



The ERISA Industry Committee

Driven By and For Large Employers

701 8th St., NW, Suite 610, Washington, DC 20001

• (202) 789-1400

• www.eric.org

James Gelfand, Senior Vice President of Health Policy

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The Honorable R. Alexander Acosta
Secretary of Labor
U.S. Department of Labor
200 Constitution Ave, NW
Washington, DC 20210

The Honorable Steven T. Mnuchin
Secretary of the Treasury
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

The Honorable Alex M. Azar II
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Recent Guidance on MHPAEA and 21st Century Cures Act

To Whom It May Concern:

The ERISA Industry Committee (ERIC) is pleased to submit these comments in response to recently-issued guidance on the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and the 21st Century Cures Act (Cures Act). The guidance was released by the Departments of Labor, Health and Human Services and the Treasury (collectively, the Departments) on April 23, 2018, and includes several documents designed to promote understanding of and compliance with MHPAEA as required by the Cures Act. The guidance documents include, among other things: (i) Proposed FAQs (Part 39); (ii) the 2018 MHPAEA Self-Compliance Tool; (iii) the Revised Draft MHPAEA Disclosure Template; (iv) the DOL 2018 Report to Congress: “*Pathway to Full Parity*;” and (v) the DOL Fact Sheet “*FY 2017 MHPAEA Enforcement*” (collectively, the MHPAEA Guidance Documents). While only the Proposed FAQs solicit public feedback, our comments will address all of the MHPAEA Guidance Documents.

ERIC’S INTEREST IN THE MHPAEA AND THE CURES ACT

ERIC is the only national trade association that advocates exclusively on behalf of large employers on health, retirement, and compensation public policies on the federal, state, and local levels. ERIC supports the ability of its large employer members to tailor retirement, health, and compensation benefits to meet the unique needs of their workforce, providing benefits to millions of workers, retirees, and their families across the country.

ERIC’s member companies offer comprehensive group health benefits to their employees in compliance with the myriad federal requirements placed upon group health plans subject to the Employee Retirement Income Security Act (ERISA), and other federal laws including Medicare. As such, ERIC members are keenly interested in the ongoing promulgation and enforcement of rules relating to these laws, in order to maximize compliance, minimize unnecessary costs and burdens, and ensure optimal health outcomes for the millions of beneficiaries ERIC companies insure.

ERIC is the only national association that advocates exclusively for large employers on health, retirement, and compensation public policies at the federal, state, and local levels.

Many ERIC member companies voluntarily offer medical coverage that includes behavioral health and substance abuse coverage. ERIC members work constantly with their third-party administrators and professional advisors to design and operate their health plans in full compliance with all applicable federal and state laws, including MHPAEA. But ERIC members have found MHPAEA compliance to be particularly challenging. Each iteration of MHPAEA guidance issued by the Departments has included new interpretations, and imposed new obligations, on health plan sponsors. In many respects, the MHPAEA guidance issued to date has been inconclusive or incomplete – key words and phrases were not defined, compliance obligations were not spelled out, and interpretations were not supported by legal authority. In some cases, regulatory guidance was in conflict with sub-regulatory guidance. These deficiencies have contributed to significant enforcement confusion – neither group health plan sponsors, health insurance issuers or Department regulators have had clear roadmaps to guide the enforcement process. The MHPAEA Guidance Documents are a step in the right direction, but ERIC members continue to have significant concerns. ***We offer the following comments, focusing specifically on the need for more time to comply with new requirements, more stakeholder input on the processes, definitions, and interpretations by the Departments, and flexibility in enforcement.***

BACKGROUND

The MHPAEA was enacted in October 2008, and significantly expanded the original 1996 mental health parity law. Among other things, the MHPAEA requires employer-sponsored health plans to ensure that the financial requirements and treatment limitations for mental health and substance use disorder benefits are no more restrictive than the predominant financial requirements/treatment limitations applied to substantially all medical and surgical benefits covered by the plan. The MHPAEA also imposes additional disclosure requirements – plan sponsors are required to disclose the criteria for medical necessity determinations for mental health/substance use disorder benefits upon request. The law does not apply to self-insured plans of small employers (not more than 50 employees), but otherwise applies to both ERISA plans and non-ERISA plans (government and church plans).¹

