ABHW

Advancing Health Care Policy
for Mental Health and Addiction

June 22, 2018

U.S. Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20710

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

U.S. Department of Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

To Whom It May Concern,

I am writing on behalf of the Association for Behavioral Health and Wellness (ABHW) to provide comments on the Department of Labor, Department of Health and Human Services, and Department of Treasury's (the Departments) request for comment on the "Proposed FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39" and the "Revised Draft Mental Health Parity and Addiction Equity Act (MHPAEA) Disclosure Template," due by June 22, 2018. Although not explicitly open for public comment, ABHW is also providing comments on the "Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA)."

Background

ABHW is the national voice for payers that manage behavioral health insurance benefits. ABHW member companies provide coverage to approximately 175 million people in both the public and private sectors to treat mental health, substance use disorders, and other behaviors that impact human health and wellness.

For the last two decades, ABHW has supported mental health and addiction parity. We were an original member of the Coalition for Fairness in Mental Illness Coverage (Fairness Coalition), a coalition developed to win equitable coverage of mental health treatment. ABHW served as the Chair of the Fairness Coalition in the four years prior to passage of MHPAEA. We were closely involved in the writing of the Senate legislation that became MHPAEA, and actively participated in the negotiations of the final bill that became law.

Since the Departments issued the Final Rules under the Mental Health Parity and Addiction Equity Act of 2008 in 2013 (the Final Rule)[1], ABHW member companies have worked vigorously to understand and implement MHPAEA. We have had numerous meetings with the regulators to help us better understand the regulatory guidance and to discuss how plans can operationalize the regulations. Our member companies have teams of dozens of people working diligently to implement and provide MHPAEA compliant mental health and substance use disorder (MH/SUD) benefits to their consumers.

[1] Final Rules under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 78 Fed. Reg. 68240 (Nov. 13, 2013).

Overarching Comments

We thank the Departments for their efforts in providing additional guidance interpreting mental health parity provisions of the Public Health Service Act and to ensure implementation that serves to protect individual plan members without excessive burden on health plans and insurers. We welcome the opportunity to provide input on the posted materials. At the outset, ABHW has a number of high level concerns regarding both the two draft documents as well as the revised version of the Self-Compliance Tool. This letter walks through our comments on each of these documents. However, we also wish to convey our belief that the Departments' issuance of these documents does not wholly fulfill the responsibilities imposed by Congress under Section 13001 of the 21st Century Cures Act ("Cures Act"), specifically with respect to the requirement for public comments. We discuss this issue in more detail below.

In addition to our recommended revisions to the Compliance Tool and draft documents, we recommend that the U.S. Department of Health and Human Services (HHS) and the U. S. Department of Labor (DOL) develop a "green flags" document to parallel the "red flags" document (titled "Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance") that was issued in 2016 and which, according to the HHS Action Plan, is expected to be reissued. Moreover, as part of the process of issuing the revised red flags or a new green flags document, we recommend that the Departments allow the public to first comment on these materials prior to their being finalized.

Comments on the FAQs

We provide herein specific concerns with several of the draft FAQs and have also included revised language for several of the ones discussed.

Discussion of FAQ 1

The Department's first FAQ addresses, at a high-level, "What are the Departments doing to promote understanding of and compliance with MHPAEA as required under the 21st Century Cures Act?" While we appreciate the Departments' continued efforts towards promoting understanding, the guidance issued to date largely does not address what may perhaps be the most vital directive under the Cures Act, which is to provide "clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage *may* use regarding the development and application of nonquantitative treatment limitations" (Emphasis added). See 42 USC § 300gg-26(a)(7)(B)(i).

The Departments have relied heavily on the issuance of FAQs to provide interpretive guidance. These FAQs describe specific fact patterns then provide the Departments' explanation of how the parity rules would apply to those fact patterns. While these FAQs can be helpful, they are often of limited use outside the specific fact patterns described. Many of these FAQs present factual scenarios at such a high and simplistic level as to be of little use to plans and issuers for whom operational circumstances are rarely so straightforward. In addition, the FAQs tend to highlight circumstances of noncompliance, rather than provide examples of permissible parity practices for plans and issuers to

employ. Moreover, many of the FAQs imply that disparate outcomes from the application of an NQTL are themselves evidence of a parity violation. Finally, key terms such as "methods," "processes," "strategies," "evidentiary standards," and "other factors," remain undefined and continue to introduce ambiguity rather than understanding within the context of the FAQs and guidance more generally. The Departments should be clear in either defining these terms or permitting plans and issuers flexibility towards understanding what methods may be used.

