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HEALTH & WELFARE PLAN LUNCH GROUP

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October 2024 Agenda

- Regulatory Update
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Regulations Status Update

Recently Finalized Rules

- DOL-EBSA Final Rule for **Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021**; received at OMB July 1, 2024; comment period for proposed rule ended Oct. 17, 2023; First released on Sept. 9, 2024 and published in FR on Sept. 23, 2024.
- HHS-CMS proposed rule **Notice of Benefit and Payment Parameters 2026**; received at OMB July 17, 2024; proposed rule issued on Oct. 4, 2024; to be published in the FR on Oct. 10, 2024.
  - Stated the intent of HHS, DOL and Treasury to propose future rulemaking to align standards applicable to large group market health plans and self-insured group health plans with those applicable to individual and small group market plans.
  - This would result in treating Rx covered by the plan in excess of the EHB-benchmark plan as EHB for purposes of lifetime and annual limits and the annual limitation on cost sharing.
  - At issue is the applicability of drug manufacturer support to the annual limitation on cost sharing (as raised in *HIV and Hepatitis Policy Institute et al. v. U.S. Department of Health and Human Services et al.*, Civil Action No. 22-2604 (D.D.C. Sept. 29, 2023))

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Recently Finalized Rules

- DOL **Definition of "Employer"--Association Health Plan** Notice of Proposed Rulemaking to rescind 2018 AHP Rule (December 20, 2023); comment period ended February 20, 2024; Final Rule published in FR on April 30, 2024.
- DOL Proposed Rule on **Definition of an Investment Advice Fiduciary** and Proposed Changes to Related PTEs (Nov. 3, 2023); comment period ended Jan. 2, 2024; Final Rule published in FR on April 25, 2024.
- HHS Office of Civil Rights (OCR) Final Rule on the **HIPAA Privacy Rule and Reproductive Health Care** (Apl. 17, 2023); comment period ended June 16, 2023; Final Rule published in FR on April 26, 2024.
- HHS-OCR Proposed Rule on **Nondiscrimination in Health Programs and Activities (1557)** (Aug. 4, 2022); comment period ended October 2022; Final Rule published in FR on May 6, 2024.

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At the Office of Management and Budget

- HHS-CMS proposed rule for **Enhancing Coverage of Preventive Services under the Affordable Care Act**; proposed rule received at OMB Aug. 30, 2024; no sign of final rule for HHS-CMS final rule at OMB for **Coverage of Certain Preventive Services Under the Affordable Care Act** (published Feb. 2, 2023).

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Disaster Relief Filing Extensions

Deadlines vary depending upon the disaster and locality. Details on all recent disaster relief for presidentially-declared disasters are on the Around the nation page on IRS.gov. Currently:

- Taxpayers in parts of Arkansas, Florida, Iowa, Kentucky, Mississippi, New Mexico, Oklahoma, Texas and West Virginia have until **Nov. 1, 2024**, to file their 2023 tax year return.
- Taxpayers in all or parts of Connecticut, Florida, Illinois, Kentucky, Louisiana, Minnesota, Missouri, New York, Pennsylvania, Puerto Rico, South Dakota, Texas, Vermont, Virgin Islands and Washington state have until **Feb. 3, 2025**, to file their 2023 tax year returns.
- Taxpayers affected by Helene in all or parts of Alabama, Florida, Georgia, North Carolina, South Carolina, Tennessee and Virginia will have until **May 1, 2025**, to file their 2023 tax year returns.

- The IRS automatically provides filing and penalty relief to any taxpayer with an IRS address of record located in the disaster area. The DOL automatically recognizes these extensions for Form 5500 filing. Visit https://www.irs.gov/newsroom/tax-relief-in-disaster-situations for more information.

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Compliance Reminders

- **HSA/Telehealth Extension Ends for Plan Years beginning on or after January 1, 2025**.
  - Generally, telehealth services provided before the statutory minimum HDHP deductible (except for permissible coverage like preventive care or permitted insurance/coverage) can cause a loss of HSA eligibility.
  - CARES Act enacted during COVID allows pre-HDHP deductible coverage for telehealth and other remote care services. This provision has been extended twice.
  - Currently, no legislation has been passed to further extend or make permanent the CARES Act provision that allows pre-HDHP deductible coverage for telehealth and other remote care services for plan years beginning after December 31, 2022, and before January 1, 2025.
  - Non-calendar year plans may still extend pre-HDHP deductible to telehealth coverage into 2025 so long as the plan year began after December 31, 2022, and before January 1, 2025.
- **Medicare Notice of Creditable Coverage due by Oct. 14, 2024.**
  - Entitled to a notice if (i) enrolled in Medicare Parts A or B or (ii) lives in a service area of a Part D plan.
  - Not limited to retiree plans. Active employees (or their spouses) can be enrolled in Medicare Part A or Part B and the employer would have no way of knowing.

