Final Mental Health Parity NQTL Regulations: Technical Summary

Key Aspects of the Final Regulations

- *The Departments' Decision NOT to Finalize the Mathematical "Substantially All Test" and "Predominant Test"*
- *Test #1 of the Remaining 2-Part Test: The "Design and Application Requirements"*
- *Test #2 of the Remaining 2-Part Test: The "Relevant Data Evaluation Requirements"*
- *"Network Composition" Requirements*
- *"Meaningful Benefits" Requirement*
- *NQTL Comparative Analysis and Required "Content Elements"*
- *Fiduciary Certification*
- *Timing for Furnishing the Comparative Analysis to the Departments Upon Request and Timing for Notifying Participants for Non-Compliance*
- *Effective Dates*

Two Rules Within the Final Rule: (1) The "Benefit Coverage Requirements" and (2) The "NQTL Comparative Analysis Requirements"

It is important to note that the final regulations include two different sets of legal requirements that must be satisfied, with two different sets of consequences for failing to satisfy each of these respective legal requirements.

- **Rule #1: "*Benefit Coverage Requirements*"** – These final regulations set forth a **2-Part Test** (discussed more fully below) for determining whether greater restrictions (here, **Non-Quantitative Treatment Limitations [NQTLs]**) are being designed and applied to mental health and substance use disorder (MH/SUD) benefits (including NQTLs related to MH/SUD "**Network Composition**") as compared to NQTLs designed and applied to medical and surgical (M/S) benefits (including NQTLs related to M/S "**Network Composition**").

  There is also a new standard that requires a self-insured plan or insurance carrier to provide "**meaningful benefits**" for MH/SUD benefits measured by comparing coverage for a "**core treatment**" for MH/SUD benefits relative to a "**core treatment**" for M/S benefits.

  If the Federal Departments determine that a plan/carrier does NOT comply with these "**Benefit Coverage Requirements,**" the Departments can require the plan/carrier to ***STOP*** imposing the NQTL on MH/SUD benefits (including those NQTLs related to "**Network Composition**"), which could have significant financial consequences for a plan/carrier with respect to the plan's/carrier's continued coverage of MH/SUD benefits.

- **Rule #2: *"NQTL Comparative Analysis Requirements"*** – The other set of legal requirements apply to the NQTL comparative analysis itself. These final regulations add to the 2021 CAA's, existing NQTL comparative analysis provisions by requiring a plan/carrier to explain in excruciating detail – through six "**Content Elements**" – how and why the plan/carrier satisfies the "**Benefit Coverage Requirements**" in their comparative analysis

  More specifically, the plan/carrier must describe in significant detail whether and how the plan/carrier performed – and is complying with – the **2-Part Test,** including descriptions and demonstrations of how "**processes**," "**strategies**," "**evidentiary standards**," and "**factors**" (discussed more fully below) are used in designing and applying NQTLs to the MH/SUD benefits, along with whether there are "**material differences**" in access to MH/SUD benefits compared to M/S benefits; whether and what "r**easonable actions**" the plan/carrier is taking to address the "**material differences**"; and whether and how the plan/carrier is providing "**meaningful benefits**."

  Here, if the Federal Departments ultimately determine that the plan's/carrier's NQTL comparative analysis does NOT comply with these "**NQTL Comparative Analysis Requirements**," the plan/carrier must send a notification to ALL plan participants informing them that the Departments have concluded that the plan's/carrier's NQTL comparative analysis did NOT comply with the law, and the plan/carrier must send to the Departments confirmation that this notification was timely sent to participants. The name of the plan/carrier will also be included in the Departments' Report to Congress on MHPAEA compliance.

I. "Benefit Coverage Requirements"

A. Definitions for Purposes of Compliance

The Federal Departments defined what "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" mean for purposes of complying with MHPAEA. Here, the Federal Departments confirmed these definitions must be consistent with generally recognized independent standards of *current* medical practice and in accord with generally accepted, peer-reviewed, nonprofit professional standards for diagnosis and descriptions of medical conditions, mental health conditions, and substance use disorders as set forth in the *most recent* and *current* versions of either the World Health Organization's International Classification of Diseases adopted by HHS (or "ICD") or the APA's Diagnostic and Statistical Manual of Mental Disorders (or "DSM").

By way of example, the Departments confirmed that eating disorders, such as anorexia nervosa, bulimia nervosa, and binge-eating disorder, along with Autism Spectrum Disorders (ASD), are all mental health conditions protected under MHPAEA because they are all recognized as such under generally recognized independent standards of *current* medical practice. The Departments also clarified that gender dysphoria is a mental health condition, and thus subject to the protections of MHPAEA, because the *most recent and current versions of both the ICD and DSM* include gender dysphoria as a mental health condition.

In addition, the Federal Departments confirmed that plans/carriers CANNOT rely on state law definitions of medical/surgical benefits, mental health benefits, and substance use disorder benefits if those definitions are *not* consistent with generally recognized independent standards of *current* medical practice.

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B. DROPPED: The "Substantially All Test" and "Predominant Test"

What Did the Proposed Regulations Say?