The MHPAEA defines “treatment limitations” simply as limits on “the frequency of treatment, number of visits, days of coverage, or other similar limits.”² Interim regulations issued in February 2010 (and finalized in October 2013) significantly expand the statutory definition to include both quantitative and nonquantitative treatment limitations (commonly abbreviated QTL and NQTL).³ The final regulations say that a plan may not impose NQTLs on mental health and substance use disorder benefits unless the “processes, strategies, evidentiary standards or other factors” used in applying those limitations are “comparable to and are applied no more stringently than” the processes, strategies, evidentiary standards or other factors used in applying the limitations to medical/surgical benefits. The final regulations do not define “processes, strategies, evidentiary standards or other factors” but provide an illustrative list of NQTLs. The final regulations also opine that ERISA §104(b) (which requires disclosure of “instruments under which the plan is established or operated” upon request) – obligates an ERISA plan sponsor to disclose the “processes, strategies, evidentiary standards and other factors” used to apply an NQTL with respect to *both* medical/surgical benefits and mental health/substance use disorder benefits.

¹ The MHPAEA is found at Subtitle B of Title V of Public Law 110-343 (October 3, 2008). As originally enacted, the MHPAEA included parallel provisions in ERISA, the Internal Revenue Code and the Public Health Service Act. The Affordable Care Act (ACA) extended the MHPAEA requirements to the individual health insurance market and the ACA’s essential health benefits requirement extended the MHPAEA requirements to non-grandfathered health insurance coverage in the individual and small group markets.

² ERISA §712(a)(3)(B)(iii).

³ The interim final regulations were published at 75 Fed. Reg. 5410 (February 2, 2010) and the final regulations were published at 78 Fed. Reg. 68240 (November 13, 2013).

The Cures Act was enacted in December 2016.⁴ Section 13001(b) of the Cures Act directs the Departments to clarify their previously-issued guidance and issue nine different categories of illustrative examples that group health plans “may use regarding the development and application of nonquantitative treatment limitations.” Among other requirements, the Cures Act requires the Departments to issue clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards and other factors that may be used regarding the development and application of NQTLs.

COMMENTS

I. APPLICABILITY DATE

The Cures Act does not impose direct obligations on group health plans or health insurance issuers and, for this reason, does not include a specific effective date. The only dates specified in the Cures Acts are dates by which the Departments are required to take action on various tasks. The MHPAEA Guidance Documents likewise do not specify an effective date or, more importantly, an applicability date. The Departments should clarify that the new guidance in the MHPAEA Guidance Documents is prospective.

It goes without saying that group health plan sponsors and health insurance issuers should *always* be given sufficient time to implement new legal or regulatory requirements. The Departments recognize this principle and, in fact, delayed the applicability date of the MHPAEA final regulations for a significant period of time. Although the final MHPAEA regulations appeared in the Federal Register on November 13, 2013, the Departments delayed the applicability date until plan years beginning on or after July 1, 2014. This simple decision gave group health plan sponsors and health insurance issuers ample time to comply.

The MHPAEA Guidance Documents include new, and highly detailed, requirements (see next topic). It is not accurate to characterize these requirements as simple “clarifications” of prior guidance, nor is it appropriate to assert that these requirements should be retroactively effective. Group health plan sponsors and health insurance issuers will need time to work with their vendors to evaluate the new requirements in the MHPAEA Guidance Documents and develop robust compliance approaches. It is imperative that the Departments provide sufficient time for this process to occur. ***We believe the applicability date of the new requirements in the MHPAEA Guidance Documents should be delayed until plan years beginning on or after a specified future date, at a minimum July 1, 2019.***

II. NEW REQUIREMENTS VS CLARIFICATIONS

The Cures Act did not authorize the Departments to introduce new MHPAEA requirements, whether through sub-regulatory guidance or otherwise. ***To the extent the MHPAEA Guidance Documents provide new requirements (and create new compliance obligations), we believe those requirements should be formally adopted through the standard regulatory process in compliance with the Administrative Procedure Act, with opportunity for public comment and in conformance with all applicable Executive Orders.*** Our specific comments follow.

