Parity Implementation Coalition

INTRODUCTION

The Parity Implementation Coalition (PIC) submits these comments in response to the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments) April 23, 2018 joint request for comments on "[Proposed] FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part XX."

The PIC is an alliance of mental health and substance use disorder consumer and provider organizations. Members include the American Society of Addiction Medicine, Depression and Bipolar Support Alliance, Hazelden Betty Ford Foundation, Mental Health America, National Association for Behavioral Healthcare, National Alliance on Mental Illness, National Association of Addiction Treatment Providers, and Young People in Recovery. In an effort to end discrimination against individuals and families who seek services for mental health and substance use disorders, many of these organizations have advocated for more than nineteen years in support of the passage of parity legislation, issuance of regulations and enforcement of both.

We remain committed to working with the Administration on the prompt, effective implementation and enforcement of the Mental Health Parity and Addiction Equity Act (MHPAEA). We are hopeful that all sub-regulatory guidance and the Model Form to Request Documentation from an Employer-Sponsored Health Plan or an Insurer Concerning Treatment Limitations will be finalized and an enforcement strategy developed prior to the 10th anniversary of the enactment of MHPAEA on October 3, 2018.

We applaud the Departments for an excellent job in meeting the requirements of Section 13001 of the *21st Century Cures Act* (PL 114-146) ("CURES") by issuing the Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act and Model Disclosure Form with the proposed FAQs. Together, these documents are consistent with and reinforce prior guidance released by the Departments clarifying that s plans are required to conduct these types of compliance analyses for each non-quantitative treatment limitation (NQTL), both in writing and in operation, the methods for conducting such analyses, and the evidence and documentation relating to such compliance analyses that plans must disclose to beneficiaries and their authorized representatives.

Ensuring that plans are required to disclose all NQTL analyses and relevant documentation to a beneficiary or authorized representative is particularly critical as one of the primary complaints from our members on behalf of their patients is lack of disclosure on NQTL development and application by health plans and insurance issuers. Consumers and providers serving as a patient's authorized representative are entitled to plan documents and information regarding the development and application of NQTLs that a plan imposes to limit access to benefit coverage and how those limitations are comparable to and no more stringently applied to substance use/mental

800 Maine Ave, SW • Suite 800 • Washington, DC • 20024

health benefits than to medical/surgical benefits. PIC members consistently report that although they request this type of information, in particularly, on appeal from denied claims, plans are either non- responsive, or respond with generic summaries of the law and regulations, or summaries that are not fact specific to the NQTL utilized to deny the claim at issue. To the extent there has been enforcement in this area from the Departments, we have yet to see evidence that plans have changed their practices. Absent this information, consumers and providers are unable to determine whether or not the plan is in compliance with the parity law and its regulations.

Considering that clear guidance for disclosure has been in place since at least the Final Rules issued in November 2013, followed up by issuance of clear sub-regulatory guidance, including several FAQs, Warning Signs, etc., we recommend immediate enforcement of the disclosure requirements with the 10 largest insurers nationwide.

This PIC comment letter includes the following attachments:

1. Self-Compliance Tool comments for the Office of Management and Budget;
2. Key Take Aways from the April 23, 2018 CURES Guidance;
3. Prior DOL/HHS Guidance Consistent with CURES Guidance;
4. Standardized and Feasible Methodology for Measuring and Reporting Denial Rates;
5. Five Proposed New FAQs on network adequacy, reimbursement rates and disclosure; and
6. Amendments to Q2 (level of disparity) and to Q5 (diagnostic exclusions).

SUMMARY OF RECOMMENDATIONS

A. The PIC applauds the Departments for issuing this sub-regulatory guidance with additional examples, which had been requested by consumers, providers and plans. We urge the Departments to swiftly finalize this guidance. We also recommend immediate enforcement in those areas for which guidance has been in place for several years.

The PIC has performed a detailed analysis of key compliance program guidance and FAQs based on the Self- Compliance Tool (Attachment 1) and combined Self-Compliance Tool and Model Disclosure Form with proposed FAQs (Attachment 2). We also conducted a review of the Departments' prior guidance with an eye toward demonstrating how the current CURES guidance is entirely consistent with and reinforces prior guidance (Attachment 3). We have highlighted in the attached documents at least 4 key areas that are illustrated in the recent CURES parity guidance, which are consistent with and reinforce prior guidance:

1. Denial rates and other measures of outcomes are essential in analyzing NQTL rule compliance, particularly, as applied in operation;

2. Multiple key steps are necessary in order to conduct a compliant NQTL analysis (each and every step is necessary, e.g., factors without the evidentiary standards used to evaluate them is insufficient);

800 Maine Ave, SW • Suite 800 • Washington, DC • 20024

3. Compliant disclosure requires that <u>all steps</u> of a plan's NQTLs analyses must be provided to consumers and authorized providers;

4. Quantitative analyses of evidentiary standards and other aspects of NQTL development and application are essential in determining compliance.

B. The Departments should provide technical assistance to consumers, providers, plans, and states. This technical assistance should:

- Further develop the interactive portal for consumer and providers to allow for the uploading of complaints and clear timelines for responses
- Provide on-site state and regional workshops on MHPAEA implementation and enforcement based on the April 23, 2018 guidance implementing Section 13001 of the *21st Century Cures Act*
- Develop a model "authorized representative" form so there is a consistent format consumers, providers and payers use for this purpose
- Clarify that denial rates and other outcomes are proper and essential parts of an NQTL analysis

C. The Departments should issue additional FAQs on outstanding issues, including: network adequacy, reimbursement rates and disclosure. Examples of the types of FAQs PIC members recommend are included as attachments to these comments.

D. The Department of Labor (DOL) should work with Congress to provide DOL with the authority it requests to levy monetary penalties on insurers and funders.

Recommendation 1: Enforce the prior guidance and finalize the recent guidance

<u>A. Denial Rates and other measures of outcomes are essential in analyzing NQTLs.</u>

The proposed FAQs released on April 23, make clear that denial rates and other outcomes data are required to be measured and calculated in any NQTL analysis of "in operation" as set forth in the new CURES guidance as well as regulatory and sub-regulatory guidance issued from 2011 to 2017. This is consistent with and an essential part of the "five steps" process set forth in the new CURES guidance, as well as sub-regulatory guidance issued in 2016.

Many PIC members have worked with Congress and the Administration for nearly two decades to enact, implement and enforce the federal parity law. During these years concerted efforts in good faith were undertaken by all stakeholders to reach consensus between consumers, providers, health plans and issuers and their respective trade groups on proper implementation and compliance with MHPAEA. Progress was made in some areas; in other areas, major differences remain. In particular, most plans continue to state that guidance has not been clear in the area of proper analyses of NQTLs and the types and extent of disclosure of plan documents that are required under the law. The PIC and most consumers and providers who often serve as their patient's authorized representative believe that the Departments' regulatory and sub-regulatory guidance to date has been very clear in these areas.

800 Maine Ave, SW • Suite 800 • Washington, DC • 20024

We also believe the current array of model forms, self-compliance tools and sub-regulatory guidance has added additional clarity and it is our hope that plans will move into full compliance. One of the most important actions we believe is necessary to accomplish this is to increase enforcement of the guidance already given. It is apparent that market forces alone have not helped to achieve equity in access to mental health and substance use disorder treatment services in proportion to the demand caused by the twin epidemics of opioids misuse and overdoses and suicides.

For example, a recent Milliman report found that "patients used an out-of-network provider for a substantially higher proportion of behavioral care than they did for medical/surgical care. Between 2013 and 2015, the proportion of inpatient facility services for behavioral healthcare that were provided out-of-network was 2.8 to 4.2 times higher than for medical/surgical services, and the proportion of outpatient facility services for behavioral healthcare that were provided out-of-network was 3.0 to 5.8 times higher than for medical/surgical services. Additionally, the proportion of behavioral office visits that were provided out-of-network was 4.8 to 5.1 times higher than for medical/surgical primary care office visits, and 3.6 to 3.7 times higher than for medical/surgical specialist office visits (primary care and specialist providers in this report are medical/surgical providers)." The Milliman report highlighted the lack of plan compliance and enforcement, as these significant areas of disparities worsened from 2013 to 2015, despite the MHPAEA regulations.