It is imperative that the Departments provide guidance that identifies compliant behavior and not simply behaviors to avoid. This would provide more certainty for plans and issuers in structuring benefits and operational procedures. The FAQs should also clarify that it is the "methods, processes, strategies, evidentiary standards, and other factors" that must be applied no more stringently to mental health/substance use disorders (MH/SUD) than to medical/surgical services and not the outcomes of the application of these factors.

We propose the following FAQs be adopted to provide helpful clarifying guidance:

Proposed FAQ 1a:

FAQ 1a: Does MHPAEA require that any specific process, strategy, or evidentiary standard or other factor be used in applying a particular NQTL? Or, do plans and issuers have flexibility to determine what may be used in applying any NQTL.

Proposed Response to FAQ 1a:

MHPAEA and its related regulations do not require that any specific process, strategy, evidentiary standard or other factor be used in applying an NQTL. In order to determine compliance, plans and issuers should evaluate processes, strategies, evidentiary standards and other factors actually used by the plan or issuer when applying an NQTL.

Proposed FAQ 1b:

FAQ 1b: Is an evidentiary standard required to be used for each and every factor used in applying an NQTL?

Proposed Response to FAQ 1b:
An evidentiary standard is not required to be used for each and every factor used in applying an NQTL. The Departments recognize that not all NQTLs have an evidentiary standard associated with them. For example, factors typically considered for provider admission to participate in a network include: provider type and/or specialty, geographic market, supply of provider type and/or specialty, demand for provider type and/or specialty, and provider licensure and/or certification. In this example, there is not an evidentiary standard associated with the provider admission to participate in a network NQTL.

Plans and issuers have flexibility to determine whether or not to apply an evidentiary standard, or to apply specific factors to evidentiary standards, when applying NQTLs.

Proposed FAQ 1c:

FAQ 1c: If the similar processes, strategies, evidentiary standards and other factors result in greater frequency of NQTL application, such as fail first, is that evidence of a parity violation?

Proposed Response to FAQ 1c:

If the plan uses similar processes, strategies, evidentiary standards, and other factors, and these criteria are applied in a comparable fashion and are not more stringently applied for both medical/surgical and mental health/substance use disorder services, it is not a violation of MHPAEA if the application of these criteria result in greater frequency of NQTL application.

Proposed FAQ 1d:

FAQ 1d: What do the following terms mean for purposes of MHPAEA compliance: processes, strategies, evidentiary standards, and factors? Do regulations allow plans and issuers flexibility as to how these terms are defined and applied under the law?

Proposed Response to FAQ 1d:

MHPAEA and its related regulations do not define these terms. Plans and issuers are provided flexibility under the regulations as to how these terms may be defined and applied under a particular plan design and/or operational procedures.

Discussion of FAQ 2 and FAQ 3

FAQ 2 discusses coverage of Applied Behavioral Analysis (ABA) therapy as a treatment for children with Autism Spectrum Disorder (ASD). We strongly request that the Departments amend FAQ 2 to clarify that the statement that non-coverage of ABA therapy violates parity is specific to the circumstances discussed in the scenario. In other words, the assessment of noncompliance for non-coverage of ABA therapy under the given facts does *not* mean that plans and issuers must cover ABA therapy or cover it in all circumstances.

In addition, the phrasing of FAQ 2 implies that the parity analysis can look to denial rates as a means of assessing parity. Denial rates in and of themselves do not prove a lack of parity compliance.

Our specific request is as follows:

- Revise FAQ 2 to state that the result of the parity analysis is specific to the given fact pattern and that one or more changes to the fact pattern could result in a scenario that is found to be compliant with parity rules.
- Revise FAQ 2 to clarify that disparate denial rates across parallel MH/SUD and medical/surgical classifications do not suffice to demonstrate parity noncompliance.
- Add language to FAQ 2 to explicitly state that federal parity rules do not require that plans and issuers must cover ABA therapy or cover it in all circumstances.