NQTL Documentation Requirements. The final MHPAEA regulations include a requirement that “any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification.” But the regulations never define, or explain, the scope of the “processes, strategies, evidentiary standards, or other factors” to be taken into account.

The 2018 Self-Compliance Tool provides, *for the first time*, examples of the “processes, strategies and evidentiary standards” and “factors and sources of factors” to be used in evaluating whether NQTLs for mental health or substance use disorder benefits are comparable to the NQTLs for medical and surgical benefits. The 2018 Self-

⁴ The Cures Act is found at Title XIII of Public Law 114-255 (December 13, 2016).

Compliance Tool seems to assume that group health plan sponsors and health insurance issuers already know what all of these terms mean and already have supporting documentation to demonstrate compliance.⁵

These are new requirements, not clarifications – neither the final MHPAEA regulations nor subsequent sub-regulatory guidance impose an affirmative duty on group health plan sponsors or health insurance issuers to prepare and maintain the extensive NQTL documentation described in the 2018 Self-Compliance Tool. If the Departments believe there is an affirmative duty to create this documentation, then the required NQTL obligation should be conspicuously described in regulations and plan sponsors and issuers need ample time to comply.⁶

Other MHPAEA Documentation Requirements. The final MHPAEA regulations mention the word “documentation” only eight times, and all of those references deal with supporting actuarial documentation for the increased cost and small employer exemptions. But the regulations never require group health plan sponsors or health insurance issuers to perform specific tests (such as the predominant/substantially all tests applicable to quantifiable treatment limitations),⁷ nor do the regulations require sponsors or issuers to maintain specific supporting MHPAEA documentation.⁸

The MHPAEA Guidance Documents reveal, *for the first time*, the comprehensive scope of the Departments’ view of the MHPAEA documentation requirements. For example:

- The 2018 Self-Compliance Tool indicates (at pages 20-21) that group health plan sponsors and health insurance issuers should be prepared to provide: (i) an analysis showing that the plan meets the predominant/substantially all tests; (ii) a description of each applicable treatment limitation for medical/surgical and mental health/substance use disorder benefits, including references to specific plan documents; (iii) information regarding factors or guidelines; (iv) a description of the applicable treatment limitation used in any given adverse benefit determination; and (v) medical necessity guidelines for in- and out-of-network medical/surgical and mental health/substance use disorder benefits.⁹

⁵ The 2018 Self-Compliance Tool indicates (at page 20) that plans and issuers should be “prepared” to provide: (1) a list of NQTLs for all benefits; (2) records documenting NQTL processes and how NQTLs are being applied; (3) appropriate documentation relied upon as the basis for compliance with the “comparable to and applied no more stringently than” requirement (including details as to how guidelines/standards were applied and any internal testing, review or analysis to support the compliance finding); and (4) a record of all claims submitted and denied within each classification of benefits. We believe that most plans are not prepared to provide this information at this time.

⁶ The DOL’s “*Self-Compliance Tool for Part 7 of ERISA: Health Care-Related Provisions*” available prior to April 23, 2018 includes 13 pages of discussion on the MHPAEA requirements. In contrast, the recently-released 2018 Self-Compliance Tool includes 23 pages of discussion on the MHPAEA requirements. Compare <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/compliance-assistance-guide-appendix-a.pdf> (pages 77-89) with <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/compliance-assistance-guide-appendix-a-mhpaea.pdf>.

⁷ The preamble to the final regulations discusses the predominant/substantially all tests and mentions that “a plan or issuer is not required to perform the parity analysis each plan year unless there is a change in plan benefit design, cost-sharing structure or utilization that would affect a financial requirement or treatment limitation within a classification or (sub-classification).” 78 Fed. Reg. 68243 (November 13, 2013). But the final regulations never say the tests are required, do not provide any details about when or how the tests should be performed, or discuss any documentation or record retention requirements relating to the test results.