With respect to outcomes measurements, the PIC analysis found 6 examples (from both FAQs Part 39 and the Self Compliance Tool), that demonstrate that measurement of outcomes (e.g., denial /approval rates) is an ESSENTIAL part of determining NQTL compliance. While we are aware that DOL has issued guidance reflecting that outcomes alone are not determinative of compliance, we have summarized how multiple FAQs clearly demonstrate that NQTL compliance CANNOT be determined WITHOUT an assessment of denial rates and other outcomes (See Attachments 1 and 2). In addition, we have highlighted 4 FAQs from prior guidance (one of which dates back to 2011), in which measuring outcomes, such as denial rates, in and out of network use, frequency of reviews, number of available providers in a geographic area, etc. is an essential component of determining NQTL compliance. (See Attachment 3).

We highlight these examples, in particular, because a number of plans are interpreting both the CURES guidance and prior guidance as NOT requiring ANY measure of outcomes, whether denial rates, in and out of network disparities, or otherwise, as part of an analysis of NQTL operational compliance. We recommend that the Departments' make clear that a plan is required to access, measure and report outcomes data as an essential component of a plan's NQTL operational compliance analysis under MHPAEA, even though denial rates and other outcomes alone may not be determinative of compliance. We have outlined a feasible and standardized methodology for measuring and reporting denial rates. (See Attachment 4, Standardized and Feasible Methodology for Measuring and Reporting Denial Rates).

B. Multiple key steps are necessary to conduct a compliant NQTL analysis.

The Model Form adds clear guidance on the steps required to be analyzed and disclosed, especially steps 4 and 5, for assessment of NQTL compliance. Most plans have failed to identify the

800 Maine Ave, SW • Suite 800 • Washington, DC • 20024

evidentiary standards used to define and evaluate a factor; have failed to analyze how those evidentiary standards are applied, both in writing and in application; and have failed to disclose the results from these analyses.

While this type of guidance has been given many times before, the new CURES guidance breaks out the specific steps in a clearer manner such as steps 4 and 5 in the Model form:

> **"4. Identify the methods and analysis used in the development of the limitation; and 5. Provide any evidence and documentation to establish that the limitation is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits."** (Emphasis supplied).

In addition, the Self Compliance Tool and the FAQS illustrate the types of steps needed and analyses required for a compliant analysis of each NQTL.

C. Compliant Disclosure requires that all steps of a plan's NQTLs analyses must be provided to consumers and authorized providers.

The most significant problem area of MHPAEA and ERISA compliance during the last 7 years has been and remains the unwillingness of plans to provide consumers and authorized providers with a detailed summary of the key steps taken to analyze a NQTL when requested to do so. This failure occurs consistently, even when a benefit denial is appealed and a request for disclosure of the 5 step analyses as set forth in sub-regulatory guidance is made as part of the appeal in order to attempt to determine whether and how that NQTL meets the parity law and regulatory requirements. As outlined in the first two attachments, the Departments have issued very specific guidance on what needs to be disclosed for several years. For example, Q9 issued in 2016, was very clear that all key analyses on how an NQTL is developed and applied is necessary for compliant disclosure.

This guidance was reinforced in the Model Form and the Self-Compliance Tool. Specifically, Example 9 clearly outlines that a plan must disclose the following types of information and documentation: identification of specific evidentiary standards that define any factor used, the types of analyses conducted on both MH/SUD and medical/surgical services, when these evidentiary standards are used, the results of these analyses, the types of audits conducted (including denial rates) and the results of these audits. This data, with specific results can be summarized in a relatively brief format. The PIC is attaching to this submission a proposed FAQ of what constitutes non-compliant disclosure, and a proposed FAQ of what would constitute compliant disclosure of information and documents. (See attached proposed FAQs).

D. Quantitative Analyses of Evidentiary Standards and other aspects of NQTLs are essential in determining compliance.

The FAQs and the Self Compliance Tool have multiple examples and directions clarifying that NQTLs can be expressed numerically or quantitatively and that quantitative analyses are required when assessing NQTL compliance as reflected in B. and C. above.

800 Maine Ave, SW • Suite 800 • Washington, DC • 20024

Recommendation 2: Provide Technical Assistance for Consumers, Providers, Plans and States
Unfortunately, as the 10th anniversary of the enactment of MHPAEA approaches on October 3, 2018, our members report that enrollees still have limited knowledge of their rights and benefits under the parity law. Moreover, a National Alliance on Mental Illness (NAMI) survey found that barriers still exist such as limited access to in-network providers, which results in higher out-of-pocket costs. The Departments have provided information on websites, held a national policy forum for states on this topic, convened a teleconference for states and conducted a parity listening session in DC. DOL and the Center for Consumer Information and Insurance Oversight (CCIIO) have help lines, but the information provided on the help lines to consumers is often too complicated and overly comprehensive for them to understand (e.g., legislative background on HIPAA and MHPAEA). In certain states, state officials have told enrollees that the state is not required to implement or enforce MHPAEA and have outdated information on their websites about the law. Additionally, the Centers for Medicare and Medicaid Services (CMS) said they are enforcing MHPAEA in Missouri, Oklahoma, Texas and Wyoming because the states have elected not to enforce or have failed to enforce the law.

We have also found that when plan members are aware of the parity law and believe a plan has violated it, they struggle with how and where to file a complaint given the myriad of federal and state entities with enforcement authority over MHPAEA. While the new consumer portal has more information on plan type and which state or federal agency oversees these plans, consumers must be able to receive help in uploading complaints and getting them in front of the proper state or federal agency.

- **Recommendations**
    - Technical assistance in the form of regional workshops should be directly provided to states by the Departments in order to ensure that state regulators have the tools they need to fully implement and enforce the law. States should then provide workshops for plans consumers and providers so all stakeholders are better educated on their right and obligations under the law.
    - An interactive consumer parity portal should be developed by the Departments within 6 months to allow consumers to easily access all publicly available parity information and submit complaints to a central online clearinghouse. ***While the current portal was an important first step, it does not allow a patient to upload a complaint and have it routed to the correct Agency for assistance.***
    - A model "authorized representative" form should be developed so all stakeholders use a consistent form for this purpose
    - There should be clarity that both denial rates and outcomes are an essential part of an "in operation" analysis as demonstrated by the steps in the Self Compliance Tool and Model Form and six examples in the FAQs. Six FAQs and Section F of the Self Compliance Tool articulate that measurement of denial rates is an essential

800 Maine Ave, SW • Suite 800 • Washington, DC • 20024

part of an NQTL analysis[1,2] (See also Attachments 1, 2 and 3). While the PIC does not take the position that DOL has said that outcomes alone can be used as a sole determent of NQTL compliance, DOL has provided clear guidance that denial rates are an essential part of NQTL compliance analysis.

Recommendation 3: The Departments should issue additional FAQs on outstanding issues, which include: network adequacy, reimbursement rates, and disclosure

Attached to these comments are 4 proposed FAQs on outstanding issues. These proposed FAQs address critical areas where plans state that ambiguity exists. This misperceived ambiguity continues to limit patient access to care. These areas include:

- Compliant disclosures
- Network adequacy
- Reimbursement rates

We again thank the Departments for issuing the Proposed FAQs on April 23. The clear sub-regulatory guidance released on April 23 is critical to ensuring that patients, providers and payers understand the rights, benefits and obligations afforded under MHPAEA. We hope that the Departments will swiftly finalize the CURES parity sub-regulatory guidance and issue additional FAQs that will further eliminate any areas of perceived ambiguity.

Recommendation 4: The DOL Should Work with Congress to Obtain the Authority to Levy Monetary Penalties on Insurers and Funders as Requested by the Secretary

The President's Commission on Combatting Drug Addiction and the Opioid Crisis' Final Report included a recommendation to give DOL enhanced enforcement authority over MHPAEA. This authority is important to ensuring that Americans can access the treatment benefits promised to them under the parity law. Specifically, the Commission recommended, "Because the Department of Labor (DOL) regulates health care coverage provided by many large employers, **the Commission recommends that Congress provide DOL increased authority to levy monetary penalties on insurers and funders, and permit DOL to launch investigations of health insurers independently for parity violations**."

As the Commission's report noted, "while parity is a legal requirement, the existing means of monitoring and enforcing the parity act are insufficient. The sole means of enforcement under the parity act is equitable relief against the buyer of the insurance plan; and for the employer-based

---

[1] See FAQs About Affordable Care Act Implementation Part 43 and Mental Health and Substance Use Disorder Parity Implementation, Part 34 available at: https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf

[2] See 2018 MHPAEA Self Compliance Tool, Section F available at: https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/compliance-assistance-guide-appendix-a-mhpaea.docx

800 Maine Ave, SW • Suite 800 • Washington, DC • 20024

plans that are self-funding, DOL is presently permitted to enforce MHPAEA against only the employer, rather than the insurance company administering the benefits."

