HEALTHCARE REGULATORY ROUND-UP #86

The American Relief Act, 2025

How We Got Here, What It Means, Where We're Headed

January 15, 2025

Introductions

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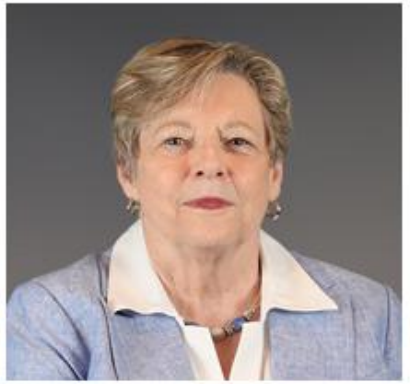

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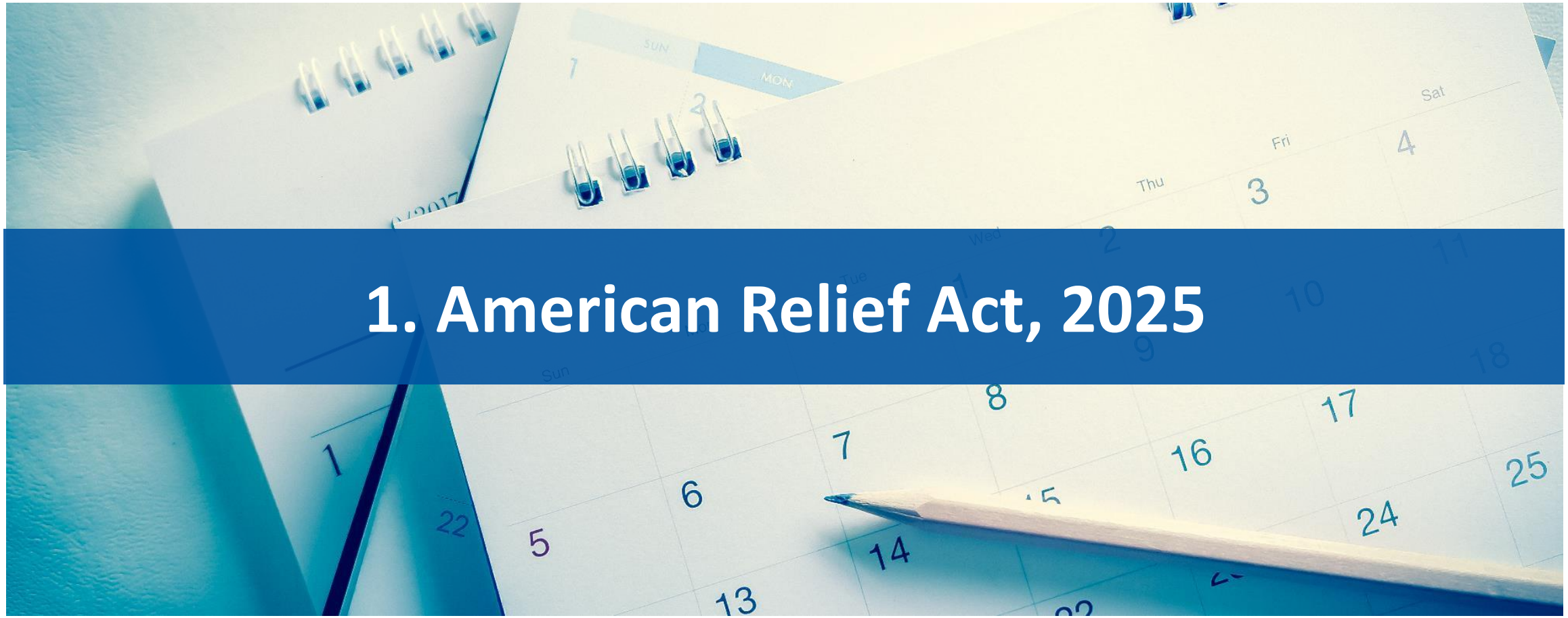
Today's Agenda

1. American Relief Act, 2025
2. So, Now What?
3. CY 2026 Medicare Advantage and Part D Policy & Technical Changes Proposed Rule + Advance Notice
4. Proposed Changes to the HIPAA Security Rule
5. Consumer Financial Protection Board Final Rule on Medical Debt



