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HEALTH & WELFARE PLAN LUNCH GROUP

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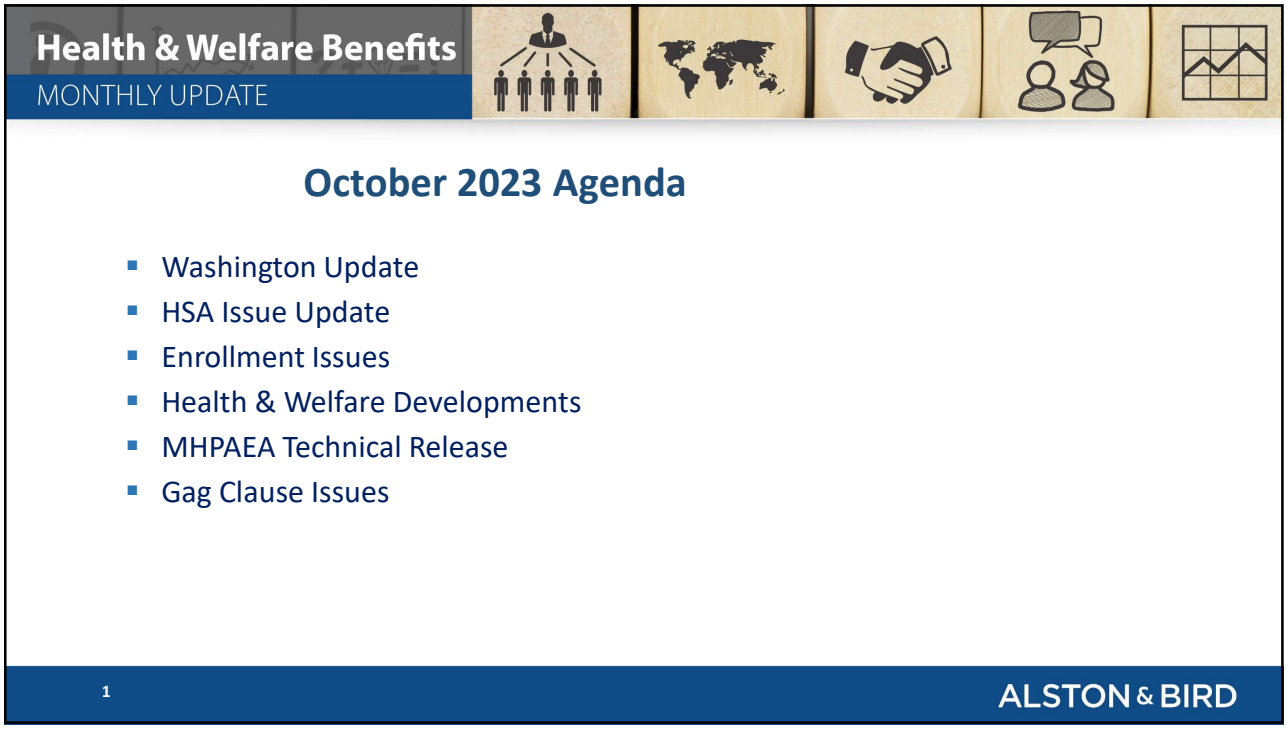
INDEX

ALSTON & BIRD

0



1

Health & Welfare Benefits
MONTHLY UPDATE

WASHINGTON UPDATE

2

Health & Welfare Benefits
MONTHLY UPDATE

General legislative environment - out of the frying pan, into the fire

- Government funding
  - Shut down averted on September 30 (end of the federal fiscal year) by passage of a temporary funding bill through Nov. 17, 2023
  - Shut down once again possible in November if funding is not extended
- House of Representatives in disarray
  - Kevin McCarthy (R-CA) ousted as Speaker of the House
  - Patrick McHenry (R-NC) is temporary Speaker
  - House activity limited until a new Speaker is elected

3

Health & Welfare Benefits
MONTHLY UPDATE

PBM Legislation -- House

- Education & the Workforce
  - H.R. 4507 - Transparency in Coverage Act of 2023 (reported favorably by a vote of 38-1 on July 12, 2023)
  - H.R. 4508 - *Hidden Fee Disclosure Act of 2023* (reported favorably by a vote of 38-1 on July 12, 2023)
- Energy & Commerce
  - H.R. 3561 - *Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act of 2023* (reported favorably by a vote of 49-0 on May 24, 2023)
  - H.R. 3285 - *Fairness for Patient Medications Act* (reported favorably by voice vote on May 17, 2023)
- Ways & Means
  - H.R. 4822 - *Health Care Price Transparency Act of 2023* (reported favorably by a vote of 25-16 on July 26, 2023)