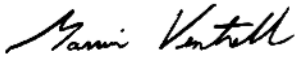
We do not believe it was Congress' intent to limit DOL's enforcement authority to only the self-funded employer when an insurance company is administering the employer's benefits. The DOL should have the authority to levy monetary penalties on insurers and funders and launch investigations into health insurers for parity violations will ensure that all parties are held accountable for providing equitable coverage of mental health and substance use disorder treatment benefits consistent with MHPAEA.

Without a more comprehensive federal and state approach to parity enforcement, improved access to care for those with severe substance use and mental health disorders will not be achieved and the recent substantial federal investments in combatting the opioid misuse and overdose epidemic will be undermined.

CONCLUSION

The PIC would be pleased to discuss these recommendations in greater detail and we stand ready to serve as a resource to the Administration. Our Coalition Coordinator, Carol McDaid, may be reached at cmcdaid@capitoldecisions.com.

Sincerely,



Mark Covall
Co-Chair
Parity Implementation Coalition

Marvin Ventrell
Co-Chair
Parity Implementation Coalition

800 Maine Ave, SW • Suite 800 • Washington, DC • 20024

Attachment 1

Attachment on Self-Compliance Tool for Office of Management and Budget

The Self-compliance Tool adds additional detail to the Model Form and the FAQs regarding the steps and analyses required in assessing each NQTL, and what is required by plans for disclosure to providers and consumers. SECTION F on NQTLs elucidates how NQTLs can be applied in a numerical way and the standards can rely on numerical standards:

> "While NQTLs are generally defined as treatment limitations that are not expressed numerically, the **application of an NQTL in a numerical way does not modify its nonquantitative character." (emphasis supplied).**

"For example, standards for provider admission to participate in a network are NQTLs because such standards are treatment limitations that typically are not expressed numerically. See 29 CFR 2590.712 (c)(4)(ii), 45 CFR 146.136(c)(4)(ii). **Nevertheless, these standards sometimes rely on numerical standards, for example, numerical reimbursement rates.** In this case, the numerical expression of reimbursement rates does not modify the nonquantitative character of the provider admission standards; accordingly, standards for provider admission, including associated reimbursement rates to which a participating provider must agree, are to be evaluated in accordance with the rules for NQTLs." (Page 13, emphasis supplied).

The Compliance Tips on Page 17 highlight what analyses are required for compliance:

- "Look for compliance as written **AND IN OPERATION**.
- Determine whether there are exception processes available and when they may be applied.
- **Determine how much discretion is allowed in applying the NQTL and whether such discretion is afforded comparably for processing MH/SUD benefit claims and medical/surgical benefits claims**.
- Determine who makes denial determinations and if the decision-makers have comparable expertise with respect to MH/SUD and medical/surgical benefits.
- **Determine average denial rates and appeal overturn rates for concurrent review and assess the parity between these rates for MH/SUD benefits and medical/surgical benefits.**
- Document your analysis, as a best practice." (Page 17, emphasis supplied).

"NOTE: While outcomes are NOT determinative of compliance, **rates of denials may be reviewed as a warning sign, or *indicator* of a potential operational parity noncompliance.** For example, if a plan has a **34% denial rate** on concurrent reviews of psychiatric hospital stays in a 12 month period and a **5% denial rate** on concurrent review for medical hospital stays in

that same 12 month period, the concurrent review process for both psychiatric and medical hospital stays should be carefully examined to ensure that the concurrent review standard is not being applied more stringently to MH/SUD benefits than to medical/surgical benefits in operation." (Page 17, emphasis supplied).

The Self-compliance Tool and the FAQs provide specific examples as to what analyses are required. Here is one example from Page 19 of the Self-compliance Tool:

"A patient with chronic depression has not responded to five different anti-depressant medications and therefore, was referred for outpatient treatment with repetitive transcranial magnetic stimulation (rTMS). This specific treatment has been approved by the FDA and has been the subject of more than six randomized controlled trials published in peer reviewed journals. The plan denies the treatment as experimental. The plan states that it used the same criteria to deny the rTMS as it does to approve or deny any MH/SUD or medical/surgical benefits under the plan. The plan identifies its standard for both medical/surgical benefits and MH/SUD benefits as requiring that at least two randomized controlled trials showing efficacy of a treatment be published in peer reviewed journals for any new treatment for either medical or behavioral conditions to be covered by the plan.

However, the plan indicates that while more than two randomized controlled trials regarding rTMS have been published in peer reviewed journals, a committee of medical experts involved in plan utilization management reviews reviewed the journals and determined that only one of the articles provided sufficient evidence of efficacy. The plan did not identify what specific standards were used to assess whether a peer review had adequately evidenced efficacy and what the qualifications of the plan's experts are. Lastly, the plan does not impose this additional level of scrutiny with respect to reviewing medical/surgical treatments beyond the initial requirement that the treatment has been the subject of the requisite number and type of trials.

Conclusion: The plan's exclusion fails to comply with MHPAEA's NQTL requirements because, in practice, the plan applies an additional level of scrutiny with respect to MH/SUD benefits and therefore the NQTL more stringently to mental health benefits than to medical/surgical benefits without additional justification." (Page 19, emphasis supplied).

This example along with others in the Self-compliance Tool and the FAQs highlight that, in developing the NQTL of experimental or investigative, the plan is not compliant as it adds a more stringent standard for MH/SUD than what is required for medical/surgical. Further, the example demonstrates that a plan must audit the approvals and denials of both medical/surgical and MH/SUD to establish whether or not the standards are being applied, operationally, in a compliant manner.

Attachment 1

The Self-compliance Tool specifically sets forth that plans should be prepared to provide the following information for NQTL compliance analyses:

- "All appropriate documentation including any guidelines or other standards that the plan or issuer relied upon as the basis for its compliance with the requirement that any NQTL applicable to MH/SUD benefits was comparable to and applied no more stringently than the NQTL as applied to medical/surgical benefits.

This should include details as to how the standards were applied, and any internal testing, review or analysis done by the plan or issuer to support the rationale that the NQTL is being applied comparably and no more stringently to MH/SUD benefits and medical/surgical benefits.

If the standards that are applied to MH/SUD are more stringent than those in nationally recognized medical guidelines, but the standards that are applied to medical/surgical benefits are not, an explanation of the reason for the application of the more stringent standard for MH/SUD benefits.

For the period of coverage under review, plans and issuers should be prepared to provide a record of all claims (MH/SUD and medical/surgical) submitted and the number of those denied within each classification of benefits." (Page 20, emphasis supplied).

Parity Implementation Coalition Summary of Key Take Aways from 21st Century CURES Act Guidance on MHPAEA Released by DOL/HHS On April 23, 2018

I. MODEL FORM. This form outlines specific steps that are needed for a compliant NQTL analysis both in writing and in operation. These steps re-enforce prior examples and FAQs from DOL that exemplify the analyses plans must conduct and the methods for conducting those analyses for each NQTL, AND the evidence and documentation that plans must disclose for both in writing and in operation compliance analyses.

> " **2. Identify the factors used in the development of the limitation** (examples of factors include, but are not limited to, excessive utilization, recent medical cost escalation, high variability in cost for each episode of care, and safety and effectiveness of treatment);
>
> **3. Identify the evidentiary standards** used to evaluate the factors. Examples include, but are not limited to, the following:
>
> • Excessive utilization as defined by two standard deviations above average utilization per episode of care;
> • Recent medical cost escalation as defined by medical costs for certain services increasing 10% or more per year for 2 years;
> • High variability in cost per episode of care as defined by episodes of outpatient care being 2 standard deviations higher in total costs than the average cost per episode 20% or more of the time in a 12-month period; and
> • Safety and efficacy of treatment modality as defined by 2 random clinical trials required to establish a treatment is not experimental or investigational;
>
> **4. Identify the methods and analysis used in the development of the limitation; and**
>
> **5. Provide any evidence and documentation to establish that the limitation is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical and surgical benefits."(Emphasis supplied).**

Key Take Aways on NQTL Compliance: The Model Form adds clear guidance on the steps required to be analyzed and disclosed, especially steps 4 and 5, for assessment of NQTL compliance.