Proposed Response to FAQ 2:

We propose adding the following language to the draft FAQ 2 response, after the paragraph that begins "A medical management standard . . . . "

> However, the result of the parity analysis is specific to a given fact pattern. One or more changes to the fact pattern could result in a scenario that is found to be compliant with parity rules. For example, if, in the given scenario, there were no clinically appropriate standards of care regarding use of ABA therapy and fewer than two randomized controlled trials available to support the treatment's use in children with ASD, the plan's exclusion of this treatment as experimental or investigative would comply with parity.
>
> Federal parity rules do not require that plans and issuers cover ABA therapy or any other specific item or service. Even if a particular item or service is covered, parity rules do not require that it be covered in all circumstances. Moreover, the fact that a plan denies a higher percentage of a MH/SUD service as compared to medical/surgical services in the same classification does not, absent additional facts, indicate that a plan is out of compliance with parity rules.
>
> The scenarios in both FAQ 2 and FAQ 3 involve exclusion of treatments considered experimental or investigative. We note that such determinations are typically reviewed by panels of medical experts and are not based simply on one or two individual studies, as implied by the questions provided. As such, we recommend that the discussion of experimental or investigative treatments in one of these FAQs include

statements that parallel the statements in parity regulations at 45 C.F.R. 146.136(c)(4)(iii) Example 4, whereby a plan complies with parity rules in determining the NQTL of medical appropriateness for both MH/SUD and medical/surgical treatments "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." Most importantly, the FAQs should make clear that such practices would comply with parity requirements even if the evidentiary standards and their application to MH/SUD and medical/surgical treatments lead to different outcomes.[2]

Discussion of FAQ 7

The scenario discussed in FAQ 7 presents a parity analysis of the reimbursement NQTL under circumstances that are unrealistically simplistic as compared with the way we as plans and issuers set provider reimbursement rates, which involves a complex analysis of a range of varying factors. This false simplicity is both misleading to consumers and unhelpful to plans and issuers in its failure to provide effective guidance and insight as to the factors that would be acceptable setting reimbursement rates for providers of MH/SUD services as compared to providers of medical/surgical services. The

[2] The regulation reads, in relevant part, that "the plan complies with [the parity requirements described in] the rules of this paragraph (c)(4) 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. 45 C.F.R. 146.136(c)(4)(iii) Example 4.

Departments themselves previously acknowledged the complexity of plans' and issuers' processes for setting reimbursement rates yet do not accurately reflect that complexity in the draft FAQ.[3]

In addition to more accurately describing how plans and issuers set reimbursement rates, we strongly recommend that the Departments discuss within the FAQ a scenario in which a reimbursement NQTL is found to comply with parity requirements and elaborate on the key factors supporting this determination. For example, it would be highly illustrative if the analysis of the reimbursement factor discussed a scenario determined to be non-compliant and then identified changes to one or more of the key facts which would be sufficient to render the scenario compliant.

We provide below a proposed FAQ that we believe more accurately describes the parity assessment to apply to the NQTL of reimbursement in explaining why, as explained previously by the Departments under parity regulations, as long as the plan or issuer uses methods, processes, strategies, evidentiary standards, and other factors in setting reimbursement for MH/SUD services that are no more stringent than those used for setting reimbursement for medical/surgical services in the same category across, the NQTL should be found to comply with parity.[4]

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[3] *See* Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008; Technical Amendment to External Review for Multi-State Plan Program, 78 FR 68240, 68256 (November 13, 2013).

[4] *See* 78 FR 68240, 68256 ("The Departments believe that the process of establishing rate schedules is already complex, that MBHOs that contract with other multiple plans are likely to already have multiple rate schedules, and that adding a parity requirement *to ensure that rates for behavioral health providers are based on comparable criteria to those used for medical/surgical providers* does not add much to this complexity." Emphasis added.)

Proposal for revised FAQ 7:

FAQ 7. For MH/SUD benefits, the plan pays lower reimbursement rates. Is this permissible under MHPAEA?

Proposed Response to FAQ 7:

It depends. While a plan is not required to pay identical provider reimbursement rates for medical/surgical and MH/SUD providers in the same classification, 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.

For example, if a plan's methodology for setting outpatient provider reimbursement rates consists of three factors: training, licensure, and experience, and the plan was paying a lower reimbursement amount to a practitioner of outpatient MH/SUD services as compared to the practitioners of the medical/surgical benefits in the same classification who have the identical level of training, licensure, and experience, the plan would not be compliant. Under these circumstances, the plan would not be in compliance with parity rules as it would be applying a more stringent standard to MH/SUD in operation to the NQTL of reimbursement rates than as applied to medical/surgical services.

However, if the plan were to use a methodology for setting reimbursement rates that uses the same three factors along with other factors that are variable by nature, such as Medicare reimbursement rates, geographic market, demand for providers, provider use of more expensive office equipment, etc., which result in the plan's payment of higher reimbursement rates for medical/surgical providers as compared to MH/SUD providers in the same classification who have the same training, licensure and experience, this may not indicate a lack of compliance with parity rules. Under these circumstances, the plan's application of its NQTL of setting reimbursement rates is comparable and being applied no more stringently to the MH/SUD providers even though the actual reimbursement rates may vary considerably as between medical/surgical and MH/SUD providers with the same level of training, licensure and experience. This is an example where the methodology for determining the reimbursement rates applies the same factors and processes but because the inputs for some of those factors are variable, the resulting reimbursement rates diverge.

