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AHA Washington Update

A2 Financial Specialists

September 2024

Shannon Wu, Director Payment Policy

Michelle Millerick, Director Coverage Policy

DC's Hottest Drink: The Wolf Spritzer

- No other cocktail embodies summer 2024 like a refreshing spritz mixed with a sense of excitement and dread

Agenda

- Legislative Report
- Regulatory Report

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Key Dates

- **September 9:** Congress returns from summer recess
- **September 10:** (Second) Presidential debate
- **September 11:** Absentee ballots mailed in Alabama
- **September 16:** Early voting begins in Pennsylvania
- **October 1:** Fiscal Year 2024 Funding expires
- **October 1:** Vice presidential debate
- **November 5:** 2024 election
- **Nov / Dec:** Lame Duck session
- **January 2025:** Statutory PAYGO cuts take effect; debt ceiling expires
- **Dec 31, 2025:** ACA premium subsidies and Trump tax cuts expire

Government Funding

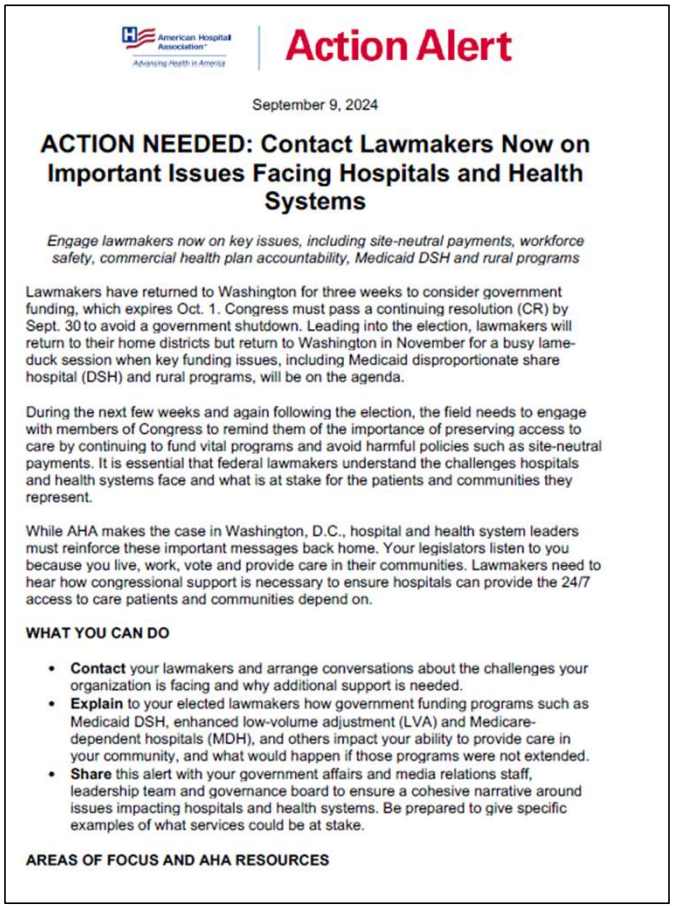
- **House Republicans want a funding bill through March 28**
  - ➢Will attach legislation that would require proof of citizenship to register to vote in a federal election
- **This approach will not be supported by Congressional Democrats and the White House**
  - ➢Think funding level is inadequate
  - ➢Already illegal for non-citizens to vote in federal elections
- **Possible outcome: CR extended into December**
  - ➢May include disaster assistance funding

Health Policy Legislative Tracker

Issue	House	Senate
Site-Neutral Payment (Medicare) Cuts	"Lower Costs, More Transparency Act" Passed House; 12/11/23 "Healthy Competition for Better Care Act;" "Transparent Telehealth Bills Act" Passed Education & Workforce; 9/11/24 (banning hospital contract practices; telehealth facility fees)	"Primary Care and Health Workforce Act" Passed Senate HELP; 9/23/23 (unique Identifier; telehealth and evaluation and management facility fees; banning hospital contract practices)
Hospital Price Transparency	"Lower Costs, More Transparency Act" Passed House; 12/11/23	No action
$35 insulin prices (for all)	No action	No action
Telehealth Waiver	Approved by Ways and Means Expecting action by Energy & Commerce	No action
Hospital at Home Waiver	Approved by Ways and Means Expecting action by Energy & Commerce	No action
Labor-HHS Appropriations	Approved by Appropriations Committee	Approved by Appropriations Committee
PBM Overhaul	Some proposals passed "Lower Costs, More Transparency Act"	Approved by Finance, HELP