According to the proposed regulations (originally issued back in July 2023), plans/carriers would NOT be permitted to impose NQTLs on MH/SUD benefits unless:

1.The NQTL is no more restrictive as applied to MH/SUD benefits than to M/S benefits (referred to as the "No More Restrictive Requirement," which included the "Substantially All Test" and the "Predominant Test"); AND

2.The plan/carrier satisfies requirements related to the design and application of the NQTL (referred to as the "Design and Application Requirements"); AND

3.The plan/carrier collects, evaluates, and considers the impact of relevant data on access to MH/SUD benefits relative to access to M/S benefits, and subsequently takes reasonable action as necessary to address any material differences in access shown in the data to ensure compliance with the rules (referred to as the "Relevant Data Evaluation Requirements")

This 3-Part Test was the most noteworthy aspect of the proposed regulations. It generated pointed arguments from the plan sponsor and insurance carrier communities that this 3-Part Test would be impossible to satisfy in operation.

What Did the Final Regulations Say?

IMPORTANTLY, the final regulations do *NOT* include the "Substantially All Test" and the "Predominant Test." In other words, the Departments *DECLINED* to finalize the "Substantially All Test" and the "Predominant Test."

Instead, the Departments reiterate the statutory requirement for the "No More Restrictive Requirement," explaining that plans/carriers may not impose any NQTL with respect to MH/SUD benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all M/S benefits in the same classification.

The Departments further explained that to demonstrate compliance with the statutory "No More Restrictive Requirement," a plan/carrier must satisfy the (1) "Design and Application Requirements" and (2) "Relevant Data Evaluation Requirements." In other words, to comply with the "No More Restrictive Requirement," plans/carriers MUST comply with a new 2-Part Test: (1) The "Design and Application Requirements" and (2) The "Relevant Data Evaluation Requirements."

Exceptions To The Proposed 3-Part Test DROPPED As Well

The proposed regulations provided that a plan/carrier would automatically satisfy various parts of the originally proposed 3-Part Test (1) if the NQTL impartially applies generally recognized independent professional medical or clinical standards to MH/SUD benefits and M/S benefits and/or (2) the NQTL applies standards related to fraud, waste, and abuse that meet specific requirements.

Due in large part to the Departments *DECLINING* to finalize the "Substantially All Test" and the "Predominant Test," the Departments *DECLINED* to finalize these exceptions. BUT, the Departments added language to the final regulations explaining how plans/carriers should analyze and account for independent professional medical or clinical standards and fraud and abuse measures in designing and applying their NQTLs.

C. Test #1 of the 2-Part Test: The "Design and Application Requirements"

1. ***In General***

Under the final "Design and Application Requirements," a plan/carrier must consider whether 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, those utilized in *designing* and *applying* NQTLs to M/S benefits in the classification.

In an effort to assist plans/carriers in complying with this requirement, the Federal Departments attempted to explain what constitutes relevant "processes," "strategies," "evidentiary standards," and other "factors," as summarized below:

- "**Processes**" and "**Strategies**" – The Departments define "**processes**" as relating to the application of an NQTL, while "**strategies**" relate to the *design* of an NQTL. The Departments explained that "**processes**" and "**strategies**" are types of **"factors**," rather than components of a "**factor**," to be separately evaluated.
- "Processes" include, but are not limited to:
  - Prior authorization procedures.
  - Provider referral requirements.
  - The development and approval of a treatment plan.
  - Specific procedures used by staff or other representatives of a plan/carrier (or the service provider of a plan/carrier) to administer the application of NQTLs, such as:
    - How a panel of staff members applies the NQTL (including the qualifications of staff involved, number of staff members allocated, and time allocated).
    - Consultations with panels of experts in applying the NQTL.
    - Reviewer discretion in adhering to criteria hierarchy when applying an NQTL.

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- "**Strategies**" are practices, methods, or internal metrics that a plan/carrier considers, reviews, or uses to design an NQTL including:
  - The development of the clinical rationale used in approving or denying benefits.
  - Deviation from generally accepted standards of care.
  - The selection of information (such as from medical or clinical guidelines) deemed reasonably necessary to make a medical necessity determination.
  - Reliance on treatment guidelines or guidelines provided by third-party organizations.
  - Rationales used in selecting and adopting certain threshold amounts, professional protocols, and fee schedules.

- "**Strategies**" also include:
  - The creation and composition of the staff or other representatives of a plan/carrier (or the service provider of a plan/carrier) that deliberates, or otherwise makes decisions, on the design of NQTLs, including the plan's/carrier's decisions related to qualifications of staff involved, number of staff members allocated, and time allocated.
  - Breadth of sources and evidence considered and consultations with panels of experts in designing the NQTL.
  - The composition of the panels used to design an NQTL.

- "**Evidentiary Standards**" – The Departments explained that "evidentiary standards" are not considered to be "factors." Instead, "evidentiary standards" mean any evidence, sources, or standards that a plan/carrier considered or relied upon in designing or applying a "factor" with respect to an NQTL, including specific benchmarks or thresholds.
  - "Evidentiary standards" may be:
    - Empirical.
    - Statistical.
    - Clinical in nature.

"**Evidentiary standards**" may include sources acquired or originating from an objective third-party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the "usual, customary, and reasonable" rates paid for items and services), and clinical treatment guidelines.