1. American Relief Act, 2025

National Health Expenditures - 2023

- NHE grew 7.5% to $4.9 trillion, $14,570 per person, 17.6% of GDP
- Medicare spending grew 8.1% to $1.03 trillion (21% of total NHE)
- Medicaid spending grew 7.9% to $871.7 billion (18% of total NHE)
- Private health insurance spending grew 11.5% to $1.47 trillion (30% total NHE)
- Out of pocket spending grew 7.2% to $505.7 billion (10% of total NHE)
- Hospital expenditures grew 10.4% (vs. 3.2% in 2022) to $1.52 trillion
- Physician & clinical services expenditures grew 7.4% (vs. 4.6% in 2022)to $978.0 billion
- Prescription drug spending increased 11.4% (vs. 7.8%) to $449.7 billion

American Relief Act, 2025 – What's In

- Three-month extensions (through 3/31/2025)
  - Temporary changes to low volume hospital payment adjustment
  - Medicare Dependent Hospital program
  - Add-on payments for ambulance services
  - Work geographic practice cost index (GPCI) floor (calculation of MPFS payments)
  - Acute hospital care at home waivers
  - $8B reduction in Medicaid disproportionate share

Medicare Telehealth Coverage Waivers

1. Geographic and originating site restrictions for medical telehealth services
   - Patient must be physically present at clinic or facility located in rural area
   - Restrictions no longer apply to tele-behavioral health services (CAA, 2021)
2. Required in-person visit within 6 months of initiating tele-behavioral health services
3. Expanded list of telehealth providers
   - All providers eligible to bill Medicare vs. physicians and non-physician practitioners only
4. RHCs and FQHCs as distant site providers
   - 2025 MPFS Final Rule – 42 CFR 405.2464(g)
5. Audio-only telehealth services
   - 2025 MPFS Final Rule – 42 CFR 410.78(a)(3)

What's Out

- Reversal of 2.83% cut in MPFS conversion factor
  - Includes hospital services reimbursed under MPFS, e.g., mammography, therapies
- Advanced APM incentive payments for 2025
- Requiring separate NPI and attestation for off-campus hospital outpatient departments
- Site neutral payments for drug administration
- Pharmacy benefit manager regulation

2. So, Now What?

One Big, Beautiful Bill?

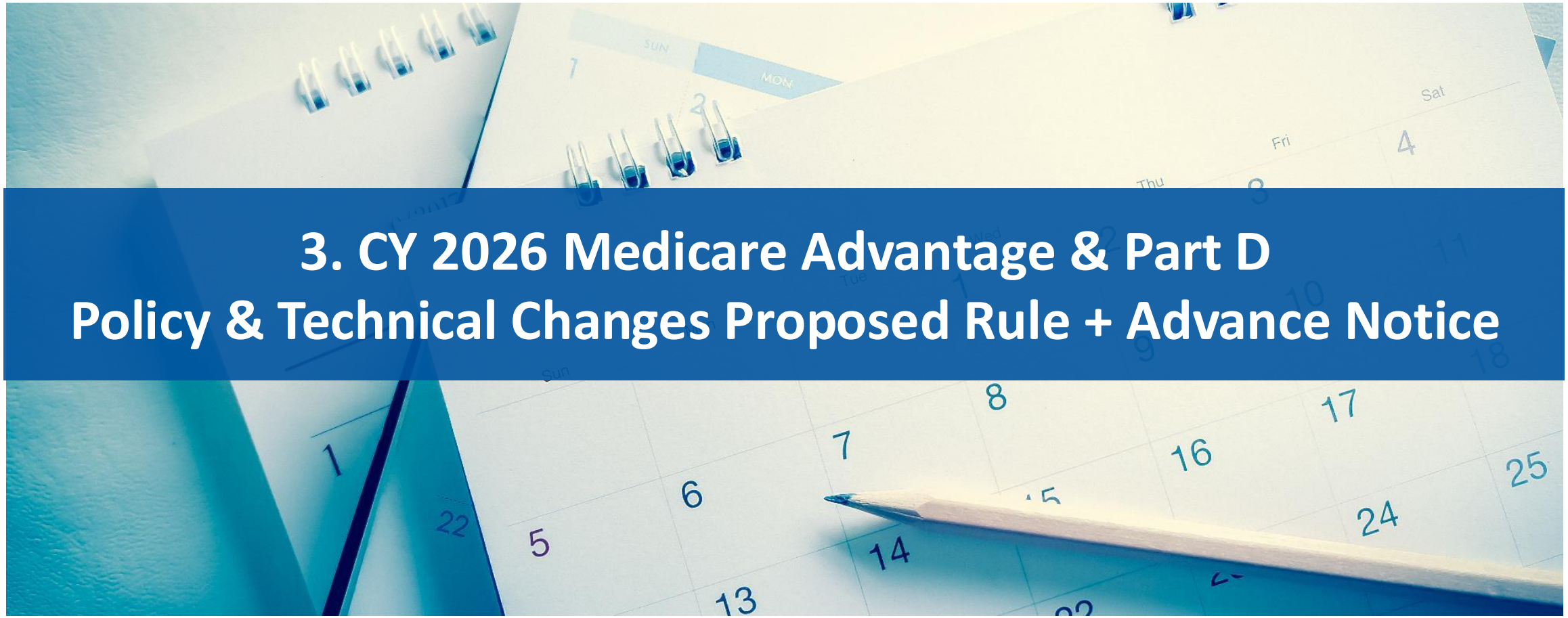
- Use budget reconciliation process to bypass Senate filibuster rules
  - Extension of 2017 tax cuts (set to expire later this year) + eliminate federal taxes on tips
  - Debt ceiling
  - Border security
  - Energy
  - Defense
  - Spending cuts focused on mandatory spending (but will not cut Medicare benefits “in any way or anything”)
- Byrd Rule
  - Cannot affect Social Security program
  - Cannot add to the deficit after 10 years
- On the President’s desk by Memorial Day