⁸ ERISA’s general record retention requirement is limited to records pertaining to agency filings and participant or beneficiary disclosures, and doesn’t address other categories of supporting documentation. See ERISA §107.

⁹ We recognize that this same list appeared in the DOL’s Compliance Assistance Guide prior to the release of the MHPAEA Guidance Documents on April 23, 2018. What is new is that the 2018 Self-Compliance Tool explains “processes, strategies, evidentiary standards and other factors” in far more detail, thereby significantly expanding the scope of these documentation requirements.

- The Draft Disclosure Template indicates (at pages 4-5) that group health plan sponsors and health insurance issuers should be prepared to provide the following information with respect to each treatment limitation: (i) the specific plan language regarding the limitation and a list of all the medical/surgical and mental health/substance abuse disorder benefits to which it applies in each relevant benefit classification; (ii) the factors used in the development of the treatment limitation; (iii) the evidentiary standards used to evaluate the factors; (iv) the methods and analysis used to develop the treatment limitation; and (v) evidence and documentation to establish that a treatment limitation is applied no more stringently to mental health and substance use disorder benefits than to medical and surgical benefits.
- The 2018 Report to Congress “*Pathway to Full Parity*” refers to a publication co-developed by DOL and the Substance Abuse and Mental Health Services Administration (SAMHSA) called the “*Consumer Guide to Disclosure Rights: Making the Most Of Your Mental Health and Substance Use Disorder Benefits*.”¹⁰ That publication indicates that, in addition to the items mentioned above, group health plan sponsors and health insurance issuers should be prepared to provide: (i) reports of pharmacy and therapeutics committees (page 10); and (ii) standards for provider admission to participate in a network, including reimbursement rates, and the underlying reasons for certain requirements (such as supervised clinical experience) (page 11).

These are new requirements, not clarifications - neither the final MHPAEA regulations nor subsequent sub-regulatory guidance impose an affirmative duty on group health plan sponsors or health insurance issuers to prepare and maintain the extensive documentation described in the various MHPAEA Guidance Documents. ***If the Departments believe there is an affirmative duty to create this documentation, then the required documentation should be conspicuously described in regulations and plan sponsors and issuers need ample time to comply.***¹¹

Additionally, this guidance could serve as an opportunity for the Departments to provide clarity about a number of points of contention regarding MHPAEA requirements. For instance, more information is needed regarding the classification of certain mental health and substance use disorder treatments. While the Departments continue to be clear that MHPAEA is not a benefit mandate, plan sponsors are under immense pressure regarding certain treatments which medical authorities regard as experimental, unproven, or lacking sufficient quality metrics. Take for example autism applied behavioral analysis for certain patients, certain opioid and substance use treatments, wilderness or equine therapy, and the like. Plan sponsors could be spared unnecessary litigation and costs if the Departments would include FAQs to settle some of these ongoing disputes.

III. DISCLOSURE REQUIREMENTS

The MHPAEA added a new disclosure requirement for group health plans and health insurance issuers. Under the law, plans and issuers are required to disclose to a participant, beneficiary or contracting provider upon request “the criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits.”¹² The final MHPAEA regulations significantly expand the statutory requirement, and require plans and issuers to also disclose to plan participants on request “the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical

¹⁰ Available here - <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/mental-health-parity/disclosure-guide-making-the-most-of-your-mental-health-and-substance-use-disorder-benefits.pdf>

¹¹ To the extent that detailed MHPAEA documentation is required, there should be one list of the required documentation elements. It is inappropriate for the Departments to communicate different MHPAEA documentation elements in different forms of sub-regulatory guidance.

¹² See ERISA §712(a)(4).

benefits and mental health or substance use disorder benefits.”¹³ This expanded disclosure requirement is based on DOL’s position that these processes, strategies, standards and factors are “other instruments under which the plan is established or operated,” and that their disclosure is required within 30 days of request under ERISA §104(b).¹⁴

Although the DOL interprets the “other instruments” clause in ERISA §104(b)(4) broadly, that position has not been shared by the courts. Most of the courts that have reviewed the “other instruments” clause have interpreted the term narrowly. See, e.g., *Faircloth v. Lundy Packing Co.*, 91 F.3d 648, 654 (4th Cir. 1996) (if Congress intended section 104(b)(4) “to encompass all documents that provide information about the plan and benefits, Congress could have used language to that effect”).¹⁵ Based on the case law, we question whether the DOL’s position that processes, strategies, standards and factors are “other instruments” subject to disclosure under ERISA §104(b)(4) is appropriate.