- "**Evidentiary standards**" may also include:
  - Internal plan/carrier data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers.
  - Benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

- "**Factors**" – With respect to **"factors**," the Departments explained that the definition of the term "**factors**" should be read broadly so that **"factors**" are all information, including "processes" and "strategies" (but not "evidentiary standards"), that a plan/carrier considered or relied upon to design an NQTL or to determine whether or how the NQTL applies to benefits under the plan or coverage. The Departments went on to explain that "factors" include, but are not limited to:
  - Provider discretion in determining 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

2. ***Prohibition on Discriminatory "Factors" and "Evidentiary Standards"***

For purposes of determining comparability and stringency under the "Design and Application Requirements," plans/carriers are prohibited from relying upon any "factor" or "evidentiary standard" if the information, evidence, sources, or standards on which the "factor" or "evidentiary standard" are based discriminate against MH/SUD benefits as compared to M/S benefits.

The Departments explained that this test specifically focuses on the importance of ensuring that the "factors" and "evidentiary standards" relied upon by plans/carriers in designing NQTLs do not have built-in biases against MH/SUD benefits as compared to M/S benefits at the time NQTLs are designed.

The final regulations provide that a "factor" or "evidentiary standard" is discriminatory if the information, evidence, sources, or standards on which the "factor" or "evidentiary standard" are based are biased or not objective in a manner that discriminates against MH/SUD benefits as compared to M/S benefits.

The final regulations clarify that information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against benefits as compared to M/S benefits if, based on all the "relevant facts and circumstances," they systematically disfavor access or are specifically designed to disfavor access to MH/SUD benefits as compared to M/S benefits.

For purposes of determining whether information, evidence, sources, or standards are considered to be biased or not objective, such "relevant facts and circumstances" may include, but are not limited to:

- The reliability of information, evidence, sources, or standards, including any underlying data.
- The independence of the information, evidence, sources, and standards relied upon.
- The analyses and methodologies employed to select the information, evidence, sources, and standards and the consistency of their application.
- Any known safeguards deployed to prevent reliance on skewed data or metrics when determining whether they are biased or not objective.

Lastly, according to the final regulations, information, evidence, sources, and standards are not considered biased or not objective for purposes of the prohibition on discriminatory "factors" and "evidentiary standards," if a plan/carrier has taken steps necessary to address the bias or lack of objectivity by correcting, curing, or supplementing the information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps. If information, evidence, sources, or standards are corrected, cured, or supplemented, they may be used by plans/carriers as the basis for "factors" and "evidentiary standards" used to design an NQTL.

D. Test #2 of the 2-Part Test: "Relevant Data Evaluation Requirements"

1. ***In General***

According to the "Relevant Data Evaluation Requirements," when designing and applying an NQTL, a plan/carrier must collect and evaluate "relevant data" in a manner reasonably designed to assess the impact of the NQTL on relevant "outcomes" related to access to MH/SUD benefits and M/S benefits and must consider the impact as part of the plan's/carrier's NQTL comparative analysis of whether such NQTL – in operation – is compliant with the final regulations.

To the extent the "relevant data" collected and evaluated by the plan/carrier show "material differences" in access to MH/SUD benefits as compared to M/S benefits, the "differences" are considered to be a strong indicator that the plan/carrier is not compliant with MHPAEA.

In these instances, a plan/carrier must take "reasonable action" to address any "material differences" in access as necessary to ensure compliance, and they must document the "reasonable action" that has been or is being taken by the plan/carrier to mitigate any "material differences" in access in the plan's/carrier's NQTL comparative analysis for the NQTL in that classification.

The Departments explained that the existence of "material differences" in access do not automatically result in a finding of non-compliance because plans/carriers have the opportunity to provide the Departments additional information, data, explanatory material, and evidence of "reasonable actions" to address any "material differences" as part of the NQTL comparative analysis process.

2. ***Material Differences***

The Departments were asked for guidance on how to determine whether a "difference" is "material" for purposes of the "Relevant Data Evaluation Requirements." In response, the Departments explained that "relevant data" are considered to suggest that the NQTL contributes to "material differences" in access to MH/SUD benefits as compared to M/S benefits if, based on all "relevant facts and circumstances," and taking into account specific considerations, the "difference" in the data suggests that the NQTL is likely to have a negative impact on access to MH/SUD benefits as compared to M/S benefits.

For this purpose, the final regulations specify that "relevant facts and circumstances" may include, but are not limited to, the:

- Terms of the NQTL at issue.
- The quality or limitations of the data.
- Causal explanations and analyses.
- Evidence as to the recurring or non-recurring nature of the results.
- The magnitude of any disparities.

Notwithstanding this non-exhaustive list, the Departments did note that in their view, the quality or limitations of the data are key considerations in determining whether a "difference" in the data suggests that the NQTL contributes to a "material difference" in access to MH/SUD benefits as compared to M/S benefits.

The Departments were also asked to provide guidance on what constitutes "reasonable action" to address any "material differences." The Departments did not provide an exhaustive list, but noted that plans/carriers may:

- Increase spending and/or raise reimbursement rates for MH/SUD services.
- Invest in programs to help participants identify the need for MH/SUD care to connect them to the appropriate services as early as possible.
- Develop mental health assessment screening tools for youth populations to detect those at risk.
- With respect to "Network Composition" (discussed more fully below), strengthen efforts to recruit and encourage a broad range of available MH/SUD providers and facilities to join the plan's/carrier's network by increasing compensation or inducements, streamlining credentialing processes, and expanding the availability of telehealth services.

