



June 20, 2018

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Ave., NW
Washington, D.C. 20710

Centers for Medicare & Medicaid Services
Department of Health and Human Services
The Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

Internal Revenue Service
U.S. Department of Treasury
1500 Pennsylvania Ave., NW
Washington, D.C. 20220

**RE: Proposed FAQs About Mental Health and Substance Use Disorder Parity
Implementation and the 21st Century Cures Act Part 39**

Submitted electronically to: E-OHPSCA-FAQ39@dol.gov

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing on behalf of our members in response to the proposed guidance from the Departments of Labor (DOL), Health and Human Services (HHS), and Treasury (collectively, the Departments) that was recently issued in the form of FAQs on mental health and substance use disorder parity implementation and the 21st Century Cures Act. AHIP is the national association whose members provide coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

Our members have worked diligently to ensure compliance with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) by involving clinical and administrative personnel across medical, behavioral and pharmacy departments to promote understanding and implementation of parity rules. Reports issued by both federal and state governments, including

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DOL¹, have repeatedly shown progress made by plans in recent years, while also recognizing the complexity of implementation.² Moreover, our members have been leaders in pioneering innovative programs focused on ensuring that patients have affordable access to quality, evidence-based treatments, emphasizing proactive identification and outreach as well as coordination and integration of services.³

We welcome the opportunity to provide comments on the recently issued FAQs regarding nonquantitative treatment limitations (NQTLs) and disclosure requirements in connection with MHPAEA. Interpreting MHPAEA's application to NQTLs has proven to be particularly challenging for all stakeholders. As evidenced by the DOL's April report to Congress, approximately half of the overall small number of citations (92) issued in 2017 for MHPAEA violations pertained to NQTLs. Our members have long sought additional guidance from the Departments that is consistent with the underlying intent of the law to ensure that any processes, strategies, evidentiary standards, or other factors used in applying an NQTL to MH/SUD benefits in a given classification are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to medical/surgical benefits in the same classification.

However, we believe the recently issued guidance goes far beyond the law's intent and risks significant unintended consequences that could undermine the progress made to date in designing robust and evidence-based MH/SUD benefits. Our comments are focused on the following areas:

- The highly granular direction of the guidance and the updated Self-Compliance Tool Kit, which will increase burden and associated costs with little to no additional value to consumers;
- The insufficient acknowledgment that parity can still result in permissible differences between medical/surgical and MH/SUD benefits and application of NQTLs;
- Recommended modifications to specific draft questions and request for new FAQs; and

¹ Improving Health Coverage for Mental Health and Substance Use Disorder Patients: Including Compliance with the Federal Mental Health and Substance Use Disorder Parity Provisions: Report to Congress. January 2016.

<https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/mental-health-parity/improving-health-coverage-for-mental-health-and-substance-use-disorder-patients.pdf>

² Report to Congress: Compliance of Group Health Plans (and Health Insurance Coverage Offered in Connection with Such Plans) With the Requirements of the Mental Health Parity and Addiction Equity Act of 2008. January 1, 2012. <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/mhpaea-report-to-congress-2012.pdf>

³ Ensuring Access to Quality Behavioral Health Care: Health Plan Examples. May 2016. https://www.ahip.org/wp-content/uploads/2016/05/AccessToBehavioralCare_May-2016.pdf

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- Accompanying recommendations on the Self-Compliance Tool Kit.

Granular Direction of Guidance

The increasingly granular direction of the guidance makes the process of demonstrating that NQTLs are being applied comparably and no more stringently to MH/SUD benefits than to medical/surgical benefits extremely burdensome. We believe this increased burden will result in significant administrative costs with little to no additional value to consumers. The information that will have to be provided to consumers will be in the form of large quantities of technical information, such as comparative effectiveness studies, clinical trials, professional protocols, published research studies, thresholds for evidentiary standards, such as “two standard deviation higher in total cost than the average cost per episode 20 percent of the time in a 12-month period”, and internal claims database analyses, among other examples. In the experience of many of our members, such information has rarely if ever been requested and is unlikely to provide benefit to the consumer in understanding his or her benefits or benefit denial. Such voluminous information may have the potential to overwhelm the consumer and, of greater concern, detract from the information the consumer is actually seeking and would be most valuable to them.