Healthcare in the 119th Congress

- Price transparency (more requirements, more penalties)
- Medicare Advantage (expansion vs. regulation)
- ACA repeal (limited benefit insurance coverage)
- Drug pricing
- 340B Program
- Opioid epidemic
- Artificial intelligence
- Rural Emergency Hospital program
- Make America Healthy Again agenda
- Department of Government Efficiency (DOGE) recommendations

What Happens to Biden Administration Regulations?

- Amend or repeal final rules through notice and comment rulemaking
  - Regulations considered “final” if published in *Federal Register* or released for public inspection even if delayed effective date
  - Likely targets: nursing home staffing levels, HIPAA reproductive rights, Section 1557
  - Exception: Under Congressional Review Act, new Congress can rescind regulations finalized after 8/1/24
- Place moratorium on effective date of final rules not yet in effect
  - Allows new administration time to review
  - Typically not applied to rules required under statute or by judicial decision
- Amend or repeal guidance documents
  - Generally does not require notice and comment rulemaking
- Stop, delay, or withdraw proposed rules
  - Issue moratorium on rules under development
  - Medicare Advantage/Part D proposed rule?
- Exercise enforcement discretion



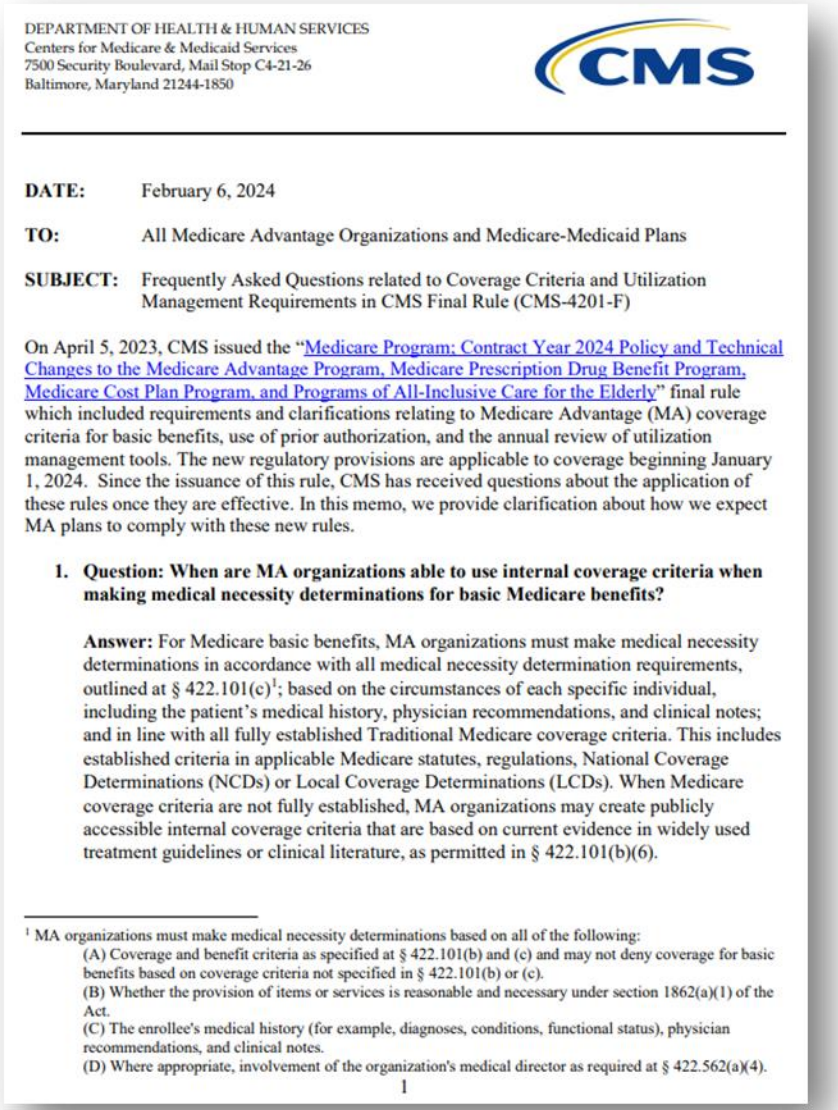
3. CY 2026 Medicare Advantage & Part D Policy & Technical Changes Proposed Rule + Advance Notice

2024 MA & Part D Final Rule (effective 01/01/2024)

1. MA plan must comply with traditional Medicare NCDs, LCDs, and general coverage and benefit conditions
   - Including coverage criteria for inpatient, IRF, and SNF admissions and HHA services
   - Specifically, admissions for surgeries on inpatient only list and admissions meeting two midnight benchmark (but not the two-midnight presumption applied for medical review purposes)
2. If (and only if) coverage criteria not fully defined by above, may establish internal coverage criteria
   - Must be based on current evidence in widely used treatment guidelines or clinical literature