II. SELF-COMPLIANCE TOOL

The Self-compliance Tool adds additional detail to the Model Form and the FAQs regarding the steps and analyses required in assessing each NQTL, and what is required by plans for disclosure to providers and consumers. SECTION F on NQTLs elucidates how NQTLs can be applied in a numerical way and the standards can rely on numerical standards:

> "While NQTLs are generally defined as treatment limitations that are not expressed numerically, the **application of an NQTL in a numerical way does not modify its nonquantitative character."(emphasis supplied).**
>
> "For example, standards for provider admission to participate in a network are NQTLs because

such standards are treatment limitations that typically are not expressed numerically. See 29 CFR 2590.712 (c)(4)(ii), 45 CFR 146.136(c)(4)(ii). **Nevertheless, these standards sometimes rely on numerical standards, for example, numerical reimbursement rates.** In this case, the numerical expression of reimbursement rates does not modify the nonquantitative character of the provider admission standards; accordingly, standards for provider admission, including associated reimbursement rates to which a participating provider must agree, are to be evaluated in accordance with the rules for NQTLs." (Page 13, emphasis supplied).

The Compliance Tips on Page 17 highlight what analyses are required for compliance:

- "Look for compliance as written **AND IN OPERATION**.
- Determine whether there are exception processes available and when they may be applied.
- **Determine how much discretion is allowed in applying the NQTL and whether such discretion is afforded comparably for processing MH/SUD benefit claims and medical/surgical benefits claims**.
- Determine who makes denial determinations and if the decision-makers have comparable expertise with respect to MH/SUD and medical/surgical benefits.
- **Determine average denial rates and appeal overturn rates for concurrent review and assess the parity between these rates for MH/SUD benefits and medical/surgical benefits.**
- Document your analysis, as a best practice." (Page 17, emphasis supplied).

"NOTE: While outcomes are NOT determinative of compliance, **rates of denials may be reviewed as a warning sign, or *indicator* of a potential operational parity noncompliance.** For example, if a plan has a **34% denial rate** on concurrent reviews of psychiatric hospital stays in a 12 month period and a **5% denial rate** on concurrent review for medical hospital stays in that same 12 month period, the concurrent review process for both psychiatric and medical hospital stays should be carefully examined to ensure that the concurrent review standard is not being applied more stringently to MH/SUD benefits than to medical/surgical benefits in operation." (Page 17, emphasis supplied).

The Self-compliance Tool and the FAQs provide specific examples as to what analyses are required. Here is one example from Page 19 of the Self-compliance Tool:

"A patient with chronic depression has not responded to five different anti-depressant medications and therefore, was referred for outpatient treatment with repetitive transcranial magnetic stimulation (rTMS). This specific treatment has been approved by the FDA and has been the subject of more than six randomized controlled trials published in peer reviewed journals. The plan denies the treatment as experimental. The plan states that it used the same criteria to deny the rTMS as it does to approve or deny any MH/SUD or medical/surgical benefits under the plan. The plan identifies its standard for both medical/surgical benefits and MH/SUD benefits as requiring that at least two randomized controlled trials showing efficacy of a treatment be published in peer reviewed journals for any new treatment for either medical or behavioral conditions to be covered by the plan.

However, the plan indicates that while more than two randomized controlled trials regarding rTMS have been published in peer reviewed journals, a committee of medical experts involved in plan utilization management reviews reviewed the journals and determined that only one of the articles provided sufficient evidence of efficacy. The plan did not identify what specific standards were used to assess whether a peer review had adequately evidenced efficacy and

what the qualifications of the plan's experts are. Lastly, the plan does not impose this additional level of scrutiny with respect to reviewing medical/surgical treatments beyond the initial requirement that the treatment has been the subject of the requisite number and type of trials.

Conclusion: The plan's exclusion fails to comply with MHPAEA's NQTL requirements because, in practice, the plan applies an additional level of scrutiny with respect to MH/SUD benefits and therefore the NQTL more stringently to mental health benefits than to medical/surgical benefits without additional justification." (Page 19, emphasis supplied).

***Key Take Aways on NQTL Compliance*:** This example along with others in the Self-compliance Tool and the FAQs highlight that, in developing the NQTL of experimental or investigative, the plan is not compliant as it adds a more stringent standard for MH/SUD than what is required for medical/surgical. Further, the example demonstrates that a plan must audit the approvals and denials of both medical/surgical and MH/SUD to establish whether or not the standards are being applied, operationally, in a compliant manner.

The Self-compliance Tool specifically sets forth that plans should be prepared to provide the following information for NQTL compliance analyses:

- "All appropriate documentation including any guidelines or other standards that the plan or issuer relied upon as the basis for its compliance with the requirement that any NQTL applicable to MH/SUD benefits was comparable to and applied no more stringently than the NQTL as applied to medical/surgical benefits.

  This should include details as to how the standards were applied, and any internal testing, review or analysis done by the plan or issuer to support the rationale that the NQTL is being applied comparably and no more stringently to MH/SUD benefits and medical/surgical benefits.

  If the standards that are applied to MH/SUD are more stringent than those in nationally recognized medical guidelines, but the standards that are applied to medical/surgical benefits are not, an explanation of the reason for the application of the more stringent standard for MH/SUD benefits.

- **For the period of coverage under review, plans and issuers should be prepared to provide a record of all claims (MH/SUD and medical/surgical) submitted and the number of those denied within each classification of benefits."** (Page 20, emphasis supplied).

III. FAQs PART 39

"Q2. My health plan document states that it excludes treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD services…For the most recent plan year, the plan denied all claims for ABA therapy to treat children with Autism Spectrum Disorder under the rationale that the treatment is experimental or investigative. With respect to medical/surgical conditions, the plan approved treatment when supported by one or more professionally recognized treatment guidelines and two or more controlled randomized trials. Is this permissible?"

"No…Although the plan as written purports to exclude experimental or investigative treatment for both MH/SUD and medical/surgical benefits using the same standards, in practice, it

> imposes this exclusion more stringently on MH/SUD benefits, as the plan denies all claims for ABA therapy, despite the fact that professionally recognized treatment guidelines and the requisite number of randomized controlled trials support the use of ABA therapy to treat children with Autism Spectrum Disorder."

***Key Take Aways on NQTL Compliance*:** This example documents that a **quantitative analysis** of the application of this properly developed NQTL, i.e. **denials of treatments** for both medical treatments and ABA treatments is necessary to determine operational compliance. In this example, an audit of denial rates of medical treatments based on experimental or investigative was conducted. The example further reflects that an audit of denials of ABA treatments was also conducted. The denial rate data showed that all ABA treatments were denied, even if they met the NQTL standards as defined by the plan. Further, the example concludes that the denial rates for ABA treatments **determined** that the plan was applying this NQTL more stringently and thereby not compliant with MHPAEA.

> "Q3: My health plan generally excludes treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD services…the plan reviews and covers certain treatments for medical/surgical conditions that have a rating of "C" on a treatment-by-treatment basis, while denying all benefits for MH/SUD treatment that have a rating of "C" or below, without reviewing the treatments…Is this permissible under MHPAEA?"
>
> "No…Here, although the text of the plan sets forth the same evidentiary standard for defining experimental as the Hayes Medical Directory ratings below "B," the plan applies a different evidentiary standard, which is more stringent for MH/SUD benefits than for medical surgical benefits because the unconditional exclusion of treatments with a "C" rating for MH/SUD benefits is not comparable to the conditional exclusion of those treatments with a "C" rating for medical/surgical benefits. Because of the **discrepant application** of the evidentiary standard used by the plan, the fact that the plan **ultimately denies some medical/surgical benefits** that have a rating of "C" does not justify the **total exclusion of treatments with a "C" rating for MH/SUD**. Accordingly, t**he plan does not comply with MHPAEA."**

***Key Take Aways on NQTL Compliance*:** This example documents that the NQTL of experimental or investigative, while comparable in writing, is APPLIED in a non-comparable manner, e.g., using a different evidentiary standard, and is thereby noncompliant. The example demonstrates that a **quantitative analysis** for purposes of the IN OPERATION compliance testing (i.e., how many medical treatments vs. MH/SUD treatments are approved or denied based on the specific standard), is **essential** in order to assess compliance. The example further documents that the quantitative disparity in denial rates (some medical vs. all behavioral), is what demonstrated that the plan was applying the standard differently, in operation.

> Q4: "My health plan documents state that the plan follows professionally-recognized treatment guidelines when setting dosage limits for prescription medications, **but the dosage limit set by my plan for buprenorphine to treat opioid use disorder is less** than what professionally-recognized treatment guidelines generally recommend. **The dosage limits set by my plan with respect to medical/surgical benefits are not less than the limits** such treatment guidelines recommend. Is this permissible under MHPAEA?"
>
> "No…Even though these medical management techniques may result in **numerically expressed limitations** (such as dosage limits), **the techniques are nevertheless NQTLs.**"

> "If the plan follows the dosage recommendations in professionally-recognized treatment guidelines to set dosage limits for prescription drugs in its formulary to treat medical/surgical conditions, it must also follow comparable treatment guidelines, and apply them no more stringently, in setting dosage limits for prescription drugs, including buprenorphine, to treat MH/SUD conditions."