3. ***Relevant Data***

The Departments explained that the term "relevant data" is meant to be interpreted broadly and does not require a plan/carrier to collect and evaluate duplicative or overlapping data that reflect the same analysis. More specifically, the obligation is to collect and evaluate "relevant data" in a manner reasonably designed to assess the impact of NQTLs, and it is not a requirement to exhaustively survey all available data, nor a requirement that plans/carriers evaluate additional data that is duplicative or unlikely to change the determination of whether there is a "material difference" in access to MH/SUD benefits as compared to M/S benefits.

3. ***Relevant Data***

The Departments explained that the term "relevant data" is meant to be interpreted broadly and does not require a plan/carrier to collect and evaluate duplicative or overlapping data that reflect the same analysis. More specifically, the obligation is to collect and evaluate "relevant data" in a manner reasonably designed to assess the impact of NQTLs, and it is not a requirement to exhaustively survey all available data, nor a requirement that plans/carriers evaluate additional data that is duplicative or unlikely to change the determination of whether there is a "material difference" in access to MH/SUD benefits as compared to M/S benefits.

The Departments noted that a plan's/carrier's data collection and evaluation approach will *not* be considered to be conducted in a manner reasonably designed to assess the impact of an NQTL on relevant "outcomes" related to access to the MH/SUD and M/S benefits if the plan/carrier does not consider data that it knows or reasonably should know that the NQTL is associated with a "material difference" in access. The Departments expect that, in designing their data collection and evaluation approach, plans/carriers will consider "outcomes data" as necessary to assess the impact of the NQTL on access to MH/SUD benefits as compared to M/S benefits in the same classification.

Importantly, the Departments declined to provide a list of "outcomes data" required to be collected and evaluated by plans/carriers. However, the Departments did provide that "outcomes data" for the majority of NQTLs could include but are not limited to:

- The number and percentage of claims denials in a classification of benefits.
- Any other data relevant to the NQTL required by State law or private accreditation standards.
- Utilization data for MH/SUD services and M/S services.

The Departments also explained that, for example, in the case of NQTLs such as prior authorization, "outcomes data" could include but are not limited to:

- Rates of approvals and denials of prior authorization requests.
- Rates of denials of post-service claims.
- Application of penalties for a failure to obtain prior authorization.
- Turnaround times for prior authorization requests.

The Departments noted that whether any particular type of data is relevant for a plan or coverage is based on each plan's or coverage's unique design. The Departments signaled that they intend to issue in future guidance the type, form, and manner of collection and evaluation for the data required and the lists of examples of data that are relevant across the majority of NQTLs.

E. "Network Composition"

1. ***DROPPED: Special Rule for NQTLs Related to "Network Composition"***

Under the proposed regulations, the Departments developed a special rule when designing and applying one or more NQTLs related to "Network Composition" standards, providing that a plan/carrier would fail to meet the requirements of the proposed regulations if the "relevant data" show "material differences" in access to in-network MH/SUD benefits as compared to in-network M/S benefits in a classification.

This standard proposed to set a higher bar for NQTLs related to "Network Composition" than for other NQTLs by treating "material differences" in access to in-network MH/SUD benefits as compared to in-network M/S benefits as an automatic failure to meet the requirements of MHPAEA, instead of merely as a strong indicator of a violation of MHPAEA.

Importantly, the Departments DECLINED to finalize this proposed special rule for NQTLs related to "Network Composition" and are instead including language in the final regulations to explain how plans/carriers are expected to comply with the "Relevant Data Evaluation Requirements" with respect to those NQTLs (discussed more fully in the immediate section below).

2. ***Collecting and Evaluating "Relevant Data" for NQTLs Related to "Network Composition"***

With regard to NQTLs related to "Network Composition," a plan/carrier must collect and evaluate "relevant data" in a manner reasonably designed to assess the aggregate impact of all such NQTLs on access to MH/SUD benefits and M/S benefits, instead of evaluating "relevant data" for each NQTL separately (which is generally required under the final regulations for NQTLs other than those related to "Network Composition"), to determine if there is a "material difference" in access.

"Relevant data" for NQTLs related to "Network Composition" standards could include but are not limited to:

- 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).
- Provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

The Departments go on to provide some additional examples of "relevant data" that a plan/carrier may collect and evaluate such as looking at:

- 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).
- Provider reimbursement rates (for comparable services and as benchmarked to a reference standard).
- The turnaround time for applications to be approved for a provider to join the plan's/carrier's network and the approval and denial rates for applications submitted by MH/SUD providers as compared to M/S providers.
- The percentage of participants and beneficiaries who can access, within a specified time and distance by county-type designation, one (or more) in-network provider(s) who is/are available to accept new patients for MH/SUD and M/S provider categories.
- The median in-network reimbursement rates for services with the same CPT codes, as well as median in-network reimbursement rates for inpatient MH/SUD benefits and M/S benefits, as compared to Medicare rates, and median in-network reimbursement rates for outpatient MH/SUD benefits and M/S benefits, as compared to Medicare rates.

