ERIC | THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

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Submitted Electronically via: ***www.regulations.gov***

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N–5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210
Attention: 1210–AC11

RE: Requirements Related to the Mental Health Parity and Addiction Equity Act (EBSA-2023-0010-0001)

To Whom It May Concern:

The ERISA Industry Committee ("ERIC") respectfully submits the following comments in response to the Notice of Proposed Rulemaking ("NPRM"), setting forth proposed requirements that would require self-insured health plans and insurance issuers to collect specified data and undertake a detailed evaluation to assess the impact of a nonquantitative treatment limitation ("NQTL") applicable to mental health and substance use disorder ("MH/SUD") benefits as compared to medical/surgical ("M/S") benefits. In the preamble to the NPRM, the Departments of Health and Human Services, Labor, and the Treasury (the "Departments") explained that the collection of this additional information and subsequent evaluation is intended to help federal and state regulators determine if plans/issuers are designing and implementing NQTLs that impose greater limits on *access* to MH/SUD benefits as compared to M/S benefits, and correspondingly, whether plans/issuers are out of compliance with the Mental Health Parity and Addiction Equity Act ("MHPAEA").

ERIC is the only national trade association that advocates exclusively on behalf of large employers on health, retirement, and compensation public policies on the federal, state, and local levels. ERIC's member companies offer comprehensive group health benefits to their employees in compliance with the myriad federal laws including the Internal Revenue Code ("Code"), the Employee Retirement Income Security Act ("ERISA"), and the Public Health Service ("PHSA"). ERIC supports the ability of its large employer member companies to tailor retirement, health, and compensation benefits to meet the unique needs of their workforce, providing benefits to millions of workers, retirees, and their families across the country.

COMMENTS

I. The Proposed Regulations May Result In Decreased Access to Mental Health and Substance Use Disorder ("MH/SUD") Benefits

As the Departments are aware, the law *does not* require employers to offer health benefits to their employees.

However, employers *choose to voluntarily* offer health benefits to (1) attract and retain talented workers and (2) keep their employees healthy and productive.

To achieve each of these stated goals – and to meet employee demands – employers *voluntarily* offer *comprehensive* and *quality* health coverage. This includes offering health plans with broad provider networks and comprehensive coverage options, including 80 percent or higher actuarial value plans. This also includes voluntary coverage of the Affordable Care Act's ("ACA") essential health benefits, and often coverage of many services and products beyond what is typically covered in the fully-insured market.

In the case of self-insured health plans sponsored by ERIC member companies, our members traditionally go beyond the typical health plan offerings sponsored by other employers. Here, our member companies offer robust prescription drug coverage, including coverage for gene and cell therapy and other specialty drugs. Plan beneficiaries often have access to concierge medicine or direct primary care, enhanced telehealth services, fertility or benefits not traditionally covered by a health plan. Member companies also provide enhanced services for various medical episodes through Centers of Excellence and other value-based insurance programs. Additionally, they offer their employees access to transparency, wellness, and financial well-being tools.

ERIC member companies also recognize the importance of mental health, and the growing need for access to mental health and substance use disorder items and services. As a result, our members offer a wide array of MH/SUD benefits – *voluntarily*. They believe in caring for the whole patient and have increased MH/SUD benefit offerings in pursuit of patient total care.

As the Departments are also aware, the law *does not* require employers to cover any MH/SUD benefits under their health plan. In this case, MHPAEA's requirements *do not* apply.

If, however, an employer *chooses to voluntarily* provide coverage of a wide-array – or even a select few – of MH/SUD benefits, MHPAEA's requirements *do* apply. Here, the employer *must* ensure that its health plan complies with *all* MHPAEA's requirements.

ERIC members believe that compliance with the laws that govern employer-sponsored health benefits is essential. However, the proposed regulations are so burdensome that many of our members will have no other choice but to re-think the type and level of their plans' coverage of MH/SUD benefits.

To be clear, such a dramatic shift in coverage is *not* because our members want to adopt changes to their current coverage. However, the significant burdens associated with the proposed regulations will increase administrative costs (in time and labor, as well as monetary expenditures), taking valuable and finite resources away from providing additional coverage and care. Many of our member companies will find themselves struggling to justify the significantly greater cost of providing the type and level of their plans' current coverage of MH/SUD benefits.

As you know, ERIC and our member companies have worked with the Departments for many years to ensure compliance with the implementation of MHPAEA and subsequent revisions to the law. However, any benefit-related changes would be a *direct result* of the proposed requirements which, in their current form, are *so unworkable* that our members would be confronted with the choice to (1) reduce coverage for MH/SUD benefits or (2) modify or eliminate the NQTLs applicable to M/S benefits. From our members' perspective, it appears that the Departments' goal is to dissuade the implementation of most NQTLs, which is not in accord with the Departments' statutory authority.

Moreover, given our expertise in the field of employee benefits, we believe that other employer sponsors (i.e., non-ERIC members) could have a more extreme reaction to maintaining the type and level of coverage of MH/SUD and M/S benefits due to the increased cost and regulatory burden flowing from these proposed rules.

In the end, if the Departments' pursue the proposed regulations as published, efforts to "increase *access* to MH/SUD benefits" – a goal noted multiple times in the preamble of the proposed rules, articulated in the Departments' press release, and heralded in the Fact Sheet developed by the White House – will actually have the *opposite* effect.

As stated above, ERIC member companies traditionally go above-and-beyond to provide access to quality care for their workers and their families. They have consistently offered plans that provide (1) comprehensive and affordable health coverage and (2) access to life-saving medical treatments and much-needed items and services to treat mental health and substance use disorders. Unfortunately, the proposed regulations will adversely impact the significant and extensive mental health and substance use disorder coverage our members provide through robust plan offerings, which could lead to the unintended consequence of *decreasing* access to MH/SUD benefits.