Discussion of FAQ 8

We again state our firm and continued belief that network adequacy is not an NQTL (as defined by the Final Rule), but, rather, is a collection of individual factors (e.g., time and distance standards) that together result in a plan having an adequate network. Notwithstanding our belief that network adequacy is not an NQTL, this proposed FAQ should be revised because it misstates how NQTL testing should be conducted under MHPAEA, the Final Rule and sub-regulatory guidance.

In the draft FAQ, as issued by the Departments, the plan is not seeking to impose a "limitation" (still assuming, arguendo, that a network adequacy standard is a NQTL) on a MH/SUD benefit, which would then require testing for comparability and stringency. Rather, this FAQ presents a plan that is imposing a service goal on its medical/surgical network –seeking to have the plan exceed "state and federal network adequacy standards by attempting to ensure that participants . . . can schedule an appointment within 15 days for non-urgent care . . . ." This provision is not one which provides a limitation on the scope or duration of MH/SUD benefits under the plan and is therefore not an NQTL and not properly a subject component of a MHPAEA NQTL analysis.

Additionally, there is robust regulation of network adequacy at the federal and state level. As such, compliance with these state and federal network adequacy regulations should be sufficient to satisfy MHPAEA's NQTL testing by its reliance on such requirements (see 2018 MHPAEA Self-Compliance Tool, at 15 which states that examples of "sources," required to be provided under comparability and stringency testing includes "state and federal requirements"). We have proposed a revised FAQ that we believe mitigates the risks discussed above.

Proposal for Revised FAQ 8:

FAQ 8: I cannot find an in-network psychiatrist that is close to my home. The closest one in the network is 7.5 miles away and there is only one other within 10 miles. However, there are 3 primary care physicians within two miles of my home, and 5 within eight miles. My health plan says that it meets applicable state and federal network adequacy standards for MH/SUD services and applies those standards to define

network access for the plan. These standards require that, for both medical/surgical and MH/SUD providers, the network include at least: 1) 1 provider within 8 miles for members in an urban area; 2) 1 provider within 15 miles for members in a suburban area; and 3) 1 provider within 40 miles for members in a rural area. Does the fact that the plan has more primary care physicians in the network (that are within the distance requirements under the state and federal network adequacy standards) than the plan has psychiatrists in the network that meet those same standards, mean that the plan does not comply with MHPAEA?

Proposed Response to FAQ 8:

No. The Departments' regulations require that the processes, strategies, evidentiary standards, or other factors used in applying an NQTL to MH/SUD benefits be comparable to and applied no more stringently than the processes, strategies, evidentiary standards, or other factors used in applying the NQTL to treat medical/surgical conditions. Here, the plan meets and relies on applicable state network adequacy standards both as written and in operation, for both the plan's network of medical/surgical providers and the plan's network of MH/SUD providers and as such, the plan complies with MHPAEA because it meets these standards for both medical/surgical and MH/SUD providers.

Discussion of FAQ 10

FAQ Q10 discusses classification of emergency care benefits, but, in doing so, presents a false dichotomy. The question posed in this FAQ asks about the

treatment of acute conditions affecting physical health that arise as a complication of a mental health condition or substance use disorder. The discussion wrongly implies that plans and issuers make distinctions when addressing acute conditions if the condition is tied to a MH/SUD as opposed to having arisen in some other manner. Plans and issuers do not make such distinctions in addressing coverage of emergency room treatment. The FAQ wrongly discusses coverage and payment for treatment of a patient's wrist lacerations as if these might vary if due to accident versus intentional self-harm. In fact, coverage and payment would be the same for such services regardless of how the injuries arose.

The proposed FAQ 10 appears to establish a framework in which the application of MHPAEA to a given benefit under a plan would vary depending on the circumstances of an individual patient covered under the plan. We do not believe this was the Departments' intent in this FAQ as it would create an ambiguous framework under which plans would be required to design and apply plan terms and conditions such as quantitative treatment limitations (QTLs), financial requirements and nonquantitative treatment limitations (NQTLs).