F. Meaningful Benefits

1. ***In General***

According to the final regulations, if a plan/carrier provides any benefits for a MH/SUD condition or disorder in any classification of benefits, the plan/carrier must provide "meaningful benefits" for that MH/SUD condition or disorder in every classification in which M/S benefits are provided. Whether the benefits that are provided are "meaningful benefits" is determined in comparison to the benefits provided for M/S conditions and procedures and requires – at a minimum – coverage of benefits for that MH/SUD condition or disorder in each classification in which the plan/carrier provides benefits for one or more M/S conditions or procedures.

Importantly, a plan/carrier does *not* provide "meaningful benefits" unless the plan/carrier also provides benefits for a "core treatment" for that MH/SUD condition or disorder in each classification in which the plan/carrier provides benefits for a "core treatment" for one or more M/S conditions or procedures.

2. ***Core Treatment***

The Departments explained that a "core treatment" for a MH/SUD condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice.

The final regulations do not set forth specific requirements to determine what constitutes a "core treatment" for any particular condition or disorder. However, the Departments explained that plans/carriers – in determining a "core treatment" for a condition or disorder in this context – should rely on current evidence-based medical and clinical information.

The Departments also noted that a "core treatment" for a particular MH/SUD condition or disorder may not necessarily refer to a single item or service but may instead encompass a suite of items and services that together constitute a "core treatment," depending on the relevant generally recognized independent standards of current medical practice. In such a case, the Departments said that they expect that plans/carriers will cover all components of at least one "core treatment" if the items and services provided as part of the treatment span a number of classifications, provided the plan/carrier provides benefits for one or more "core treatments" for any M/S conditions or procedures in those classifications.

In the preamble to the final regulations, the Departments gave an example of how the above described concept may work in practice, explaining that:

- One "core treatment" for major depressive disorder generally includes prescription drugs and psychotherapy. However, a "core treatment" may also include only prescription drugs or only psychotherapy (and in cases of severe depression, may also include inpatient hospitalization or other types of residential or outpatient treatment). The Departments noted that here, a "core treatment" may include the same item or service in other benefit classifications. For example, for major depressive disorder, psychotherapy could be a "core treatment" with respect to both the outpatient, in-network and outpatient, out-of-network classifications.

To further assist plans/carriers in understanding how to satisfy the "meaningful benefits" and related "core treatment" requirements, the Departments included various examples in the regulations including Example 5 (which discusses "core treatments" for ASD), Example 7 (which discusses "core treatments" for eating disorders), and Example 8 (which discusses "core treatments" for Opioid Use Disorder).

II. "NQTL Comparative Analysis Requirements"

A. Required "Content Elements"

In enacting the CAA, 2021, Congress sought to expressly require plans/carriers that offer MH/SUD benefits and impose NQTLs on these MH/SUD benefits to perform and document a comparative analysis of the design and application of NQTLs and make their comparative analysis and certain information available to the Departments or state regulators upon request.

Under the proposed regulations, the Departments proposed that plans/carriers must include in their comparative analysis with respect to each NQTL imposed on MH/SUD benefits six "content elements" including:

1. A description of the NQTL.
2. The identification and definition of the factors used to design or apply the NQTL.
3. A description of how factors are used in the design or application of the NQTL.
4. A demonstration of comparability and stringency, *as written*.
5. A demonstration of comparability and stringency, *in operation*.
6. Findings and conclusions.

The Departments effectively finalized these six "content elements" with minor modifications, but not before reminding plans/carriers that what constitutes a compliant NQTL comparative analysis will depend on all facts and circumstances, including the provisions of the plan or coverage and the relevant NQTL.

Content Element #1: A Description of the NQTL

Under the first "content element," a plan/carrier is required to identify and describe the NQTL that is the subject of the comparative analysis, including 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, and the applicable sections of any other relevant documents, such as provider contracts that describe the NQTL.

In other words, whether a plan's/carrier's NQTL analysis is compliant with the below described "**content elements**" will be determined by the Federal Departments in their sole discretion, based on all of the facts and circumstances presented to the Departments.

Furthermore, each plan/carrier is required to identify and describe all MH/SUD and M/S benefits to which the NQTL applies and describe which benefits are included in each classification.

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Content Element #2: The Identification and Definition of the "Factors" Used to Design or Apply the NQTL

Under the second "content element," the plan/carrier must identify and define every "factor" – as well as every "evidentiary standard" – considered or relied upon to design or apply each "factor" and the evidence or sources from which each "evidentiary standard" was derived, in determining which MH/SUD benefits and which M/S benefits are subject to the NQTL.

The Departments confirm that it is important for the comparative analysis to include detailed information about "factors," "evidentiary standards," and their sources when the plan/carrier starts to perform and document their comparative analysis to support the plan's/carrier's analysis of how "factors" and "evidentiary standards" are used to design and apply the NQTL.

The Departments remind plans/carriers that without such information, the plan's/carrier's comparative analysis might not accurately describe "factors" and their sources and would not demonstrate that when the "factors" are used to design or apply an NQTL to MH/SUD benefits that they are comparable to and not more stringently applied than the NQTL applicable to M/S benefits.