★ House Committees on Education & the Workforce, Energy & Commerce, and Ways & Means
  - HR 5378, Lower Costs, More Transparency Act (introduced September 8, 2023)
  - Combines the work of the three committees

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MONTHLY UPDATE

PBM Legislation – Senate

- Senate HELP Committee
  - S. 1339 - Pharmacy Benefit Manager Reform Act (reported favorably by a vote of 18-3 on May 11, 2023)
- Senate Finance Committee
  - Modernizing and Ensuring PBM Accountability Act (reported favorably by a vote of 26-1 on July 26, 2023)
  - Addresses Medicare Part D only
- Senate Commerce Committee
  - S 127, Pharmacy Benefit Manager Transparency Act of 2023 (approved by the Committee on a bi-partisan basis on March 22, 2023)
  - No new requirements for group health plans; targeted directly at PBMs

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MONTHLY UPDATE

PBM Legislation - Key Topics*

- PBM transparency
  - PBMs are required to report detailed information to plan sponsors
  - Contracts between plans and PBMs cannot limit disclosure of information necessary to make the reports
- PBM compensation disclosure
  - Amends the ERISA compensation disclosure provisions added by CAA 2021 to clarify the PBM compensation that must be disclosed to plan fiduciaries
- Prohibition on gag clauses that would prevent pharmacists from communicating lower cost drug options to patients
- Disclosure of common ownership information to plan sponsors
- Cost-sharing restrictions for "highly rebated drugs"
- Rebate pass through
- Prohibition on PBM spread pricing
- Amendments to health coverage transparency requirements (for plans)
- Hospital pricing transparency
- Changes to current gag clause attestation requirements
- Preemption

*The specifics of each bill varies.

Health & Welfare Benefits
MONTHLY UPDATE

Other legislation

- Cap on insulin cost-sharing
  - Extend Medicare Part D $35 limit on cost-sharing for insulin to the commercial market
  - For example:
    - Affordable Insulin Now Act of 2023, S. 954, introduced by Raphael Warnock (D-GA)(bi-partisan)
    - Affordable Insulin Now Act, HR 1488, introduced by Angie Craig (D-MN)
- Extend Medicare Part D inflation rebates to commercial market
  - Inflation Reduction Act provides that HHS will negotiate prices for certain prescription drugs, and that drug manufacturers must pay a rebate to the federal government if drug price increases exceed inflation
  - Both of these provisions apply only to Medicare Part D
  - Lower Drug Costs for Families Act, S. 1139, introduced by Catherine Cortez Masto (D-NV) would take into account commercial sector drug sales in calculating inflation rebates

Health & Welfare Benefits
MONTHLY UPDATE

Regulations status update

- MHPAEA comment period on proposed rule extended to October 17, 2023
- DOL fiduciary proposed rule under review at OMB since Sept. 8, 2023
- DOL Association Health Plan proposed rule under review at OMB since Sept. 8, 2023
- HHS Notice of Benefit and Payment Parameters for 2025, proposed rule under OMB review since Aug. 24, 2023
- Section 1557 proposed rule -- comment period closed in October 2022 (still waiting for further action)
- DOL employee v. independent contractor classification under the FLSA, final rule under review by OMB since Sept. 28, 2023

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HSA Issues Update

- House W&M Passes HSA Improvement Bills
- HSA COLA Adjustments impact minimum HDHP deductible
- HSA Unclaimed Property/Escheat issues
- DOL fiduciary proposed rule

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MONTHLY UPDATE

HSA Bills Approved By Ways and Means

- Telehealth Expansion Act of 2023, HR 1843
  - Would permanently extend the ability of HSA compatible HDHPs to pay for telehealth and other remote services before the deductible is met
  - The current temporary provision expires for plan years beginning after Dec. 31, 2024
  - Approved by House Ways & Means Committee on June 7, 2023, by a vote of 30-12 (with 5 Democrats voting in favor)
  - The bill is estimated to lose $5 billion over the 10-year budget window
  - Companion Senate bill is S. 1001
- Chronic Disease Flexible Coverage Act, HR 3800
  - Would codify the IRS guidance regarding preventive services in Notice 2019-45
  - The Notice expanded the list of permitted preventive services to include certain treatments for chronic conditions
  - Approved by House Ways and Means Committee on June 7, 2023 (by a vote of 34-6)
  - Estimated to have a minimum impact on federal revenues

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10

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MONTHLY UPDATE

HSA Bills Approved By Ways and Means

On September 28th the Ways and Means Committee approved two HSA improvement measures