***Key Take Aways on NQTL Compliance*:** This example further clarifies that NQTLs can include a quantitative measure and that an analysis of in writing and in operation requires an analysis of how the NQTL is applied. The example is also contingent on a **quantitative audit** of what specific dosage limits are approved or denied for medical vs. MH/SUD prescriptions. The denial rates for specific dosages is essential information evidencing noncompliance.

> "Q6: My health plan requires step therapy for both medical/surgical and MH/SUD inpatient, in-network benefits. The plan requires a participant to have **two unsuccessful attempts** at outpatient treatment in the past 12 months to be eligible for certain inpatient in-network SUD benefits. However, the plan only requires **one unsuccessful attempt** at outpatient treatment in the past 12 months to be eligible for inpatient, in-network medical/surgical benefits. Is this permissible under MHPAEA? "
>
> "Probably not.… Unless the plan can demonstrate that evidentiary standards or other factors were utilized comparably to develop and apply the differing step therapy requirements for these MH/SUD and medical/surgical benefits, this NQTL does not comply with MHPAEA."

***Key Take Aways on NQTL Compliance*:** This example illustrates that the NQTL of step therapy is using a quantitative evidentiary standard that is more stringent and non-comparable for SUD than what is used for medical. The language in the example also documents that an analysis of "in operation" would require an audit of how a properly developed NQTL of step therapy which uses a quantitative evidentiary standard is applied in operation. Specifically, this would require a **quantitative audit of which medical services vs. SUD services were approved or denied** on two unsuccessful attempts vs. one unsuccessful attempt at outpatient treatment in the past 12 months.

> "Q8: My health plan meets applicable State and Federal network adequacy standards for MH/SUD services. With respect to medical/surgical providers, the plan exceeds State and Federal network adequacy standards by attempting to ensure that participants and beneficiaries can schedule an appointment with a network provider within 15 days for non-urgent care when the individual has symptoms of a condition. The plan does not utilize a standard relating to availability of appointments in creating its provider network for MH/SUD services. Is this permissible under MHPAEA?"
>
> "No… As explained in the preamble to the Departments' final rules implementing MHPAEA, plan standards such as **network adequacy (although not specifically enumerated in the illustrative list of NQTLs), must be applied in a manner that complies with the regulation**s [footnote removed]."
>
> "Here, while the plan meets applicable State and Federal network adequacy standards, the plan does not consider **how long participants and beneficiaries may have to wait for appointments for services** as a factor in developing its network of MH/SUD providers, even though the plan considered it in developing the network for medical/surgical providers. Accordingly, the plan does not comply with MHPAEA."

Key Take Aways on NQTL Compliance: The guidance clearly states (consistent with prior guidance), that network access standards such as wait times and distance are NQTLs and that these must be comparable, both in writing and in operation. This example illustrates that a plan must conduct an analysis of how these factors and evidentiary standards are developed in a comparable manner and conduct similar analyses to validate that they are applied in a comparable and no more stringent manner. The factor of wait times is quantifiable and an evidentiary standard of 15 days was developed and applied for medical/surgical; however, such standard is not considered in assessing MH/SUD network adequacy. Based on this example, the tests of as written and in operation compliance would require a measurement of actual wait times for both medical and MH/SUD to assess comparability.

Prior DOL/HHS Guidance Consistent with Model Form, FAQs Part 39 and Self-compliance Tool

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION (PART VII) AND MENTAL HEALTH PARITY IMPLEMENTATION issued Nov 17, 2011

> "Q3: My group health plan requires prior authorization from the plan's utilization reviewer that a treatment is medically necessary for all inpatient medical/surgical benefits and for all inpatient mental health and substance use disorder benefits. In practice, inpatient benefits for medical/surgical conditions are routinely approved for seven days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. On the other hand, for inpatient mental health and substance use disorder benefits, routine approval is given for only one day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Is this permissible?
>
> No. The plan is applying a stricter nonquantitative treatment limitation in practice to mental health and substance use disorder benefits than is applied to medical/surgical benefits. While some differences in prior authorization practices with respect to individual conditions or treatments might be permissible based on recognized clinically appropriate standards of care, the interim final regulations do not permit a plan to apply stricter nonquantitative treatment limitations to all benefits for mental health or substance use disorders than those applied to all medical/surgical benefits. The application of nonquantitative treatment limitations -- both with respect to the plan's benefits and its care management practices -- must comply with the nonquantitative treatment limitation rules."

Key Take Aways for NQTL Compliance: This FAQ documents that a quantitative analysis of the application of the prior authorization requirement for inpatient days for both medical and MH/SUD is required (i.e. documentation of the number of days/length of stay that is approved for medical/surgical vs. MH/SUD benefits demonstrates a more stringent application) and is essential in determining compliance in operation. This same clarification of what types of analyses are needed is consistent with the examples in FAQs Part 39.

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 34 AND MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION issued October 27, 2016

> "Q5: Before authorizing coverage for inpatient treatment for a substance use disorder, my plan requires that I first enroll in an intensive outpatient program. My plan applies similar requirements to medical/surgical benefits. However, unlike medical/surgical benefits for which the requirements can be satisfied by programs offered in my geographic area, no intensive outpatient programs are available to treat my substance use disorder in my geographic area. **I alerted my plan that no outpatient program is available in my geographic area, but the plan indicated that there are no exceptions. Is this permissible?**
>
> No. The requirement to try an intensive outpatient program before being admitted for inpatient treatment is a type of NQTL, often referred to as a fail-first or step-therapy requirement. The Departments' regulations require that a plan or insurance issuer may not impose an NQTL with respect to MH/SUD benefits in a benefit classification unless, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, or other factors used in

applying the NQTL are comparable and applied no more stringently with respect to MH/SUD benefits than with respect to medical/surgical benefits in the same classification. If a fail-first requirement that applies to MH/SUD benefits includes a condition that an individual cannot reasonably satisfy (in this case, a condition to first attempt an intensive outpatient program, although there are no programs available), and the lack of access to programs necessary to satisfy the requirement exists only with respect to MH/SUD benefits, then the fail-first requirement is, in operation, applied more stringently with respect to MH/SUD benefits than medical/surgical benefits. Because the Departments' prior guidance did not address the application of fail-first requirements in situations involving lack of access and may have reasonably been interpreted in an alternative manner, the Departments will apply this clarifying guidance for plan years (or, in the individual market, policy years) beginning on or after March 1, 2017." (emphasis supplied)

Key Take Aways for NQTL Compliance: This FAQ documents that a quantitative analysis of network adequacy, i.e. the number of network providers that are available to provide a level of service required by the carrier's "fail first" standard, is required to determine whether the "fail first" requirement is applied more stringently or is compliant in operation. This same clarification of what types of analyses are needed is consistent with the examples in FAQ Part 39.

"Q6: My plan requires prior authorization from the plan's utilization reviewer that buprenorphine is medically necessary for the treatment of my opioid use disorder. The plan says the prior authorization requirement is imposed due to safety risks associated with buprenorphine. Although there are prescription drugs to treat medical/surgical conditions that have similar safety risks, **my plan does not impose similar prior authorization requirements on those drugs. Is this permissible?**

No. A plan may impose an NQTL, including a prior authorization requirement for buprenorphine, if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its prior authorization requirement with respect to buprenorphine to treat an opioid use disorder are comparable to, and applied no more stringently than, those used in applying its prior authorization requirement with respect to medical/surgical benefits in the prescription drug classification under MHPAEA. In this scenario, the plan imposes the prior authorization requirement due to stated safety concerns. **However, the prior authorization requirement is applied more stringently to buprenorphine when used to treat opioid use disorder than it is applied to prescription drugs with similar safety risks to treat medical/surgical conditions. Accordingly, the plan's prior authorization requirement on buprenorphine does not comply with MHPAEA." (emphasis supplied)**

"Q7: My plan requires that I meet specific non-pharmacological fail-first requirements (for example, that I have tried counseling alone, failed at recovery, and resumed substance use) before it will authorize coverage for buprenorphine to treat my opioid use disorder. While comparable evidentiary standards and other factors indicate that similar fail-first requirements could be imposed on certain prescription drugs covered by my plan for medical/surgical conditions, the plan does not impose fail-first requirements in these instances. Is this permissible?

