Update on Mental Health Parity Enforcement and Emerging Regulatory Guidance

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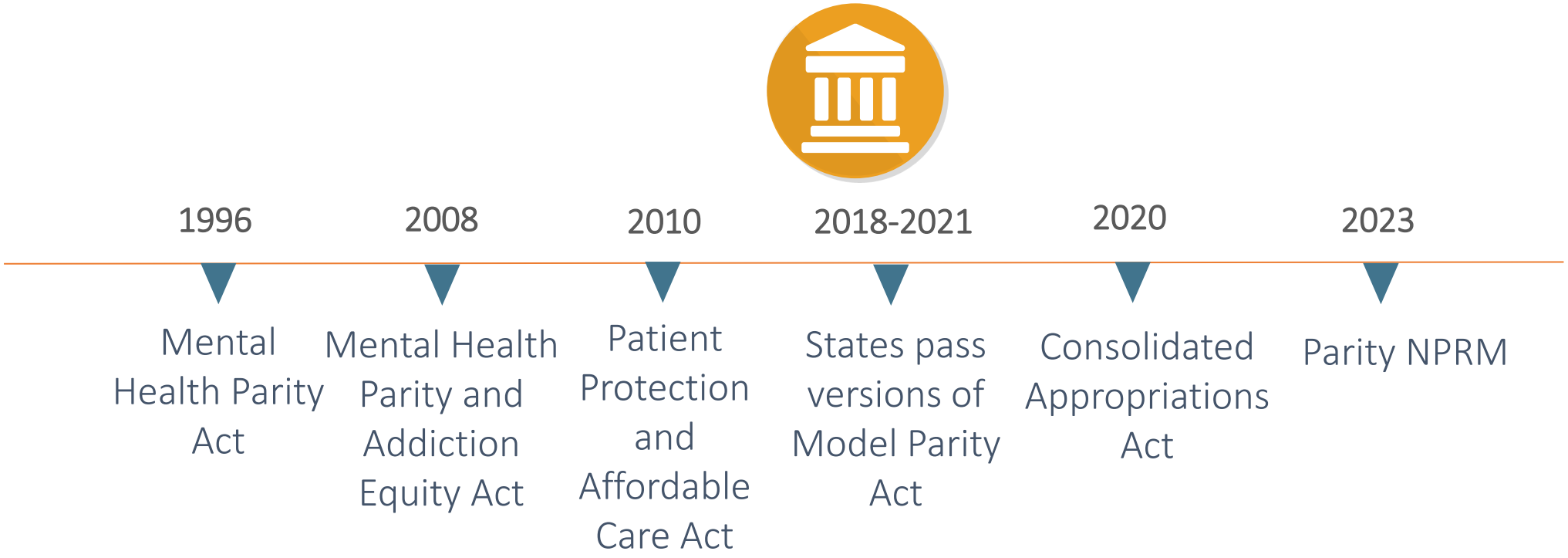
Agenda

- Overview of MHPAEA Requirements
- High Level Overview of NPRM
- Definitions
- New NQTL 3 Part Test
  - No More Restrictive-- Quantitative Testing for NQTLs
    - Exceptions for Independent Professional Medical or Clinical Standards and Standards to Detect or Prevent and Prove Fraud, Waste, and Abuse
  - Design and Application
  - Data Collection/Network Composition Analysis
- Prohibition on Discriminatory Factors and Evidentiary Standards
- Required Use of Outcomes Data
- Changes to the 6-Step NQTL Analysis
- Application to Provider Networks
- Enforcement Strategies and Potential Safe Harbor

Overview of MHPAEA Requirements

The Parity Journey



Mental Health Parity and Addiction Equity Act (MHPAEA)

- The Mental Health Parity and Addiction Equity Act (MHPAEA) requires covered health plans to ensure that beneficiaries have access to benefits that are designed and delivered in a manner that doesn't discriminate against individuals with mental health conditions or substance use disorders.
- MHPAEA is fundamentally a consumer-protection anti-discrimination statute, and as such, has more similarities to the Civil Rights Act and Americans with Disabilities Act than to most forms of managed care and insurance regulations.
- MHPAEA and its implementing regulations and sub-regulatory guidance effectuate this anti-discrimination requirement through a complex series of tests.
- Oversight and enforcement have steadily increased since 2008 and are now requiring comprehensive, organizational culture changes; analogous to the roll-out and adoption of HIPAA throughout the industry.