- The Bipartisan HSA Improvement Act (HR 5688) would allow:
  Limited direct primary care ($150/month)
  Spouse only FSA (will require that FSAs be able to differentiate spouse expenses) ;
  Limited employer clinics (but employer clinic services somewhat limited)
  FSA/HRA to HSA rollover provision similar to expired provision (would clarify that FSA/HRA conversion to limited purpose FSA/HRA in connection with HSA establishment will preserve HSA eligibility)
- The HSA Act (HR 5687) would:
  Allow HSA for those with VA coverage
  Allow HSA for those with only Medicare Part A, but disallows other medical insurance as permitted HSA expense for post-65 individuals while in Medicare and HSA;
  Allow HSA for those with Native American Health coverage
  Allow HSA for those in bronze and catastrophic plan coverage
  Allow for $500 mental health services below HDHP deductible;
  Address "establishment date issue by allowing 60 days to open HSA;
  Allow age 55 catchup for both spouses;
  Increase HSA contribution to deductible and OOP exposure (up to 7500 individual, 15k family);
  Address use of HSA distribution for LTC expenses

Next steps??

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11

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HSA Unclaimed Property Issues

- State unclaimed property laws generally apply
  - No ERISA preemption
- Majority of laws do not specifically accommodate HSAs
  - Disbursement to state (if required) would be a taxable event
- Steps to limit account dormancy
- Address Unclaimed property obligations in custodial agreement, etc.

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12

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ENROLLMENT

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13

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Enrollment: Areas of Focus

- Annual notices
- SBCs
- SMMs
- Elections

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14

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Annual Notices

- WHCRA Notice
- Primary Care Physician/Patient Protections Notice
  - both grandfathered and non-grandfathered plans (Per the CAA)
  - Does it apply if primacy care physician designations are not required?
- Part D creditable coverage notice
  - Due BEFORE October 15
  - All individuals eligible for Medicare (active and retirees)
- Grandfather Plan notice (if applicable)
- Special Enrollment Notice
  - Is this required annually?
- HIPAA Privacy Notice reminder
  - Due every 3 years BUT . . . . .
  - Most employers send every year so they don't have to track/monitor 3 year rule

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15

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Annual Notices

- CHIPRA
  - Required to be provided to all employees (not just health plan eligibles)
- Illinois Coverage Disclosure Rule
  - Must furnish a chart comparing plan's benefits to Illinois EHB
  - Is this preempted?
- Can you send electronically?
  - HIPAA notices and reminders require advance affirmative consent
  - WHCRA, PCP, CHIPRA, Part D Creditable Coverage
    - Follow ERISA's electronic disclosure safe harbor
- Be mindful of dependents with different addresses
  - E.g. alternate recipients

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SBCs

- Provide with enrollment materials
- If enrollment is provided electronically, SBC may be provided electronically
- Different rules for those currently enrolled and those eligible but not enrolled

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SMMs

- SMMs are often provided during annual enrollment to communicate changes for the upcoming year
- No prescribed format for SMMs
- Be careful about combining annual enrollment materials and SMMs
  - Most annual enrollment materials contain (and should contain) caveat that SPD controls, which could nullify impact of SMM that is included in enrollment materials
  - Participants need to be clear that SMM is intended to supplement current SPD

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Elections

- Clearly communicate benefit options
  - Consequences of not electing
    - No coverage vs. default benefits
  - EOI requirements for those electing life insurance
- Include "125" language
  - If you elect, you cannot change/revoke that election during the year unless you have a change in status event
- Obtain consent for withholding
  - Salary reductions
  - Withdrawals for erroneous HSA contributions
  - Withdrawals for unsubstantiated transactions
- Consider confirmation notices with change period
  - 125 rules do not allow election changes after start of year based on mistake
    - IRS has informally allowed for "clear and convincing" mistake but that is very hard to administer

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HEALTH AND WELFARE DEVELOPMENTS

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20

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ACA Pay or Play Affordability Threshold for 2024

- Pay or play penalty threshold for affordability with be 8.39% for 2024, down from 9.12% for 2023.
- The Federal Poverty Level (FPL) for US mainland will be $14,580 for 2024 and for employers that use the FPL Safe Harbor, the required employee contribution for self-only coverage cannot exceed $101.94 per month, down from $103.28 for 2023.