Moreover, we are concerned that this level of detail goes far beyond what is required in the law, which specifies comparability of “any processes, strategies, evidentiary standards, or other factors” used in applying NQTLs, but does not require their disclosure. FAQs and other guidance, such as the Self-Compliance Tool Kit, are intended to support implementation efforts and understanding of the law, rather than establish new law or regulations. As such, it is important to make this intention clear and be consistent with the underlying MHPAEA statute and regulations.

Recommendation: Clarify that the FAQs are intended to support implementation efforts in a manner that is consistent with the underlying MHPAEA statute and regulations, not to establish new requirements.

Permissible Differences in NQTLs

The Interim Final Rule (42 CFR §146.136(c)(4)) included language that permitted the application of “more stringent” NQTLs with respect to MH/SUD benefits, “to the extent that recognized clinically appropriate standards of care may permit a difference.” While this language was removed from the text of the Final Rule, the sentiment is included in the Preamble to the Final Rule –

“...the 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 process, 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

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disorder benefits than for medical/surgical benefits. Disparate results alone do not mean that the NQTLs in use do not comply with these requirements.” (78 Fed. Reg. 68245)

This concept should be carried through in the FAQs. Specifically, the FAQs should include examples of instances where it would not be in the consumers’ best interest to impose NQTLs in the same manner for MH/SUD as for medical/surgical. Several of the illustrations included in the DOL’s Self-Compliance Tool reflect instances where differences in NQTLs may be permissible. Similar examples should be included in the FAQs to provide balance with the existing examples, which primarily describe impermissible differences.

For example, the quantity and strength of available medical evidence and standards for assessing quality related to MH/SUD treatment trail behind available data for medical/surgical treatment, in contrast to the scenarios and conclusions in Questions 2 and 3. There often may not be valid, measurable metrics on the MH/SUD side and not all clinical studies have the same validity or applicability. While two randomized, controlled clinical trials may be sufficient evidence on the medical/surgical side, more studies may be required on the MH/SUD side because of the more limited quality and depth of evidence. Clinical discretion plays an important role in evaluating the clinical information and evidence available. Rigid application of parity could have the unintended consequence of exposing consumers to MH/SUD care that does not meet the same standards for safety, efficacy, and quality as is met for medical/surgical care.

Recommendation: The FAQs should acknowledge and allow for clinical discretion based on available information and evidence, given the differences in the quantity and strength of available medical evidence for assessing quality related to MH/SUD treatment and medical/surgical treatment. The focus should be on whether the plan is applying clinically accepted MH/SUD protocols since clinical appropriateness is inherent in medical/surgical protocols.

Question 6 acknowledges the concept of permissible differences with the statement, “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.” However, the example itself is still one of non-compliance rather than an example showing how differences in NQTLs can still be compliant.

Recommendation: The FAQs should clearly and consistently acknowledge plans are in compliance when evidentiary standards or other factors are utilized comparably to develop and apply differing NQTLs for MH/SUD and medical/surgical benefits, as stated in Question 6. The agencies should include examples in the FAQs, consistent with language in the Preamble to the Final Rule and the Self-Compliance Tool Kit, to reinforce the fact that parity does not mean equal outcomes/results and that there are instances where differences in NQTLs are permissible

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under MHPAEA. Alternatively, the FAQs could be revised to provide more detail on how the scenario would need to change for the plan to be compliant.

For example, the MHPAEA Final Rule included an example (Example 4) that better exemplifies the concept of permissible differences based on clinical appropriateness and we recommend this example be addressed in these FAQs. This approach is more reliable than an overly rigid or imprecise benefit/service crosswalk approach.