II. Difficulty In Providing Meaningful, Constructive and Productive Comments

The proposed regulations go far beyond what Congress originally intended when enacting MHPAEA. According to the House Energy and Commerce Committee report on the House bill which became MHPAEA:

> *H.R. 1424 seeks fairness in **coverage** of mental health and substance-related disorders. The bill aims to increase access to mental health treatment by prohibiting group health plans (or health insurance coverage offered in connection with a group health plan) from imposing **financial requirements** (including deductibles, co-payments, coinsurance, out-of-pocket expenses, and annual and lifetime limits) or **treatment limitations (including limitations on the number of visits, days of coverage, or frequency of treatment)** on mental health and substance-related benefits that are more restrictive than those restrictions applied to medical and surgical benefits. This legislation provides a cost-effective way of promoting increased access to mental health care.*[1]

Clearly from a reading of the Congressional intent from the development of MHPAEA, Congress was focused on financial requirements and quantifiable treatment limitations ("QTLs") when deciding which practices the statute would prohibit, *not* NQTLs.

[1] H.R. Rep. No. 110-374 Part 3, page 14 (2008) (emphasis added).

However, despite the Department's overreach regarding MHPAEA's application to NQTLs – which admittedly occurred through regulation several years ago and was subsequently referenced in the Consolidated Appropriations Act, 2021 ("CAA, 2021") through the requirement to produce a "comparative analysis" of NQTLs imposed on MH/SUD benefits covered under the plan – ERIC and our members have been willing partners in working with the Departments and other stakeholders for many years to consider how creditable, reliable, and consistent standards for evaluating MH/SUD and M/S benefits parity could be applied in the context of NQTLs.

Yet, the various tests and requirements in the proposed regulations (in particular, the "substantially all test," "predominant test," and the "relevant data and evaluation requirement") are wholly unworkable, so much so that employers are unable to provide meaningful, constructive, and productive comments to fully answer the questions the Departments raise related to these proposed tests and requirements.

The inability to analyze the impact of these proposed tests and requirements stems from the fact that much of the proposed content is new policy and/or a reversal of a decade's worth of Departmental guidance. For example, under final regulations issued in 2013, the Departments explicitly stated that they "*did not intend to impose a **benefit mandate** through the parity requirements that could require greater benefits for mental health conditions and substance [use] disorders.*"[2] Under the proposed regulations, however, the Departments' efforts to increase *access* to MH/SUD benefits through the newly proposed "substantially all test," "predominant test," and the "relevant data and evaluation requirement" – as well as the undefined "meaningful benefit" requirement – all amount to **benefit mandates**.

In addition, in the final 2013 regulations and subsequent guidance, the Departments rejected recommendations to equally apply the tests and requirements for comparing QTLs to NQTLs.[3] Specifically, the Departments recognized that plans and issuers impose a variety of NQTLs affecting the scope or duration of benefits that are not expressed numerically, and further, that while NQTLs are subject to parity requirements, NQTL limitations cannot be evaluated mathematically.[4] Conversely, the Departments are now proposing what they previously rejected -- applying numerical and mathematical tests and requirements to NQTLs that are otherwise applicable to QTLs.

Also, the Departments are effectively relying on "outcomes" data as a measure for determining whether there is adequate access to MH/SUD benefits. Outcomes data is not always a good measure for determining access, and requiring plan sponsors to evaluate outcomes data for purposes of determining whether adequate access to MH/SUD benefits indeed exists is arbitrary and unsupported by the statute. In addition, we disagree with the premise that outcomes (rather than process) should be the standard for MHPAEA compliance, and the Departments have previously acknowledged that outcomes are not dispositive of compliance with the parity requirements.[5]

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[2] 78 Fed. Reg. 68240, 68246 (Nov. 13, 2013) (emphasis added).
[3] *Id*. at 68245.
[4] *Id*.; *see also*, *Understanding Implementation of Mental Health Parity and Addiction Equity Act of 2008*, Q&A-6 at https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/understanding-implementation-of-mhpaea.pdf.
[5] 78 Fed. Reg. at 68245-46 (Nov. 13, 2013).

More specifically, the proposed rules provide that "material differences" in outcomes data will be viewed as a strong indicator of noncompliance to the extent that outcomes are more stringent for MH/SUD benefits than for M/S benefits. In addition, where network composition is concerned, a material difference in outcomes data *will be considered noncompliance*. This is, in our view, wholly out of step with the applicable provision of the statute, as well as the 2013 final regulations in which the Departments explained:[6]

> *[These final] regulations do not require plans and issuers to use the same NQTLs for both mental health and substance use disorder benefits and medical/surgical benefits, but rather that the processes, strategies, evidentiary standards, and other factors used by the plan or issuer to determine whether and to what extent a benefit is subject to an NQTL are comparable to and applied no more stringently for mental health or substance use disorder benefits than for medical/surgical benefits.* ***Disparate results alone do not mean that the NQTLs in use do not comply with these requirements.***

There can be many reasons why results might be disparate, particularly with respect to network composition. The reference to "*processes, strategies, evidentiary standards, and other factors*" does not contemplate parity of outcomes. Analyzing outcomes data is a long-recognized and widely accepted *tool* in population health management. The proposed regulations turn this tool into a compliance standard that is virtually impossible to satisfy.

With respect to network composition, the Departments also overlook the fact that plan sponsors have no control over providers who choose to eschew networks, or who choose only to accept cash and refuse to file claims with insurers. In addition, plan sponsors have no control over states that enact laws that limit provider competition. We believe that there is a reason why Congress opted against imposing network adequacy requirements for self-insured group health plans. However, the Departments – through regulations – are essentially doing just that -- imposing network adequacy standards through the guise of MHPAEA compliance.