21

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21

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Request for Information (RFI) OTC Preventive Care

- Departments of Treasury (IRS), Health and Human Services (HHS) and Labor (EBSA) have issued the RFI seeking public input on application of the preventive care services requirement under the ACA to over-the-counter (OTC) preventive items and services such as contraception, tobacco cessation products, and breastfeeding supplies.
- The RFI is seeking comments on the potential benefits, costs, and challenges associated with coverage of OTC preventive items and services without cost share and without a prescription by a health care provider.
- Although no changes are required yet, the Departments may require non-grandfathered group health plans, individual plans, and issuers to cover OTC preventive care items and services with requirements similar to those used for OTC COVID-19 diagnostic tests.
- https://www.federalregister.gov/public-inspection/2023-21969/request-for-information-coverage-of-over-the-counter-preventive-services

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Surprise Billing IDR Process Temporarily Halted

- In *Tex. Med. Ass'n v. United States HHS*, 2023 U.S. Dist. LEXIS 135310, (N.D. Tex. August 3, 2023), the court invalidated:
  - the increased fee to participate in IDR for 2023 $350 (up from $50); and
  - the batching rule that makes it more difficult to batch multiple, qualified IDR dispute items and services to be considered jointly as part of a single determination.
- HHS published proposed regulations addressing the fees associated with the IDR process and the batching rule on September 26, 2023, 2023-20799.pdf (govinfo.gov)
  - Comments are due by October 26, 2023
  - Revised fees will be effective the later of the effective date of the final regulations or January 1, 2024.

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Qualifying Payment Amount (QPA) Calculation in Interim Final Regulations Invalidated

- In the ongoing litigation by the Texas Medical Association, the court, invalidated additional provisions of the interim final regulations on QPA calculations in *Tex. Med. Ass'n v. United States HHS,* 2023 U.S. Dist. LEXIS 149393, (N.D. Tex. August 24, 2023).

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QPA Calculations Continued

- The following areas of the interim final regulations were invalidated by the court:
  - **Contracted Rates**: Issuers and plans when determining contracted rates cannot include "ghost rates" in calculating the QPA – ghost rates are rates for items and services that are not provided, and providers have no intention to provide.
  - **Specialties**: Median contacted rates must be calculated by provider specialty. Issuers and plans cannot include out-of-specialty rates.
  - **Total Maximum Payment**: QPA calculations must include bonuses and incentives.
  - **Self-funded Plans**: Cannot use the median contracted rates based on the TPA's or ASO's book of business.
  - **Single Case Agreements**: Single case agreements must be factored into QPA.

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2024 Cost-of-living Adjustments for H&W Benefits

BENEFIT,	2024	2023
HSA contribution max (including employee and employer contributions)	$4,150/$8,300 Rev. Proc. 2023-23	$3,850/$7,750 in 2023
HSA additional catch-up contributions	$1,000	$1,000
HDHP annual deductible minimum	$1,600 ($3,200 family)	$1,500 in 2023
Limit on HDHP OOP expenses	$8,050 ($16,100 family)	$7,500 ($15,000 family)
ACA limit on OOP expenses	$9,450 ($18,900 family)	$9,100 ($18,200 family)
Limit on amounts newly available under an Excepted Benefit HRA	$2,100	$1,950

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MONTHLY UPDATE

2024 Cost-of-living Adjustments for H&W Benefits Projected

BENEFIT	2024	2023
Health FSA salary reduction max [projected]	$3,200	$3,050
Health FSA carryover max [projected]	$640	$610
Transit and parking benefits [projected]	$315	$300

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MONTHLY UPDATE

Medicare Creditable Coverage

- Medicare Part D notices (either creditable or non-creditable coverage) are due prior to October 15 (October 14th).
  - Notices must be sent to Medicare eligible participants, spouses, and dependents who are covered under or eligible for the plan.
  - Includes all plans - active, retire or a plan for disabled employees.
  - Includes individuals covered under COBRA
- Online disclosure to CMS is due no later than 60 days after the beginning date of the plan year (contract year, renewal year, etc.) and upon change of the plan's creditable coverage status.
- NOTE: prescription drug cost reductions for Medicare enrollees in the Inflation Reduction Act may impact analysis of whether employer sponsored prescription drug coverage is creditable

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Updated CHIP Notice

- The 2023-2024 revised CHIP Notice may be found at: https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/chipra/model-notice.pdf

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Confirm EOI Approval Before Collecting Premiums

- Employers will want to verify Evidence of Insurability (EOI) before premiums are withheld from the employees' pay.
- Investigations into life insurance companies' practices surrounding evidence of insurability are ongoing by the US Department of Labor.
- So far, the DOL has entered into settlement agreements with Prudential Insurance Company of America ("Prudential") and Mutual of Omaha Insurance Company on their practices of accepting premiums and denying claims due to lack of EOI.

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MONTHLY UPDATE

DOL Settlement with Prudential

- The settlement prohibits Prudential from denying claims based on the failure to submit EOI if it has accepted at least three months of premiums for coverage and requires Prudential to notify employers not to collect premiums until EOI has been approved.
- In addition, the settlement provides existing participants additional protections to ensure that coverage is not denied more than a year after they started paying premiums based on insurability, or based on evidence that they were no longer insurable after they first began making premium payments.
- Prudential agreed to reprocess denied claims dating back to June 2019 and provide benefits for the claims previously denied based solely on lack of evidence of insurability.