The proposed FAQ correctly notes that whether a given service or benefit is subject to MHPAEA as a MH/SUD benefit is dependent on how the plan defines the benefits consistent with federal and state law as well as generally recognized independent standards of medical practice. However, we believe the draft FAQ stops short of fully explaining the process by which a plan may define medical/surgical versus MH/SUD benefits and the proposed response to the FAQ leaves the impression that the underlying condition (medical or MH/SUD)

of a given patient may require a different application of MHPAEA under the same plan for the same benefit. For example, using the scenario in the proposed FAQ, a patient receiving emergency room treatment for a laceration due to a car accident would not be considered subject to MHPAEA's protections but if that same patient came in with a laceration resulting from a psychotic episode, MHPAEA would apply. We do not believe this is the guidance intended by the proposed FAQ.

We note that CMS previously addressed this question – of defining benefits in the case of a treatment or service that is used to treat both medical/surgical and MH/SUD conditions – in an FAQ issued in October 2017 regarding MHPAEA compliance for Medicaid and CHIP programs and plans. We believe that guidance is instructive for all scenarios where a plan must assign a treatment/service to one category or the other of benefits for purposes of plan design and administration of plan terms and conditions including financial requirements, QTLs and NQTLs.

Plans must have the ability to define benefits and determine MHPAEA compliance for the plan as a whole not at an individual patient level. It is important to note that there are services and treatments which can treat both medical/surgical conditions and MH/SUD. However, the plan has to be able to designate these services as either medical/surgical or MH/SUD for the purposes of calculating financial requirements, quantitative treatment limitations and establishing and applying any associated NQTLs. While we believe the proposed FAQ establishes this principle in the proposed response to the FAQ, it does not clearly carry it through in the latter portion of the proposed answer in discussing the framework's application to the emergency room/laceration

scenario. Accordingly, we have proposed a revised FAQ that we believe: (1) articulates the principle of how medical/surgical and MH/SUD are defined under the plan – consistent with federal and state law as well as generally accepted standards of medical care; (2) discusses reasonable methods by which a plan may achieve such definition (for which we have drawn upon the previous guidance from CMS referenced above); and (3) shows the application of the principles through an example of a single patient who receives the same service under two different circumstances but with a consistent application of the principles and MHPAEA.

Proposal for Revised FAQ10:

FAQ 10: My health plan provides benefits for physical therapy. The physical therapy visits are subject to a $20 copayment and an annual limit of 30 visits per calendar year. If my son requires physical therapy for treatment related to his ASD, are those visits subject to a $20 copay and a visit limit of 30 visits annually or are these physical therapy visits considered MH/SUD benefits for the purposes of MHPAEA?

Proposed Response to FAQ10:

It depends. The Departments' regulations implementing MHPAEA define "medical/surgical benefits" as benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable federal and state law, but not including mental health or substance use disorder benefits. Similarly, "mental health benefits" and "substance use disorder benefits" are defined as benefits with respect to items or services for mental health conditions or

substance use disorders, as defined under the terms of the plan or health insurance coverage and in accordance with applicable federal and state law. Mental health conditions must be defined to be consistent with generally recognized independent standards of current medical practice.

There are services and treatments which may be used to treat only MH/SUD conditions (e.g., psychotherapy) and ones which may be used only to treat medical/surgical conditions (e.g. cardiac surgery). For these services, it is a fairly straightforward matter to define the benefit as either medical/surgical or MH/SUD services consistent with the regulations and requirements noted above. However, there are a number of services/treatments that can be used to treat both medical/surgical conditions and MH/SUD. Physical therapy is one such service which can be used to treat both a mental health condition like, as here, ASD and a medical condition, such as a dislocated knee. A plan must have the ability to establish terms and conditions – such as copayment amounts and visit limits – in a consistent fashion for these benefits for the plan and for all beneficiaries under the plan. Accordingly, a plan must use a reasonable method for defining such services as medical/surgical or MH/SUD benefits such as a method which defines the service based on whether the service is most commonly or frequently used for a medical/surgical or MH/SUD using the plan's annual claims experience spending on the service in question. (Note a plan may be able to define other reasonable methods.)

In this example, if the member's plan uses annual claims experience for physical therapy services and finds that 87% of claims for physical therapy have a medical/surgical diagnosis and 13% have a MH/SUD diagnosis, the plan may

then define physical therapy as a medical benefit for purpose of defining the applicable quantitative limits (e.g., annual visit limit) and financial requirements (e.g., copayment). This means that for this member the copayment amount and annual visit limit would not be subject to the requirements of MHPAEA since those requirements govern MH/SUD benefits and not medical/surgical benefits. If however, the plan's claim experience showed that 48% of claims for physical therapy were for a medical/surgical diagnosis and 52% were for a MH/SUD diagnosis, the plan would have to treat physical therapy as a mental health benefit. In that case, the copayment associated with physical therapy and the annual visit limit would need to comply with the requirements of MHPAEA applicable to determining whether the copayment was the predominant copayment applied to substantially all medical/surgical benefits (which cannot be determined just from the primary care copayment amount) and whether the annual visit limit applied to substantially all benefits in the applicable classification on benefits.