The Draft Disclosure Template is structured as a written letter that allows participants (and their authorized representatives) to request information about a health plan’s treatment limitations. The letter includes check boxes on which a participant indicates whether she or he is submitting a general information request or a claim/denial information request. The general information request check box then has two further sub-check boxes – one to request information about mental health and substance use disorder benefits generally and a second to request information about a specific treatment for a condition or disorder (and the participant fills in a blank to indicate the specific treatment). The claim/denial information request check box has *ten* sub-check boxes designed to indicate the participant’s understanding of why a claim was denied. The instructions tell the participant to check all boxes that apply. The letter concludes with an admonition (in bold text) that the plan must provide the requested information within 30 days, then enumerates the lengthy list of documents described above.

Let us examine a scenario where a group health plan sponsor receives a general information request from a participant for “mental health and substance use disorder benefits, *generally*.” Is the sponsor required to provide “processes, strategies, evidentiary standards and other factors” for *all* medical/surgical benefits and *all* mental health and substance use disorder benefits covered by the plan? First the plan sponsor will need to confirm that the request is from a participant and identify the medical plan in which the person is enrolled. Then the plan sponsor will need to pass the request on to its third-party administrator, because the plan sponsor doesn’t have the requested information. Last, the third-party administrator will need to generate a response and include what may be hundreds or thousands of pages of text. How does this help the participant?

Next let us consider a scenario where a group health plan sponsor receives a claim/denial information request (with all 10 sub-boxes checked) from a participant who has received an explanation of benefits denying a claim for a mental health/substance use disorder condition. Let us assume that the plan sponsor has delegated the plan’s

¹³ DOL Reg. §2590.712(d)(3).

¹⁴ *Id.* Note that the requirement to disclose “other instruments” appears in ERISA §104(b)(4). The 30-day response requirement is not found in ERISA §104(b)(4), but in ERISA §502(c)(1)(B) which allows a court to impose penalties, in its discretion, if a plan administrator fails or refuses to comply with a request for documents within 30 days.

¹⁵ Appellate decisions consistent with *Faircloth* include: *Brown v. American Life Holdings, Inc.*, 190 F.3d 856, 861 (8th Cir. 1999) (the “other instruments” clause means “not any document relating to a plan, but only formal documents that establish or govern the plan.”); *Ames v. American National Can Co.*, 170 F.3d 751, 758 (7th Cir. 1999) (instruments “refers to a specific set of documents: those under which a plan is established or operated”); *Board of Trustees of the CWA/ITU Negotiated Pension Plan v. Weinstein*, 107 F.3d 139 (2nd Cir. 1997) (“that clause was meant to refer to formal documents that govern the plan, not to all documents by means of which the plan conducts operations”). A contrary appellate decision appears in *Bartling v. Fruehauf Corp.*, 29 F.3d 1062 (6th Cir. 1994) (“all other things being equal, courts should favor disclosure where it would help participants understand their rights”).

claim and appeal procedures to a third-party administrator. How should the plan sponsor handle the request? The most likely process flow is that the plan sponsor will send the request to the third-party administrator, and the third-party administrator will handle the request as part of the administrative record for the claim. But what if the request is misdirected? And what if the participant misses her window to appeal the denied claim? The Draft Disclosure Template could cause confusion with the plan's existing claims procedure and is likely to be inconsistent with the appeal instructions included with the explanation of benefits.

ERIC members are concerned that the Draft Disclosure Template will create more problems than it will solve. Participants will be confused, and plan sponsors and their third-party administrators will be saddled with the responsibility of responding to hundreds or thousands of individual requests. And unfortunately, many of the requests will be generated by out-of-network healthcare providers on fishing expeditions. Plan sponsors are already dealing with spurious document requests from out-of-network providers, and the Draft Disclosure Template is an invitation for more of the same. The exclusive focus on a written document request seems particularly misplaced – why, in the 21st century, wouldn't the Departments consider electronic alternatives? If it's permissible to maintain and disclose network provider lists electronically, then why shouldn't it be permissible to maintain information about treatment limitations (and the processes, strategies, evidentiary standards or other factors) in a similar fashion?