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MONTHLY UPDATE

DOL Settlement with Prudential Continued

- The settlement also says that after receiving the notice, employers may be liable to the beneficiaries of the policy if the employer collects premiums for an employee or eligible dependent before confirming EOI approval.
- Press release:
  - US Department of Labor reaches settlement with Prudential Insurance Company of America to revise life insurance practices that denied claims | U.S. Department of Labor (dol.gov)
- Settlement Agreement: SOL20230649.pdf (dol.gov)

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MONTHLY UPDATE

DOL Settlement with Omaha

- An investigation by the DOL found Omaha often accepted premiums for years without determining if insurability requirements were satisfied, causing participants and their beneficiaries to believe they had coverage
- After the participant died, Omaha would then often deny claims for benefits on the grounds the company never received the participant's evidence of insurability.
- The settlement gives United 90 days after it receives a participant's first premium payment to determine whether the participant has satisfied any applicable evidence of insurability requirements.
  - After the 90-day period expires, the company cannot deny a claim for life insurance benefits for reasons related to evidence of insurability.
  - These requirements also apply to United's parent company — Mutual of Omaha Insurance Co. — and United's subsidiary, Companion Life Insurance Co.
- Omaha voluntarily reprocessed claims dating back to February 2018 to provide benefits for claims denied based solely on a participant's failure to provide evidence of insurability.
- A copy of the press release and settlement:
  https://www.dol.gov/newsroom/releases/ebsa/ebsa20230929

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MHPAEA Drill Down: Technical Release 2023-01P

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34

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MHPAEA: Technical Release 2023-01P (TR)

- On July 25, 2023, the DOL, on behalf of the Departments, issued Technical Release 2023-01P (TR) along with the 2023 Proposed Rules for Requirements Related to the Mental Health Parity and Addiction Equity Act (MHPAEA)(the "Proposed Rule")
- DOL is requesting comments through the TR for relevant data requirements for the network composition NQTLs
  - Goal is to set forth a specific data-driven approach for assessing whether the network composition NQTLs comply with MHPAEA.
  - Depts envision future guidance to address the type, form, and manner of the data and define standards for specified data elements.
- TR includes a proposal for an enforcement safe harbor

35

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35

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MONTHLY UPDATE

2023 Proposed Rule: Overview

The Proposed Rule has three basic requirements:

- "No more restrictive": MH/SUD NQTLs can be no more restrictive than the predominant NQTL that applies to substantially all Med/Surg benefits within the same classification.
- Design & application: Processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits must be comparable to, and applied no more stringently than, those used in designing and applying the NQTL to Med/Surg benefits within the same classification.
- Outcomes Data: Collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs on access to MH/SUD benefits and Med/Surg benefits. A "material difference" in outcomes represents a "strong indicator" of a NQTL violation generally and establishes an *actual* violation for the network composition NQTL specifically.
  - "Material differences" not defined; comments requested.

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MONTHLY UPDATE

Proposed Rule: Outcomes Data

- In designing and applying a NQTL, the Proposed Rule requires plans to
  - collect and evaluate relevant data to assess impact of NQTL on MH/SUD compared to Med/Surg;
- *All NQTLs.* "Relevant data" includes:
  - number/percentage of claims denials
  - data required by state law or private accreditation standards.
- *Network Composition NQTLs.* Additional data collection includes:
  - in-network and out-of-network utilization rates;
  - network adequacy metrics (including time/distance data, and data on providers accepting new patients); and
  - provider reimbursement rates (including as compared to billed charges).

Technical Release 2023-01P

- The TR notes particular concern and focus by the Depts on network adequacy and finds:
  - "[A] growing disparity in reimbursement rates (as a percentage of Medicare-allowed amounts") between in-network MH/SUD providers and Med/Surg providers.
  - "Participants, beneficiaries, and enrollees must utilize out-of-network providers for MH/SUD benefits significantly more often than when accessing Med/Surg benefits."
- DOL officials have informally said that the TR is the area where they would most appreciate comments. Comment period extended to October 17th.

Technical Release 2023-01P

The TR describes the following four types of outcomes data the Depts are considering for collection and evaluation by plans/issuers for the comparative analysis:

- Out-of-network utilization;
- Percentage of in-network providers actively submitting claims;
- Time and distance standards for MH/SUD as compared to Med/Surg;
- Reimbursement rates of in-network MH/SUD providers as compared to Med/Surg.