High Level Overview of NPRM

High Level Overview of NPRM

- As proposed, the rule would create new requirements to:
  - **Significantly increase operational requirements for plan or issuer to demonstrate that it is not violating parity**
  - Apply “Substantially All” and “Predominant” quantitative tests to nonquantitative treatment limits (“NQTLs”)
  - Create a new distinction between “design factors” and “process factors” for analyzing NQTLs
  - Require plans and issuers to ensure that the factors used to design and apply NQTLs do not discriminate against MH/SUD benefits
    - Would apply an “outcomes-based” approach to assessing whether a factor is “discriminatory,” in direct conflict with existing guidance
  - Require plans and issuers to collect and evaluate data metrics on outcomes as part of NQTL analysis
    - Data showing a material difference in access to MH/SUD benefits relative to M/S benefits would be a “strong indicator” of noncompliance
  - Authorize the Departments to require plans and issuers to halt the application of NQTLs to MH/SUD benefits if the plan or issuer fails to appropriately demonstrate that their NQTL analyses comply with parity standards

Definitions

Definitions – Impactful Changes

- Mental Health Benefits
  - Defined to include all covered conditions that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter of the current ICD or current Diagnostic and Statistical Manual of Mental Disorders ("DSM") (except SUD conditions)
    - Autism spectrum disorder ("ASD") and eating disorders must be defined as mental health conditions
    - Plans may not use definitions for MH/SUD benefits otherwise required under state law to the extent that those laws exclude any condition in the ICD chapter or the DSM
  - Would limit plan discretion to define benefits
- More definitions will be discussed throughout this presentation including
  - Substance Use Benefits, Medical or Surgical Benefits, Factors, Evidentiary Standards, Treatment Limitation
- **No definition provided for "NQTL" or "variation" of an NQTL**

Definitions (cont.)

Factors

ALL information, including processes and strategies that are considered or relied on to design an NQTL or used to determine whether or how the NQTL applies to benefits under the plan or coverage

- Provider discretion in determining diagnosis or type or length of treatment
- Clinical efficacy of treatment or service
- Claim types with a high percentage of FWA
- Quality standards
- Treatment outcomes
- Severity of condition
- Variability in the cost of an episode of care
- High-cost growth
- Variability in cost and quality
- Current and projected demand
- Licensing and accreditation of providers
- Geographic location

Evidentiary Standards

Any evidence, source, or standard considered or relied on in designing or applying a factor, including specific benchmarks or thresholds

- Recognized medical literature
- Professional standards protocols
- Published research studies
- Payment rates
- Clinical treatment guidelines
- Internal plan/issuer data

3-Part Test for Nonquantitative Treatment Limitations

Three Part Test for NQTLs

- Plans and issuers may not impose an NQTL unless:
  1. the NQTL is **no more restrictive** as applied to MH/SUD benefits than the **predominant variation** of the NQTL that is applied to **substantially all** M/S benefits (the **"no more restrictive" requirement**)
  2. the plan or issuer satisfies requirements related to the **design and application** of the NQTL, including the **prohibition on discriminatory factors**; and
  3. the plan or issuer **collects, evaluates, and considers relevant data on access to MH/SUD benefits relative to M/S benefits**, and **takes reasonable action to address any material differences** in access shown in the data (the **"relevant data evaluation"** requirement)
- ***Failure to meet any of the three requirements*** with respect to an NQTL in a classification would mean that the NQTL violates MHPAEA and may not be imposed on MH/SUD benefits in the classification
- This test is ***in addition to*** the NQTL comparative analyses

Quantitative Testing for NQTLs

“Predominant” and “Substantially All” Tests Would Apply to NQTLs

NQTLS would be subjected to a modified version of the quantitative “predominant” and “substantially all” tests currently applied to quantitative treatment limits (“QTLs”)

NQTLs applied to MH/SUD benefits are **“no more restrictive”** than the **“predominant”** NQTL that applies to **“substantially all”** M/S benefits in a particular classification

Step 1 - "Substantially All"