Another significant reason for being unable to provide meaningful, constructive and productive comments is due to the almost insurmountable challenge in accessing reliable data. This is arguably one of the most critical issues underpinning the Departments' entire proposed regulations. More specifically, to perform the proposed tests and to comply with the proposed requirements, the Departments presume there is – or will be in short order – access by plan sponsors to the accurate, complete, and up-to-date data necessary to ensure compliance.

As the Departments are aware, plan sponsors continue to struggle – to no avail – to obtain their own plan's claims data from owners of the plan's provider networks or third-party administrators ("TPAs").

This problem is <u>*not*</u> new, and it is a problem that ERIC has continually communicated to the Departments during, for example, the implementation of the Transparency in Coverage Rule, and most recently, during the implementation of the transparency provisions enacted through the CAA, 2021 (e.g., the Data-Sharing/Gag Clause Prohibition and the Reporting of Pharmacy Benefits and Drug

[6] *Id*. (emphasis added).

Costs).[7] The House Education and Labor Committee's Leadership has also brought this issue to the Departments' attention.[8]

III. Comments Relating to the Three-Part Test for Imposing NQTLs on MH/SUD Services

A. *The Relevant Data Evaluation Requirement*

According to the proposed regulations, plan sponsors would be required to **collect claims data** for purposes of determining the impact of an NQTL on access to MH/SUD benefits relative to access to M/S benefits. Plan sponsors would then be required to evaluate the claims data to determine **outcomes**, analyzing the **outcomes** to then determine whether there is a **material difference** in access to MH/SUD benefits as compared to M/S benefits. If a plan sponsor reasonably determines that there is a **material difference** in access between benefits, the plan sponsor must take specific action to correct the material differences in access.

1. *The Data Evaluation Requirement Is Wholly Unworkable – Incorrectly Presumes Access to Data*

As noted above, under the proposed regulations, plan sponsors would be required to collect claims data (e.g., claims paid and claims denied) for purposes of determining the impact of an NQTL on access to MH/SUD benefits relative to access to M/S benefits. The Departments ask: *Do self-insured plans collect such claims data as part of their normal business operations?* The answer is: No.

As the Departments are aware, self-insured plans continue to struggle with accessing much needed data from their service providers, including health insurers, pharmacy benefit managers ("PBMs"), TPAs, and other third-parties and consultants, to assure they are meeting their ERISA fiduciary obligations under current law, including new ones set forth by the CAA's Gag Glause "attestation" requirement. Self-insured plan sponsors are routinely denied access to accurate, complete, up-to-date, and relevant claims data sets with these business partners who are acting on their behalf and on behalf of their plan participants. Unless data-sharing requirements are enacted by Congress – or until the Departments fully implement current transparency and data-sharing requirements by which there are no gaps or loopholes – plan sponsors will continue to struggle to access the data, so we question how the Departments expect self-insured plan sponsors to comply with the new proposed requirement to collect the plan's claim data.

2. *The Data Evaluation Requirement Is Wholly Unworkable – Plan Sponsors Are Unable to Evaluate Claims Data to Determine Outcomes*

As stated above, self-insured plan sponsors would be required to evaluate the claims data to determine outcomes. If plan sponsors do not have access to reliable claims data, how can they evaluate the data to be compliant with the proposed regulations?

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[7] *See* ERIC, *Request for Clarifying Guidance on Prohibited Gag Clauses*, Jan. 19. 2022 at https://www.eric.org/wp-content/uploads/2022/01/01-19-22-CAA-Section-201-Guidance-Letter.pdf.
[8] *See* Bipartisan Scott-Foxx Letter to EBSA *RE: Health Transparency*, Dec. 14, 2022 at https://democrats-edworkforce.house.gov/imo/media/doc/bipartisan_scott-foxx_letter_to_ebsa_re_health_transparency.pdf.

Self-insured plan sponsors rely on their TPAs and/or the owners of the provider networks to (1) develop plan designs (e.g., whether to cover certain MH/SUD benefits or not) and (2) develop and impose NQTLs on both MH/SUD and M/S benefits. It is the TPA or the owner of the provider network that must undertake this evaluation, especially in cases where the TPA or owner of the provider network will not share the claims data.

Here, the self-insured plan sponsor *cannot* evaluate the data to determine whether a material difference exists. Yet, the plan sponsor would ultimately be liable for non-compliance if, for example, the TPA or owner of the provider network determines that there is no material difference, but the Departments determine that a material difference indeed exists pursuant to an audit. The lack of control by plan sponsors over the compliance of their business partners cannot be overstated and should be recognized by the Departments.

Furthermore, the Departments also direct self-insured plans to collect and evaluate additional relevant data for NQTLs related to network composition, including but 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), and provider reimbursement rates (including as compared to billed charges).

Again, plan sponsors do <u>*not*</u> have access to this data. Instead, self-insured plan sponsors rely on their TPAs or owners of the provider networks to build the networks of MH/SUD providers on behalf of the plans. Despite our members' best efforts, the TPAs and owners of the provider networks routinely deny requests by plan sponsors for data associated with plan networks. Absent the Departments – or Congress – taking action to clarify explicitly (1) that a plan owns its complete data and (2) that the plan sponsor should have access to it freely, many self-insured plan sponsors (despite their best efforts) will continue to struggle to obtain the requisite data needed for compliance with *existing regulations*, much less the comprehensive set of *new* regulatory mandates set forth in these proposed rules.

Even if plan sponsors could access an accurate and reliable data set, the proposed requirements are so unworkable that compliance with the proposed rules is not achievable. That is not just our opinion. We understand that the insurance issuers – who serve as our partners and upon whom we primarily rely for purposes of complying with MHPAEA and the NQTL comparative analysis requirement – are informing the Departments that they need more workable tests if they are expected to comply with the proposed rules. If the issuers cannot comply, then plan sponsors cannot comply, whether we have access to reliable data or not.