No. A fail-first requirement is an NQTL that must comply with the requirements of MHPAEA. A plan or issuer cannot impose a fail-first requirement on coverage for buprenorphine for opioid

use disorder unless, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in designing and imposing this fail-first requirement are comparable to, and applied no more stringently than the processes, strategies, evidentiary standards, or other factors used in applying fail-first requirements to medical/surgical benefits in the prescription drug classification under MHPAEA. In this case, the plan is imposing a non-pharmacological requirement that the individual fail first at recovery with counseling alone before the plan will authorize coverage of benefits for buprenorphine. While comparable evidentiary standards and other factors indicate that similar fail-first requirements could be appropriate before authorizing coverage for certain other prescription drugs covered by the plan for medical/surgical conditions, the plan does not in fact impose fail-first requirements in any of these instances. Accordingly, the fail-first requirement imposed on buprenorphine is an NQTL that the plan applies more stringently to a substance use disorder condition than medical/surgical conditions. This disparity violates MHPAEA."

Key Take Aways for NQTL Compliance: These FAQs document that a quantitative analysis of "fail first" requirements for Buprenorphine prescriptions vs. prescriptions for other drugs for medical/surgical conditions (i.e. an audit of the number of medications that have a "fail first" requirement because of a safety risk or other factors) is required and is essential in determining compliance in operation. This same clarification of what types of analyses are needed is consistent with the examples in FAQ Part 39.

> "Q8: My group health plan states that it follows nationally-recognized treatment guidelines for setting prior authorization requirements for prescription drugs, but requires prior authorization for my buprenorphine/naloxone combination at each refill (every 30 days) for my opioid use disorder, which is not consistent with nationally-recognized treatment guidelines. Is this permissible?
>
> No. In setting the NQTL of prior authorization for the substance use disorder medication, buprenorphine/naloxone, a plan or issuer must apply comparable processes, strategies, evidentiary standards, and other factors no more stringently to buprenorphine/naloxone than those applied to medical/surgical medications. The plan states that it follows nationally recognized guidelines. However, these guidelines, such as the American Society of Addiction Medicine (ASAM) national practice guidelines, do not support 30-day authorization practices for buprenorphine/naloxone. Furthermore, the plan does not deviate from nationally-recognized treatment guidelines when establishing prior authorization requirements for any prescription drugs to treat medical/surgical conditions. Accordingly, although the plan asserts that its process of setting the NQTL of prior authorization -- following nationally-recognized treatment guidelines -- is comparable as written, in operation, the plan's process departs from and provides less coverage than recommended under nationally-recognized treatment guidelines for buprenorphine/naloxone, in violation of MHPAEA. However, as an alternative to simply mirroring nationally-recognized treatment guidelines, many plans' and issuers' use Pharmacy and Therapeutics (P&T) committees in deciding how to cover prescription drugs and evaluating whether to follow or deviate from nationally-recognized treatment guidelines for setting the prior authorization requirements. The Departments' note that while the use of P&T committees to inform prior authorization requirements for prescription drugs in this manner may not violate MHPAEA per se, these processes must also comply with ..."

Key Take Aways for NQTL Compliance. This FAQ documents that an analysis of the application of the factors identified for imposing a prior authorization NQTL is required and is essential in evaluating whether a pre-authorization reviews are compliant both in writing and in operation. Specifically, it requires an identification of a factor and an evidentiary standard, e.g., the use of specific professional standards for prescriptions of drugs, an analysis of how those standards are being developed in writing, and an analysis of the plan's process in operation (i.e. an audit of the number of medications to which the factors are, in fact, faithfully assessed), in applying those standards. The clarification of essential steps in a proper NQTL analysis (outlined in these examples) have been reinforced in the 2018 Model Form and Self Compliance tool.

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 31, MENTAL HEALTH PARITY IMPLEMENTATION, AND WOMEN'S HEALTH AND CANCER RIGHTS ACT IMPLEMENTATION issued on April 20, 2016

"Q9: I am a provider acting as an authorized representative for an ERISA group health plan participant. The health plan has requested that I complete a pre-authorization form after the patient's 9th visit for the treatment of depression. I understand that there are a number of documents that plans must provide upon request. Which of those documents would generally be most helpful for me to request regarding the plan's compliance with MHPAEA? You may request the following documents and plan information, which could be helpful in evaluating the plan's compliance with MHPAEA. While it may not be necessary to review all of the following documents and plan information, the plan must provide any of these documents and plan information to you if requested, when you as a provider are acting as an individual's authorized representative:

1. A Summary Plan Description (SPD) from an ERISA plan, or similar summary information that may be provided by non-ERISA plans;

2. The specific plan language regarding the imposition of the NQTL (such as a preauthorization requirement);

3. The specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that were relied upon and were rejected) in determining that the NQTL will apply to this particular MH/SUD benefit;

4. Information regarding the application of the NQTL to any medical/surgical benefits within the benefit classification at issue;

5. The specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that were relied upon and were rejected) in determining the extent to which the NQTL will apply to any medical/surgical benefits within the benefit classification at issue; and

6. Any analyses performed by the plan as to how the NQTL complies with MHPAEA.

For example, if the plan can demonstrate that it imposes pre-authorization requirements for both MH/SUD and medical/surgical benefits in the outpatient, in-network classification when the length of treatment for a condition exceeds the national average length of treatment by 10% or

more, it has identified a factor on which the NQTL is based. Furthermore, to the extent the plan can document, via studies, schedules or similar documents that contain relevant information or data, that the national average length of outpatient treatment for depression is eight visits, it has identified an evidentiary standard used to evaluate the factor. Finally, by applying the eight visit standard to the case at hand, it demonstrates how the evidentiary standard is applied and the result.

Accordingly, to be in compliance with the MHPAEA and ERISA disclosure requirements, the plan must furnish to the provider sufficient documentation of the NQTL factor, evidentiary standard and the analysis outlined above. Additionally, it must produce documentation of how the factor, evidentiary standard and analysis is applied in the outpatient, in-network classification for medical/surgical benefits to demonstrate that the NQTL is not being applied to MH/SUD benefits more stringently than to medical/surgical benefits in the classification. As the Departments indicated in prior guidance, the fact that any information (including factors and evidentiary standards used for medical/surgical benefits) may be characterized as proprietary or commercially valuable is not legitimate grounds for not providing the information.)"

Key Take Aways for NQTL Compliance: This guidance on disclosure of NQTL information is very specific and the analytical steps are fully consistent with the more detailed self-compliance tool issued by DOL in April 2018. The Self-compliance Tool's Compliance Tip for Step 4, which addresses both the "as written and in operation" NQTL compliance requirements, directs plans to "Document your analysis, as a best practice." (P. 17). For disclosure purposes, it is very clear that a plan must disclose to a provider or a beneficiary the multiple steps required in analyzing all NQTLs including the evidentiary standards and "Any analyses performed by the plan as to how the NQTL complies with MHPAEA." Taken together, the DOL guidance demonstrate that the plan must conduct and document its analyses and then disclose those analyses.

Attachment 4

Standardized and Feasible Methodology for Measuring and Reporting Denial Rates

PIC has developed the following methodology for measuring and reporting denial rates in consultation with actuaries certified by the American Academy of Actuaries and various employer groups.

Denial rates are an outcomes measure that is an essential component of an analysis to determine whether a plan is in compliance with MHPAEA in the application of certain NQTLs, in operation.

A denial is defined as a refusal to pay or reimburse for any or all parts of a service requested or performed in any of the following 3 settings: (1) office visits; (2) outpatient facility visits; and (3) inpatient facility stays.

Any "modified" authorizations, i.e., for lower-cost services than requested by the provider, are to be considered a denial.

Any "partial denials" i.e., number of days or visits approved are less than what the provider requested, are to be considered a denial unless subsequently approved on concurrent or retrospective review.

Denials should be audited and reported separately for (1) lack of medical necessity reasons and (2) any other administrative reasons (other than lack of eligibility).

Please provide information on the number of denials and percent of denials for MH/SUD services compared to medical/surgical services.

Inpatient facility stay is defined as a hospital, non-hospital based facility or residential treatment facility and encompasses all medical and surgical admissions to general acute care hospitals, long-term acute care hospitals, inpatient rehabilitation facilities and skilled nursing facilities; all MH/SUD admissions to psychiatric hospitals, general acute care hospitals, non-hospital based inpatient facilities and residential treatment facilities.

Outpatient facility is defined as physical, occupational, speech, and cardiovascular therapy, surgeries, radiology, pathology and pharmacy services for medical or surgical care provided in an outpatient setting; intensive outpatient and partial hospitalization services for behavioral health conditions in an outpatient setting.