For each type of data, Depts may require TPAs to collect and evaluate the data in the aggregate for plans that use the same network or reimbursement rates. Future guidance would specify prospective date for plans/issuers to include the data in the comparative analysis.

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MONTHLY UPDATE

Out-of-Network Utilization

- Depts believe a disproportionately high use of OON MH/SUD providers as compared to OON Med/Surg may be evidence of network composition NQTLs being applied more stringently to MH/SUD. Items and services under Depts' consideration:
  - Inpatient, hospital-based services;
  - Inpatient, non-hospital-based services (for MH/SUD this would include non-hospital-based inpatient and residential treatment facilities);
  - Outpatient facility-based items and services;
  - Outpatient office visits; and
  - Other outpatient items and services.
- Look-back Period: Data would be gathered from the two most recent and complete calendar years that ended at least 90 days prior to the start of the plan/policy year during which the comparative analysis was conducted.
  - Example: for a comparative analysis conducted during a plan year beginning 1/1/2026, plan would be required to collect and evaluate data from calendar years 2023 and 2024.

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MONTHLY UPDATE

Out-of-Network Utilization: Comments Sought

Depts seeking comment on several aspects of proposal and ask 21 separate questions, including:

- How Depts can ensure proposed data is a meaningful representation;
- Should additional data or subsets be added;
- Whether different categories of items or services should be used instead;
- How to present data--% of claims, # of claims, total $ of claims? Something else? What counts as a "claim (multiple lines on one claim)"?
- How to control for OON treatment for which no claim was submitted;
- How to take geographic area into account;
- Analogous data for HMO/EPO/closed network plans and non-traditional networks (e.g., reference-based pricing)

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MONTHLY UPDATE

General: Comments Sought

For out-of-network utilization, as well as all other outcomes data noted in the TR, the Depts also seek comment on:

- Other plan designs that may require additional guidance/alternatives
- Ways that the relevant data could be manipulated to create false appearance of compliance;
- Terminology that needs to be better defined
- Which existing models/methodologies should be used, and their pros/cons

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In-Network Provider Percentage Actively Submitting Claims

- Depts concerned about "ghost networks" not actively providing MH/SUD to participants.
- Depts believe plans should be required to collect/evaluate data on the frequency with which in-network MH/SUD and Med/Surg providers submit claims for unique participants. Relevant data being considered:
  - Percentage of in-network providers who submitted no in-network claims
  - Percentage of in-network providers who submitted claims for fewer than five unique participants
- Look-back Period: Percentage of in-network providers actively submitting claims from the six full calendar months that ended 90 days prior to the month in which the comparative analysis was conducted.
  - Example: For a comparative analysis conducted on 2/1/2026, the plan or issuer would be required to collect and evaluate data from 5/1/2025 – 10/31/2025.

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Types of Providers

Depts contemplate requiring plans to collect and evaluate data for different types of providers and make comparisons between a type of MH/SUD provider and an analogous type of Med/Surg provider. Currently being considered:

- MH/SUD providers: child psychiatrists and psychologists; other psychiatrists and psychologists; psychiatric nurse practitioners; master's level MH counselors, marriage and family therapists, independent clinical social workers, and advanced social workers; non-master's level MH counselors; board certified SUD addiction medicine physicians; and other non-physician SUD professionals
- Med/Surg providers: cardiologists; neurologists; orthopedists; pediatricians; other specialty physicians; physician primary care providers (other than pediatricians); non-physician primary care providers; and non-physician specialty providers

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In-Network Provider Percentages: Comments Sought

Depts seeking comment on several aspects of proposal and ask 16 separate questions including:

- Is data a meaningful representation
- Should provider groups should be categorized differently, and how Depts should approach of the comparison
- Which NQTLs impact % of network providers actively submitting claims and how Depts should analyze data for MHPAEA compliance
- Whether Depts should also require data on the total # of active in-network providers per participant
- How place of service or availability of telemedicine benefits factor into analysis and whether settings for care should be defined
- How to take geographic area into account.
- Whether to include percentage of network providers accepting new patients
- Analogous data for non-traditional network (e.g. referenced-based pricing plans)

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MONTHLY UPDATE

Time and Distance Standards

- Depts are considering requiring the collection/evaluation of data on the percentage of participants who can access, within a specified time and distance by county-type designation, one (or more) in-network providers within certain Med/Surg categories and within MH/SUD categories, such as:
  - MH/SUD: psychiatry, inpatient care, residential treatment, mobile crisis units, opioid treatment providers, child and adolescent providers, geriatric providers, eating disorder providers, and Autism spectrum disorder providers)
- Depts envision using the same county-type designations used for Medicare Advantage plans (e.g.; Large Metro, Metro, Micro, Rural, and Counties with Extreme Access Considerations).
- Look-back period: Collect/evaluate relevant time and distance data for a specified period of time that ended at least 90 days prior to the date a comparative analysis is conducted. Depts request comment on what this specified period of time should be.