The Departments further clarify that plans/carriers must describe any steps taken to correct, cure, or supplement any information, evidence, sources, or standards that are the basis for a "factor" or "evidentiary standard" and that would otherwise have been considered biased or not objective in the absence of such steps.

Content Element #3: A Description of How "Factors" Are Used In the Design or Application of the NQTL

For the third "content element," a plan/carrier must include a detailed description of how each "factor" identified and defined in the second "content element" (described above) is used in the design or application of an NQTL to MH/SUD and M/S benefits in a classification.

This description must include a detailed explanation of how each identified and defined "factor" is used to determine which benefits are subject to the NQTL, and also include an 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 benefits or M/S benefits are subject to the NQTL.

This description must include a detailed explanation of how each identified and defined "factor" is used to determine which benefits are subject to the NQTL, and also include an 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 benefits or M/S benefits are subject to the NQTL.

Content Element #2: The Identification and Definition of the "Factors" Used to Design or Apply the NQTL

The Departments explained that if the application of a "factor" depends on specific decisions made in the administration of benefits, the comparative analysis must also provide information on the nature and timing of the decisions, and the professional designations and qualifications of each decision maker. In addition, if there is more than one "factor," the comparative analysis must explain:

- How all of the "factors" relate to each other.
- The order in which all of the "factors" are applied, including when they are applied.
- Whether and how any "factors" are given more weight than others.
- The reasons for the ordering or the weighting of the "factors."

The comparative analysis must also explain any deviation(s) or variation(s) from a "factor," its applicability, or its definition (including the "evidentiary standards" used to define the "factor" and the information or sources from which each "evidentiary standard" was derived), such as how the "factor" is used differently to apply the NQTL to MH/SUD benefits as compared to M/S benefits, and a description of how the plan/carrier establishes such deviation(s) or variation(s) (note, the terms "deviation(s)" or "variation(s)" refer to any differences in how a "factor" is applied with respect to an NQTL).

Content Element #4: A Demonstration of Comparability and Stringency, As Written

For the fourth "content element," plans/carriers must evaluate whether, in any classification, under the terms of the plan or coverage – as written – 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 M/S benefits.

For this fourth "content element," plans/carriers must also include, in each classification in which the NQTL applies, a comparison of how the NQTL – as written – is applied to MH/SUD and to M/S benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the NQTL or that address the application of the NQTL.

Here, plans/carriers must include documentation of each "factor" that was identified and applied – as written – to determine whether the NQTL applies to MH/SUD and M/S benefits in a classification. Plans/carriers must also include documentation demonstrating 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. Such documentation could include – but is not required to include – the use of:

- Quantitative data.
- Calculations.
- Other analysis showing whether, in each classification in which the NQTL applies, MH/SUD and M/S benefits meet or did not meet any applicable threshold identified in the relevant "evidentiary standard" and the evaluation of "relevant data" to determine that the NQTL would or would not apply.

Such documentation, however, must include *records* maintained by the plan/carrier documenting the consideration and application of all "**factors**" and "**evidentiary standards**," as well as the results of their application. These records could include meeting minutes or calculations related to quantitative factors, such as costs.

If there is any deviation(s) or variation(s) in the application of a "factor," the plan/carrier must include an explanation of the reason(s) for such deviation(s) or variation(s) in the application of a "factor" used to apply the NQTL to MH/SUD benefits as compared to M/S benefits in the same classification. The explanation must also describe how the plan/carrier establishes such deviation(s) or variation(s), including in the definition of the "factors," the "evidentiary standards" used to define the "factors" and the sources from which the "evidentiary standards" were derived in the design of the "factors" or "evidentiary standards" or in the application or design of the NQTL (as noted above, "deviation(s)" or "variation(s)" refer to the differences in how a "factor" is applied with respect to an NQTL).

Content Element #5: A Demonstration of Comparability and Stringency, In Operation

Similar to the fourth "content element," this fifth "content element" requires plans/carriers to evaluate whether, in any classification, the "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 M/S benefits in operation.

For the fifth "content element," a plan's/carrier's comparative analysis must include a comprehensive explanation addressing the comparability and stringency of these "processes," "strategies," "evidentiary standards," and other "factors." Plans/carriers must also include a comprehensive explanation of how the plan/carrier evaluates – in operation – compliance with the "Design and Application Requirements" and provide an explanation of any methodology and underlying data used to demonstrate the application of the NQTL, along with the sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the MH/SUD benefits and M/S benefits to which the NQTL is applicable.

To comply with the fifth "content element," plans/carriers must also identify the "relevant data" collected and evaluated in their comparative analysis and provide documentation of the "outcomes" that resulted from the application of the NQTL to MH/SUD benefits and M/S benefits. This also includes a reasoned justification and analysis that explains whether and why the plan/carrier concluded that "differences" in the "relevant data" do or do not suggest that the NQTL contributes to "material differences" in access to MH/SUD benefits as compared to M/S benefits as required under the "Relevant Data Evaluations Requirement."

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Plans/carriers must also provide a detailed explanation of any "material differences" in access to MH/SUD benefits demonstrated by the "outcomes" evaluated, including a reasoned explanation of any "material differences" in access that are not attributable to "differences" in the comparability or relative stringency of an NQTL as applied MH/SUD benefits and M/S benefits.