AHA's Fall Agenda

- **Reject Medicare (site-neutral) payment cuts**
- **Hold commercial health plans accountable**
- **Prevent Medicaid DSH cuts**
- **Extend MDH / LVA hospital programs**
- **Support hospital at home and telehealth waivers**
- **Enact the Safety from Violence for Healthcare Employees (SAVE) Act**



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Action Alert

September 9, 2024

ACTION NEEDED: Contact Lawmakers Now on Important Issues Facing Hospitals and Health Systems

Engage lawmakers now on key issues, including site-neutral payments, workforce safety, commercial health plan accountability, Medicaid DSH and rural programs

Lawmakers have returned to Washington for three weeks to consider government funding, which expires Oct. 1. Congress must pass a continuing resolution (CR) by Sept. 30 to avoid a government shutdown. Leading into the election, lawmakers will return to their home districts but return to Washington in November for a busy lame-duck session when key funding issues, including Medicaid disproportionate share hospital (DSH) and rural programs, will be on the agenda.

During the next few weeks and again following the election, the field needs to engage with members of Congress to remind them of the importance of preserving access to care by continuing to fund vital programs and avoid harmful policies such as site-neutral payments. It is essential that federal lawmakers understand the challenges hospitals and health systems face and what is at stake for the patients and communities they represent.

While AHA makes the case in Washington, D.C., hospital and health system leaders must reinforce these important messages back home. Your legislators listen to you because you live, work, vote and provide care in their communities. Lawmakers need to hear how congressional support is necessary to ensure hospitals can provide the 24/7 access to care patients and communities depend on.

WHAT YOU CAN DO

- **Contact** your lawmakers and arrange conversations about the challenges your organization is facing and why additional support is needed.
- **Explain** to your elected lawmakers how government funding programs such as Medicaid DSH, enhanced low-volume adjustment (LVA) and Medicare-dependent hospitals (MDH), and others impact your ability to provide care in your community, and what would happen if those programs were not extended.
- **Share** this alert with your government affairs and media relations staff, leadership team and governance board to ensure a cohesive narrative around issues impacting hospitals and health systems. Be prepared to give specific examples of what services could be at stake.

AREAS OF FOCUS AND AHA RESOURCES

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Health Care Issues: "Must Pass"

- **Physician Payment**
- **Medicaid DSH cut relief**
- **GPCI**
- **Ambulance add-on**
- **Telehealth waiver extension**
- **Hospital at home waiver extension**
- **MDH / Low Volume Adjustment**
- **Community health centers funding**
- **Teaching Centers GME**

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Health Care Issues: "Offsets"

- **Medicare site-neutral payment cuts**
- **Requiring unique identifiers for HOPDs**
- **Medicare sequestration**
- **Lab delay (PAMA)**
- **Hospice**
- **PBM reform**
- **Nursing home staffing rule**