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Compliance Reminders—Annual Notices

- **Summary of Benefits and Coverage (SBC)**: Provide at initial and annual enrollment to all eligible employees.
- **HIPAA Special Enrollment Notice**: Provide at or before the time an eligible employee is first offered an enrollment opportunity in the health plan.
- **Women's Health and Cancer Rights Act Notice**: Upon enrollment,
- **HIPAA Privacy Notice**: Provide to individuals upon enrollment in Medical, Dental, Vision, Health FSA, and EAP. Every 3 years must notify covered individuals that a privacy notice is available and how to obtain it.
- **COBRA General/Initial Notice**: Provide to covered individuals within 90 days after coverage under begins.
- **CHIPRA (Children's Health Insurance Program Reauthorization Act)**: Provide to ALL employees.

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MHPAEA FINAL RULE

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MHPAEA Final Rule

- Issued on September 9, 2024 by the Departments of Labor, Treasury and Health and Human Services (Departments).
  - Over 9,500 comments submitted on the July 2023 Proposed Rule
  - Final Rule is 536 pages.
  - Primarily focused on requirements for nonquantitative treatment limitations (NQTLs) and the codification of the requirement to perform a NQTL comparative analysis as mandated by the Consolidated Appropriations Act, 2021 (CAA).
- No court challenges yet, but expected based on the Supreme Court's decision in *Loper Bright*.

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Changes from Proposed Rule

- Major Changes
  - Did not finalize the mathematical substantially all/predominant test as it applies to NQTLs. Still applies to quantitative treatment limitations (QTLs).
  - Did not finalize the special rule regarding data collection for network composition NQTLs.
- Other Changes
  - Modified the fiduciary certification of a NQTL comparative analysis.
  - Added a "core treatment" component to the "meaningful benefit" requirement.
  - Modified how generally recognized independent professional medical or clinical standards and measures detect or prevent and prove fraud waste and abuse are applied.
  - Did not (as of yet) adopt a data collection safe harbor for network composition NQTLs
  - Provided further detail on what is considered information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder (MH/SUD) benefits as compared to medical and surgical (Med/Surg) benefits.

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Effective Dates

- Generally effective for the plan year beginning on or after January 1, 2025.
- The following have an effective date of the first day of the plan year beginning on or after January 1, 2026.
  - The meaningful benefits standard,
  - The prohibition on discriminatory information used in the design and application requirement, and
  - The relevant data evaluation requirement
- Any aspect of the comparative analysis that requires disclosure or analysis of these provisions are also not appliable until the first day of the plan year beginning on or after January 1, 2026. All other provisions regarding the comparative analysis are effective January 1, 2025.

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NQTL Background

- 2013 final rule
  - Standards for QTLs and NQTLs. Rules on QTLs largely still intact from the 2013 final rule.
- CAA
  - Added the requirement for a NQTL comparative analysis requirement.
  - NQTL comparative analysis required as of February 10, ***2021***
- FAQs Part 45 in April 2021 provided guidance the content of a NQTL comparative analysis.
- July 2023 Proposed Rule on NQTLs and the NQTL comparative analysis.

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The 2013 Final Rule

QTLs and NQTLs are subject to separate provisions within the 2013 Rule.

- **QTLs** that apply to MH/SUD benefits are required to be "no more restrictive" than the "predominant" QTLs that apply to "substantially all" Med/Surg benefits in a classification (the "substantially all/predominant test").
  - "substantially all" means at least two-thirds
  - "predominant" means more than one-half
- Six benefit classifications: inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs.
  - Outpatient subclassifications allowed for office visits, in-network subclassification allowed for tiered networks
- NQTLS are subject to a "comparable to/no more stringently than" rule with respect to the application of any processes, strategies, evidentiary standards, or other factors as compared to Med/Surg benefits in the same classification.
  - 2024 Final Rule and CAA provide guidance/rules on what it means to be comparable to and no more stringently applied.

