be responsible for bearing the costs associated with the program. HRSA is accepting comments for 30 days following the publication, and the AAMC plans to respond. Earlier this year, the AAMC submitted a letter to HHS Secretary Robert F. Kennedy Jr. outlining the association's concerns with the 340B rebate models (PDF) proposed by five drug manufacturers and cautioning the department against adopting rebate models in upcoming guidance [refer to Washington Highlights, May 30].

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AAMC Joins Amicus Brief Urging Appeals Court to Prevent 340B Rebate Models

The AAMC on Aug. 5 joined the American Hospital Association, Children's Hospital Association, and America's Essential Hospitals to file an amicus brief in the U.S. Court of Appeals for the D.C. Circuit supporting the Health Resources and Services Administration's (HRSA's) authority to prevent drug companies from implementing 340B rebate models (PDF). This brief was filed as part of a consolidated appeal in which five drug companies (Johnson & Johnson, Bristol Myers Squibb, Eli Lilly, and Novartis, and Sanofi) appealed the ruling by the U.S. District Court that drug manufacturers must obtain preapproval from HRSA before implementing rebate models under the 340B program [refer to *Washington Highlights*, Nov. 14, 2025, Nov. 22, 2025, March 7].

The brief stated that as the drug companies seek to boost their profits, these rebate policies "will devastate safety-net hospitals, vulnerable patients, and the struggling rural and urban communities they serve." The brief further described how "the rebate policies will require hospitals to float significant sums to drug companies," and "hospitals have reported that they, in turn, will have to restrict or close healthcare services lines, thus directly harming the patients that the 340B program is supposed to help." The brief urged the court to rule that the 340B statute itself bars the drug company rebate models at issue in the case.

The 340B Drug Pricing Program requires pharmaceutical manufacturers to provide outpatient drugs at discounted prices to health care providers that care for many uninsured and low-income patients. Hospitals use 340B savings to expand health services to the patients and communities they service.

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CMS Releases FY26 Inpatient Prospective Payment System Final Rule

The Centers for Medicare & Medicaid Services (CMS) released the Fiscal Year (FY) 2026 Inpatient Prospective Payment System (IPPS) final rule. Provisions go into effect Oct. 1 unless otherwise noted.

CMS finalized a 2.6% increase in payment for items and services paid under IPPS for FY 2026, reflecting an FY 2026 hospital market basket percentage increase of 3.3%, reduced by a 0.7 percentage point productivity adjustment. The agency finalized total uncompensated care-based payments equal to $7.71 billion (up from the proposed $7.14 billion and an increase of $2.07 billion from FY 2025) and empirically justified disproportionate

share hospital payments equal to $4.14 billion in FY 2026 (up from $3.92 billion in the proposed rule). CMS is also discontinuing its low-wage index policy for FY 2026 and beyond and finalizing a narrow budget-neutral transitional policy in FY 2026 for hospitals significantly impacted by the elimination of the policy, similar to what was implemented in the FY 2025 IPPS interim final rule.
For graduate medical education (GME) updates, CMS provided clarification for its policy of calculating full-time equivalent (FTE) counts for cost reporting periods other than 12 months. In a separate rule, the Inpatient Psychiatric Facility PPS, the CMS finalized an increase to the teaching status adjustment factor and a new policy to allow inpatient psychiatric facility FTE cap increases associated with the portion of resident training for awarded positions under Section 4122 of the Consolidated Appropriations Act, 2023 (P.L. 117-328).
The rule finalized several changes to the inpatient quality reporting and value programs, including the removal of quality measures on health equity and social determinants of health, as well asl COVID-19 vaccination, and proposes the inclusion of Medicare Advantage patients in certain existing measures. The rule retained the mandatory Transforming Episode Accountability Model finalized last year that will bundle payment for certain surgical procedures for a subset of selected hospitals beginning Jan. 1, 2026. CMS finalized some modifications to quality measurement in the model, changes to the payment methodology and risk adjustment, expansion of the skilled nursing facility three-day waiver, and removal of the decarbonization and resilience initiative.
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HHS ASTP/ONC Finalizes New Rule on Health Data, Technology, and Interoperability
The HHS Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) included a new final Health Data, Technology, and Interoperability (HTI) rule within the FY26 IPPS final rule issued by CMS. This rule finalized a subset of policies from the HTI-2 proposed rule [refer to *Washington Highlights*, July 12, 2024] and builds form the HTI-2 and HTI-3 final rules issued in December 2025 [refer to *Washington Highlights*, Dec. 20, 2024].
The policies in this rule focus on the ONC's certification standards for health IT modules, including certified electronic health records technology (CEHRT) required for health care providers under various Medicare payment programs. Vendors of CEHRT will have to modify their products to now meet revised conditions for electronic prescribing and adopt new standards for real-time prescription benefit information sharing and electronic prior authorization for providers. More information can be found in the ASTP's fact sheet on the rule (PDF).
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HHS Announces Request for Nominations of Members to Serve on Federal Healthcare Advisory Committee
HHS and CMS together announced on August 21 the establishment of a new Healthcare Advisory Committee along with a request for nominations for members to form the Committee. The advisory committee will focus on developing policy initiatives to promote chronic disease prevention and management, opportunities to reduce regulatory burden to improve safety and outcomes, levers to advance a real-time data system (including rapid claims processing and quality measurement), opportunities to improve quality for the most vulnerable in the Medicaid program, and sustainability of the Medicare Advantage program. CMS Administrator Dr. Oz will appoint 15 individuals to the Committee, based on nominations submitted via the process details in the Federal Register notice. HHS states it is looking for nominations from the provider community, academia, and other sectors with demonstrated expertise in the US health care system. Nominations are due Sep. 22, 2025.
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AAMC COMMENT LETTERS:

COMMENT DEADLINES:
Due Date: September 8, 2025: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program
Due Date: September 12, 2025: CY26 PFS and QPP Proposed Rule

Due Date: September 15, 2025: CY 2026 OPPS Proposed Rule

RECORDED WEBINARS:

- CY 2026 Proposed Rules for the Quality Payment Program (QPP), Shared Savings Program (SSP), and a New CMMI Ambulatory Specialty Model - August 7
- CY 2026 Medicare Physician Fee Schedule Proposed Rule (PFS) - August 19
- CY 2026 Outpatient Prospective Payment System Proposed Rule - August 21

UPCOMING WEBINARS:

- Fiscal Year (FY) 2026 Inpatient Prospective Payment System Final Rule - September 10