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Regulatory Report

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Regulatory Calendar

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2024 Regulatory Calendar

#	Rule Title	Proposed Rule (Actual / expected)	Final Rule (Actual / expected)	Effective Date
	Medicare Payment Rules			
1	FY 2025 Inpatient and LTCH PPS	April 10	Aug. 1	Oct. 1
2	FY 2025 IRF PPS	March 27	Aug. 1	Oct. 1
3	FY 2025 SNF PPS	March 28	Aug. 1	Oct. 1
4	FY 2025 IPF PPS	April 3	Aug. 1	Oct. 1
5	CY 2025 HH PPS	June 26	Nov. 1	Jan. 1, 2025
6	CY 2025 Outpatient and ASC PPS	July	Nov. 1	Jan. 1, 2025
7	CY 2025 Physician Fee Schedule	July	Nov. 1	Jan. 1, 2025
	Medicaid Rules			
8	DSH Third-Party Payer	N/A - Final Rule	Feb. 23	April 23
9	Medicaid FFS Access	N/A - Final Rule	April 22	varies
10	Medicaid MCO Access	N/A - Final Rule	April 22	varies
11	Streamlining the Medicaid, CHIP, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes	N/A - Final Rule	March 27	varies
	Medicare Advantage Rules			
12	2025 MA Final Rule	N/A - Final Rule	April 4	Jan. 1, 2025
13	2026 MA Proposed Rule	Nov. / Dec.	March/April 2025	Jan. 1, 2026
	Commercial Insurance Rules			
14	Short-term Limited Duration Plan Rule	N/A - Final Rule	April 3	June 17
15	2025 Notice of Benefit and Payment Parameters	N/A - Final Rule	April 15	2025
16	Association Health Plan Rules	Dec. 20, 2023	April 30	July 1
17	IDR Operations Rule	N/A - Final Rule	unknown	unknown
18	2026 Notice of Benefit and Payment Parameters	Q3 or Q4	2025	2026
	Behavioral Health Rules			
19	Confidentiality of Substance Use Disorder Patient Records (HHS/SAMHSA) (42 CFR Part 2)	N/A - Final Rule	Feb. 8	implementation April 9, 2024; compliance April 9, 2026
20	HIPAA Notice of Privacy Practices	N/A - Final Rule	April 22	60 days after final rule
21	HHS/Treasury/DOL Requirements Related to Mental Health Parity and Addiction Equity Act	N/A - Final Rule	unknown	unknown
22	Substance Use Disorder Patient Antidiscrimination	unknown	unknown	unknown
	HIT / Admin Simp Rules			
23	CISA Cyber Incident Reporting for Critical Infrastructure Act (CIRCIA) Reporting Requirements	April 4	unknown	Q4 2025
24	HTI-2 - Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability	Q3	unknown	unknown
25	CMS Interoperability and Prior Authorization Final Rule	N/A - Final Rule	Jan. 17	2026 and 2027
26	21st Century Cures Act: Establishment of Disincentives for Health Care Providers who Have Committed Information Blocking	N/A - Final Rule	July 1	July 31
27	Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures, and Modification to Referral and Authorization Standard	N/A - Final Rule	Q3/Q4	unknown
	Additional Rules			
28	Appeal Rights: Changes in Patient Status	Dec. 27, 2023	unknown	60 days after final rule
29	OSHA Emergency Response Standard for Hospital-based EMS	Feb. 5	unknown	unknown
30	Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions	Feb. 8	unknown	unknown
31	Laboratory-developed Tests	N/A - Final Rule	April 29	May 6, 2025 (to begin 4-year phase in)
32	OSHA: Infectious Diseases	unknown	unknown	unknown
33	340B Administrative Dispute Resolution Final Rule	N/A - Final Rule	April 19	June 10
34	Increasing Organ Transplant Access Model	May 17	Sept.	Jan. 1, 2025
35	Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient have not had a Prior In-person Medical Evaluation	July	Oct.	Nov.
36	Long-term Care Nurse Staffing Rule	N/A - Final Rule	April 26	varies
37	Transforming Episode Accountability Model	April 10	Aug. 1	Jan. 1, 2026
38	Draft Guidance on Medicare Drug Price Negotiation (IRA)	May 3	Q3 /Q4	Jan. 1, 2026
39	Mitigating the Impact of Anomalous Increases in Billing on Medicare Shared Savings Program Financial Calculations	June 28	Sept.	Oct.