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Time and Distance: Comments Sought

Depts seeking comment on 25 separate questions including:

- Whether other measures, such as wait times, should be considered;
- Whether accepting new patients should be a relevant data element, and whether such information is available for collection;
- How to determine where a participant is traveling from and whether availability of public transportation should be considered;
- How to account for difficulties faced by underserved and minority communities;
- How telehealth should factor into the analysis;
- Analogous data for non-traditional network (e.g. referenced-based pricing plans)

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MONTHLY UPDATE

Reimbursement Rates

- Depts state that reimbursement rates for in-network MH/SUD professionals are generally lower than for Med/Surg counterparts. Relevant data under consideration:
  - In-network payments and billed charges for
    - In-patient benefits,
    - outpatient office visits
    - all other outpatient
  - Allowed amounts for CPT codes 99213 (office/outpatient visit 20-29 minutes) and 99214 (office/outpatient visit 30-39 minutes) as well as CPT codes 90834 (psychotherapy 45 minutes) and 90837 (psychotherapy 60 minutes) for specific types of MH/SUD and Med/Surg providers.
- Look-back Period: data from the two most recent and complete calendar years that ended at least 90 days prior to the start of the plan/policy year during which the comparative analysis was conducted.
  - Example: For an analysis conducted during a plan/policy year beginning 1/1/2026, the plan/issuer would be required to collect/evaluate data from calendar years 2023 and 2024.

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MONTHLY UPDATE

Reimbursement Rates: Comments Sought

- Depts seeking comment on 19 separate questions including:
  - Which types of MH/SUD and Med/Surg providers should be considered and which types are appropriate for comparison with the other;
  - Whether "average" charges and amounts be calculated as a mean, median, or mode;
  - How data can account for non-fee-for-service payments, quality incentives, facility fees, or other payments not accounted for in a reimbursement rate;
  - Whether the National Medicare Fee Schedules is helpful for the comparison and, if not, why is it not helpful;
  - How geographic area should be accounted for;
  - Whether a different look-back period should be considered
  - Other CPT codes that would be useful;

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MONTHLY UPDATE

Aggregate Data Collection

- The Depts are considering requiring relevant data in the aggregate by the TPA/service provider for all plans/policies that use the same network of providers or reimbursement rates because. The Depts assume that TPAs and other service providers are already working with self-insured and full-insured plans to document and prepare the comparative analysis.
- Reasoning: (i) plan-level data may have insufficient claims experience to provide enough data and (ii) aggregate data approach would create economies of scale by limiting the number of individualized data sets they would otherwise have to produce.
- Comments requested

Health & Welfare Benefits
MONTHLY UPDATE

Technical Release--Possible Safe Harbor

- TR raises possibility of future safe harbor for the network composition NQTL. If a plan meets or exceeds future specified standards on the four data elements, plan would not be subject to an enforcement action with respect to network composition NQTL for a period of time specified in future guidance.
- Possible safe harbor would be for two calendar years beginning with the time the comparative analysis is requested and would include a "variety of metrics":
  - in-network and out-of-network utilization rates (including data related to provider claim submissions);
  - network adequacy metrics (including time and distance data, and data on providers accepting new patients);
  - reimbursement rates (including as compared to billed charges);
  - Others to be determined.

Health & Welfare Benefits
MONTHLY UPDATE

Technical Release--Possible Safe Harbor

- Depts to conduct ongoing assessment of effectiveness and operation of the safe harbor.
- Depts would retain the ability to update or modify its terms.
- States could adopt a similar enforcement safe harbor with respect to health insurance issuers when the state is the primary regulator of MHPAEA.
- Reliance on proposed safe harbor would be contingent on not making changes that would affect the network composition NQTLs covered by the safe harbor.
- Proposed safe harbor would set a "high bar" but may involve a phased-in approach in which plans can demonstrate progress toward meeting or exceeding the standards over the course of multiple plan years.

Health & Welfare Benefits
MONTHLY UPDATE

Safe Harbor Comments Sought

- What are appropriate standards for each data element;
- Whether relief should still be granted for plans failing all safe harbor standards if improvements can be demonstrated, and how to measure such improvements and determine appropriate time periods;
- Safeguards for extending the safe harbor to plans demonstrating improvement but still not meeting all standards;
- Other requirements to add to safe harbor to protect participants and prevent compliance loopholes.