NQTLs applied to MH/SUD benefits are "no more restrictive" than the "predominant" NQTL that applies to "substantially all" M/S benefits in a particular classification

First – Calculate the portion of payments expected to be subject to the particular NQTL in a classification

- "Any reasonable method may be used to determine the dollar amount expected to be paid … for M/S benefits"
- Plan-level data, as opposed to product-level data, is most appropriate to utilize, when possible
- Only if the plan does not have adequate data (as determined by its actuary) may the plan use "other reasonable claims data" to calculate the projection
- Determining the portion of payments for M/S services subject to the NQTL need only be redone for a future plan year if the plan's benefit design or utilization changes in a manner that impacts a particular NQTL's classification

Then – Determine whether the NQTL applies to substantially all M/S benefits in the classification

- NQTL applies to substantially all M/S benefits within a classification if it is applicable to two-thirds or more of all M/S benefits in that classification.
- Applicability would be determined "without regard to whether the NQTL was triggered based on a particular factor or evidentiary standard"

Step 2 – Predominant Test

NQTLs applied to MH/SUD benefits are "no more restrictive" than the "predominant" NQTL that applies to "substantially all" M/S benefits in a particular classification

Determine the **predominant variation of the NQTL** that is applied to substantially all M/S benefits subject to the NQTL in the classification

- Predominant means "the most common or frequent variation of an NQTL within a benefit classification"
- The predominant variation is identified based on the dollar amount of plan payments expected to be paid for the M/S services subject to the variation
- The predominant variation is the most common or frequent variation, i.e., the variation applicable to "the highest portion of all [M/S] benefits within a classification"

Examples of variations

- If a plan applies concurrent review commencing at different points in time, each different point in time would be considered a variation of the NQTL
- If a plan applies prior authorization in a way that contains differences based on the manner of review, e.g., "auto-adjudication vs. manual review" and based on the number of levels of review, e.g., "first-level review vs. first-level review and peer-to-peer review" each difference is considered an NQTL variation

No More Restrictive Test

NQTLs applied to MH/SUD benefits are **"no more restrictive"** than the **"predominant"** NQTL that applies to **"substantially all"** M/S benefits in a particular classification

An NQTL is "restrictive" to the extent that it "imposes conditions, terms, or requirements that limit access to benefits under the terms of the plan or coverage"

- "Conditions, terms, or requirements include, but are not limited to, those that compel an action by or on behalf of a participant or beneficiary to access benefits or limit access to the full range of treatment options available for a condition or disorder under the plan or coverage"
- "No more restrictive" test is not intended "to prevent plans and issuers from applying reasonably designed and carefully circumscribed measures . . . for . . . detecting or preventing and proving fraud, waste, and abuse"

Exceptions for Independent Professional Medical or Clinical Standards and Standards to Detect or Prevent and Prove Fraud, Waste, and Abuse

- An NQTL that "impartially applies independent professional medical or clinical standards or applies standards to detect or prevent and prove fraud, waste, and abuse" to MH/SUD benefits will not be considered to violate the "no more restrictive" requirement
- The exception only applies if plans use "indicia of fraud, waste, and abuse that have been reliably established through objective and unbiased data."

Required Use of Outcomes Data

"Relevant Data Evaluation" Requirement

USE OF OPERATIONS MEASURES

- Plan or issuer would be required to collect and evaluate relevant data metrics in designing and applying an NQTL in a manner ***reasonably designed to assess the impact*** of the NQTL on access to MH/SUD benefits and M/S benefits
- Departments propose to require evaluation of certain data measures, including the number and percentage of claims denials as well as any other data relevant to the NQTL required by State law or private accreditation standards
  - Also allows for the Departments to identify additional required measures in sub-regulatory guidance

“Relevant Data Evaluation” Requirement

USE OF OPERATIONS MEASURES

- Outcomes data must also be included in step 5 of the plan’s comparative analyses, as part of the plan’s demonstration of in-operation comparability of the NQTL
  - The comparative analysis must include an explanation of the methodology used for the data measure and must provide the raw or underlying data, including:
    - the sample period
    - inputs used in any calculations
    - a detailed explanation of material differences found in the data outcomes
    - a discussion of any measures implemented to mitigate any material differences
- Plans that impartially apply ***independent professional medical or clinical standards*** are not required to comply with the “relevant data evaluation” requirement
  - No exception to the “relevant data evaluation” requirement based on standards to detect or prevent and prove fraud, waste, and abuse