 | Updated June 2024 | | www.aha.org

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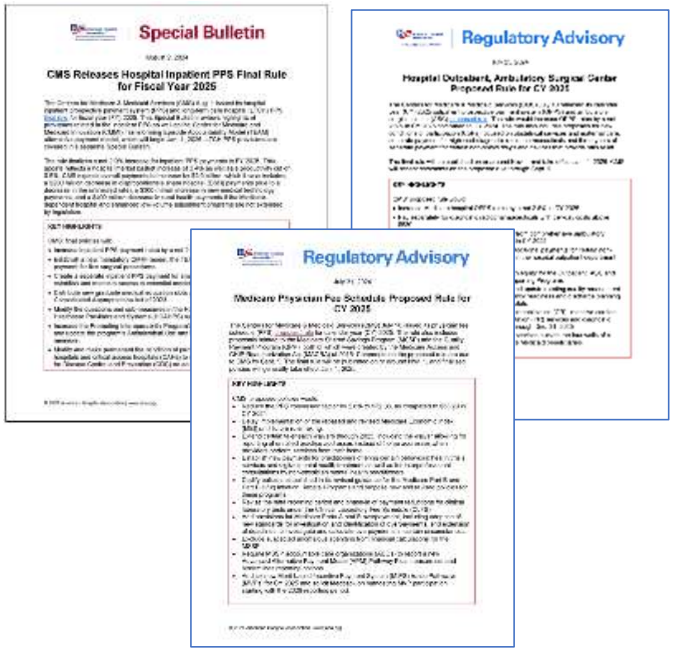
Medicare Payments Still a Challenge

2025 Final and Proposed Rules Have Inadequate Updates

- IPPS Final
  - ➢Payment update 2.9%
  - ➢Decrease in DSH of $200M
- OPPS Proposed
  - ➢Payment Update 2.6%
- Physician Fee Schedule Proposed
  - ➢Reduce conversion factor by 2.8%



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CMS Using CoPs as Policy Lever

Provisions Impose Requirements with Unclear Tie to Outcomes

- **Weekly reporting of respiratory illness data to CDC**
  - ➢Includes inpatient rehab, psych
- **Obstetrical and Emergency Care**
  - ➢Minimum organization, staffing and delivery requirements
  - ➢Emergency readiness standards, regardless of OB
  - ➢Discharge planning
- **Cybersecurity**

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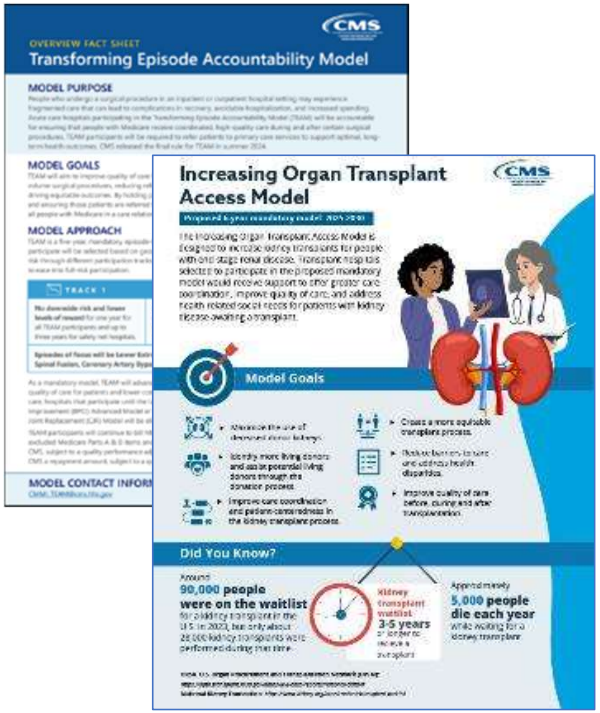
More Mandatory CMMI Models

CMMI Shifting Strategy after Report Finds Government Losses

- Transforming Episode Accountability Model (TEAM)
  - ➢5 years beginning 2026
  - ➢Mandatory for 751 hospitals
  - ➢Lower discount factor; longer glidepath to two-sided risk
- Increasing Organ Transplant Access (IOTA)
  - ➢6 years beginning 2025
  - ➢50% of donor service areas
- MSSP: excluding anomalous vendor spending