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Final Rule Overview: Two Basic Requirements

- Design and Application Requirement
  - The 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.
- Relevant Data Evaluation Requirement
  - Collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs on access to MH/SUD benefits relative to access to Med/Surg benefits. A "material difference" in outcomes represents a "strong indicator" of a NQTL violation. Under the Proposed Rule there was a special rule for network composition NQTLs finding an *actual* violation for material differences. ***The special rule for network composition NQTLs was not finalized.***

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Separate No More Restrictive Requirement Not Finalized

- The No More Restrictive Requirement from the Proposed Rule ***Was Not Finalized***
  - Under the Proposed Rule an NQTL that applies to MH/SUD benefits can be no more restrictive than the predominant NQTL that applies to substantially all (2/3) Med/Surg benefits within the same MHPAEA benefit classification. "Predominant" means "most common or frequent".
  - Similar to the current requirement for QTLs.
  - Much push back in comments to the Proposed Rule.
    - Mathematical test for something that was inherently nonquantitative.
    - Would not further the purpose of the Proposed Rule,
    - Exceeded the Departments authority,
    - Unworkable
  - Likely Departments also had concerns with this requirement not withstanding judicial scrutiny under *Loper Bright.*

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Stated Purpose of the Final Rule

- MH/SUD benefits are not subject to more restrictive lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all Med/Surg benefits covered by the plan.
- Plans must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to MH/SUD benefits under the plan than they impose on access to Med/Surg benefits in the same classification.
- All statutory and regulatory provisions with respect to MHPAEA should be interpreted in a manner consistent with the stated purpose

Note: Although the statement of purpose may appear broad and generic, it evidences the Departments' intent to take a "holistic" approach to enforcement to make sure that there is actual parity in operation--requiring a plan to establish that it provides appropriate access to MH/SUD benefits. Focus is especially on access to ***in-network*** *MH/SUD benefits*

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New Definitions

- Mental health and substance use disorder benefit definitions:
  - New definition limits effect of state law
  - Specifically requires the definition to align with "generally recognized independent standards of current medical practice"—i.e., most current versions of the Diagnostic and Statistical Manual of Mental Disorders (DSM) or the International Classification of Diseases (ICD)
  - Final rule gives further guidance on the appropriate versions of the ICD and DSM and the timing on the required use of any new versions.

The preamble specifically mentions autism spectrum disorder (ASD) and eating disorders as MH/SUD conditions based on the DSM and/or ICD. In the past some plans have tried to classify these conditions as Med/Surg based on state law. In addition to ASD, the preamble calls out anorexia, bulimia, and binge eating disorder as MH/SUD conditions. Finally, the preamble notes that gender dysphoria is currently listed as a MH/SUD condition in both the ICD and DSM and therefore subject to MHPAEA

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New Definitions

- New definitions for "factors," "processes," "strategies," and "evidentiary standards"
  - All terms were used in 2013 Rule but not defined.
  - All terms are used in the CAA for the NQTL comparative analysis requirement.
- NQTLs: Limitations "(such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan."

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New Definitions

Factors: all information, including processes and strategies (but not evidentiary standards), that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan.

Processes (a type of factor): actions, steps, or procedures a plan uses to apply NQTL, including actions, steps, or procedures established by the plan as requirements for a participant to access benefits.

Strategies (a type of factor): practices, methods, or internal metrics that a plan considers, reviews, or uses to design an NQTL.

Evidentiary standards (not a type of factor): any evidence, sources, or standards that a plan considered/relied on in designing/applying a factor for an NQTL, including specific benchmarks or thresholds. May be empirical, statistical, or clinical in nature.

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Factors

Factors: all information, including processes and strategies (but not evidentiary standards), that a plan considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan. Include but not limited to:

- provider discretion in determining a diagnosis or type or length of treatment;
- clinical efficacy of any proposed treatment or service;
- licensing and accreditation of providers;
- claim types with a high percentage of fraud;
- quality measures;
- treatment outcomes;
- severity or chronicity of condition;
- variability in the cost of an episode of treatment;
- high cost growth;
- variability in cost and quality;
- elasticity of demand;
- geographic location.

