Federal Health Policy Update

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Roadmap

- Association Health Plans (NPRM preview)
- Notice of Benefit and Payment Parameters 2025
 - SBM Minimum Standards
 - Essential Health Benefits
 - Standardized Plans
 - Prescription Drugs
- Transparency In Coverage Rule
- Pharmacy Benefit Managers
- Other issues

AHP Proposed Rule - Background

- 1983: The Erlenborn-Burton Amendment
 - Provided states the authority to regulate MEWAs
- Success of state enforcement
 - State cease & desist orders enable quick closing of unauthorized entities
 - Across same time period, states shut down 41 illegal AHP-selling operations while DOL shut down 3
- Continued issues of fraud & insolvency
 - Between 2000 and 2002, AHP scams affected > 200,000 policyholders
 - Over \$252 million in unpaid medical bills

Source: https://hpi.georgetown.edu/ahp/#_ga=2.140044026.810276806.1692809850-2139153476.1675112314

AHP Proposed Rule – Previous Regulation

"Look Through" doctrine

- Long-standing regulation reiterated by CMS in 2011
- The size of each employer in the association determines whether that employer's coverage is subject to the small group market or the large group market rules

Bona fide associations

- "Rare" exception to the "look through" doctrine
- Combine employees of all employers to attain ACA status as a large group plan, exempt from EHBs and community rating
- Three criteria of bona fide associations: (1) Employers share organizational purposes; (2) Employers have commonalities unrelated to the provision of benefits; and (3) Employers exercise control over the program

AHP Proposed Rule – 2018 Rule & NY Lawsuit

- Executive Order 13813 & "Pathway 2" AHPs
 - DOL rule modified the definition of "employer" to allow more employer groups and associations to form AHPs
 - Easier pathway to bona fide association status to be regulated as large group coverage
 - Permitted sole proprietors to be treated as small employers and join an AHP
- State of New York v. United States Department of Labor
 - Court ruled the DOL exceeded its rulemaking authority under the ERISA
 - Appeal held in abeyance, Biden admin to engage in notice-and-comment rulemaking to revisit the rule

NBPP Proposed Rule – SBM Minimum Standards

- New steps to the process of moving from the federal platform to a state-based marketplace (SBM)
- Centralized eligibility and enrollment platform
- National standards for web brokers and direct enrollment
- Standard open enrollment periods
- Network adequacy minimum standards

NBPP Proposed Rule – Essential Health Benefits

- Remove regulatory provision prohibiting non-pediatric health services as EHB (§156.115(d))
 - Would allow states to add adult dental to EHB benchmark
 - Also remove prohibition on adult vision, home health, and orthodontia?
 - Gives states new flexibility to address unmet health needs and advance health equity
 - See NHeLP Letter to CCIIO on Legal Authorities and Regulatory Changes for Essential Health Benefits

NBPP Proposed Rule – EHB Benchmarking

- Consolidates options for state benchmarks
- Removes generosity standard and revises typicality standard
- Clarifies applicability of EHB benchmark to Basic Health Plans and Medicaid Alternative Benefit Plans

NBPP Proposed Rule-Standard Plans

- Continued Requirement
 - Allowed to have 2 non-standardized for each standard plan
 - Proposes an exceptions process to benefit consumers with chronic and high-cost conditions
 - Patient cost-sharing must be 25% lower than the non-standard plan

NBPP Proposed Rule-Prescription Drug Issues

- All covered drugs in excess of state benchmark are to be considered essential health benefits
- Add Patient Representative to P&T Committees
 - Beginning 2026
- Seek comment on new Drug Classification System
 - From US Pharmacopeia (USP) Medicare Model Guidelines to USP Drug Classification System
- Warn issuers against discriminatory plan design (Letter to Issuers)
 - Placing all or a majority of drugs to treat a condition is presumptive discrimination
 - Will conduct adverse tiering reviews
 - HIV, Hepatitis C, MS, Rheumatoid Arthritis

Transparency In Coverage Rule

- Cost-sharing for services must be available on-line
- In network provider rates and out-of-network allowed amounts on website
- Negotiated rates and historical net prices for prescription drugs in three machine-readable files
 - Enforcement has been delayed
 - CMS announced in September 2023 general delay lifted
 - Will review enforcement on a case-by-case basis

US Congress PBM Updates

- Ownership Disclosures
- Reporting of Compensation, Fees, Rebates
- Spread Pricing Bans
- Beneficiary Cost-sharing
- Rebate Pass Through
- Delink Price of Drug from PBM fees
- Reports to Congress

Other Issues

- No Surprise Act Implementation
- Interoperability Rule- Final Rule
- 1557 Nondiscrimination Rule Final Rule
- Section 504 Disability Protections Rule Proposed Rule
- OTC Coverage of Preventive Services RFI

Questions?

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