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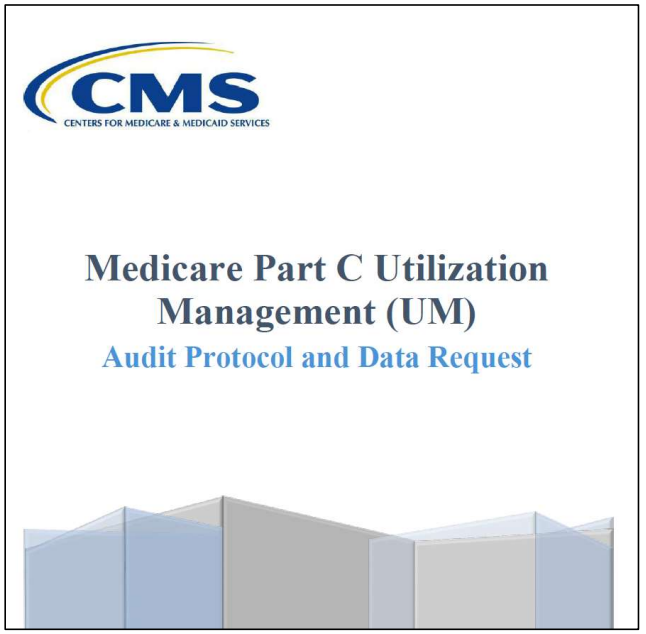
Progress with MA Compliance

Increasing Oversight of Plan Behavior

- **CMS proposed plan for data collection and audit requirements** to evaluate MA plan compliance with CY24 MA Final Rule
  - ➢60 day comment period until Nov. 12



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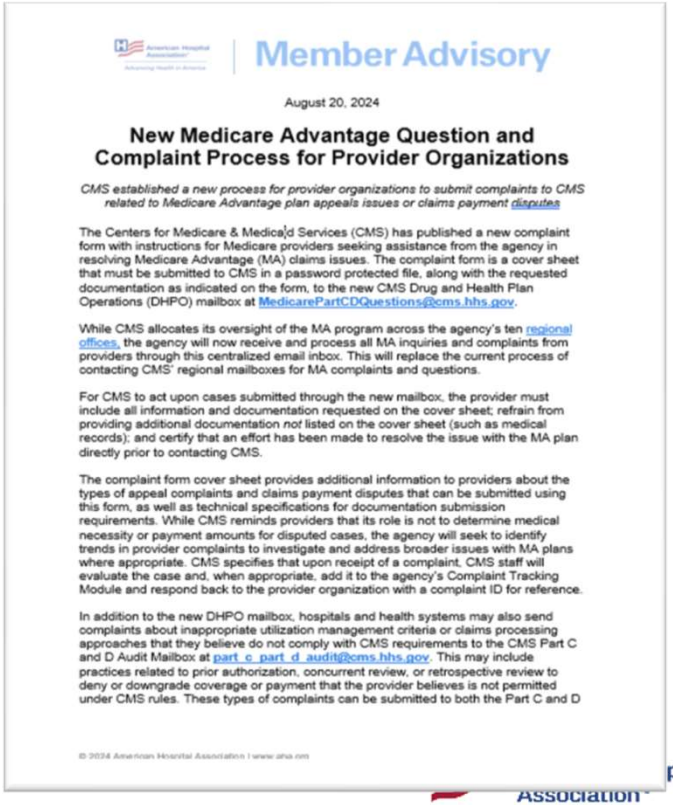
New Medicare Advantage Question and Complaint Process for Providers

- CMS established a new process for provider organizations to submit complaints to CMS related to Medicare Advantage plans

- Details in AHA Member Advisory
  - ➢MedicarePartCDQuestions@cms.hhs.gov
  - ➢Part_C_Part_D_audit@cms.hhs.gov

- Complaints will be tracked in CMS' Complaint Tracking Module
  - ➢# of CTM complaints per 1000 members is a Star Ratings measure for MA plans



Member Advisory

August 20, 2024

New Medicare Advantage Question and Complaint Process for Provider Organizations

CMS established a new process for provider organizations to submit complaints to CMS related to Medicare Advantage plan appeals issues or claims payment disputes

The Centers for Medicare & Medicaid Services (CMS) has published a new complaint form with instructions for Medicare providers seeking assistance from the agency in resolving Medicare Advantage (MA) claims issues. The complaint form is a cover sheet that must be submitted to CMS in a password protected file, along with the requested documentation as indicated on the form, to the new CMS Drug and Health Plan Operations (DHPO) mailbox at MedicarePartCDQuestions@cms.hhs.gov.