3. <u>*The Data Evaluation Requirement Is Wholly Unworkable – Relies on an Undefined Term*</u>

The term "material difference" is not defined for purposes of compliance with this proposed requirement. The Departments request stakeholders to comment if material difference could be defined "*in a manner that translates into tangible quantitative research methods that would ensure that data is analyzed using statistical tools and results in meaningful information for plans and issuers to use in addressing barriers to accessing benefits*." The Departments additionally seek comment on "*whether 'materiality' should be defined in terms of the results of statistical testing and requesting feedback from interested parties on the optimal method for assembling data and statistical analysis*."

It is hard to determine where to begin when contemplating the myriad of questions with unknown answers and the universe of unknown factors to consider when evaluating this term. This is a perplexing supposition and one where it is difficult to provide a meaningful, productive, and constructive comment. Using statistical tools to address barriers to access? Is that possible? Defining "materiality" based on statistical testing? We know of no method for assembling data for the purpose of performing this statistical analysis.

As we explained above, the Departments have accepted – and clearly communicated to stakeholders in published guidance – that NTQLs (1) are not expressed numerically and (2) cannot be evaluated mathematically, and that tests and requirements for comparing QTLs cannot be used to compare NQTLs. Yet, in these proposed regulations, the Departments propose to require statistical testing, tools, and analyses for comparing NQTLs. The impossibility of this proposal and unworkable nature of it cannot be overstated, particularly given the very real threat the proposed regulations pose to the ability of employer-sponsored plans to continue to offer robust and compliant MH/SUD benefits.

For these reasons, we request that the Departments re-issue this proposal – and the Departments' request for comments on how to define material difference – as a Request for Information.[9] This way, stakeholders with differing interests will have the opportunity to suggest an appropriate definition and all stakeholders will have an opportunity to examine these suggestions and further opine on a workable definition that the Departments may consider.

To do otherwise, the Departments are setting up a process where this very important – yet undefined – term will be finalized and effective January 1, 2025, which will make it exceedingly difficult for plan sponsors to attempt to be compliant, given the short time between the issuance of these proposed rules and January 1, 2025.

B. ***The No More Restrictive Requirement***

Under this proposed requirement, self-insured plans must determine (1) the portion of plan payments for M/S benefits subject to an NQTL in a classification, (2) whether the NQTL applies to substantially all M/S benefits in the classification (i.e., the "substantially all test"), (3) the predominant variation of the NQTL that applies to M/S benefits in the classification (i.e., the "predominant test"), and (4) whether the NQTL, as applied to MH/SUD benefits in the classification, is more restrictive than the predominant variation of the NQTL as applied to substantially all M/S benefits.

1. *Self-Insured Plan Sponsors Do Not Have Reliable Access to Data to Perform the Substantially All Test*

With respect to the substantially all test, plans would be required to determine the portion of plan payments for M/S benefits expected to be subject to the NQTL based on the dollar amount of all plan payments for M/S benefits in the classification expected to be paid under the plan for the plan year.

[9] For example, the Departments should consider issuing a Request for Information ("RFI") with a 90-day comment period. Then, re-issuing proposed regulations no earlier than 90 days after the close of the RFI's comment period, with another 90-day comment period associated with the newly proposed regulations.

The Departments note that for the method for determining the dollar amount expected to be paid under the plan to be considered reasonable, the plan would be required to consider plan-level claims data. If, however, the actuary for the plan determines that the plan does not have sufficient data at the plan level for a reasonable projection of future claims, the Departments suggest that the plan should "utilize other reasonable claims data to make a projection to conduct actuarially-appropriate analyses."

There are significant challenges in obtaining plan-level claims data. As discussed above, plan sponsors do not have access to a complete and reliable set of claims data. If plan sponsors do not have access to claims data, they cannot consider plan-level claims data for purposes of determining whether the NQTL satisfies the substantially all test. In addition, if plan sponsors cannot consider plan-level claims data for purposes of satisfying the substantially all test, plans cannot rightfully "document the assumptions used in choosing a data set and making projections," as the Departments would require.

2. *Self-Insured Plan Sponsors Are Unable to Perform the "Two-Thirds Test"*

As part of performing the substantially all test, the Departments propose that if an NQTL does not apply to at least two-thirds of all M/S benefits in a classification, then that NQTL would not be permitted to be applied to MH/SUD benefits in that classification. The Departments explain that whether the NQTL applies to at least two-thirds of all M/S benefits would be determined without regard to whether the NQTL was triggered based on a particular factor or evidentiary standard, but instead, based on plan payments for M/S benefits subject to an NQTL as a portion of the dollar amount of all plan payments for M/S benefits in the classification expected to be paid under the plan. This "two-thirds test" (as it is known) is used when analyzing QTLs.

In the preamble of the proposed regulations, the Departments acknowledge that there are significant differences between QTLs and NQTLs. Yet, the Departments are seeking to apply a QTL-related test to NQTLs, which is a reversal of the Departments' long-held position articulated in previously issued Departmental guidance. We recognize that different administrations are permitted to change their interpretation of a statute, provided the administration has a factual basis for the new interpretation and adheres to the proper notice and comment period requirements as set forth in the Administrative Procedures Act. However, as stated, we do not believe that the Departments' interpretation of the statute – as set forth in these proposed regulations – is consistent with Congressional intent with regards to MHPAEA.

Case-in-point, during the House Energy and Commerce Committee vote on the House bill, which led to the passage of MHPAEA, there was discussion regarding the application of the substantially all and the two-thirds tests. According to the transcript of the Committee meeting, the clear intent was that the application of these tests were intended to apply in the context of financial limitations, such as co-payments, *not* NQTLS. Below is an excerpt from the transcript:

> Mr. DEAL: *So it does apply. All right. Now with regard to the underlying bill, one of the problems that I have is this issue of applying co-payments or beneficiary contributions based on whether substantially all of the services are included. First of all, does the amendment that we are considering now have any such similar requirement*?
> Ms. KEMPF: *I am sorry. Similar requirement as to*?