The biggest challenge is that a significant amount of time will be needed to prepare for the coming burdensome disclosure requirements. As we've noted, the MHPAEA Guidance Documents have only recently described the "processes, strategies, evidentiary standards or other factors" that must be identified, and only recently enumerated the extensive supporting documentation the Departments believe should be maintained. Group health plans and health insurance issuers have only begun to digest the guidance. If one of the template letters were to arrive today, plan sponsors and issuers would be hard pressed to respond. The Draft Disclosure Template should not be released until it is refined, and until reasonable alternative disclosure approaches are considered and developed. The Departments should clarify that group health plans and health insurance issuers are not required to respond to information requests submitted on the Draft Disclosure Template until further notice and take steps to remove it from Department websites immediately.¹⁶

IV. GUIDANCE ON COMPARABILITY

As noted, the regulations say that a plan may not impose NQTLs on mental health and substance use disorder benefits unless the "processes, strategies, evidentiary standards or other factors" used in applying those limitations are "comparable to and are applied no more stringently than" the processes, strategies, evidentiary standards or other factors used in applying the limitations to medical/surgical benefits. The Proposed FAQs go to great lengths to illustrate the "no more stringently than" part of the test – five of the eight substantive questions address this topic.

But there's no similar guidance on the "comparable to" part of the test. Questions 7 and 8 mention comparability, but don't explain or illustrate either what comparability means or how comparability is determined. Question 7 concludes that a plan isn't using a comparable process to determine reimbursement rates for mental health/substance use disorder non-physicians. This conclusion rests on the statement that reimbursement rates for medical/surgical physicians and non-physicians are "generally the same" while the plan pays "reduced" reimbursement rates for mental health/substance abuse disorder non-physicians. Question 8 concludes that a plan doesn't have a comparable network adequacy standard because the plan has an appointment scheduling standard for medical/surgical providers but doesn't have an appointment scheduling standard for mental health/substance use disorder providers.

¹⁶ The posted version is misleading. Although the website caption uses the word "Revised Draft," there's no indication in the Form or the instructions that the Form itself is still in draft form. See <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/mental-health-parity/mhpaea-disclosure-template-draft-revised.pdf>.

One of the most significant defects in the MHPAEA regulations is the lack of clarity regarding the use of the phrase “comparable to.” Does “comparable to” mean equivalent, or roughly equivalent? How is comparability measured? If some degree of variation is permitted between medical/surgical NQTLs and mental health/substance use disorder NQTLs, what degree of variation is permitted? For example, let’s go back to question 7 of the Proposed FAQs and the statement that reimbursement rates for medical/surgical physicians and non-physicians are “generally the same.” What does that mean? How were the reimbursement rates for physicians and non-physicians measured for medical/surgical providers and for mental health/substance abuse disorder providers? Were the rates determined separately for each MHPAEA benefit classification (or sub-classification)? Were the rates based on simple averages (based on physician/non-physician headcount) or weighted averages (based on the dollar amount of claims paid for physician/non-physician services)? Were rate differentials different across physician specialty practices? Were the rates evaluated (and weighted) separately based on the type of business (such as commercial rates vs. Medicare/Medicaid rates) or across different blocks of business (such as individual, small group and large group)?

The answers to these questions are of fundamental importance. ***Without measurement criteria, the comparability standard is impossibly vague.*** The application of the standard is left to the whim of reviewers and won’t be consistently applied. Moreover, a reasonable group health plan sponsor or health insurance issuer can’t possibly maintain the data necessary to demonstrate compliance, because the compliance standard *isn’t known or determinable*. Group health plan sponsors and health insurance issuers are left to guess what the standard is and what data to maintain in hopes of demonstrating compliance. And bear in mind that the regulations require this vague test to be applied not to one NQTL but to *all* NQTLs for *all* benefits and across *all* of the “processes, strategies, evidentiary standards, or other factors” related to those NQTLs.