While CMS allocates its oversight of the MA program across the agency's ten regional offices, the agency will now receive and process all MA inquiries and complaints from providers through this centralized email inbox. This will replace the current process of contacting CMS' regional mailboxes for MA complaints and questions.

For CMS to act upon cases submitted through the new mailbox, the provider must include all information and documentation requested on the cover sheet; refrain from providing additional documentation *not* listed on the cover sheet (such as medical records); and certify that an effort has been made to resolve the issue with the MA plan directly prior to contacting CMS.

The complaint form cover sheet provides additional information to providers about the types of appeal complaints and claims payment disputes that can be submitted using this form, as well as technical specifications for documentation submission requirements. While CMS reminds providers that its role is not to determine medical necessity or payment amounts for disputed cases, the agency will seek to identify trends in provider complaints to investigate and address broader issues with MA plans where appropriate. CMS specifies that upon receipt of a complaint, CMS staff will evaluate the case and, when appropriate, add it to the agency's Complaint Tracking Module and respond back to the provider organization with a complaint ID for reference.

In addition to the new DHPO mailbox, hospitals and health systems may also send complaints about inappropriate utilization management criteria or claims processing approaches that they believe do not comply with CMS requirements to the CMS Part C and D Audit Mailbox at part_c_part_d_audit@cms.hhs.gov. This may include practices related to prior authorization, concurrent review, or retrospective review to deny or downgrade coverage or payment that the provider believes is not permitted under CMS rules. These types of complaints can be submitted to both the Part C and D

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CMS MA Provider Complaint Process

CMS Office of Program Operations & Local Engagement (OPOLE)

- Oversees Regional Offices
- Responsible for individual casework
- Confirm that you have tried to address issue with the plan first
- Will not intervene in payment/contractual disputes
- Use "Version 5" Complaint Form
- Use for any type of question or complaint

Email Completed Form to:
MedicarePartCDQuestions@cms.hhs.gov

CMS Medicare Parts C and D Oversight and Enforcement Group (MPCDOEG)

- Oversees Audit/Enforcement of MA Plans
- Generally will not solve individual cases but will help to track/trend patterns of problem areas to target audit activity
- Specifically focused on violations of CMS rules (e.g., non-compliant UM criteria)
- No Standardized Form
- Anticipate transitioning to a portal

Email Directly:
Part_C_Part_D_audit@cms.hhs.gov

Consider copying both email addresses

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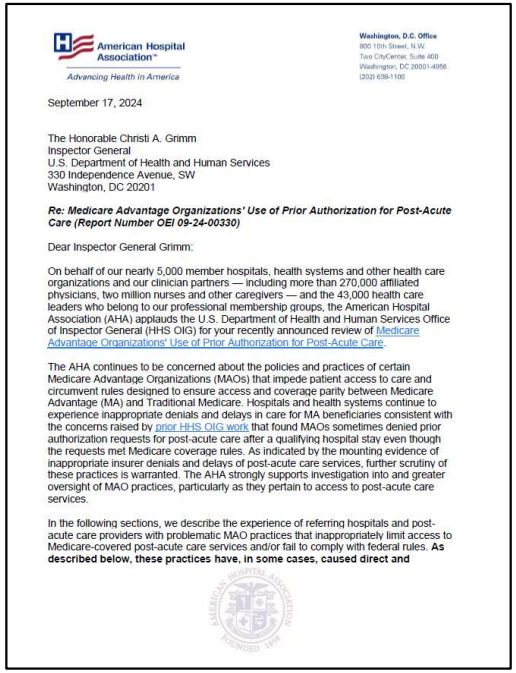
OIG to Investigate Prior Authorization for Post-Acute Care in MA

U.S. Department of Health and Human Services
Office of Inspector General

"Prior OIG work found that MAOs sometimes denied prior authorization requests for post-acute care after a qualifying hospital stay even though the requests met Medicare coverage rules. We will examine selected MAOs' processes for reviewing prior authorization requests for post-acute care in long-term acute care hospitals, inpatient rehabilitation facilities, and skilled nursing facilities. We will also review the extent to which the selected MAOs denied requests for post-acute care and examine the care settings to which patients were discharged from the hospital."