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Processes—a type of Factor

Processes: actions, steps, or procedures a plan uses to apply NQTL, including actions, steps, or procedures established by the plan as requirements for a participant to access benefits. Examples:

- procedures to submit information to authorize coverage for item/service prior to receiving or while treatment is ongoing (including requirements for peer or expert clinical review);
- certain referral requirements;
- development and approval of a treatment plan;
- specific procedures used by plan to administer the application of NQTL, such as
  - how a panel of staff members applies the NQTL (including qualifications of staff, allocation of number of staff and time),
  - consultations with panels of experts in applying the NQTL, and
  - the degree of reviewer discretion in adhering to criteria hierarchy when applying an NQTL.

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Strategies—a type of Factor

Strategies: practices, methods, or internal metrics that a plan considers, reviews, or uses to design an NQTL. Examples:

- Development of clinical rationale used in approving/denying benefits;
- Method of determining whether or how to deviate from generally accepted standards of care in concurrent review;
- Reliance on treatment guidelines;
- Selection of information deemed reasonably necessary to make a medical necessity determinations;
- Rationales used in selecting/adopting certain threshold amounts to apply to NQTLs:
- Professional standards and protocols to determine utilization management standards;
- Fee schedules used to determine provider reimbursement rates as part of a NQTL;
- Method of determining the composition of the staff, representatives or service providers that deliberate, or otherwise makes decisions, on the design of a NQTL--including the qualifications of staff involved, number of staff members allocated, and time allocated;
- Consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a NQTL.

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Evidentiary Standards—*not* a type of factor

Evidentiary standards: any evidence, sources, or standards that a plan considered/relied on in designing/applying a factor for an NQTL, including specific benchmarks or thresholds. May be empirical, statistical, or clinical in nature, and include:

- Sources acquired/originating from objective 3rd party, such as:
  - recognized medical literature, professional standards and protocols (e.g., comparative effectiveness studies, clinical trials),
  - published research studies
  - payment rates for items and services (e.g., publicly available databases of UCR rates)
  - clinical treatment guidelines
- Internal plan or issuer data, such as
  - Claims/utilization data/criteria for assuring sufficient mix/number of network providers
- Benchmarks or thresholds, such as:
  - measures of excessive utilization
  - cost levels
  - time or distance standards
  - network participation percentage thresholds

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NQTLs: Six Classifications

- Final Rule reinforces that the following classifications should be used for NQTLs in addition to QTLs:
  - Inpatient, in-network
  - Inpatient, out-of-network
  - Outpatient, in-network
  - Outpatient, out-of-network
  - Emergency care
  - Prescription drugs
- Permitted outpatient subclassification for office visits and permitted inpatient subclassifications for network tiers.
- Proposed Rule clarifies that there are ***no other permitted classifications*** or subclassifications.
- Telehealth/virtual care is not a permitted classification or subclassification. Different co-pays often apply to telehealth raising some QTL issues. Limitation of availability of telehealth for MH/SUD conditions can raise NQTL issues.

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NQTLs: Limitations Which Otherwise Limit the Scope or Duration of Benefits

***Non-Exclusive* List (Departments declined to provide an exclusive list).**

- Medical management standards:
  - Prior authorization
  - Medical necessity or medical appropriateness
  - Experimental or investigative
- Formulary design for prescription drugs
- Network tier design
- ***Standards related to network composition***
  - ***Standards for provider and facility admission to participate in a network or for continued network participation***
  - ***Methods for determining reimbursement rates***
  - ***Credentialing standards***
  - ***Procedures for ensuring the network includes an adequate number of each category of provider and facility***
- Methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges
- Fail-first policies or step therapy protocols
- Exclusions based on failure to complete a course of treatment
- Restrictions based on geographic location, facility type, provider or specialty and other criteria that limit the scope or duration of benefits for services provided under the plan.

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The Design and Application Requirement

- An NQTL cannot be imposed "under the terms of the plan as written and in operation" unless any ***processes***, ***strategies***, ***evidentiary standards***, or other ***factors*** used in designing and applying the NQTL to MH/SUD benefits in the classification are comparable to, and are applied no more stringently than, the ***processes***, ***strategies***, ***evidentiary standards***, or other ***factors*** used in designing and applying the NQTL with respect to Med/Surg in the classification.
- Nearly identical to 2013 Final Rule—the term "designing" has been added to the Final Rule to align with the CAA NQTL comparative analysis requirement.