Discussion of FAQ 11 and FAQ 12

While we recognize that FAQ 11 and FAQ 12 discuss ERISA disclosure requirements as applied to provider network directories, we believe that it would be more appropriate to release these two FAQs in a document separate from the ten parity-related FAQs or at least add a more distinct separator between the two topics. Inclusion of these two items within the larger parity discussion implies that directory issues raise parity concerns.

Self-Compliance Tool

Section 13001(b)(C) of the Cures Act directs the Departments to issue clarifying guidance on parity requirements, to include information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of NQTLs to ensure compliance with MHPAEA. To fulfill this mandate, and along with the proposed guidance discussed elsewhere in this letter, the Departments issued the Self-Compliance Tool for MHPAEA ("Compliance Tool"). Although the revised Compliance Tool is not identified as open for public comment, the revisions in Section F represent new standards with respect to assessing NQTL parity compliance and, therefore, must be open for comment as the Cures Act requires public comment on draft guidance relating to NQTLs prior to its being finalized.[5]

The new standards imposed under the Compliance Tool are most evident in the Compliance Tool's description of the steps involved in completing a parity analysis. Regulations state that a group health plan or issuer

> may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, ***any processes, strategies, evidentiary standards, or other factors used*** in applying the nonquantitative treatment limitation to MH/SUD benefits in the classification are comparable to, and are applied no more

[5] Sec. 13001(b)(C)(D) of the 21st Cent. Cures Act.

> stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification.

42 C.F.R. 146.136(c)(4) (emphasis added). The regulation uses "processes," "strategies," "evidentiary standards," and "other factors" as equivalent terms, indicating that "processes," "strategies," and "evidentiary standards" are types of "factors." The NQTL analysis provided in the revised Compliance Tool changes the analysis as described in the regulation by introducing a **new requirement not referenced in the regulatory text nor discussed in previous parity guidance.** The Compliance Tool's four-step analysis is to:

1. Identify the NQTL.
2. Identify the factors the plan or issuer considered in the design of the NQTL.
3. Identify the sources (including any processes, strategies, and evidentiary standards) used to define the factors identified in Step 2 to design the NQTL, including any threshold at which each factor will implicate the NQTL.
4. Evaluate whether the processes, strategies, and evidentiary standards used in applying the NQTL are comparable and no more stringently applied to MH/SUD than to medical/surgical benefits.

In Steps 2 and 3, the Departments erroneously separate out "processes, strategies and evidentiary standards" from their equivalent "factors" used in applying the NQTL. In addition, in Step 3, the Departments go on to introduce the term "source" and categorize the processes, strategies and evidentiary standards as sources, rather than factors, as they are identified in the regulatory text. Instead of bringing clarity to the

NQTL analysis as required by the Cures Act, the Departments have added further complexity to the process in their articulation of Step 2 and Step 3 of the analysis defined in the Compliance Tool. Plans and issuers have no context and no resources to reference in clarifying how to interpret the meaning of "source" because it has not previously been used or defined in the parity regulation or associated guidance. It is also not clear how a "source" in Step 3 differs from a "factor" in Step 2 or whether the Departments are making an intentional distinction between these terms by included them in two separate steps. ABHW views Steps 2 and 3 to be part of a singular analysis, and, as the requirement to consider sources is absent from the parity rule, we recommend the Departments combine Step 2 and Step 3 into one step.

This new combined step should also be revised to address several areas of concern in the current Step 3. First, the current Step 3 implies that plans and issuers should use multiple factors and "sources" in compliantly imposing an NQTL on MH/SUD services as compared to medical/surgical services, by directing plans and issuers to "[i]dentify the sources (including any processes, strategies, ***and*** evidentiary standards)" Emphasis added. Step 3 also implies that there should be an evidentiary standard for each source/factor which in practice is not the case and has never been articulated as a requirement for parity compliance. The examples discussed in Steps 2 and 3 do not provide sufficient clarity with respect to the rigor plans and issuers must apply in assessing each NQTL for parity compliance. Furthermore, there are additional methods that a plan or issuer may use instead of or in addition to the examples prescribed in the Compliance Tool. We recommend DOL revise the Compliance Tool to explicitly state that issuers and plans have flexibility in determining the appropriate factors and sources to apply and to also state the fact that not every NQTL has an associated evidentiary standard whether as applied to MH/SUD or medical surgical services.