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Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

September 17, 2024

The Honorable Christi A. Grimm
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Advantage Organizations' Use of Prior Authorization for Post-Acute Care (Report Number OEI 09-24-00330)

Dear Inspector General Grimm:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations and our clinician partners — including more than 270,000 affiliated physicians, two million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) applauds the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) for your recently announced review of Medicare Advantage Organizations' Use of Prior Authorization for Post-Acute Care.

The AHA continues to be concerned about the policies and practices of certain Medicare Advantage Organizations (MAOs) that impede patient access to care and circumvent rules designed to ensure access and coverage parity between Medicare Advantage (MA) and Traditional Medicare. Hospitals and health systems continue to experience inappropriate denials and delays in care for MA beneficiaries consistent with the concerns raised by prior HHS OIG work that found MAOs sometimes denied prior authorization requests for post-acute care after a qualifying hospital stay even though the requests met Medicare coverage rules. As indicated by the mounting evidence of inappropriate insurer denials and delays of post-acute care services, further scrutiny of these practices is warranted. The AHA strongly supports investigation into and greater oversight of MAO practices, particularly as they pertain to access to post-acute care services.

In the following sections, we describe the experience of referring hospitals and post-acute care providers with problematic MAO practices that inappropriately limit access to Medicare-covered post-acute care services and/or fail to comply with federal rules. **As described below, these practices have, in some cases, caused direct and**

Announced June 2024 / Report Expected 2026

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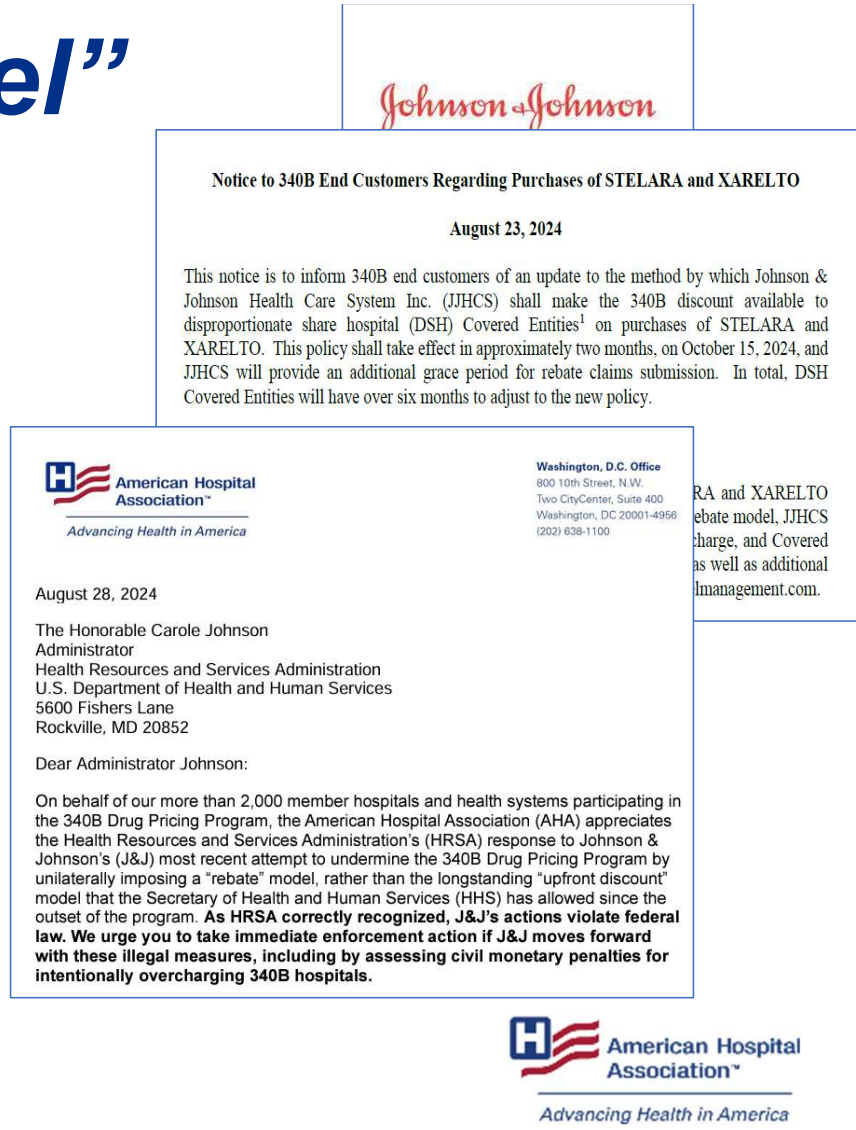
Advancing Behavioral Health