"A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that is based on clinically appropriate standards of care for a condition. In this Example...the plan complies with the rules...because the processes for developing the evidentiary standards used to determine medical appropriateness and the application of these standards to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition." 78 FR 68272

Additionally, Question 2 could be revised or supplemented to (1) make it applicable to more situations and (2) provide an affirmative example of compliance that is consistent with Example 8 provided in the MHPAEA Final Rule. (78 FR 68273)

Recommendation: Question 2 should be revised (or an additional FAQ should be added) that retains much of the language of the existing Question 2 but is applicable to a much broader range of situations. The revised question could read as follows:

Q2: My health plan document states that it excludes treatment that is experimental or investigative for both medical/surgical benefits and 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. Is this permissible?

A: Yes. 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 exclusion of treatment that is experimental or investigative with respect to MH/SUD

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benefits are comparable to, and applied no more stringently than, those applied with respect to medical/surgical benefits.

Recommended Modification to Question 4 Regarding Dosage Limits and P&T Committees

Question 4 discusses use of Pharmacy and Therapeutics (P&T) committees to decide how to cover prescription drugs and evaluate whether to follow or deviate from professionally-recognized treatment guidelines for setting dosage limits. The draft response indicates that the use of P&T committees must comply with MHPAEA's NQTL standard, and in the case of a deviation from nationally-recognized treatment guidelines for a MH/SUD medication but not for a medical/surgical medication, the deviation should be evaluated for compliance with MHPAEA's NQTL requirements. According to the draft response, this evaluation should look at: (1) whether the expertise of the members of the P&T committee in MH/SUD conditions is comparable to their expertise in medical/surgical conditions; and (2) whether the committees' evaluation of nationally-recognized treatment guidelines in setting dosage limits for medications for both MH/SUD and medical/surgical conditions is comparable. However, the focus should be on the process and whether the process in setting dosage limits is comparable across both MH/SUD and medical/surgical medications.

Recommendation: Evaluation of deviations from professionally-recognized treatment guidelines based on a P&T committee recommendation should be based on whether the committee's evaluation of nationally-recognized treatment guidelines in setting dosage limits for medications for both MH/SUD and medical/surgical conditions is comparable, not the composition of the P&T committee.

Recommended Modification to Question 7 Regarding Provider Reimbursement

The current FAQ focuses on the rate outcome rather than the process used to set the reimbursement rates. A more illustrative FAQ would show how disparate reimbursement rates could still result in compliance. Like network adequacy (addressed below), there are many factors that affect provider reimbursement, such as service type, geographic market, demand for services, supply of providers, provider practice size, Medicare reimbursement rates, and training, experience and licensure of providers. The FAQ should emphasize that it is the process of determining provider reimbursement that must be comparable, not the resulting reimbursement rates. The FAQs should recognize that parity in process does not necessarily result in equal dollar amounts for medical/surgical and MH/SUD providers. To provide balance and be consistent with illustrations included in the Tool Kit, the FAQ should be revised to show how factors used in determining provider reimbursement, when applied in a manner that is comparable to and no more stringent for MH/SUD as for medical/surgical benefits, can result in different dollar amounts that are permissible under MHPAEA.

Recommendation: Revise Question 7 (or provide an alternate scenario) to reinforce that the process, factors, and standards for determining provider reimbursement rates must be

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comparable but the outcomes, or dollar amounts, may differ and still be compliant with MHPAEA.

Recommended Modification to Question 8 Regarding Network Adequacy

While standards for provider admission to participate in a network was included as an NQTL in the MHPAEA Final Rule's illustrative list of NQTLs, network adequacy was not, and we remain concerned that the Departments are treating network adequacy as an NQTL with the inclusion of Question 8.

Recommendation: Revise Question 8 to address standards for provider admission to participate in a network, consistent with MHPAEA regulations.

