HEALTHCARE REGULATORY ROUND-UP - Episode #56

It’s Q&A Day! Trending Topics in Healthcare Regulatory Compliance

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Introductions

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Looming Government Shutdown

Washington's To-Do List

- By September 30 - approve FY2023 funding for all federal agencies or approve short-term spending patch until agreement reached on FY2023 funding
  - Republicans' proposed FY2023 spending is $119 billion less than agreed to in Fiscal Responsibility Act (debt ceiling deal)
  - Senate Appropriations Committee has approved spending bills consistent with FRA provisions
- New wrinkle: FRA requires 1% across the board cut in federal spending if FY2023 funding for all federal agencies is not finalized by 12/31/23
- Consolidated Appropriations Act, 2024?

No Surprises Act – At An Impasse

NSA Litigation Update

- A 4th victory for providers and the Texas Medical Association
- Rulings favorable to providers
  - Use of “ghost” rates
  - Use of specialty rates
  - ERISA plan administrator rates
- Current status
  - Previously submitted IDRs are being processed
  - No new IDRs are being accepted through the portal
  - Impact on patient cost sharing
  - Proposed regulations to be published later this fall

OMB List of Regulatory Actions Currently Under Review

AGENCY: HHS-CMS	**RIN:** 0938-AV15	**Status:** Pending Review	Request EO Meeting
TITLE: Independent Dispute Resolution Operations (CMS-9897)			
STAGE: Proposed Rule	**SECTION 3(f)(1) SIGNIFICANT:** Yes		
RECEIVED DATE: 08/29/2023	**LEGAL DEADLINE:** None		
AGENCY: HHS-CMS	**RIN:** 0938-AV39	**Status:** Pending Review	Request EO Meeting
TITLE: Federal Independent Dispute Resolution Process Fees (CMS-9890)			
STAGE: Proposed Rule	**SECTION 3(f)(1) SIGNIFICANT:** Yes		
RECEIVED DATE: 08/29/2023	**LEGAL DEADLINE:** None		

Federal vs. State Process

- Federal independent dispute resolution (IDR) process applies to disputes involving self-funded plans
  - Except in **Georgia, Maine, Nevada, New Jersey, Virginia, and Washington**, where state law permits self-funded plan to opt into state process
- State law process determines OON rate in disputes involving fully-insured plans in the following states (exceptions apply)
  - **California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Maine, Maryland, Michigan, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, Ohio, Texas, Virginia, Washington**

Price Transparency

Regulatory Developments

- Comments on OPPS proposed rule were due September 11
  - Providers urged to look closely at layout requirements in CMS sample formats for machine-readable files *(https://www.cms.gov/files/document/hpt-machine-readable-file-sample-format-webinar-july-2023.pdf)*
- 10 more providers fined this summer, bringing total to 14
  - https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/enforcement-actions
  - Includes CMS communications with provider regarding fines and penalties

H.R. 5378 - The Lower Costs, More Transparency Act

- Transparency provisions
  - Codifies (with some modifications) existing hospital price transparency requirements
  - Extends certain transparency requirements to diagnostic labs, providers and suppliers furnishing imaging services, ASCs
  - Creates new beneficiary cost sharing and provider rate and payment transparency requirements for group health plans to be implemented by 2026
  - Updates Transparency in Coverage provisions from CAA21 with 2026 compliance date
  - Requires PBMs to provide employers with data on drug acquisition costs, total out-of-pocket spending, formulary placement rationale, and rebate information
- Establishes parity in Medicare payments for off-campus HOPD drug administration services
- Requires separate provider ID for each off-campus outpatient department
- Extends funding due to expire on 09/30/23 for Community Health Centers, National Health Service Corps, Teaching Health Centers Graduate Medical Education Program
- Delays start of Medicaid DSH cuts until FY26

CMS Billing Updates

Validation Edits for Providers with Multiple Service Locations

- Must report service facility location for off-campus, outpatient, provider-based department on claim (2310E loop of the 837i; Form Locator 01 on paper claims)
- CMS will validate service facility location is Medicare-enrolled location
- Enforcement effective August 1
  - Verify that claims data matches that in PECOS
  - Even slightest discrepancies (e.g., “Road” instead of “RD”) may prove problematic