Regulatory Improvements in Payment, Coverage and GME

- Mental Health Parity Final Rule
  - ➢Clear requirements about use of non-quantitative treatment limitations on BH coverage
- Physician Fee Schedule
  - ➢New payments for crisis services, interprofessional consultations for non-MDs
- 200 Medicare-funded residency slots for psych in 2026

J&J 340B "Rebate Model"

- Starting Oct 15, J&J will enforce a new policy where 340B DSH hospitals can only access 340B pricing for Stelara and Xarelto through a back-end rebate instead of an upfront discount
- J&J policy will require hospitals to:
  - Purchase Stelara and Xarelto at full price
  - Submit claims data to J&J
  - Wait for data verification by J&J
  - Receive a rebate for the difference between the amount paid and the 340B price
- HRSA notified J&J that their model requires approval by Secretary of HHS which it was not given
- Aug 28, AHA wrote to HRSA urging the agency to refer J&J to the OIG to impose CMPs for this unlawful policy
- Sept 17, HRSA told J&J that their rebate model violates obligations under the 340B statute and directs J&J to cease implementation
- **All affected hospitals should communicate the potential financial and operational impact to HRSA as soon as possible.**
- Hill strategy and sign-on letter



Johnson & Johnson

Notice to 340B End Customers Regarding Purchases of STELARA and XARELTO

August 23, 2024

This notice is to inform 340B end customers of an update to the method by which Johnson & Johnson Health Care System Inc. (JJHCS) shall make the 340B discount available to disproportionate share hospital (DSH) Covered Entities[1] on purchases of STELARA and XARELTO. This policy shall take effect in approximately two months, on October 15, 2024, and JJHCS will provide an additional grace period for rebate claims submission. In total, DSH Covered Entities will have over six months to adjust to the new policy.

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RA and XARELTO
ebate model, JJHCS
charge, and Covered
as well as additional
lmanagement.com.

August 28, 2024

The Honorable Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Dear Administrator Johnson:

On behalf of our more than 2,000 member hospitals and health systems participating in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the Health Resources and Services Administration's (HRSA) response to Johnson & Johnson's (J&J) most recent attempt to undermine the 340B Drug Pricing Program by unilaterally imposing a "rebate" model, rather than the longstanding "upfront discount" model that the Secretary of Health and Human Services (HHS) has allowed since the outset of the program. **As HRSA correctly recognized, J&J's actions violate federal law. We urge you to take immediate enforcement action if J&J moves forward with these illegal measures, including by assessing civil monetary penalties for intentionally overcharging 340B hospitals.**

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DEA Telemedicine Prescribing of Controlled Substances

- During the PHE, the DEA waived requirements for in-person visits prior to the prescribing of controlled substances via telemedicine
- Last year, DEA released two proposed rules on telemedicine prescribing of controlled substances without a prior in-person evaluation which were overly restrictive
- AHA submitted comments to DEA urging the creation of a special registration process to permanently waive in-person visit requirements
- In response, the DEA extended waivers through 2024
- New proposed rules are at OMB for telemedicine prescribing, but have yet to be released and have the potential to impose more barriers to access
- Given timeline to end of year we will be urging for waiver extensions