This is not a new problem – the comparability standard first appeared in the interim regulations in February 2010. But almost six years later and, even with the final regulations and the MHPAEA Guidance Documents, it is still unclear what the comparability standard requires or how it should be applied.¹⁷ We suggest several steps to address this problem:

- First, standardize the list of NQTLs. It doesn’t have to be an exhaustive list, and the Departments could reserve discretion to address abusive situations. But a standardized list is important because it gives group health plan sponsors and health insurance issuers the ability to conduct internal compliance audits and create the databases necessary to demonstrate compliance. If the Departments need to add additional NQTLs, then advance notice should be provided to give group health plan sponsors and health insurance issuers ample time to develop compliance protocols for the new NQTLs.¹⁸
- Second, develop an overall comparability standard that accommodates some degree of variation. In this regard, the Departments need to recognize and accept that many mental health and substance use disorder benefits are not strictly comparable to medical or surgical benefits, and that the evidence base for certain mental health and substance use disorder benefits is not as well defined as it is for most medical and surgical benefits. The Departments should invite comment to more fully understand the existing degree of variation in clinical practice among medical/surgical providers and mental health/substance use disorder providers before articulating this overall comparability standard.

¹⁷ Many of the examples in the final regulations suffer from the same problem, focusing far more on the “no more stringently than” standard than on the “comparable to” standard. The examples that mention the comparability standard do so in the most obvious of ways – see example 3 (25% penalty differential is not comparable), example 5 (unconditional exclusion for drugs with black box warnings is not comparable), example 6 (requiring exhaustion of EAP benefits is not comparable), example 9 (unconditional exclusion of non-hospital treatment is not comparable), example 10 (blanket exclusion for out-of-state treatment is not comparable) and example 11 (prior authorization rule with pre-determined caps on visit limits is not comparable). See DOL Reg. §2590.712(c)(4)(iii).

¹⁸ The interim regulations list six NQTLs, the final regulations list eight NQTLs (and mention an additional eight NQTLs in the preamble), and the 2018 Self-Compliance Tool lists 13 NQTLs.

- Third, develop specific comparability standards (and examples) for each of the listed NQTLs, again with input from stakeholders, including details of the processes, strategies, evidentiary standards or other factors that may be taken into account to demonstrate compliance with the NQTL-specific standards. Doing so will provide group health plan sponsors and health insurance issuers with the information they need to evaluate their business operations and collect the documentation necessary to demonstrate compliance.¹⁹

We believe that the comparability standard must be objective, not subjective, and that all stakeholders have an interest in promoting this outcome. The Departments should focus enforcement efforts on abusers and provide simplified compliance approaches for the great majority of group health plan sponsors and health insurance issuers for whom compliance is an accepted best practice.

V. ENFORCEMENT

The DOL Report to Congress “*Pathway to Parity*” and the DOL Fact Sheet “*FY 2017 MHPAEA Enforcement*” describe a top-down enforcement regime. DOL enforcement of the MHPAEA is focused *exclusively* on an audit approach under which group health plan sponsors and health insurance issuers must endure a gauntlet of DOL requests, including: (1) send the plan documents; (2) send the service contracts; and (3) send claims data showing covered and denied claims. Armed with this information, the DOL conducts its review, retaining unidentified subject matter experts, and coordinating its findings first within DOL and then, more broadly, with HHS and Treasury and, in the case of insurance companies, with the applicable State insurance department. If it is determined that a plan violates the MHPAEA, the DOL attempts to achieve voluntary correction, either individually or globally, through a voluntary compliance letter which outlines required correction steps (including, in many cases, reprocessing of claims) and updating plan documents. If voluntary correction cannot be achieved, the matter is referred to the DOL’s solicitor’s office.

The DOL Report to Congress describes this as “an arduous process” and we agree. The DOL Fact Sheet says that DOL identified and cited a grand total of 92 violations for MHPAEA during FY 2017. Neither the DOL Report to Congress nor the DOL Fact Sheet describe the cost of all this enforcement activity, but it certainly isn’t inexpensive. All of which leads to a logical question – are there other approaches that might be used to enforce the MHPAEA, and might these approaches more effectively use limited resources?