> Mr. DEAL: *As to the substantially all category on the underlying bill as a prerequisite for requiring things like co-payments*.
> Ms. KEMPF: *Yes. I am sorry. Ms. Wilson's amendment, counsel corrected me, does not*.
> Mr. DEAL: *And FEHBP does not either, does it*?
> Ms. KEMPF: *Not to my knowledge, but I have to just clarify that I am not an expert on FEHBP*.
> Mr. DEAL: *All right. Now what that means then in clear terms would be that if a majority of the categories of a health coverage plan do not require co-pays then no mental health services could require co-pays, is that correct? Is that the way it would work*?
> Ms. KEMPF: *The rule under HR 1424 states that if substantially all of the benefits in a specific category do not have some sort of beneficiary financial requirement that includes co-pays, deductibles, co-insurance, and other things--*
> Mr. DEAL: *And I think we established that the definition of substantially all is two-thirds*.
> Ms. KEMPF: *That is what has currently been operationalized in current law by HHS*.
> Mr. DEAL: *So therefore my question is if on the physical side, physical health side of it, if only a majority, not two-thirds, of the benefits there require co-pays then you could charge no co-pays for any mental health services under the underlying bill*?
> Ms. KEMPF: *I am sorry. Maybe my counsel can help me*.
> Mr. GROSSMAN: *I think that the fact is that if a majority of the services have a co-pay, you can charge a co-pay. Using the substantially all definition of one-third, you would have to have at least two-thirds of your medical benefits with virtually no co-pay before you would have a no co-pay rule on the mental health side*.[10]

As evidenced by the above transcript, members of the Committee contemplated the substantially all and two-thirds tests in the context of financial limitations, *not* NQTLs. As such, it is clearly a far reach to suggest that the substantially all and the two-thirds tests should also be applied to NQTLs, which are by nature not easily comparable or quantifiable, are generally considered on a case-by-case basis, or subject to the medical necessity of the treatment for a particular patient.

Nevertheless, in the context of acknowledging that there are significant differences between QTLs and the NQTLs, the Departments ask: *Do self-insured plans maintain systems capable of making such determinations (i.e., performing the two-thirds test)*? The answer is: We know of *no* system that can calculate the dollar amount of plan payments for NQTLs in the benefit classifications. Moreover, attempting to apply a mathematical method that relies on paid dollar amounts and amounts expected to be paid to NQTL analyses is not practical or possible, and nothing in the statute authorizes the Departments to mandate that the same amount or proportion of money spent on M/S benefits subject to NQTLs must similarly be spent on MH/SUD benefits.

3. <u>*Self-Insured Plan Sponsors Need More Guidance to Perform the Predominant Test*</u>

Self-insured plans would also be required to determine the predominant variation of the NQTL that is applied to substantially all M/S benefits subject to the NQTL in the classification. The Departments propose that the term "predominant" would, for this purpose, mean the most common or most frequent variation of an NQTL within a benefit classification. The most common or frequent

[10] Transcript of *Hearing to Make Permanent the Authority of the United States Postal Service to Issue a Special Postage Stamp to Support Breast Cancer Research; and Paul Wellstone Mental Health and Addiction Equity Act of 2007*, House Energy and Commerce Committee, Oct. 16, 2007, pages 89-90.

variation would be the variation that applies to the highest portion of all M/S benefits within a classification that are subject to the NQTL based on expected plan payments. For example, plans would be required to determine the portion of the benefit subject to different variations of the NQTL, if any, based on the dollar amount of all payments expected to be paid under the plan. Similar to our comments on the substantially all and two-thirds tests, we know of *no* system that can calculate the dollar amount of expected payments to determine the most common/frequent variation of an NQTL.

The Departments ask: *What additional clarifications or specificity is needed for self-insured plans to be able to determine the predominant NQTL that applies to substantially all M/S benefits in a classification, including what characteristics of a particular NQTL should be considered when determining the predominant variation when a plan imposes multiple variations, and how can you distinguish between what might be a single NQTL without any variations versus what might be variations of a single NQTL*? Because the scope of potential variations is limited only by one's creativity, the proposed requirement to apply quantitative testing for every different variation creates an impossible task for plan sponsors.[11]

This is a perfect example of a complex and convoluted test that the Departments are asking plans to not only opine on, but to provide additional clarifications or specificity on how to achieve compliance through *proposed regulations*. If the Departments want plan sponsors to assist them with developing an appropriate approach – or to suggest alternative approaches –the Departments should re-issue this proposal as a Request for Information and directly engage stakeholders through a dialogue.

C. *The Design and Application Requirement*

In the preamble of the proposed regulations, the Departments explain that a self-insured plan would not be permitted to impose an NQTL with respect to MH/SUD benefits in any classification unless, under the terms of the plan as written and in operation, 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 used in *designing and applying* the NQTL with respect to M/S benefits in the classification.

In addition, plans would be prohibited from relying upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against MH/SUD benefits as compared to M/S benefits. Information would be considered to discriminate against MH/SUD benefits if it is biased or not objective, in a manner that results in less favorable treatment of MH/SUD benefits, based on all the relevant facts and circumstances. The Departments enumerate certain facts and circumstances that may be relied upon to

[11] From a practical perspective, most NQTLs are multifactorial. For example, prior authorizations may vary based on the use of electronic prior authorization, who does the first review, what type of review is the first review, when is there a peer-to-peer review, etc. This may create dozens of potential variations on an NQTL process such that the "predominant" process is only applicable a small percentage of the time. Additionally, a process that is common for a particular NQTL on M/S benefits may not be the most appropriate process for MH/SUD benefits. For example, while electronic review may be the most common approach for M/S prior authorizations, the nature of MH/SUD conditions is such that diagnoses are subjective and not associated with clear biometric markers or objective findings. As a result, peer-to-peer review allows the provider to explain why he or she deems the prescribed level of treatment is necessary. It also represents an opportunity to explain to the health plan how applicable criteria have been met, or to justify why that level of care is medically necessary, even if it does not meet the criteria or there is a gray area in the criteria.

determine whether the information is objective or unbiased, which include, but are not limited to, the source of the information, the purpose or context of the information, and the content of the information. Such a facts and circumstances-based determination is by definition a *subjective* test.