(A) Pre-service denials for which no claim was submitted, shown as a percentage (%):

(1) Numerator: Pre-authorization and concurrent review denials based on lack of medical necessity for services requested in the particular setting noted.
Denominator: All pre-authorization and concurrent reviews conducted for the particular setting noted.

(2) Numerator: Pre-authorization and concurrent review denials based on administrative reasons for services requested in the particular setting noted.
Denominator: All pre-authorization and concurrent reviews conducted for the particular setting noted.

Note: Review denials and total reviews conducted should exclude those reviews for which lack of eligibility for coverage was determined.

(B) Post-service denials shown as a percentage (%) (counted as one denial for each unique claim, not counting denials on resubmissions of the same claim):

(1) Numerator: Claims denied for lack of medical necessity, including upon pre-authorization, concurrent review and retrospective review in the particular setting noted.
Denominator: Total claims submitted for the particular setting noted.

(2) Numerator: Claims denied for administrative reasons, including upon pre-authorization, concurrent review and retrospective review in the particular setting noted.
Denominator: Total claims submitted for the particular setting noted.

Note: Claims denied and total claims submitted should exclude those claims for which lack of eligibility for coverage was determined.

(C) Appeals: Denials that are reversed, in whole or in part, on level one and level two internal appeals, are to be counted as denials in (A) and (B) above. Separate appeal data on denials that are reversed on internal appeal should be shown as:

Numerator: Denied claims reversed in whole on level one internal appeal
Denominator: Total denied claims for which a level one appeal was submitted

Numerator: Denied claims reversed in part on level one internal appeal
Denominator: Total denied claims for which a level one appeal was submitted

Numerator: Denied claims reversed in whole on level two internal appeal
Denominator: Total denied claims for which a level two appeal was submitted

Numerator: Denied claims reversed in part on level two internal appeal
Denominator: Total denied claims for which a level two appeal was submitted

Note: Denials that are reversed on external appeal to an independent review organization are to be counted as denials in (A) and (B) above.

FAQ on Network Adequacy

My health plan is a Health Maintenance Organization ("HMO"). However, the in-network participating providers under the MH/SUD benefit, in particular, psychiatrists, are far less in number and availability than the in-network participating providers under the medical/surgical benefit. Due to long wait times and far distances needed to travel to see an in-network psychiatrist, I am forced to use out-of-network psychiatrists when seeking outpatient mental health treatment. My health plan states that shortages in psychiatrists have resulted in a smaller network and resulting long wait times and traveling distances to see an in-network provider. However, during the last several years, my plan addressed similar shortages in medical specialist providers, including cardiologists and neurologists, which had resulted in similar long wait times and travel distance issues, by adjusting provider admission standards through increased reimbursement rates, adding more specialists, and developing a process for accelerating enrollment in the network, to assure an adequate network. My plan is not addressing the inadequate network of psychiatrists under the mental health benefit in the same or similar manner. Is this permissible under MHPAEA?

No. The health plan is required to use comparable factors like distance standards and wait times for appointments in assessing the adequacy of its networks for both medical/surgical and MH/SUD benefits. If the health plan has assessed inadequate networks for medical specialists by evaluating these factors, and remedied such inadequate networks through adjusted provider admission standards such as increasing reimbursement rates and adding more specialists to the network, then although the plan has used comparable factors to assess inadequate networks for mental health psychiatrists, if the plan has not remedied inadequate networks by adjusting the provider admission standard of reimbursement rates and adding more psychiatrists in a comparable manner, then the plan is non-compliant with MHPAEA.

FAQ on Reimbursement Rates – Medicare Benchmark

My health plan utilizes Medicare reimbursement rates established by the Centers for Medicare & Medicaid Services ("CMS"), set forth in the Physician Fee Schedule, as a benchmark for in-network provider reimbursements for the CPT codes designated for evaluation and management services ("E/M") for both medical/surgical and MH/SUD outpatient benefits. My health plan automatically adjusts E/M reimbursement rates established by CMS upward for all physician services provided for medical/surgical conditions, while automatically adjusting E/M reimbursement rates downward for psychiatric physician services provided for MH/SUD conditions. This is the case even when psychiatrists are billing under the same CPT codes for E/M services as are medical internists or family doctors. Is this permissible under MHPAEA?

No. While a plan is not required to pay identical provider reimbursement rates for medical/surgical and MH/SUD providers under all circumstances, a plan's standards for admitting a provider to participate in a network (including the plan's reimbursement rates for providers) is an NQTL. A plan may impose an NQTL if under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its NQTL with respect to MH/SUD services are comparable to and applied no more stringently than those used in applying the NQTL with respect to medical/surgical benefits in the same classification.

Here, the plan utilizes the CMS Medicare Physician Fee Schedule (MPFS) for CPT codes as its benchmark for both medical/surgical and MH/SUD outpatient physician service reimbursements. However, the plan does not apply the benchmark comparably when it alters reimbursements by adjusting the Medicare benchmark upward for medical physicians providing E/M services, while adjusting the Medicare benchmark downward for psychiatric physicians providing identical E/M services. Accordingly, the plan's method for establishing reimbursement rates does not comply with MHPAEA.

FAQ on *Compliant* Disclosure

I am a provider acting as an authorized representative for an ERISA group health plan participant. The health plan performed a concurrent review (a type of NQTL) of outpatient psychotherapy visits and denied all visits after the 8th visit as not medically necessary. As an authorized representative for the plan participant, I did receive the medical necessity criteria for both MH/SUD and medical/surgical outpatient benefits as part of the denial letter, and I requested, in writing, the following from the plan:

1. Provide a Summary Plan Description (SPD) from the plan;

2. Provide the specific plan language regarding the NQTL of concurrent review and identification of all of the medical/surgical and mental health and substance use disorder benefits to which this limitation applies in the relevant benefit classifications or sub-classification

3. Identify the factors that were, in fact, used in the development of the limitation (examples of factors include excessive utilization, recent medical cost escalation, high variability in cost per episode of care, safety and efficacy of treatment modality);

4. Identify the evidentiary standards used to define and evaluate the factors (examples include two standard deviations above average utilization per episode, medical costs increasing 10% or more per year for 2 years, episodes of outpatient care being 2 standard deviations higher than average cost per episode 20% or more of the time in a one year period, etc.);

5. Identify the sources for each factor and evidentiary standard used (examples include internal claims analyses, expert medical review, external research studies, etc.);

6. Identify the methods and analyses used in developing and applying concurrent review to the MH/SUD and medical/surgical outpatient office visits classification of benefits;

7. Provide any evidence to establish that the limitation is comparable and applied no more stringently, as written and in operation, to mental health and substance use disorder benefits versus medical and surgical benefits.

In response to my request, the plan provided me with:

1. The SPD;

2. The specific plan language regarding concurrent review for outpatient MH/SUD and medical and surgical benefits;

3. A listing of the factors that were, in fact, considered in the development and application of concurrent review for both MH/SUD and medical/surgical outpatient office visit benefits. The factors listed were high cost variability, recent increase in costs of outpatient office visit services, excessive utilization and safety and efficacy of treatment modality.

4. A description of each evidentiary standard used to define and evaluate each factor. The plan stated that the factor of high costs variability per episode of care had an evidentiary standard of episodes of outpatient office visits for either medical/surgical or MH/SUD that were 2 standard deviations higher in total costs than the average cost per episode of care more than 20% of the time in the past 2-month period measured. Recent increase in medical costs was defined as certain benefits in the medical/surgical and MH/SUD outpatient office visits class that had increased 10% or more over the last two years. Excessive utilization was defined as 2 standard deviations or more above average utilization per episode of care. Safety and efficacy of treatment modality was defined as 2 or more random clinical trials required to establish a treatment is not experimental or investigational.

5. The plan provided the sources used to develop the factors and evidentiary standards.

6. The plan provided specific analyses and results from these analyses demonstrating that all medical services in this benefit classification that exhibited these factors as defined by the above evidentiary standards were subject to the NQTL of concurrent review. The plan disclosed a summary of an internal claims analysis that documented that all physician visits in the same classification for medical conditions had experienced increased medical costs and high cost variability as defined above. Further, the plan stated that all physician visits in the same classification were subject to the same concurrent review procedures as were applied to outpatient psychotherapy visits.

7. With respect to application of the NQTL in operation, the plan provided analyses of audits that were performed, which demonstrated that the NQTL of concurrent review was applied for MH/SUD outpatient psychotherapy visits with the same frequency and with a comparable procedure as medical/surgical outpatient visits in the same classification. Further, the plan provided a summary of claims data showing the comparability of denial rates from outpatient concurrent reviews between MH/SUD and medical/surgical, as well as a summary of data that showed that the out-of-pocket costs to plan participants for out-of-network providers for outpatient visits in the same classification were comparable between MH/SUD and medical/surgical benefits.

