

# 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

February 2026

### ANNOUNCEMENTS:

#### **AAMC Urges HRSA to Prohibit New Manufacturer 340B Claims Submission Requirements**

The AAMC sent a Feb. 4 letter to Health Resources and Services Administration (HRSA) Administrator Thomas Engels expressing [the association's concerns with new 340B Drug Pricing Program data collection requirements \(PDF\)](#) imposed by two drug manufacturers. Eli Lilly began requiring 340B covered entities to submit claims-level data for all 340B drugs, including those dispensed through in-house pharmacies, starting Feb. 1. Exelixis imposed a similar requirement that took effect Oct. 1, 2025.

In the letter, the AAMC stressed that data collection requirements are onerous, unlawful under the 340B statute, and usurp HRSA's oversight responsibilities. The AAMC asked HRSA to communicate to drug manufacturers that their actions violate the 340B statute and to use the enforcement mechanisms at the agency's disposal to follow through if manufacturers fail to comply.

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#### **CMS Updates Guidance on State Directed Payments Provision of OBBBA**

The Centers for Medicare & Medicaid Services (CMS) on Feb. 2 issued [updated guidance implementing Section 71116 \(PDF\)](#) of the One Big Beautiful Bill Act (OBBBA, [P.L. 119-21, PDF](#)) related to Medicaid state directed payments (SDPs). This updated guidance replaces previous guidance issued by the agency in September 2025 [refer to [Washington Highlights, Sept. 12, 2025](#)].

Section 71116 reduces the total payment rate for non-grandfathered SDPs to 100% of the Medicare rate for SDPs in expansion states and 110% in non-expansion states for rating periods beginning on or after the July 4 date of enactment of the OBBBA. Grandfathered SDPs can continue to be paid at their current rate, but states must begin to reduce the payment rate for grandfathered SDPs by 10 percentage points each year beginning in 2028.

In the new guidance, the CMS expanded the date range that an SDP must fall within to be grandfathered, stating that a rating period must occur within 180 business days of July 4, 2025 (as opposed to 180 calendar days in the earlier guidance). This will include SDPs in rating periods that include days from Oct. 11, 2024, to July 3, 2025, or July 7, 2025, through March 27, 2026. The CMS' new interpretation will capture SDPs with rating periods occurring in CY 2024 and CY 2026, which were previously ineligible for grandfathering based on the agency's rescinded September 2025 guidance. The CMS further stated that states cannot revise a pending or approved preprint to circumvent the requirements of Section 71116 and the guidance and that SDPs with an application approved before the Feb. 2 date of the letter will be preliminarily grandfathered. For other preprints under review, the CMS stated it will include preliminary feedback in its adjudication letters on whether that preprint is likely eligible for the grandfathering period. The agency noted its plans to issue a proposed rule to further address the topic of SDPs.

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#### **HRSA Issues RFI on Impact of 340B Rebate Model Pilot Program**

On Feb. 13, HRSA released a request for information (RFI) on [the impact of implementing the 340B Rebate Model Pilot program](#). The RFI does not include any specific proposals to modify the program, which the agency originally finalized in 2025 and was subsequently delayed due to litigation [refer to [Washington Highlights, Oct. 31, 2025](#)]. 340B rebate models would require 340B providers to purchase these drugs at significantly higher list prices and then apply for rebates from drug manufacturers. This is a significant departure from the upfront discount on covered drugs the program has offered for over 30 years. Originally the RFI was open for comments for 30 days, with comments due by March 19. This comment period was subsequently extended to April 20.

As part of this RFI, HRSA is seeking input from 340B stakeholders on multiple aspects of the proposed 340B rebate model. Specifically, the agency seeks input on current administrative costs under the upfront 340B discount model

compared to a potential rebate model; anticipated staffing impacts, systems, and infrastructure investments necessary to implement a rebate model; and the impact of a rebate model on payment timing and cash flow for covered entities. Additionally, HRSA also requests feedback in a number of areas related to operational and compliance considerations, including the process for rebate denials, covered entities' data collection related to the 340B program, drug manufacturers' current system for avoiding duplicate discounts, required reporting for manufacturer compliance, and rebates' impact on integrity of the 340B program.

The RFI follows the U.S. District Court of Maine's decision to issue a preliminary injunction on Dec. 29, 2025, against the 340B Rebate Pilot Program, prohibiting implementation of the nine individual rebate program applications [refer to [Washington Highlights, Jan. 9](#)]. The AAMC had partnered with other hospital associations to submit an amicus brief in the case, supporting the plaintiffs' motion for a temporary restraining order [refer to [Washington Highlights, Dec. 12, 2025](#)].  
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### **HRSA Extends 340B RFI Comment Deadline, Issues Information Collection Request**

In response to requests from AAMC and other stakeholders, HRSA [extended by 30 days the deadline to submit comments \(PDF\)](#) on its 340B Rebate Model Pilot Program request for information (RFI) to April 20. In the RFI, HRSA seeks input on potential 340B rebate models on issues including administrative costs, anticipated staffing impacts, systems and infrastructure investments necessary to implement a rebate model, and the impact of a rebate model on payment timing and cash flow for covered entities [refer to [Washington Highlights, Feb. 13](#)].  
[HRSA also issued an information collection request \(ICR\)](#) seeking comments on the burden associated with reporting data under a 340B Rebate Model Pilot Program. Specifically, the agency seeks feedback on the accuracy of its estimates of the burden for drug manufacturers and 340B covered entities to produce required data under a potential rebate model. The agency expects each covered entity to submit 52 responses annually, according to the request, with each response requiring five hours to complete. Comments on the ICR are due April 27.