“Relevant Data Evaluation” Requirement

“MATERIAL DIFFERENCES” STANDARD

- If data show a ***material difference*** in access to MH/SUD benefits as compared to M/S benefits, the difference is considered to be a “strong indicator” that the plan or issuer violates parity
- If a plan or issuer uncovers material differences in its data outcomes measures, they would be required to take “reasonable action” to address any material differences as necessary to ensure compliance
- Departments do not propose a definition or standard for “materiality” or “reasonable action” but seek comments on:
  - How “material difference” could be defined in a manner that translates into tangible quantitative research methods (e.g., based on the results of statistical testing)
  - What would constitute a reasonable action in response to relevant data that reveals material differences in access

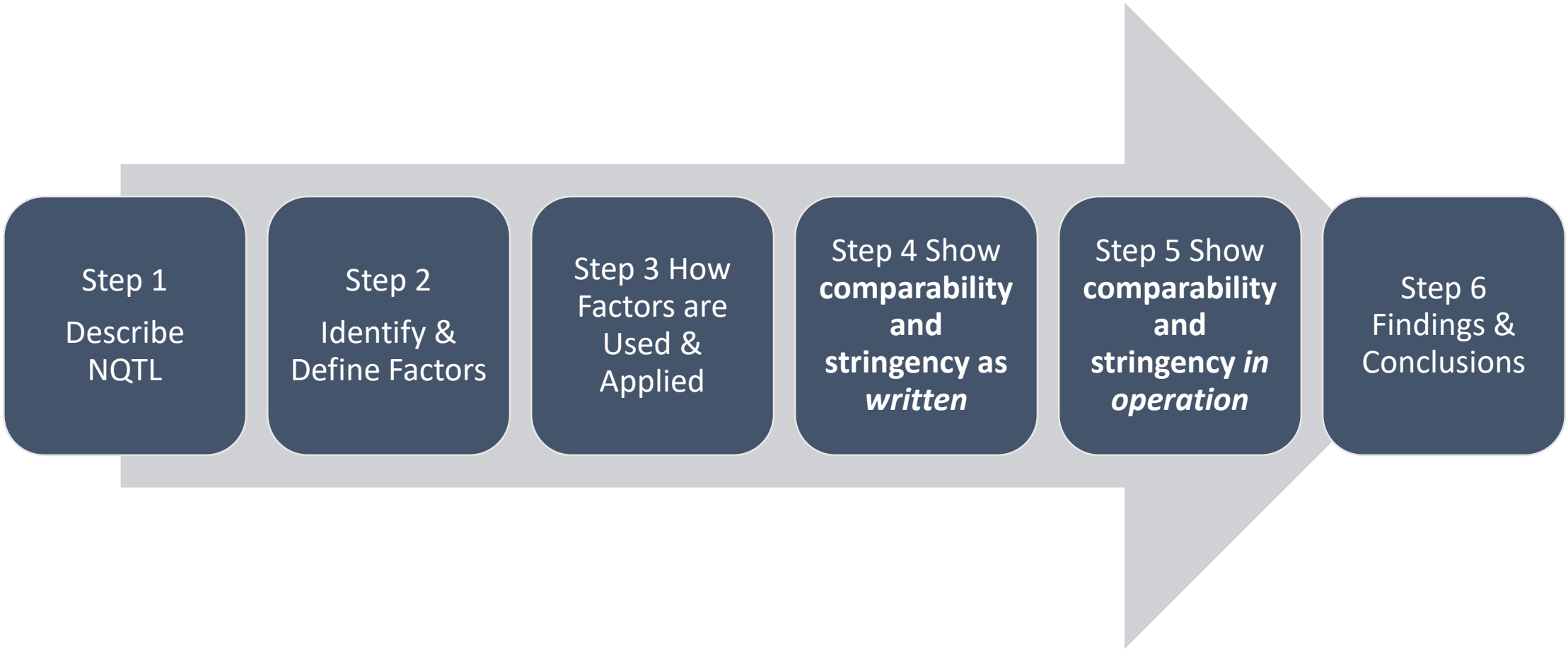
Application of NQTLs to Provider Networks