The Departments instructed plans/carriers to include a detailed *discussion* of any considerations beyond a plan's/carrier's control that contribute to the existence of "material differences," as well as a detailed *explanation* of the bases for concluding that "material differences" are not attributable to differences in the comparability or relative stringency of the NQTL. The Departments noted that such an explanation should be comprehensive and include evidence to support the conclusion that considerations beyond a plan's/carrier's control contributed to the existence of a "material difference" in access.

The Departments go on to explain that to the extent "differences" in access to MH/SUD benefits are attributable to independent professional medical or clinical standards or fraud or abuse measures, and such standards or measures are used as the basis for a "factor" or "evidentiary standard" used to design or apply an NQTL, the comparative analysis must include *documentation explaining* how any such "differences" in access are attributable to those standards or measures.

Lastly, as noted above, the comparative analysis (under this fifth "content element") must include a discussion of any "reasonable actions" or measures that have been or are being implemented by the plan/carrier to address any "material differences" in access with respect to MH/SUD benefits as compared to M/S benefits. This discussion must include, as applicable, a reasoned explanation of any "material differences" in access to MH/SUD benefits as compared to M/S benefits that persist despite "reasonable actions" that have been or are being taken.

With regard to NQTLs related to "Network Composition" (discussed above), plans/carriers must collect and evaluate "relevant data" in a manner reasonably designed to assess the aggregate impact of all such NQTLs on access to MH/SUD and M/S benefits, and here, the Departments explained that, for NQTLs related to "Network Composition," the comparative analysis should analyze their impact as a whole.

In addition, when designing and applying one or more NQTLs related to "Network Composition," the comparative analysis (under this fifth "content element") must include a discussion of the "reasonable actions" that have been or are being taken to address "material differences" in access to in-network MH/SUD benefits as compared to in-network M/S benefits, if any such "material differences" exist. The Departments noted that a comparative analysis making only a cursory reference to provider shortages with little or no explanation of "reasonable actions" taken to address "material differences" in access will likely result in a finding of non-compliant NQTL comparative analysis.

Content Element #6: Findings and Conclusions

The sixth “content element” requires a detailed discussion of findings and conclusions related to the comparability of the “processes,” “strategies,” “evidentiary standards,” and other “factors” used in designing and applying the NQTL to MH/SUD benefits and M/S benefits within each classification, and the relative stringency of their application, both as written and in operation.

Here, the comparative analysis must include any *findings or conclusions* indicating that the plan or coverage is not (or might not be) in compliance with the final regulations, including any actions the plan/carrier has taken or intends to take to address any potential areas of concern or non-compliance. The plan/carrier must also include a reasoned and detailed *discussion* of those findings and conclusions, as well as citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions.

Furthermore, the comparative analysis (under this sixth "content element") must include the date of the analysis, the title, and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis. If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan/carrier to be an expert, the comparative analysis must include an assessment of each expert’s qualifications and the extent to which the plan/carrier ultimately relied upon each expert’s evaluation in performing and documenting the comparative analysis of the design and application of each NQTL applicable to both MH/SUD and M/S benefits.

The Departments explained that while the final regulations require an assessment of each expert’s qualifications and the extent to which the plan/carrier ultimately relied on their evaluation (if at all), a plan/carrier is not required to provide the name of the expert to be included in the comparative analysis.

B.The NQTL Comparative Analysis Is an ERISA-Covered Plan Document

The final regulations clarify that a plan’s/issuer’s NQTL comparative analysis is considered to be an instrument under which a plan is established or operated, and therefore, ERISA-covered fully-insured and self-insured health plans generally must furnish their NQTL comparative analysis to plan participants and beneficiaries upon request within 30 days.

The final regulations also confirm that the NQTL comparative analysis qualifies as documents, records, and other information relevant to a participant’s claim for benefits to which plans/carriers must provide reasonable access upon request and free of charge.

C.Fiduciary Certification

The final regulations also confirm that the NQTL comparative analysis qualifies as documents, records, and other information relevant to a participant’s claim for benefits to which plans/carriers must provide reasonable access upon request and free of charge.

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C. Fiduciary Certification

The proposed regulations would have required the named fiduciary of a self-insured health plan to include in the plan's comparative analysis (1) a statement that they have reviewed the comparative analysis and (2) a "certification" that they believe the NQTL analysis complies with all of the "content elements" discussed above.

The final regulations continue to require the named fiduciary of a self-insured health plan to include a statement that they have reviewed the comparative analysis.

HOWEVER, the fiduciary is ***NOT*** required to "certify" that they believe the NQTL analysis complies with all of the required "**content elements**."

INSTEAD, the named fiduciary is required to explain that they (1) engaged in a prudent process to select a service provider to perform and document the plan's comparative analysis and (2) are continually monitoring this service provider to ensure that the service provider is developing – and has developed – a compliant NQTL comparative analysis for the plan.

The Departments went so far as to explain what they expect with regard to satisfying this "duty to monitor," noting that – at a minimum – the plan's fiduciary should:

- Review the comparative analysis prepared by the service provider.
- Ask questions and discuss the contents of the comparative analysis with the service provider to understand the findings and conclusions set forth in the analysis.
- Ensure that the service provider gives assurances that – to the best of the service provider's ability – the comparative analysis is compliant with the final regulations.