Modifiers JW and JZ

- Release of FAQs by CMS *(https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf)*
- Applies to physicians, hospitals, ASCs, other providers billing MACs for Medicare Part V drugs and biologicals from a single-dose container or single-use package
- JW: reflects discarded amounts of drugs in a single-dose container or single-use package
- JZ: reflects there is no discarded amount from single-dose containers or single-use packages

Modifiers JW and JZ

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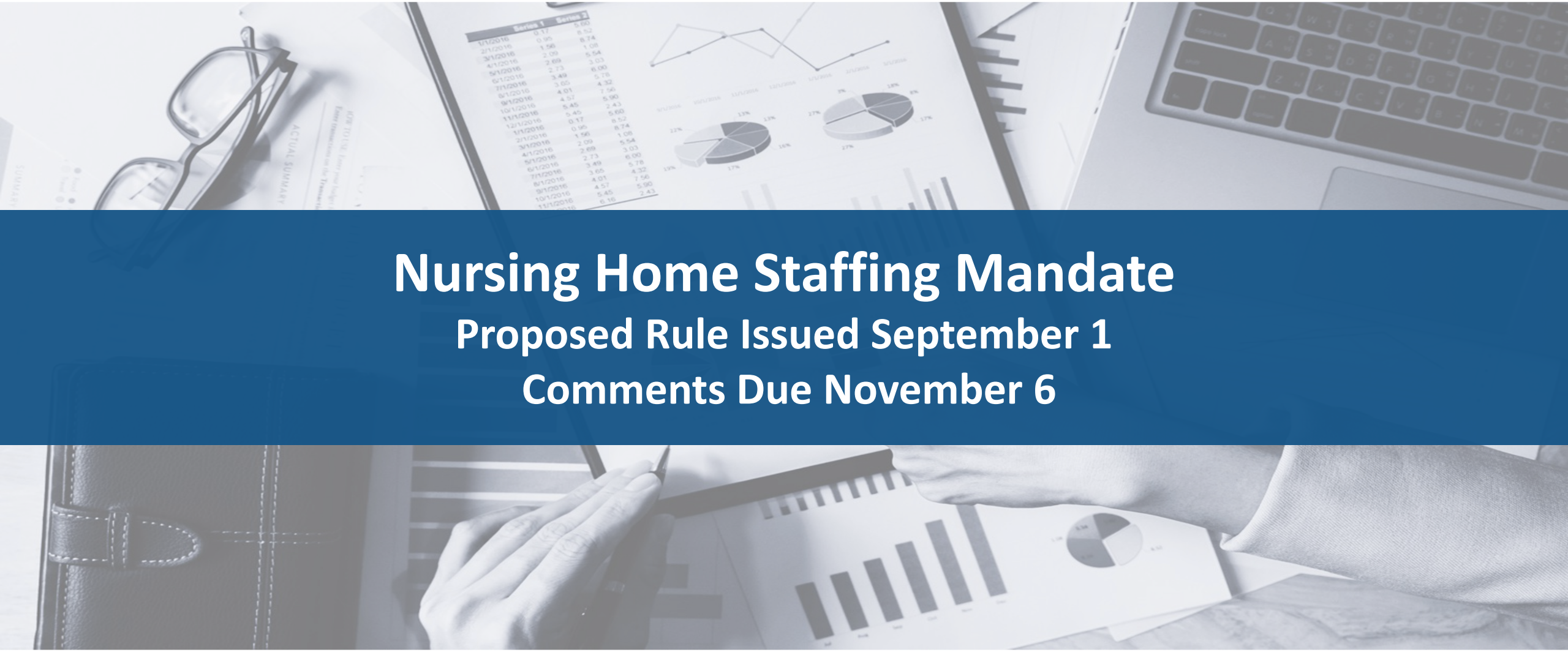
- Applies to physicians, hospitals, ASCs, other providers billing MACs for Medicare Part V drugs and biologicals from a single-dose container or single-use package
- Effective dates:
  - January 1, 2023: You may report the JZ modifier
  - July 1, 2023: You're required to use the JZ modifier on applicable claims
  - October 2, 2023: Claims editing starts when JW or JZ modifiers are not used correctly; claims may be returned as un-processable until properly resubmitted

Reporting Home Address

- Through 12/31/23, practitioner may render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location
  - Infrequent provision of services from home?
- Suppressing personal information on Care Compare website
  - "If your personal information such as phone numbers or addresses is displaying on your Care Compare profile page, send us an email with the correct contact information so we can make a manual edit to your profile page. The manual edit quickly removes this information from the website; however, the manual edits remain in effect for six months only. Therefore, you also need to update this information via PECOS to ensure your personal information will not repopulate in the future. We recommend you make the update as soon as possible."