REQUIRED DATA METRICS

- Departments propose to require that data measures for network composition NQTLs must include (but are not limited to):
  - In-network and out-of-network utilization rates (including data related to provider claims)
  - Network adequacy metrics (including time and distance, and providers accepting new patients)
  - Provider reimbursement rates (including as compared to billed charges)
- ***Per se noncompliance*** where the outcomes data for network composition NQTLs show "material differences in access to in-network [MH/SUD] benefits as compared to in-network [M/S] benefits in a classification"
  - No longer merely a "strong indicator" of noncompliance
- Where outcomes data does support a finding of compliance, the plan still has to develop and defend a comparative analysis of the strategies, processes, evidentiary standards, and other factors that are used to apply network composition NQTLs

The 6-Step Comparative Analysis for NQTLs

Six Step Process



Instructions for steps of the NQTL Comparative Analysis

STEP 1 – DESCRIPTION OF THE NQTL

- The specific terms of the plan or coverage or other relevant terms regarding the NQTL, the policies or guidelines (internal or external) in which the NQTL appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the NQTL
- Identification of all MH/SUD and M/S benefits to which the NQTL applies
- Description of which benefits are included in each benefit classification
- **Identification of the predominant NQTL variation applicable to substantially all M/S benefits in each classification**

Instructions for steps of the NQTL Comparative Analysis

STEP 2 – IDENTIFICATION AND DEFINITION OF THE FACTORS USED TO DESIGN OR APPLY THE NQTL

- Identification of all factors considered and evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which MH/SUD and M/S benefits are subject to the NQTL, to include
  - A detailed description of the factor
  - A description of each evidentiary standard (and the source)

Instructions for steps of the NQTL Comparative Analysis

STEP 3 – DESCRIPTION OF HOW FACTORS ARE USED IN THE DESIGN AND APPLICATION OF THE NQTL

- Detailed explanation of how each factor is used to determine which MH/SUD benefits and which M/S benefits are subject to the NQTL
  - If application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions and the professional designation and qualification of each decision maker
- Explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL, including in the determination of whether and how MH/SUD or M/S benefits are subject to the NQTL
- If more than one factor is identified, an explanation of how the factors are weighted
- *Any deviation(s) or variation(s) from a factor, its applicability, or its definition (including the evidentiary standards and information or sources from which each evidentiary standard was derived)*

Instructions for steps of the NQTL Comparative Analysis

STEP 4: DEMONSTRATION OF COMPARABILITY AND STRINGENCY AS *WRITTEN*

- For each factor, provide:
  - *Quantitative data, calculations or other analyses showing whether MH/SUD and M/S benefits met any threshold identified in the relevant evidentiary standards, and the evaluation of relevant data, to determine that the NQTL would or would not apply*
  - Records documenting consideration/application of all factors and evidentiary standards, and results
  - Comparison of how NQTL, as written, is applied to MH/SUD and M/S benefits, including provisions of any forms, checklists, procedures, or other documentation used in designing and applying the NQTL
  - Documentation showing how the factors are comparably applied, as written, to MH/SUD and M/S benefits in each classification, to determine which benefits are subject to the NQTL
  - *Explanation of reasons for deviations/variations in application of factors used to apply the NQTL to MH/SUD versus M/S benefits, and how the plan or issuer establishes such deviations or variations*

Instructions for steps of the NQTL Comparative Analysis

STEP 5 – DEMONSTRATION OF COMPARABILITY AND RELATIVE STRINGENCY IN OPERATION

- Comprehensive explanation of how the plan or issuer ensures that, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to MH/SUD benefits are comparable to, and applied no more stringently than for M/S benefits, including:
  - Explanation of any methodology and underlying data used; and
  - The sample period, inputs used, definitions of terms used, and any criteria used to select the benefits to which the NQTL is applied
- Identification and evaluation of data regarding the outcomes resulting from application of the NQTL to MH/SUD and M/S benefits
- *Detailed explanation of "material differences" in outcomes data and the bases for concluding that material differences in outcomes are not attributable to differences in the comparability or relative stringency of the NQTL*
- *Discussion of any measures that have been or are being implemented by the plan or issuer to mitigate any material differences in access to MH/SUD benefits*