In our opinion, this last action – *getting assurances from the service provider that the service provider believes that the comparative analysis is compliant* – is critical. It is advisable that plan fiduciaries require that such assurances are memorialized in writing.

D. Timing for Furnishing the Comparative Analysis to the Departments Upon Request and Timing for Notifying Participants for Non-Compliance

Importantly, the Departments emphasized that the law already requires plans/carriers to perform and document their NQTL comparative analysis, which means, plans/carriers should always have their comparative analysis completed and at-the-ready.

In other words, plans/carriers should not wait to receive a request from the Departments to begin the process of performing and documenting their comparative analysis. Rather, plans should immediately engage with their service provider to perform, document, and demand the delivery of a completed comparative analysis that is compliant with these final regulations (so the plan fiduciary can take the actions discussed above to satisfy their "duty to monitor").

In addition to reminding plans/carriers what the law already requires of them, the final regulations codified the process for engaging with the Departments when the Departments request a review of the plan's/carrier's comparative analysis, as follows:

- **Initial Request for Review**: When a plan/carrier does indeed receive a request for their comparative analysis, the plan/carrier must furnish their NQTL analysis to the Departments within 10 business days of receipt, although the final regulations give the Departments the flexibility to extend this deadline based on a plan's/carrier's facts and circumstances.
- **Notice of Insufficient NQTL Analysis**: If the Departments determine that the NQTL analysis did not include sufficient information, upon notification of this fact, the plan/carrier has 10 business days to furnish any additional information to the Departments. The Departments also have the flexibility to extend this deadline based on a plan's/carrier's facts and circumstances.
- **Notice of Non-Compliance**: If the Departments conclude the NQTL analysis is not compliant, plans/carriers would be required to undertake corrective actions and re-submit to the Departments a compliant NQTL analysis no later than 45 calendar days after notification of a non-compliant NQTL analysis.

The final regulations also codified the consequences for failing to have a compliant NQTL comparative analysis and explained the requirements for notifying participants of such non-compliance, as follows:

- **Final Determination of Non-Compliance and Notification to Participants**: If the plan/carrier remains out of compliance following the 45-calendar-day corrective action period, the Departments will notify the plan/carrier of this fact through a Final Determination of Non-Compliance. The plan/carrier must then notify plan participants of the plan's/carrier's non-compliance within 7 business days of the receipt of the Final Determination of Non-Compliance. The plan/carrier must also provide a copy of the participant notification to (1) the Departments, (2) any service provider involved in the claims process, and (3) any fiduciary responsible for deciding benefit claims within the same time frame.
- Note, the final regulations included some language that plans/carriers should include in their notification to participants, but in our experience, the Final Determination of Non-Compliance letter provides guidance on what information may be included in the participant notification, especially in cases where the NQTL comparative analysis is found to be non-compliant (as compared to when a plan/carrier may be found to be in non-compliance with the "Benefit Coverage Requirements" discussed above).

III. Effective Dates for These Final Regulations

The final regulations set forth two different effective dates.

Effective Date #1: The following requirements are effective starting the first day of the first plan year beginning on or after **January 1, 2025**:

- The Definitions for Purposes of Compliance.
- The "Design and Application Requirements" (but not the "prohibition on discriminatory factors and evidentiary standards" [see more below]).
- The consequence for failing to comply with the effective "Design and Application Requirements" (i.e., the plan/carrier must STOP imposing an NQTL).
- The "Content Elements" related to the effective "Design and Application Requirements."
- The Fiduciary Certification related to the NQTL comparative analysis, including compliance with the existing rules and the "Content Elements" relating to the effective "Design and Application Requirements."
- The consequence for failing to have a compliant NQTL comparative analysis, including compliance with the existing rules and the "Content Elements" relating to the effective "Design and Application Requirements" (i.e., notify participants of non-compliance).
- Treating the NQTL analysis as an ERISA-covered plan document.
- The timing for furnishing the NQTL comparative analysis to the Departments.

Effective Date #2: The following requirements apply on the first day of the first plan year beginning on or after **January 1, 2026**:

- The "prohibition on discriminatory factors and evidentiary standards" (which, as noted above, is part of the "Design and Application Requirements").
- The "Relevant Data Evaluation Requirements."
- The "Meaningful Benefits" requirement.
- The "Network Composition" requirements.
- The consequence for failing to comply with the "prohibition on discriminatory factors and evidentiary standards," the "Relevant Data Evaluation Requirements," the "Meaningful Benefits" requirement, and the "Network Composition" requirements (i.e., the plan/carrier must STOP imposing an NQTL).
- The "Content Elements" related to the "prohibition on discriminatory factors and evidentiary standards," the "Relevant Data Evaluation Requirements," the "Meaningful Benefits" requirement, and the "Network Composition" requirements.
- The Fiduciary Certification related to the NQTL comparative analysis, including compliance with the "Contents Elements" relating to all of the requirements of the final regulations.
- The consequence for failing to have a compliant NQTL comparative analysis, including compliance with the "Contents Elements" relating to all of the requirements (i.e., notify participants of non-compliance).