   - Must be publicly accessible (including summary of evidence)
   - Plan must demonstrate additional criteria provide clinical benefits highly likely to outweigh any harm (including delayed/decreased access to care)

Additional Clarification

February 6, 2024, FAQs on coverage criteria and utilization management requirements



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C4-21-26
Baltimore, Maryland 21244-1850

DATE: February 6, 2024

TO: All Medicare Advantage Organizations and Medicare-Medicaid Plans

SUBJECT: Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)

On April 5, 2023, CMS issued the "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" final rule which included requirements and clarifications relating to Medicare Advantage (MA) coverage criteria for basic benefits, use of prior authorization, and the annual review of utilization management tools. The new regulatory provisions are applicable to coverage beginning January 1, 2024. Since the issuance of this rule, CMS has received questions about the application of these rules once they are effective. In this memo, we provide clarification about how we expect MA plans to comply with these new rules.

1. **Question: When are MA organizations able to use internal coverage criteria when making medical necessity determinations for basic Medicare benefits?**

   Answer: For Medicare basic benefits, MA organizations must make medical necessity determinations in accordance with all medical necessity determination requirements, outlined at § 422.101(c)[1]; based on the circumstances of each specific individual, including the patient's medical history, physician recommendations, and clinical notes; and in line with all fully established Traditional Medicare coverage criteria. This includes established criteria in applicable Medicare statutes, regulations, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When Medicare coverage criteria are not fully established, MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature, as permitted in § 422.101(b)(6).