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The Design and Application Requirement

- Plan cannot rely on information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against MH/SUD benefits as compared to Med/Surg benefits.
  - Facts and circumstances test. Final Rule provides a non-exclusive list of facts and circumstances.
- Proposed Rule had a specific exceptions that independent professional medical or clinical standards and fraud, waste, and abuse measures would be considered nondiscriminatory.
  - The exceptions were not finalized but the Final Rule states that " generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse ***that minimize the negative impact on access to appropriate [MH/SUD] benefits*** are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against [MH/SUD] benefits as compared to [Med/Surg] benefits.
  - These standards and measures are still subject to the Final Rule generally.
  - Final Rule eliminates the word "waste" in fraud waste and abuse finding that the word "waste" was overbroad.
- The Final Rule also provides two examples of using discriminatory or biased evidence or sources of information noting, in one example, how to correct any past impermissible use
- Plan cannot rely on data prior to when the plan was subject to MHPAEA.

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Relevant Data Evaluation Requirement

- In designing and applying a NQTL, the Final Rule requires plans to
  - collect and evaluate relevant data to assess impact of NQTL on access to MH/SUD benefits as 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 (including data relative to provider claims submissions);
  - network adequacy metrics (including time/distance data, and data on providers accepting new patients); and
  - provider reimbursement rates (for comparable services as benchmarked to a reference standard).

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Relevant Data Evaluation Requirement

Preamble provides the following examples for network composition NQTLs which is a major focus of the Final Rule:

- For in-network and out-of network utilization, compare the ratio of inpatient, in-network and outpatient, in-network MH/SUD and Med/Surg claims to inpatient, out-of-network and outpatient, out-of-network MH/SUD and Med/Surg claims.
- The number of providers (or facilities) within specified MH/SUD and Med/Surg provider categories (or categories of facilities) per 1,000 participants and beneficiaries who have actively submitted claims within the past 6 months.
- Comparing MH/SUD and Med/Surg turnaround time for applications to be approved for a provider to join the plan's network as well as approval and denial rates for applications to join the network;
- Percentage of participants and beneficiaries who have access, within a specified time and distance by one (or more) in-network providers who are available to accept new patients comparing MH/SUD providers and Med/Surg providers;
- Median in-network MH/SUD and Med/Surg reimbursement rates for services with the same CPT codes;
- Median in-network reimbursement rates for inpatient MH/SUD and Med/Surg benefits, as compared to Medicare rates;
- Median in-network reimbursement rates for outpatient MH/SUD benefits, and Med/Surg benefits, as compared to Medicare rates.

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Relevant Data Evaluation Requirement

- Other than the few examples in the Final Rule itself and examples provided in the preamble, the Departments declined to provide a list of relevant data for NQTLs
  - Facts and circumstances approach.
- Preamble promises future guidance on "the data required and the lists of examples of data that are relevant across the majority of NQTLs, as well as additional relevant data for NQTLs related to network composition." This will also include an update of the MHPAEA Self-Compliance Tool to provide a "robust framework and roadmap" for plans to determine which data to collect and evaluate.
- Final Rule takes a very dim view of plans asserting there is no relevant data. Recognizes it is possible for a new NQTL, but comparative analysis must explain why there is no data, and when data will be gathered once it is available. For other NQTLs justifications in the comparative analysis for no data must be even more robust. One example in the Final Rule finds a violation of the comparative analysis requirement when a plan asserts there is no data.

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Relevant Data— "Material Differences"

- *All NQTLs.*
  - If analysis of outcomes data reveals "material differences" in access to MH/SUD as compared to Med/Surg, the Proposed Rule states this is a "strong indicator" of MHPAEA violation.
  - Must take "reasonable action" to correct and document those mitigation efforts.
  - Discussion of reasonableness of action would be part of the NQTL comparative analysis.
- ***Separate standard for network composition NQTLs not adopted in the Final Rule.***
  - Proposed Rule provided that "material differences" in access to MH/SUD as compared to Med/Surg is, in fact, a MHPAEA violation.

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Relevant Data— "Material Differences"

- Data outcomes are material if, based on facts and circumstances, it suggests that the NQTL is likely to have a negative impact on access to MH/SUD benefits in comparison with Med/Surg benefits.
- Facts and circumstances may and include the following:
  - The terms of the NQTL,
  - The quality or limitations of the data,
  - Causal explanations and analyses,
  - Evidence as to the recurring or non-recurring nature of the results, and
  - Magnitude of any disparities.
  - ***This is a non-exclusive list***
- Plans may consider other relevant factors that are not specifically listed in the Final Rule including that differences in access to MH/SUD benefits is attributable to independent professional medical or clinical standards or fraud and abuse measures.
- That materiality standard generally would not include a de minimis difference in access or a difference driven by an outlier, such as a single plan participant's claims experience or a single claim.