At the very least, the existing Question 8 should be revised to show how disparate standards could still result in compliance. Question 8 fails to acknowledge that there are many factors outside a plan's control, such as supply (or lack thereof) of quality behavioral health providers and behavioral health providers' unwillingness to contract with health plans. Given the well-documented shortage of behavioral health providers, the FAQs should recognize that parity in process does not necessarily result in equal medical/surgical and MH/SUD networks. To provide balance and be consistent with illustrations included in the Tool Kit, the FAQ should be revised to show how factors used in network admission standards, when applied in a manner that is comparable to and no more stringent for MH/SUD as for medical/surgical benefits, can result in different outcomes that are permissible under MHPAEA.

Recommendation: Revise Question 8 (or provide an alternate scenario) to reinforce that the process, factors and standards must be comparable but the outcomes (i.e., a health plan's MH/SUD and medical/surgical networks) may differ and still be compliant with MHPAEA. The revision or alternative scenario should emphasize that where standards relating to the availability of appointments are used for both MH/SUD and medical/surgical providers, the standards need not be exactly the same given the well-documented shortage of behavioral health providers.

Recommended Modification to Question 10 Regarding Complications Arising from a MH/SUD Condition

Question 10 seems to state that medical treatments or services could be considered MH/SUD benefits or medical/surgical benefits depending on the circumstances. Not only is this inconsistent with the way health plans classify benefits, but it also greatly complicates the parity analysis regarding financial requirements and quantitative treatment limitations. Page 14 of the Self-Compliance Tool Kit states "Plans and issuers should clearly define which benefits are treated as medical/surgical and which benefits are treated as MH/SUD under the plan." The FAQ can be simplified and made consistent with existing guidance issued by CMS in an October 2017 FAQ regarding MHPAEA compliance for Medicaid and CHIP programs and plans.

Recommendation: Reiterate guidance previously issued by CMS regarding MHPAEA compliance for Medicaid and CHIP programs and plans addressing the question of defining benefits in the case of a treatment or service that is used to treat both medical/surgical and MH/SUD conditions. Question 4 from the October 2017 FAQs addresses defining MH/SUD benefits and medical/surgical benefits as they apply to long term supports and services that can be provided for both MH/SUD and medical/surgical conditions. This FAQ can similarly be applied to emergency room care.

Q10: My health plan provides benefits for emergency room care. If emergency room care is provided for an acute condition affecting my physical health that arises as a complication of a mental health condition or substance use disorder, are benefits for that care considered MH/SUD benefits for the purpose of MHPAEA?

A: A variety of emergency room care benefits could be defined as either MH/SUD or medical/surgical, depending on the condition of the individual being treated. For these benefits, a reasonable method, such as whether the service is most commonly or frequently provided due to a MH/SUD or medical/surgical condition could be used. For example, if more than 50% of a plan's claims experience for physical therapy services have a medical/surgical diagnosis, the plan may define physical therapy as a medical benefit for the purpose of MHPAEA parity analysis.

Request for New FAQ

We recommend the Department add an FAQ concerning permissible disparate application of NQTLs to address fraudulent practices. As the Departments are well aware, the current opioid crisis has given rise to new areas of health care fraud, such as recovery housing/sober homes and excessive urine drug testing.⁴ A less-developed quality and oversight infrastructure of these facilities has led to deceptive business practices, insurance fraud, and poor-quality care and diminished health outcomes in many instances. An FAQ that makes clear the circumstances under which health plan efforts to target fraudulent MH/SUD-related practices are permissible under MHPAEA would help ensure that these targeted efforts to protect patients can continue.

⁴ See Substance Use Disorder: Information on Recovery Housing Prevalence, Selected States' Oversight, and Funding. March 2018. <https://www.gao.gov/assets/700/690831.pdf> and Examining Clinical Laboratory Services: A Review by the Healthcare Fraud Prevention Partnership. May 2018. <https://hfpp.cms.gov/Hfpp-White-Papers/HFPP-Clinical-Lab-Services-White-Paper.pdf>

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Recommendation: Add an FAQ to make clear that there are circumstances under which it is permissible under MHPAEA for health plans to target fraudulent MH/SUD-related practices (e.g., recovery housing/sober homes, excessive urine drug testing).