Voluntary Compliance Programs. The DOL has long maintained two voluntary compliance programs – the Voluntary Fiduciary Correction Program (VFCP) and the Delinquent Filer Voluntary Compliance Program (DFVCP). Both programs encourage ERISA plan sponsors to self-report and self-correct various ERISA compliance deficiencies by offering significant incentives, typically reduced penalties and/or protection against enforcement activity. The programs are highly successful – for FY 2017, DOL received 1,303 VFCP applications and 22,139 DFVCP filings.²⁰ Effectively, both programs promote ERISA compliance by deputizing ERISA subject matter experts – if and when an outside attorney, actuary or advisor identifies an ERISA compliance problem, the VFCP and DFVCP provide opportunities for ERISA plan sponsors to resolve that problem without having to endure the “arduous process” of a DOL audit.

We urge the Departments to develop a similar voluntary compliance program for MHPAEA compliance. Group health plan sponsors and health insurance issuers would welcome the opportunity to identify and self-correct MHPAEA compliance problems. From the plan sponsor/issuer perspective, utilizing a voluntary compliance

¹⁹ Examples 4, 7 and 8 in the final regulations are good starting points because they recite and evaluate the processes, strategies, evidentiary standards or other factors underlying specific NQTLs. See DOL Reg. §2590.712(c)(4)(iii).

²⁰ See <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/ebsa-monetary-results-2017.pdf>.

program as a MHPAEA correction mechanism is a highly preferable process to the drawn-out exercise of enduring an audit. From the Departments' perspective, a voluntary MHPAEA correction program would help to expand MHPAEA compliance and leverage limited government resources – investigators could focus on more egregious violations.

Non-Enforcement Guidance. From time to time, the Departments have exercised their enforcement discretion by issuing non-enforcement guidance as a way of achieving greater compliance with legal and regulatory requirements. In some cases, non-enforcement guidance is limited in scope or duration, or is subject to various conditions such as good-faith compliance. The Departments have been particularly generous about providing non-enforcement guidance and/or relief in connection with the implementation of various ACA requirements.²¹ Non-enforcement guidance helps all stakeholders by accommodating situations where legal or regulatory requirements aren't clear and situations where implementation of legal or regulatory requirements requires additional time to comply.

The evolving nature of the Departments' MHPAEA guidance, combined with the highly-detailed Congressional directives in the Cures Act, are well-suited for non-enforcement guidance. Group health plan sponsors and health insurance issuers should not be held accountable for compliance with new or significantly modified MHPAEA requirements, especially on a retroactive basis. In addition, plan sponsors and issuers must be given sufficient time and opportunity to comply, especially if they have been working diligently and in good faith to understand and come into compliance with existing MHPAEA requirements.

For these reasons, we urge the Departments to develop and announce non-enforcement guidance for MHPAEA violations based on a good-faith compliance standard at their earliest opportunity.

ERIC appreciates the opportunity to provide feedback at this time. We believe the comments laid out above will assist the Departments in complying with the Cures Act and improving the administration of the MHPAEA. We hope to serve as a resource through the regulatory process, and look forward to working with the Departments on regulations that recognize the important role of large plan sponsors and the benefits they provide to millions of workers, retirees and families.

Sincerely,



James P. Gelfand
Senior Vice President, Health Policy

²¹ See, e.g., ACA Implementation FAQs Part I, Q&A-1 (adopting a good faith compliance standard for ACA implementation); ACA Implementation FAQs Part XIX, Q&A-8 (extending safe harbors and enforcement relief for various SBC requirements based on good-faith compliance efforts); IRS Notices 2016-4, 2016-70 and 2018-06 (extending due dates for various ACA reporting requirements based on good-faith compliance efforts); and FAQ on Compliance Standard for Issuers in Federally-Facilitated Marketplaces (waiving civil money and decertification penalties for QHP issuers that made good-faith efforts to comply with applicable FFM standards).