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Relevant Data— "Material Differences"

- Plans should explain in their comparative analyses whether differences are, or are not, statistically significant and why such differences were determined to be, or not to be, material.
- The Final Rule does not require a plan to obtain a statistical, actuarial, or other equivalent opinion to support a conclusion as to whether a difference are material.
  - And, the Departments note that statistical significance may not always be the appropriate standard.
  - If a plan does obtain an expert opinion, then as part of the comparative analysis, the plan should document the relevance of that opinion to its conclusions on materiality. The expert's qualifications must be documented as part of the comparative analysis as well.

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Relevant Data— "Material Differences"

- If there are material differences, then plans must take corrective action that needs to be described in the comparative analysis.
- Departments believe that plans already might be taking action to expand network of MH/SUD providers because of pressure from plan sponsors as well as participants and beneficiaries.
- The Final Rule provides an illustrative list of possible actions the Departments expect plans to take, to address any material differences in access with respect to a network composition NQTLs. They include but are not limited to:
  - Increase compensation or other inducements,
  - Streamline credentialing processes,
  - Contact out-of-network to offer participation in the network,
  - Expand the availability of telehealth arrangements;
  - Provide additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities,
  - Ensure that provider directories are accurate and reliable.

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Meaningful Benefits Requirement

- 2013 Rule: If a plan provides MH/SUD benefits in any classification, those benefits must be provided in every classification.
- Final and Proposed Rule: If a plan provides any benefit for a MH/SUD condition or disorder in any classification of benefits, the plan must provide "meaningful benefits" for that condition or disorder in each classification where Med/Surg benefit are offered as determined in comparison with those Med/Surg benefits.
- Final Rule adds a "core treatment" requirement to meaningful benefits.
- Core treatment is defined as a "standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice."
- If there is no core treatment with respect to a MH/SUD condition, then a plan must still provide benefits for the condition in every classification that Med/Surg benefits are provided.
- The preamble to the Final Rule notes that there is no specific requirement on what constitutes a core treatment, and it might not necessarily be a single item or service but could be a "suite" of services.
- Four examples of "meaningful benefits" are provided in the Final Rule.

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A NQTL Cannot Apply Exclusively to MH/SUD Benefits

- A NQTL Cannot Apply Exclusively to MH/SUD Benefits.
- Statutory requirement that was not specifically mentioned in the 2013 Rule.
- Specific in both the Proposed Rule and Final Rule.
- Two examples given in the Final Rule.

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NQTL Comparative Analysis

- ***Substantial*** reorganization and additions to the NQTL comparative analysis.
  - There are six broad requirements with numerous subparts.
    1. Description of the NQTLs;
    2. Identification and definition of the factors used to design or apply the NQTLs;
    3. Description of how the factors are used in the design and application of the NQTL.
  - The fourth and fifth requirements are a descriptions of comparability and stringency of the NQTL as written (4th) and in operation (5th) which would incorporate the relevant data evaluation requirement.
    - Requires significant detail on "material differences" in data and actions taken by the plan if there are material differences.
    - Justifications and safeguards if a plan is asserting that data is not available nor not yet available.

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NQTL Comparative Analysis

- Sixth requirement is findings and conclusions.
  - Must contain a fiduciary certification.
  - Proposed Rule would have required a fiduciary to certify the results for ERISA-covered plans.
  - Final Rule requires that a fiduciary must confirm engagement in a prudent process to select one or more qualified service providers to perform and document a comparative analysis as well as satisfaction of the duty to monitor those service providers.
    - In the preamble DOL stated that it does expect that a plan fiduciary will, at a minimum, review the comparative analysis; ask questions about the analysis and discuss it with service providers, as necessary, to understand the findings and conclusions.
    - The fiduciary should also have the service provider make an assurance that, to the best of its ability, the comparative analysis complies with the requirements of MHPAEA and applicable regulations.

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Other Provisions

- Final Rule provides detail on actions for inadequate NQTL comparative analysis.
  - Must notify participants and beneficiaries.
  - Can require that the plan eliminate the NQTL as it applies to MH/SUD benefits.
    - This will be a facts and circumstances test.
  - Specific time periods provided for responding to a Department's initial request for an NQTL comparative analysis and follow up requests.
- Section ERISA 104(b)(4) status for NQTL comparative analysis, meaning analysis must be provided to participants/beneficiaries within 30 days of a written request. If not provided, the plan administrator could face up to a $110 per day penalty.
- Final Rule would implement the CAA 2023 sunset provisions for state and local governmental plan MHPAEA opt-out.