Accompanying Recommendations on the Self-Compliance Tool Kit

While the Self-Compliance Tool Kit is not officially open for public comment, its content is integrally related to the draft FAQs and Model Disclosure Request Form which are currently open for public comment. Therefore, we would like to take the opportunity to make recommendations related to the Tool Kit as the Departments plan for future updates or additional guidance on its use. Similar to our comments on the proposed FAQs, we recommend the Department clarify that the Tool Kit is intended to support implementation efforts in a manner that is consistent with the underlying MHPAEA statute and regulations, not to establish new requirements.

Step Three in the Self-Compliance Tool Kit requires plans to identify and provide the *sources* used to define the factors identified in the design of an NQTL. This is a new requirement not specified in the law and adds yet another layer of complexity and burden to a process that is already burdensome and not conducive to providing useful information for consumers. For example, the information that will have to be provided to consumers will be in the form of large quantities of technical information, such as comparative effectiveness studies, clinical trials, professional protocols, published research studies, thresholds for evidentiary standards, such as “two standard deviation higher in total cost than the average cost per episode 20 percent of the time in a 12-month period”, and internal claims database analyses, among other examples. This type of information is far from the recommended target of between a fourth and sixth grade reading level. We believe that user-friendly information in an easy-to-read format would better inform consumers about how MH/SUD benefit NQTLs are developed and applied in a way that is comparable to their development and application on the medical/surgical side. We believe further that such simplified, user-friendly information also better reflects what consumers are seeking when pursuing an information request of their health plan.

The additional layers of complexity laid out in the Tool Kit and exemplified in the proposed FAQs (as well as the Model Disclosure Request Form on which AHIP is submitting separate comments) necessitate, at the very least, a delayed effective date to enable plans to interpret and prepare for this new requirement embodied in Step Three.

Recommendation: Delete the requirement in #3. If the Self-Compliance Tool Kit remains unchanged, particularly with regard to Step Three, we recommend the Department reiterate that its use is optional and delay the effective date of the revised Tool Kit until January 1, 2019.

Additionally, a “compliance tip” in the Self-Compliance Tool Kit is inconsistent with the flexibility expressed in the Preamble of the Final Rule regarding permissible differences. The

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Preamble to the Final Rule states that “...*the 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...*” Yet page 14 of the Self-Compliance Tool Kit includes a “compliance tip” that “Any separate NQTL that applies to only the MH/SUD benefits within any particular classification does not comply with MHPAEA.” This statement is inaccurate and inconsistent with the Final Rule. Moreover, it is inconsistent with the “compliance tip” included on page 15 which states “If only certain benefits are subject to an NQTL, such as meeting a fail-first protocol or requiring preauthorization, plans and issuers should have information available to substantiate how the applicable factors were used to apply the specific NQTL to medical/surgical and MH/SUD benefits.”

Recommendation: Remove the “compliance tip” on page 14 of the Self-Compliance Tool Kit and explicitly acknowledge Example 8 from the MHPAEA Final Rule referenced above.

In summary, while we appreciate the Departments’ continuing efforts to provide guidance on NQTLs, we believe the proposed FAQs could be significantly improved by adhering to the intent of the law, moving away from granular requirements not included in the law, and including additional examples and/or detail showing where permissible differences in NQTLs would be appropriate.

We look forward to working with the Departments on these efforts and appreciate your consideration of our comments. Please contact Kate Berry, Senior Vice President of Clinical Affairs and Strategic Partnerships, at kberry@ahip.org with questions.

Sincerely,

A handwritten signature in cursive script that reads "Kate Berry".

Kate Berry
Senior Vice President, Clinical and Strategic Partnerships