This is further complicated by the fact that the proposed regulations – when considered in their entirety – essentially create a rebuttable presumption of non-compliance. As a result, ERIC member companies are faced with an impossible task: continuing to offer MH/SUD benefits for millions of employees and their families but doing so from a presumption of non-compliance. This means that self-insured plan sponsors will continue to offer these benefits at their own peril. They will do the best they can, and if and when the Departments test their compliance, they will have to disprove discrimination and will have to do so based on the subjective analysis of the Departments.

This issue of per se non-compliance is exacerbated by the fact that plan sponsors traditionally rely on their TPAs or owners of the provider networks to design and apply an NQTL to MH/SUD benefits. In cases where the TPA/owner of the provider network believes that they are relying on objective information to design and apply an NQTL, but upon the Departments' review the Departments disagree, the plan sponsor is ultimately liable for failing to be compliant. The lack of control over compliance – and the concerns associated with it – are *not* new. The proposal, if finalized, will exacerbate this problem, and plan sponsors will have to assume they are vulnerable to being held non-compliant as unable to satisfy the Departments' subjective high bar for complying with this new design and application requirement. Unfortunately, the Departments are setting plans up to fail and effectively forcing plan sponsors to offer MH/SUD benefits with no medical management, which is contrary to statute.

D. *Exceptions*

The proposed rules provide that plans and issuers would automatically satisfy the "no restrictive requirement," the "relevant data evaluation requirement," and the prohibition on discriminatory factors and evidentiary standards if the NQTL impartially applies generally recognized independent professional medical or clinical standards (consistent with generally accepted standards of care) to M/S benefits and MH/SUD benefits. In addition, the "no restrictive requirement" and the prohibition on discriminatory factors and evidentiary standards would be satisfied if the NQTL applies standards related to fraud, waste, and abuse that meet specific requirements.

While we appreciate the Departments' efforts to exempt plans from being forced to satisfy unworkable tests, we believe that the exceptions for (1) independent professional medical or clinical standards and (2) standards related to fraud, waste, and abuse are vague and undefined, leaving plans unable to confidently determine whether their NQTLs qualify for one of these exceptions.

We are also disappointed that the Departments are not considering an exception based on the quality and safety of a covered MH/SUD benefit or service that a participant may be accessing. For example, a participant may be directly harmed by eliminating an NQTL that does not otherwise satisfy the three-part test. In this case, if a plan can objectively show the Departments, based on credible data and professional judgment (e.g., medical management committee findings, clinical attestation, or claims data analysis), that eliminating an NQTL that otherwise does not satisfy the three-part test would harm the participant, the plan should be able to retain the NQTL and remain compliant, provided other applicable standards are satisfied.

In addition, the Departments could have offered simplified compliance tests or a "safe harbor" for those plans that are providing greater than average access to MH/SUD benefits. The more MH/SUD benefits a plan provides, the more complicated compliance becomes. This penalizes plan sponsors that are doing more to provide access to MH/SUD benefits. A safe harbor would create an incentive by easing the burden of regulatory compliance for those going above and beyond, which aligns with the Departments' policy goal of increasing access to MH/SUD benefits, while also broadening the benefits provided.

IV. Meaningful Benefit

The Departments introduce a new term in the proposed regulations -- "meaningful benefit." Unfortunately, this is another term without defined meaning (like "material difference" discussed above). Similarly, the Departments ask the public to help define a critical term without any basis for creating the term in the first place.

This is another prime example of regulatory overreach beyond the clear statutory intent. Moreover, the significance of creating this definition in the greater landscape of health care warrants a much broader discussion than asking the public to define the term through a proposed rule. To do so would be akin to the administration asking the public to define a federal right to privacy in a proposed rule. Such definitions are complex and must consider a number of factors greater than can be evaluated in the context of a proposed regulation.

We assert that the Departments are effectively rewriting the MHPAEA statute by requiring plans and issuers to compare the *treatments* of conditions or disorders in each classification in which M/S and MH/SUD benefits are provided instead of the *coverage* for M/S benefits as compared to *coverage* for MH/SUD benefits. Congress did not intend for such comparison of *treatments* of a condition or benefit. For example, the Chair of the House Energy & Commerce Committee specifically clarified during the mark-up of legislation which came to serve as the underlying MHPAEA statute, that Congress was requiring *coverage* for MH/SUD benefits relative to M/S benefits, and Congress was **not** requiring a particular *treatment* for such benefits.[12]

Moreover, when MHPAEA was being developed, the House bill included a reference to "minimum benefit requirements." This was subsequently dropped from the MHPAEA bill as enacted. However, this provides important insight into Congressional intent, and context that the Departments should consider regarding the meaningful benefit proposal. Specifically, according to the House Energy and Commerce Committee report on the House bill:

> *Section 3(d) is entitled "Minimum Benefit Requirements." It requires that group health plans or health insurance coverage offered in connection with such plans that provide mental health or substance-related disorder benefits shall provide* ***coverage*** *of any disorder or condition listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM) published by the American Psychiatric Association. Insurance plans retain the authority in current law to define treatment benefits that are covered under the plan and the scope of those treatments for the disorders that*

[12] Transcript of *Hearing to Make Permanent the Authority of the United States Postal Service to Issue a Special Postage Stamp to Support Breast Cancer Research; and Paul Wellstone Mental Health and Addiction Equity Act of 2007*, House Energy and Commerce Committee, Oct. 16, 2007, pages 60-64.