These clarifications are particularly important because the federal parity enforcement structure relies, in large part, on state oversight and enforcement. In the absence of more robust public guidance in this area from the Departments, state regulators are looking to the Compliance Tool for insight in interpreting federal intent when enforcing parity requirements and are often interpreting available guidance more stringently than the Departments themselves. This exacerbates the difficulties in maintaining compliance for our members who operate across multiple states and increases confusion for both plans and issuers as regulators do not interpret NQTL requirements in a uniform manner. The referenced difficulties in the revised Compliance Tool would likely intensify the confusion. As such, we strongly urge the Departments to revise/amend the Compliance Tool to ensure that states and other stakeholders do not hold a document that is interpretive in nature to be a baseline requirement for plans and issuers.

Finally, we want to reiterate our concern that the Departments are advancing a new analysis through interpretive guidance that is not currently open for public comment. The Compliance Tool deviates from MHPAEA, is not consistent with how the Administration is handling regulatory matters, and as such, we request implementation and use of the Compliance Tool be delayed until the Departments review stakeholder comments. To the extent that the Departments fail to clarify that the 4-step process does not require plans and issuers to demonstrate and rely on each of the identified factors and sources, the revised guidance should be issued with a future effective date of July 2019 sufficient to enable plans and issuers to take the necessary steps to meet what are effectively new requirements.

Comments on the Form to Request Documentation from an Employer-Sponsored Health Plan or an Insurer Concerning Treatment Limitations:

ABHW has a number of significant concerns with the revised draft Model Form to Request Documentation from an Employer-Sponsored Health Plan or an Insurer Concerning Treatment Limitations (model form) issued on April 23, 2018. The Cures Act directed the Departments to create a guidance document containing "examples illustrating requirements for information disclosures"[6] pursuant to MHPAEA, but does not impose any new disclosure requirements beyond those in existing law.[7] As currently drafted, however, the disclosure form creates new disclosure obligations to which plans and issuers must adhere.[8] In addition, the form will create an unlawful burden on plans and issuers that has not been adequately assessed under the federal Paperwork Reduction Act process. Finally, the form as currently drafted will create confusion among both enrollees seeking parity related information and plans and issuers trying to compliantly respond to such requests.

The broadly drafted disclosure form subjects plans and issuers to a "general information request" beyond the two disclosures required under MHPAEA which are: 1) "The criteria for medical necessity determinations made under

[6] Sec. 13001(a) of the 21st Century Cures Act.
[7] Federal law requires group health plans and health insurance issuers to disclose certain documents to enrollees and beneficiaries, contracting providers, or authorized representatives to ensure compliance with MHPAEA
[8] We further note that, although the Departments have submitted the draft disclosure form to the Office of Management and Budget under the Paperwork Reduction Act for review of the burden it imposes on affected entities, the burden assessment included in the submission addresses only the burden on the individuals filling out the form and not on the plans and issuers that would actually be producing the documentation requested through the form. Failure to assess how this information collection affects plans and issuers leave regulators with a false sense of the true burden posed by use of the form.

the group health plan with respect to MH/SUD benefits;" and 2) "The reason for any denial under the group health plan (or health insurance coverage offered in connection with such plan) of reimbursement or payment for services with respect to MH/SUD benefits."[9] The general information request is not only broader than the MHPAEA-required disclosures, it is also more expansive than disclosure rules under ERISA.[10] The form's creation of a new disclosure obligation for release of general information exceeds disclosure requirements in current law, subverting congressional intent as to the scope of mandated disclosure in this area.

In addition, requiring plans and issuers to supply enrollees with general information about the plan will impose an unlawful administrative burden for plans and issuers at a time when the Administration has committed to lowering the level of administrative burden on businesses. In question 12 of the Supporting Statement for this form, submitted for review under the Paperwork Reduction Act of 1995, the Departments' estimated the burden associated with completing the form but did not sufficiently capture the burden on plans and issuers.[11] The Supporting Statement includes only the burden on authorized representatives who would initially complete and submit the form but does not contemplate the burden imposed on third party administrators ("TPAs") and