Instructions for steps of the NQTL Comparative Analysis

STEP 6 – FINDINGS AND CONCLUSIONS

- Any findings or conclusions indicating the plan or coverage is not (or might not be) in compliance with the parity requirements, including any planned or implemented corrective actions
- A reasoned and detailed discussion of the findings and conclusions
- Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions
- Date of the analysis and title and credentials of all relevant persons who participated in creating it
- If the comparative analysis relied upon an evaluation by experts, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the analysis
- For plans subject to ERISA, a certification of compliance with the content requirements by one or more named fiduciaries who have reviewed the analysis

Impact to Provider Networks

Impact to Provider Networks

Oversight and enforcement focus on Provider Networks

- In-network reimbursement rates and provider admission standards
  - Data analysis considered discriminatory if network standards, rates, credentialing standards, and other factors result in less favorable treatment of mental health and substance use disorder benefits.
    - Reduced non-physician provider rates for MH/SUD providers compared to reduction for non-physicians is not applied to M/S providers
- Out-of-network reimbursement rates, which includes methods of determining usual, customary and reasonable charges
- Standards for adequacy of mental health and substance use disorder provider networks

Impact to Provider Networks

Actions plans should consider:

- Authorize greater compensation or other inducements for MH/SUD providers
- Expand telehealth for MH/SUD to manage regional shortages
- Notify participants and beneficiaries via website, employee brochures, and the summary plan description of a toll-free number for help finding in-network providers
- Ensuring that the plan or issuer's service providers (as applicable) outreach to treating providers and facilities to encourage network enrollment
- Network directory accuracy and reliability

Enforcement Processes

Enforcement Process

- Effective date for proposed enforcement strategies and processes
  - Plan years that begin on or after January 1, 2025 for most covered health plans and issuers
  - Policy years beginning on or after January 1, 2026 for individual health insurance coverage
- Timeline to respond to initial request for comparative analyses is 10 business days
- If the Secretary determines that information is insufficient, the Secretary will specify any additional information that is needed, providing 10 business days to respond unless additional time is specified
- After all information is received, the Secretary may then determine non-compliance with requirements regarding NQTLs or other provisions of law
- Plan or issuer deemed non-compliant must (i) respond with action plan that will result in compliance and (ii) provide a compliant analysis no later than 45 calendar days after initial determination
- After issuance of decision of non-compliance, non-compliant party must notify all enrolled participants and beneficiaries of the non-compliance determination within 7 calendar days of receipt of the final determination letter
- No appeal process is proposed

Potential Safe Harbor for Provider Networks

Safe Harbor for Network Composition NQTL – Open for Comment but Not Yet Proposed

- NQTLs related to network composition will be a primary focus for the Department's mental health parity compliance enforcement efforts and evaluation of comparative analyses for these NQTL types will focus heavily on data measures
- The Departments intend to create an enforcement safe harbor for group health plans and issuers that meet or exceed specific data-based standards related to network composition to be identified in future guidance
- The goal would be to promote equal access for participants, beneficiaries, and enrollees to in-network MH/SUD benefits as compared to in-network M/S benefits while giving plans flexibility in developing provider networks
- The Departments would assess the effectiveness and operation of the potential enforcement safe harbor on an ongoing basis and would retain the ability to update or modify its terms

Safe Harbor for Network Composition NQTL – Open for Comment but Not Yet Proposed

- Enforcement relief would only be granted to plans or issuers that ***clearly demonstrate*** that they provide "equal" access to in-network MH/SUD benefits as compared to in-network M/S benefits
- Departments are considering whether to permit a phased-in approach where plans or issuers could demonstrate progress toward meeting or exceeding the standards over the course of multiple plan years
- Safe harbor would apply to all NQTLs related to network composition, including admission standards, reimbursement rates, credentialing standards, and "procedures for ensuring the network includes an adequate number of each category of provider and facility to provide covered services under the plan or coverage"
- To qualify, the group health plans and issuers would have to demonstrate that they ***meet or exceed*** all defined data standards as part of their comparative analysis

Questions?

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