> *are defined by the DSM. A "mental health benefit" as defined under current section 2705(e)(4) of the Public Health Service Act and incorporating amendments made under H.R. 1424 means "benefits with respect to services for mental health conditions or substance-related disorders, as defined under the terms of the plan or coverage (as the case may be)." This provision permits a plan to define what benefits are available for the disorders listed under the DSM that are required.*
>
> *In addition,* ***this requirement does not change the current ability of an insurer or provider to determine medically necessary and appropriate care and treatment for their patients.*** *It merely ensures that patients are not denied mental health* ***coverage*** *based on the specific disorder they have. For example, a person cannot be denied coverage by their health plan merely because they have autism.* ***A plan may determine, however, whether a treatment is medically necessary or appropriate for a given person at a given time based on their individual situation.***[13]

We recognize that the Departments believe that comparing *treatments* of conditions or disorders in each classification is the proper interpretation of the statute (as noted in the 2013 Interim Final Rules and in these proposed regulations), but we disagree that this interpretation is consistent with Congressional intent. Even if the Departments pivoted away from defining meaningful benefit, and instead, sought to develop a standard the Departments are calling substantial coverage of MH/SUD benefits (or "benefits for the primary or most common or frequent types of treatment for a covered condition or disorder") in each classification in which M/S benefits are provided, we do not have a suggestion on how to define these terms because basing a comparison on *treatments* of conditions or disorders is an overreach of the Departments' regulatory authority under MHPAEA.

We believe the Departments need to go back to the drawing board on this proposed requirement. Similar to our comments relating to the definition of material difference, we believe that the Departments should re-issue their request for comments on how to define meaningful benefit in a Request for Information format. To do otherwise, the Departments are setting up a process where this very important – yet undefined – term will be finalized and effective January 1, 2025 (assuming this proposed effective date is finalized as well), which will make it exceedingly difficult for plan sponsors to attempt to be compliant, given the short time between the issuance of these proposed rules and January 1, 2025.

V. Fiduciary Certification

As plan fiduciaries, ERIC members take very seriously their fiduciary obligations, and work tirelessly to adhere to ERISA's fiduciary duties. Plan sponsors are already acting in the best interests of plan participants and to add a fiduciary certification requirement on top of a plan sponsor's existing duty to comply with the law (e.g., imposing fiduciary liability for failure to "certify" that the plan's NQTL analysis complies with the proposed requirements <u>or</u> imposing fiduciary liability in cases where a "certification" is made, but the Departments conclude that the plan's NQTL analysis is *not* compliant) is unnecessary and unreasonably burdensome.

[13] H.R. Rep. No. 110-374 Part 3, page 33 (2008) (emphasis added).

As noted above – and as the Departments clearly recognize – plan sponsors of self-insured plans rely on their TPA and/or the owner of the provider network to develop and impose NQTLs on both MH/SUD and M/S benefits. In turn, these plan sponsors rely on their TPA/service provider to conduct and produce an NQTL analysis for the plan.

In most cases, the named plan fiduciaries of a health plan do not have the requisite knowledge and experience to fully understand, dissect the findings, and ultimately conclude whether the TPA's/service provider's NQTL analysis for the plan is indeed compliant with the proposed content elements. As a result, to comply with such a certification requirement, the plan's fiduciary would likely seek an independent expert to review the TPA's/service provider's NQTL analysis. Essentially, the plan fiduciary is hiring a service provider to check up on the plan's service provider. This creates an inefficient use of resources and assets that could otherwise be used to provide access to MH/SUD benefits, but instead would be unnecessarily re-allocated to compliance reviews. Additionally, even if the hired party were charged to evaluate the analysis, again, as plan sponsors have encountered to date, there is no certainty that their hired party will get access to the requisite data or analysis to be assured that plan sponsors are in compliance.

This raises yet another concern -- this new requirement will expose plan sponsors to potential lawsuits from plan participants and/or the plan's service providers. In addition, contract negotiations between the plan sponsor and their TPA/service provider will be strained. For example, it is likely that plan sponsors will seek the inclusion of indemnification language insulating the sponsor from liability in the event the TPA/service provider produces a non-compliant NQTL analysis, which the TPA/service provider will likely reject. Similarly, the TPA/service provider will likely seek protection from any liability in the event the plan fiduciary makes a certification, but the Departments subsequently determine that the NQTL analysis is non-compliant. This is just another example of how plan resources will be diverted away from covering MH/SUD benefits, and instead, used unnecessarily to cover plan administrative matters.

VI. NQTL "Comparative Analysis" and New Content Elements

ERIC, along with a number of other stakeholders, have asked the Departments to create a model NQTL template so plan sponsors can more easily develop – and also understand the contents of – the plan's NQTL comparative analysis. However, with the amount of new information that the Departments are requiring plans to include in their NQTL analysis, it will be virtually impossible to develop a model NQTL template to aid in compliance.

We respectfully ask the Departments to reconsider the proposed content elements and the required information associated with each.. The Departments should streamline the required information to make it easier for the Departments to develop a model NQTL template for plan sponsors. This is especially important if the Departments intend to finalize the fiduciary certification requirement. A template developed by the Departments will help a plan fiduciary better understand whether a TPA/service provider correctly produced a compliant NQTL analysis. In addition, such a template will help reduce potential costs (i.e., mitigating the need to hire an independent expert to evaluate the product of the TPA/service provider).