[1] MA organizations must make medical necessity determinations based on all of the following:
(A) Coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not specified in § 422.101(b) or (c).
(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.
(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.
(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

1

https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf

CY 2026 Policy & Technical Changes Proposed Rule

- Published December 10, comments due January 27
- Prior authorizations
  - Cannot deny payment on inpatient admission for which prior authorization was given
  - Tighter standards for internal coverage criteria
  - Requirements regarding enrollee notification of appeal rights
  - Reporting requirements relating to initial coverage decisions and appeals
- Marketing
  - Pre-approval of ‘generic’ MA advertisements
  - New broker disclosure requirements (including higher cost of supplemental plan if return to traditional Medicare)
- Changes to expenses included in medical loss ratio
- Part D coverage for GLP-1s
  - New interpretation of statutory exclusion of agents when for weight loss

CY 2026 Advance Notice

- Released January 10, comments due February 10, final Rate Announcement to be published by April 7 (bids due June 1)
- Projected net increase of 4.33% ($21 billion) in payments to MA plans
  - 5.93% effective growth rate + 2.1% MA risk score trend reduced by -3.01% risk model revision and FFS normalization and -0.69% Star Ratings changes
    - If paused graduate medical education cost adjustment to effective growth rate, would increase payments by $7B
    - If paused full implementation of 2024 CMS-HCC risk adjustment model, would increase payments by $3.4 billion
  - Benchmark payments would increase by 2.23% compared to 0.16% reduction for 2025

4. Proposed Updates to the HIPAA Security Rule

HIPAA Cybersecurity Proposed Rule

- Published January 6, comments due March 7
- HIPAA Security Rule regulations last updated in 2013
- Details new obligations of providers, clearinghouses, health plans, and business associates
- Goal is to *"strengthen cybersecurity by updating the … standards to better address the ever-increasing cybersecurity threats to the health care sector"*
- Effective date = 60 days following publication of Final Rule
  - Compliance date = 180 days following effective date
  - Additional transition period to modify business associate and other written agreements
    - Date such agreement renewed following compliance date
    - One year after effective date

Key Provisions

- Make all implementation specifications “required” with limited exceptions
  - Currently includes “required” and “addressable” specs
- Update definitions and specs to reflect changes in technology and terminology
- Written documentation of all security policies, procedures, plans, and analyses
  - Vulnerability scanning at least once/6 months and penetration resting at least once/12 months
- Development and revision of technology asset inventory and network map on an ongoing basis, but at least every 12 months or in response to system changes
  - Network map details movement of ePHI through electronic information system(s) on ongoing basis
- Backup system to contain exact copies of ePHI that would be ≤48 hours older than the ePHI maintained in regular electronic health systems

Key Provisions

- Disable access of terminated staff ASAP, but ≤ 1 hour following termination
- Require notification of certain regulated entities within 24 hours when workforce member's access to ePHI or certain electronic information systems is changed or terminated
- Establish written procedures to restore loss of specified electronic information systems and data within 72 hours
- Require encryption of ePHI at rest and in transit, with limited exceptions
- Require use of multi-factor authentication, with limited exceptions
- Require use of anti-malware protection
- Require removal of extraneous software from relevant electronic information systems
- Require BA/subcontractor to notify covered entity ≤24 hours after activation of cybersecurity contingency plan
- Require BA/subcontractor to provide written verification once every 12 months of compliance with required technical safeguards

5. Consumer Financial Protection Bureau: Medical Debt

Prohibition on Use of Medical Information

- Consumer Financial Protection Bureau (CFPB) final rule issued January 7
- Consumer credit reporting agency *"generally may not furnish to a creditor a consumer report containing information on medical debt"*
  - Also prohibits lenders from considering medical information in assessing borrowers
- Expected to boost credit scores average of 20 points for those with medical debt
- Challenges to final rule from collections industry
  - Litigation filed in Texas federal court; accuses CFPB of overreach
  - Republicans have criticized CFPB; no nominee to lead agency; Elon Musk: *"Delete CFPB"*
  - Voter issue!!
- Providers' loss of leverage in collecting on unpaid bills

Our Next Healthcare Regulatory Roundup Webinars:

January 30 (Thursday): Building Your Dream TEAM - How to Win Under Episodic Payment Models

February 12: CCM and RPM Update

February 26: Deep Dive Into Proposed HIPAA Security Rule Changes

Thank you for attending!

PYA's subject matter experts discuss the latest industry developments in our popular Healthcare Regulatory Roundup webinar series twice each month.

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