Health & Welfare Benefits
MONTHLY UPDATE

General Comments Sought

Depts also seek numerous other comments including:

- Challenges in data collection and how to mitigate;
- Whether data elements require information technology systems changes or rebuilds, and what is the cost
- How much time would plans need to establish a data collection system and collect the data
- Should plan-level data be required in addition to the aggregate data
- What other data elements are relevant to network composition

Health & Welfare Benefits
MONTHLY UPDATE

What Should Plan Sponsors Be Doing Now?

- Data collection will be the most challenging aspect of the Rule if finalized.
- Many many unknowns on what the final data collection requirements will be.
- Start discussing now with TPAs/ASOs on the ability to collect the data for the four broad categories even if specifics are not known.
- Does the TPA/ASO have the technology to collect this data?
- Review ASO/TPA agreements and be sure to assign responsibilities for any future data collection requirements.

Health & Welfare Benefits
MONTHLY UPDATE

GAG CLAUSE ISSUES

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56

Health & Welfare Benefits
MONTHLY UPDATE

Guidance on Gag Clauses

- Annual attestations of compliance were required but originally delayed; first attestation covering the period December 27, 2020 to the date of the attestation is due December 31, 2023. System for submitting attestations now open.
- FAQs Part 57 issued on February 23, 2023.
- What is a Gag Clause?
  - Generally, a restriction on providing provider-specific cost or quality of care information to a referring provider, plan sponsors, participants, beneficiaries or enrollees as well as HIPAA business associates.
  - Also includes certain de-identified claims information.
  - Might be found in an agreement between a plan and a health care provider, provider network, TPA or ASO.
  - Example: Contracted rates with providers-- A contract that states rates cannot be provided to participants and beneficiaries.
  - Example: Discretion of TPA—A contract that states that plan sponsor access to provider cost and quality of care information is at the discretion of the TPA.

57

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57

Health & Welfare Benefits
MONTHLY UPDATE

Guidance on Gag Clauses—Annual Attestations

- Who must submit?
  - Health insurance issuers offering group health insurance coverage;
  - Health insurance issuers offering individual health insurance coverage, including student health insurance coverage and individual health insurance coverage issued through an association; and
  - Fully-insured and self-insured group health plans, including ERISA plans, non-Federal governmental plans, and church plans subject to the Internal Revenue Code.
    - Includes grandfathered and grandmothered plans.
- Self-funded plans can enter into an agreement with service providers (TPAs, ASOs, PBMs) to submit on their behalf but the responsibility/liability remains with the plan.
- Insurer/ASO can submit on behalf of itself, fully insured group health plan, and self-insured group health plans but must coordinate with the plans to prevent duplication.
  - For fully insured, both plan and insurer have an obligation but submission by the insurer on behalf of the plan will satisfy both.

Health & Welfare Benefits
MONTHLY UPDATE

Guidance on Gag Clauses—Annual Attestations

- Who doesn't have to submit.
  - Plans/insurers offering only excepted benefits.
  - Certain governmental benefits/plans (Medicare, Medicaid, CHIP, TRICARE, Indian Health service).
  - No enforcement against HRAs.

Health & Welfare Benefits
MONTHLY UPDATE

HR 5378: Future Changes to Attestation Requirement?

- HR 5378 introduced in the House on September 8, 2023
- Proposes changes to Gag Clause attestation that would limit attestations to plan fiduciaries or issuers and restrict plans/issuers from entering into agreements with TPAs to attest on behalf of plan/issuer
- Proposes an exception for plans/issuers that can not obtain info/data necessary for attestation
- Requires DOL to report (among other things) on the status of de-identified claims and encounter information, including whether changes to regulations or guidance would deem the info/data a plan asset, and whether restricting a fiduciary's access violates current law.
- Too soon to tell whether this bill will pass as-is, but shows that there is an awareness of these issues.

Health & Welfare Benefits
MONTHLY UPDATE

Guidance on Gag Clauses—Mechanics

- Visit https://hios.cms.gov/HIOS-GCPCA-UI to submit the attestation.
- Visit https://www.cms.gov/cciio/programs-and-initiatives/other-insurance-protections/gag-clause-prohibition-compliance to to review instructions, a user manual, as well as an Excel template for providing information required as part of the attestation.
- Attestation language is set as part of the process and displays without opportunity to modify. Attests that the plan or issuer "will not enter into an agreement, and has not, subsequent to December 27, 2020, entered into an agreement…" that violates the gag clause prohibition.
- Appears to only apply to agreements subsequent to December 27, 2020 with no affirmative requirement to amend prior agreements. But gag clause compliance necessary for any agreement after December 27,2020 or likely any agreement renewed or amended after that date.
- HR 5378: https://docs.house.gov/billsthisweek/20230918/H5378_sus_xml.pdf

Health & Welfare Benefits
MONTHLY UPDATE

Questions

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62