VII. Telehealth Issues

A. *We Are Leaders In the Use of Telehealth*

ERIC's member companies have been pioneers in offering robust telehealth benefits. Telehealth enables participants and their beneficiaries to obtain the care they need, when and where they need it, in an affordable and convenient manner. It reduces the need to leave home or work and risk infection at a physician's office, provides a solution for individuals with limited mobility or access to transportation, and has the potential to address provider shortages and improve choice and competition in health care. Nearly every ERIC member offers comprehensive telehealth benefits and did so long before the COVID pandemic. As in most aspects of health care and value-driven plan designs, self-insured plan sponsors have been the early adopters and drivers of telehealth expansion. With the onset of the pandemic, ERIC's member companies led the way in rolling out telehealth improvements – held back only by various federal and state government barriers.

B. *Telehealth Increased Access to MH/SUD Benefits*

The use of telehealth has proven to be an effective tool for *increasing access* to MH/SUD benefits, which is the stated goal of the Departments and the White House in the context of these proposed regulations. As the COVID pandemic began, ERIC members rushed to implement telehealth services, not just for physical health, but for mental and behavioral health services as well. For example, according to Mercer, expanding access to behavioral health care was the #1 priority among employers with 20,000 or more employees and #2 among employers with 500 or more employees back in 2021.[14] Over the past two to three years, 69 percent of large employers enhanced or expanded their EAP services and 42 percent added a supplemental network for virtual or in-person behavioral healthcare.[15] Access to virtual behavioral care spiked during the pandemic with around 50 percent of all behavioral health visits being furnished through telebehavioral health providers throughout 2020, with only a modest decline in the ensuing years, standing steady at 30 percent of all behavioral health visits throughout 2023.[16]

The fact that access to MH/SUD benefits *increased* substantially on account of telehealth services cannot be overstated. Based on such evidence, a better way of accomplishing the Departments' stated policy goal of increasing access to MH/SUD benefits is by continuing to rely on telehealth services and the private marketplace, instead of requiring plan sponsors to attempt to comply with unworkable tests and mandates through the proposed rules. To this latter point, the Departments agree, recommending that Congress consider ways to permanently expand access to telehealth and remote care services, and further explaining in the 2022 MHPAEA Report to Congress:[17]

> *Telehealth has become a vital means of providing health care, including MH/SUD health care, especially in light of the COVID-19 pandemic. Nonetheless, there are noteworthy barriers to ensuring access to telehealth services, including limited broadband access and interstate*

[14] *See* Mercer, *What's working to expand behavioral healthcare access: 5 best practices*, Oct. 5, 2023 at https://www.mercer.com/en-us/insights/us-health-news/whats-working-to-expand-behavioral-health-care-access/.
[15] *Id.*
[16] *Id.*
[17] 2022 MHPAEA Report to Congress, page 53 at https://www.cms.gov/files/document/2022-mhpaea-report-congress.pdf.

licensing requirements. The Departments recommend that Congress take steps to ensure access to telehealth services and look forward to working with Congress and stakeholders to identify ways to achieve this goal.

ERIC has identified a useful way to achieve this goal: Amending ERISA's preemption provision to preempt state licensure requirements, which stand as a significant barrier to achieving improved access for patients, especially in areas with mental and behavioral health provider shortages.

C. *Flexibility In Offering Telehealth Services Should Continue and Be Expanded*

Another useful way of ensuring access to telehealth services is by extending the Departments' guidance that temporarily allowed self-insured health plans to offer benefits for telehealth and remote care services to employees and dependents who are not eligible for coverage under any other group health plan offered by that employer. This flexibility ended with the expiration of the COVID Public Health Emergency ("PHE"), but we see no reason why the Departments cannot continue to allow self-insured plan sponsors to offer telehealth services to those part-time, temporary, or seasonal employees who may not otherwise be eligible for major medical coverage under the employer's group health plan.

ERIC also believes that Congress should enact legislation allowing telehealth services to be considered an "excepted benefit" under ERISA. Telehealth offered as an excepted benefit provides workers with another destigmatizing option for obtaining health care services, including in some cases, more robust networks of mental health professionals with more availability and accessibility. By way of example, health care providers across the continuum saw increases in patient engagement and access to care through telehealth, and peer-reviewed research shows that during the pandemic, virtual care provided crucial longitudinal care for chronic conditions and behavioral health care.[18] Using zip-code and geo-located data, this research showed that there was a 58 percent increase in telehealth use from patients in urban areas and 68 percent increase in patients from rural areas.[19] Roughly 50 percent of these telehealth visits came from patients in areas with a per capita income of <$20,000.[20]

Contrary to popular belief, telehealth providers and traditional brick-and-mortar providers are not competing with each other for patients. Similar to a traditional health care experience, telehealth enhances the longitudinal patient-provider relationship. More often than not, telehealth providers work collaboratively to ensure optimal care coordination and care management when needed which reduces fragmentation, duplication of services, and delays in receiving necessary care.

Unlike the Departments' guidance during the COVID PHE, it is important to emphasize that MHPAEA does not apply to an excepted benefit. However, this does not change the social benefits that have become evident from the flexibility to allow telehealth services to be attained during the COVID pandemic. It is clear that such social benefits should be continued in some form.

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[18] *See* Journal of Medical Internet Research, *Where Virtual Care Was Already a Reality: Experiences of a Nationwide Telehealth Service Provider During the COVID-19 Pandemic* at file:///C:/Users/cecon/Downloads/Where_Virtual_Was_Already_Reality_The_Experiences_.pdf.
[19] *Id.*
[20] *Id.*

VIII. No Comments on Technical Release 2023-01P

Please note, the foregoing comments are limited to the Departments' proposed regulations. We do not address any of the Departments' requests for public feedback on proposed new data requirements for limitations related to the composition of a plan's or issuer's network set forth in Technical Release 2023-01P. In time, ERIC may consider submitting comments on the Technical Release.

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Thank you in advance for considering these comments. Please do not hesitate to contact me at 202-789-1400 or jgelfand@eric.org with any questions or if we can serve as a resource on these very important issues.

Sincerely,

James P. Gelfand
President & CEO