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### **CMS Issues 2027 Notice of Benefit and Payment Parameters Proposed Rule**

On Feb. 9, CMS issued the [Notice of Benefit and Payment Parameters proposed rule for 2026](#), relating to issuers offering qualified health plans (QHPs) through federally facilitated Marketplace and state-based Exchanges on the federal platform. Exchanges are entities, established under the Patient Protection and Affordable Care Act ([P.L. 111-148, PDF](#)), through which qualified individuals and qualified employers can purchase health insurance coverage in QHPs.

Highlights of the proposed rule include:

- Allowing issuers greater flexibility to offer catastrophic plans for terms of one year or up to ten consecutive years.
- Permitting the use of low-deductible plans with higher out-of-pocket maximums.
- Adding hardship exemptions for individuals 30 years of age or older to allow them to enroll in catastrophic coverage.
- Revising Essential Health Benefits so federal subsidies are not used to cover certain state-mandated benefits.

Making changes to network adequacy and provider access reviews. CMS is accepting comments until March 13.

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### **COMMENT LETTERS:**

#### **AAMC Responds to CMS Proposal to Update Mandatory Kidney Transplant Model**

The AAMC [submitted Feb. 6 comments \(PDF\)](#) to CMS regarding proposed changes to the Innovation Center's mandatory Increasing Organ Transplant Access (IOTA) Model. Recognizing the evolving regulatory landscape broadly impacting the nation's organ transplant system, the AAMC emphasized the need to ensure the model's policies do not create confusion and frustration for patients or impose significant new operational burdens on transplant programs. The letter recommended the agency reconsider updating and revising the IOTA Model's policies or only do so with additional performance periods with no downside financial penalties.

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#### **AAMC Responds to HHS RFI on Accelerating Use of AI in Clinical Care**

The AAMC submitted a [Feb 23 response \(PDF\)](#) to the Department of Health and Human Services (HHS) Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology request for information, “Accelerating the Adoption and Use of Artificial Intelligence (AI) as Part of Clinical Care.” The AAMC’s letter highlighted several examples of how academic health systems utilize AI to enhance care delivery as well as the significant challenges with AI adoption due to the uncertainty around reimbursement and unclear return on investment. The letter also reviewed additional barriers to adoption and use of AI tools including liability concerns, the unclear patchwork of state laws and regulations, interoperability limitations, and privacy and security concerns. The AAMC recommended that the department consider a broad framework for establishing different payment pathways for different tools. The letter also noted several areas of potential research to support the adoption of AI in clinical care, such as implementation science to improve data hygiene and monitoring and evaluation frameworks.

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### **AAMC Submits Comments on Medicare Part B and D Drug Payment Models**

The AAMC submitted comments in response to two new CMS drug payment models aimed to address the provisions of a 2025 executive order focused on lowering prescription drug prices [refer to [Washington Highlight, Dec. 31, 2025](#)]. The Global Benchmark for Efficient Drug Pricing (GLOBE) Model targets certain drugs payable under Medicare Part B if their prices exceed those paid in economically comparable countries. The Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model is similar, but targets certain drugs paid under Medicare Part D. Both are proposed mandatory models with a five-year performance period.

In [response to GLOBE \(PDF\)](#), the AAMC urged the agency to conduct a thorough analysis of any unintended consequences of the model before finalizing the rule, including how the model could interact with other drug pricing policies and potential patient safety concerns. The AAMC requested that CMS address how to implement the model in a way that minimizes imposing administrative burden on providers related to identifying GLOBE model beneficiaries and billing them adjusted coinsurance amounts.

The AAMC’s [response to GUARD \(PDF\)](#) included similar comments but departed from the GLOBE model comments on coinsurance, as the GUARD model did not include a mechanism to address cost sharing for beneficiaries. Instead, comments on the GUARD model raise concerns that, as currently designed, the model may not adequately address prescription drug affordability for patients and could jeopardize the agency’s ability to negotiate on drugs selected for Inflation Reduction Act drug price negotiation, ultimately eroding potential savings. Lastly, comments asked CMS to remove incentives for manufacturers and health plans to engage in white-bagging (in Part B) and brown-bagging (in Part D) in order to preserve patient safety.

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### **UPCOMING COMMENT LETTER DEADLINES:**

- **Due March 13, 2026:** Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2027; and Basic Health Program
- **Due March 30, 2026:** Request for Information (RFI) Related to Comprehensive Regulations To Uncover Suspicious Healthcare (CRUSH)
- **Due March 30, 2026:** Medicare Program; Ensuring Safety Through Domestic Security With Made in America Personal Protective Equipment (PPE) and Essential Medicine Procurement by Medicare Participating Hospitals
- **Due April 20, 2026:** Request for Information: 340B Rebate Model Pilot Program