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What Should Plan Sponsors Be Doing Now?

- Comply with the comparative analysis requirements for 2025.
  - Do you have a comparative analysis?
    - If not prepare one.
    - If you do, then review the six detailed requirements and be prepared to update the comparative analysis for all except for:
      - The meaningful benefits standard,
      - The prohibition on discriminatory information used in the design and application requirement, and
      - The relevant data evaluation requirement
    - Review the certification requirement with applicable plan fiduciaries.
  - Make sure any ASO/TPA agreement addresses responsibilities for a comparative analysis.
  - Has QTL testing been done?

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What Should Plan Sponsors Be Doing Now?

- Identify any areas where there may be a plan design issue with the "meaningful benefits/core treatment" requirement and be prepared to address those in 2026.
- Data collection will be the most challenging aspect of the Final Rule.
  - Still many unknowns on what the final data collection requirements will be.
  - Watch for further guidance on data collection including an updated MHPAEA Self-Compliance Tool from the Departments.
  - Discuss with TPAs/ASOs on the ability to collect the data.
  - Does the TPA/ASO have the technology to collect this data?
- Be prepared to review/revise TPA/ASO agreements with respect to NQTLs generally not just the comparative analysis but the meaningful benefit requirement, data collection, whether the TPA/ASO is using any discriminatory data and also make sure QTLs are covered.
- Watch for developments in the courts and whether the Final Rule is challenged under *Loper Bright* or otherwise. In particular, there may be challenges to the relevant data evaluation and meaningful benefits requirements.

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EBSA CYBERSECURITY GUIDANCE FOR HEALTH AND WELFARE PLANS

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EBSA Compliance Assistance Release No. 2024-01

- On September 6, 2024, EBSA issued Compliance Assistance Release No. 2024-01 (Release) confirming that the cybersecurity guidance issued by EBSA in April 2021 generally applies to *all employee benefits plans*, including health and welfare plans. https://www.dol.gov/agencies/ebsa/key-topics/retirement-benefits/cybersecurity/compliance-assistance-release-2024-01
- In 2021, EBSA issued cybersecurity guidance to help plan sponsors, fiduciaries, service providers and participants in employee benefit plans safeguard plan data, personal information, and plan assets. However, this guidance only specifically mentioned retirement plans.
- EBSA says in the Release that health and welfare service providers have told plan fiduciaries and EBSA investigators that the 2021 guidance only applied to retirement plans. In 2022 the ERISA Advisory Council recommend that EBSA clarify that the guidance also applies to health benefit plans.

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Updates to the 2021 EBSA Cybersecurity Guidance

- EBSA Cybersecurity Guidance has 3 parts:
  - **Tips for Hiring a Service Provider**: contains recommended RFP questions and contract terms for plan sponsors
  - **Cybersecurity Program Best Practices**:
    - Lists 12 cybersecurity best practices for service providers that EBSA would expect to see if auditing the plan or service provider.
    - States that pension and health and welfare plans are tempting targets for cyber criminals because the plans: (i) often hold millions of dollars in assets; and (ii) store and/or transfer participants' personally identifiable data.
  - **Online Security Tips**: Contains tips for participants and beneficiaries to reduce the risk of fraud.
- EBSA also referred to HHS publications for health plans and their service providers to maintain good cybersecurity practices
  - Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients
  - Technical Volume 1: Cybersecurity Practices for Small Healthcare Organizations
  - Technical Volume 2: Cybersecurity Practices for Medium and Large Healthcare Organizations

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Takeaways From the Cybersecurity Guidance

- EBSA is auditing cybersecurity practices of health and welfare plans and their service providers.
  - This includes *all welfare plan benefits* – not just health plans covered by HIPAA.
- EBSA thinks that ERISA plan fiduciaries have a duty under ERISA to prudently select a service provider with strong cybersecurity practices and monitor its activities.
- EBSA also thinks that responsible plan fiduciaries have an obligation to ensure proper mitigation of cybersecurity risks.
- EBSA expects plan fiduciaries to distribute the online security tips to plan participants and beneficiaries who check their plan information online.

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QUESTIONS