Nursing Home Staffing Mandate

Proposed Rule Issued September 1

Comments Due November 6

Three Core Staffing Proposals

- Minimum nurse staffing requirements
  - RN - 0.55 hours per resident day (HPRD); nurse aides - 2.45 HPRD
  - Would increase staffing at 75% of facilities nationwide; standard is higher than any state-based requirements
  - Limited exception when workforce unavailable (good faith efforts, financial commitment to staffing, no significant harm resulting from insufficient staffing)
- RN on site 24/7/365
- Enhanced facility assessment requirements
  - Use evidence-based methods in care planning (including residents with behavioral health needs)
  - Use facility assessment to gauge specific needs of each resident; adjust as needed
  - Include facility staff input
  - Develop staffing plan to maximize staff recruitment and retention

Staggered Implementation: Urban Facilities

- **Phase 1** Comply with assessment requirements within *60 days* of final rule publication date
- **Phase 2** Comply with RN onsite 24/7 requirement within *2 years*
- **Phase 3** Comply with minimum HPRD staffing requirements within *3 years*

Staggered Implementation: Rural Facilities

- **Phase 1** Comply with *assessment requirements* within *60 days* of final rule publication date
- **Phase 2** Comply with RN onsite 24/7 requirement within *3 years*
- **Phase 3** Comply with minimum HPRD staffing requirements within *5 years*

Still Waiting . . .

No Timeline for Final Rules

- Standard for Identification Under 60-day Overpayment Rule
  - Knowingly receives or retains overpayment
  - Had been included in proposed MA Policy and Technical Changes for CY2024; CMS indicated it would be subject of separate final rule
- Advancing Interoperability and Improving Prior Authorization Processes
  - Procedural requirements to protect patients/providers
- Nondiscrimination in Health Programs and Activities
  - Revise section 1557 regulations to cover all HHS-administered health programs and health insurance issuers that receive federal funds; mandates policies and trainings
- HIPAA Privacy Rule
  - 2020 proposed rule addressing individual rights, reducing administrative burden
  - 2023 proposed rule updating information blocking requirements
  - 2023 proposed rule on reproductive health care
- Tele-prescribing of controlled substances

OIG Compliance Program Guidance (CPG)

- Between 1998 and 2008, OIG issued CPGs specific to hospitals; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics, and supply industry; hospices; Medicare Advantage organizations; nursing facilities; ambulance suppliers; physicians; and pharmaceutical manufacturers
- In April 2023, OIG announced plans to improve and update existing CPGs and to deliver new industry-specific CPGs
- Nothing new yet…

CMMI Models

Latest Models

- **Making Care Primary Model**
  - Advanced primary care payment model aligned with state Medicaid programs in 8 states
  - Accepting applications through 11/30/23
- **Guiding and Improved Dementia Experience (GUIDE) Model**
  - Funding for care coordination and management to keep individuals with dementia in non-institutional care settings
  - Non-binding letters of intent due September 15; NOFO to be released later this fall
- **States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model**
  - Opportunity for up to 8 states to receive up to $12 million in infrastructure support payments
  - Establish specific goal of increasing statewide primary care investment in proportion to total cost of care
  - Pairing hospital global budgets with advanced primary care
  - Flexible framework to implement advanced primary care in alignment with existing Medicaid primary care program activities

Internal Audit Committee
2024 Priorities

Looking Into Our Crystal Ball

- Price transparency
- Good faith estimates
- Diagnosis coding accuracy
- Provider Relief Fund audits
- Documentation to support virtual direct supervision
- Cybersecurity
- Complexity add-on code
- Modified practices to address site neutrality

OUR NEXT HEALTHCARE REGULATORY ROUND-UP WEBINAR

The Pursuit Is On: Community Benefit

Thursday, September 28