Is this plan response complete?

YES. The plan has made complete disclosure for this NQTL. The plan was responsive with respect to identifying factors and evidentiary standards and the sources used to identify same. The plan also provided the analyses that were conducted to compare the MH/SUD and medical/surgical benefits in the same classification that demonstrated that concurrent review was developed in a comparable manner. The plan also provided summaries of data that demonstrated that this NQTL was being applied, in operation, in a comparable and no more stringent manner.

FAQ on *Non-Compliant* Disclosure

My group health plan is subject to ERISA and denied the continuation of inpatient psychiatric hospital stay based on a lack of medical necessity on concurrent review after the first 5 days of pre-authorized treatment. My authorized representative appealed the adverse benefit determination and requested copies of all documents, records and other information relevant to my claim for benefits. My representative specifically requested documents and other information regarding the processes, standards, and other factors used to develop and apply the nonquantitative treatment limitation of concurrent review with respect to both inpatient medical/surgical benefits and inpatient mental health benefits under the plan. The request for information and documentation on appeal specifically asked that, within 30 days of the date of the request, the plan:

1. Provide the specific plan language regarding concurrent review and identification of all of the medical/surgical and mental health benefits to which it applies in the inpatient benefit classification;

2. Identify the factors used in the development of concurrent reviews for both medical/surgical and mental health care. Examples of factors include, but are not limited to, excessive utilization, recent medical cost escalation, high variability in cost per episode of care, and safety and effectiveness of treatment;

3. Identify the evidentiary standards used to evaluate the factors. Examples include, but are not limited to, the following:

    - Excessive utilization as defined by two standard deviations above average utilization per episode of care;
    - Recent medical cost escalation as defined by medical costs for certain services increasing 10% or more per year for 2 years;
    - High variability in cost per episode of care as defined by episodes of inpatient care being 2 standard deviations higher in total costs than the average cost per episode 20% or more of the time in a 12-month period;
    - Safety and efficacy of treatment modality as defined by 2 random clinical trials required to establish a treatment is not experimental or investigational.

4. Identify the methods and analyses used in the development of concurrent reviews for both medical/surgical and mental health care

5. Provide evidence and documentation to establish that concurrent review is applied no more stringently, as written and ***in operation***, to mental health benefits than how it is applied to medical/surgical benefits, with such evidence and documentation to include denial rates on concurrent reviews of psychiatric hospital stays in a 12 month period and

denial rates on concurrent review for medical hospital stays in that same 12 month period.

My plan provided my authorized representative with my clinical case file and a link to the plan's informational page on MHPAEA and NQTLs. My authorized representative and I believe that the plan's response is inadequate and that the information provided is non-compliant with the Availability of Plan Information requirements under MHPAEA, including ERISA claims and appeals rules. Is the plan's response permissible?

No. The plan has failed to comply with the claims procedure and the internal claims and appeals processes under ERISA, which require disclosure of all documents, records and other information relevant to the claimant's claim for benefits. This includes documents with specific information regarding the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation, such as concurrent review, with respect to medical/surgical benefits and mental health and substance use disorder benefits under the plan, as outlined in requests 2 through 5 herein. The plan's failure to comply with these disclosure requirements under ERISA subjects the plan to a regulatory investigation by the Department of Labor and the imposition of taxes by the Department of Revenue for failure to comply with group health plan requirements. You may submit complaints to:

Link to Online Complaint Submission

FAQ on Reimbursement Rates - Market Forces

My health plan documents state that in-network provider reimbursement rates are based on provider supply and service demand in the geographic market, service type, and other factors such as training, licensure and expertise. However, the plan reduces reimbursement rates to psychiatrists delivering comparable services and with comparable training, licensure and expertise as primary care physicians. This is the case despite it being far more difficult to find an in-network psychiatrist taking new patients in the geographic market than to find an in-network primary care physician, due to a shortage in supply of psychiatrists in relation to demand for services. Is this permissible under MHPAEA?

No. While a plan is not required to pay identical provider reimbursement rates for medical/surgical and MH/SUD providers, a plan's standards for admitting a provider to participate in a network (including the plan's reimbursement rates for providers) is an NQTL. A plan may impose an NQTL if under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing its NQTL with respect to MH/SUD services are comparable to and applied no more stringently than those used in applying the NQTL with respect to medical/surgical benefits in the same classification.

Here, the plan has reduced its reimbursement rates for psychiatrists even though they are medical doctors with comparable training, licensure and expertise as primary care doctors, delivering comparable services. In addition, there is no supply and demand factor, such as a disproportionately abundant supply of psychiatrists in the geographic market, that the plan may have considered to justify reduced reimbursement rates for psychiatrists. Accordingly, the plan's use of this NQTL does not comply with MHPAEA

Attachment 6

Amendment to Q2 Proposed FAQs Part 39 (*amended language is italicized*).

My health plan document states that it excludes treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD services. For both medical/surgical benefits and MH/SUD services, the plan generally follows current medical evidence and professionally recognized treatment guidelines on the efficacy of treatment. With respect to both medical/surgical benefits and MH/SUD services, the plan's documents state that the plan denies a treatment as experimental for a given condition when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the condition.

The plan defines Autism Spectrum Disorder as a mental health condition. More than one professionally recognized treatment guideline and more than two controlled randomized trials support the use of Applied Behavioral Analysis (ABA) therapy to treat certain children with Autism Spectrum Disorder. For the most recent plan year, *the plan denied 25% of claims* for ABA therapy to treat children with Autism Spectrum Disorder under the rationale that the treatment is experimental or investigative. With respect to medical/surgical conditions, *the plan approved 100%* of treatment when supported by one or more professionally recognized treatment guidelines and two or more controlled randomized trials. Is this permissible?

No. A medical management standard limiting or excluding benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA.4 A group health plan may impose an NQTL if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors considered by the plan in implementing the NQTL are comparable to and are applied no more stringently than the processes, strategies, evidentiary standards, and other factors used in applying the NQTL to medical/surgical benefits in the same classification. Although the plan as written purports to exclude experimental or investigative treatment for both MH/SUD and medical/surgical benefits using the same standards, in practice, it imposes this exclusion more stringently on MH/SUD benefits, *as the plan denies 25% of* the claims for ABA therapy, despite the fact that professionally recognized treatment guidelines and the requisite number of randomized controlled trials support the use of ABA therapy to treat children with Autism Spectrum Disorder, *while approving 100% of treatment when the same guidelines are met for medical/surgical conditions*. Accordingly, *while denial rates alone are not determinative of operational compliance, a disparity in denial rates of 25% or more creates a rebuttable presumption that the plan is applying the NQTL more stringently to mental health benefits than to medical/surgical benefits. The plan is required to provide additional evidence demonstrating operational compliance.*

Amendment to Q5 from Proposed FAQs Part 39 (*amendments in italics*)

Q5: My large group health plan or large group insurance coverage provides benefits for prescription drugs to treat both medical/surgical and MH/SUD conditions but contains a general exclusion for items and services to treat bipolar disorder, including prescription drugs. Is this permissible under MHPAEA?

Yes, although if the plan is insured, it would depend on whether State law permits such an exclusion for large group insurance coverage. Generally, MHPAEA requires that treatment limitations imposed on MH/SUD benefits cannot be more restrictive than treatment limitations that apply to medical and surgical benefits. An exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of the definition of "treatment limitations" in the MHPAEA regulations. Small employer group health insurance coverage and individual health insurance coverage are subject to the requirement to provide essential health benefits, and the determination of whether certain benefits must be covered under the requirements for essential health benefits depends on the benefits in the applicable State's EHB benchmark plan.

However, MHPAEA does require that if any MH/SUD benefits are offered for a particular MH/SUD diagnosis in any of the 6 classifications of benefits, then the plan must offer benefits for that diagnosis on par with all of the classifications of benefits offered by the plan under the medical/surgical benefits. In this example, if in operation, the plan does reimburse primary care physicians for prescribing psychotropic drugs related to bipolar disorder, or if the plan does reimburse for treatment provided in an emergency room for symptoms related to bipolar disorder (e.g. acute psychotic episode, suicide attempt), then the plan is required to offer benefits for bipolar disorder in all classifications for which the plan offers benefits for medical/surgical conditions. Under these circumstances, the plan would not be compliant with MHPAEA.