[9] Public Health Service Act Sec. 2726(a)(4) (42 U.S.C. 300gg–26(a)(4)); 45 C.F.R. 146.136(d).
[10] The summary plan description includes information on: cost-sharing provisions; any annual or lifetime limits; coverage of preventive services, existing and new drugs, and medical tests, devices and procedures; rules on use of network providers, the makeup of the provider network and rules on its use; coverage for out-of-network services; conditions or limits on the selection of primary care providers or medical specialists; conditions or limits on emergency medical care; and any provisions requiring preauthorizations or utilization review as a condition to obtaining a benefit or service under the plan. 29 C.F.R. §2520.102-3(j)(3).
[11] "Supporting Statements for Paperwork Reduction Act of 1995 Submissions," OMB Control No. 1210-0138 (April 2018), *available at* https://www.reginfo.gov/public/do/DownloadDocument?objectID=74490300.

issuers who must create such disclosures and then must respond to the information requests. We believe that the vast majority of the burden associated with such disclosures has fallen, or will fall, on issuers and TPAs. Thus, the Departments' calculation is insufficient to contemplate the actual burden resulting from use of the form.

To fulfill the intent of the Cures Act, plans and issuers expected the Departments to provide clarifying guidance on the MHPAEA disclosures that would simplify the process. However, the form does not appear to be aimed at providing clarifying guidance to the plans and issuers as was required under the Cures Act. Rather, the form seems to be directed at enrollees in elaborating on the range of information they may want to request. This is not useful for the plans and issuers to assess compliance with MHPAEA and also does not fulfill the Cures Act mandate. Plans and issuers do not feel that the form provides sufficient guidance regarding the content that they must disclose with respect to NQTLs upon a request from an enrollee. The Departments claim that the aim of the form is "to simplify the process of requesting relevant disclosures for patients and their authorized representatives."[12] However, the practical effect of the form will be to introduce ambiguity, confusion, and complexity into the disclosure process.

The form does not identify the requisite disclosure being requested, but rather, enables the enrollee to request the broadest range of information that may be available without necessarily understanding the nature of those materials. Similarly, based on this form, a plan or issuer has no way of assessing the

[12] "Supporting Statements for Paperwork Reduction Act of 1995 Submissions," OMB Control No. 1210-0138 (April 2018), *available at* https://www.reginfo.gov/public/do/DownloadDocument?objectID=74490300.

quantity or usefulness of materials being sought, from the perspective of a layman's review. The form seems to imply that there is no limit to the size and scope of information requests to which plans and issuers must respond because the form allows for enrollees to request information not associated with a particular treatment or condition. As mentioned above, MHPAEA sets forth two required disclosures – the criteria for medical necessity determinations for MH/SUD services and the reasons for denial of a MH/SUD benefit. Applicable guidance from the Departments does not currently require inclusion of the specific information requested under the form as part of MHPAEA disclosures. Should this form be finalized, it would require plans and issuers to create customized disclosures based upon the language describing the general information request and the demands of the requesting enrollee, rather than applicable statutes and regulations. In sum, the burden and costs associated with an undefined disclosure obligation is not evaluated under the Information Collection Request, is unknown, and may be immense.

With respect to disclosures regarding specific treatments, the form does not identify the specific documents that must be disclosed, such as a summary plan description (SPD), certificate of coverage, plan instrument, relevant documents in the context of full and fair review/ERISA claim appeal and/or relevant documents under MHPAEA and its implementing regulations or under ERISA requirements. If inclusion of specific content is not required within these specified disclosures, may plans create generalized disclosures for purposes of improving transparency with respect to NQTLs? Does MHPAEA require disclosure of data that is not otherwise required to be reported to the DOL under a Form 5500?

In addition, several aspects of the form will likely lead to confusion both for the enrollee as well as the plans and issuers. Use of the checkbox list of potential bases for the claim denial will invite enrollee confusion and may end up creating additional work for plans or issuers in trying to clarify the basis for a denial that had previously been communicated. In fact, the enrollee's understanding of the basis for the denial is extraneous to the disclosure request as the plan or issuer already has this information.

Another aspect that could lead to confusion is the request for plans or issuers to "[i]dentify the factors used in the development of the limitation and the evidentiary standards used to evaluate the factors." There is no guidance from the Departments on what types of information this sentence would require, or what documents specifically an enrollee should expect in response. Moreover, the list of information requested may lead enrollees to believe they are entitled to categories of information that may not exist or may force the plan or issuer to develop materials specifically to fulfill disclosure requests. To the extent that enrollees do not receive all of the listed categories of information, they may believe the plan is not in compliance with MHPAEA.

The form further asks plans or issuers to identify all of the medical/surgical and MH/SUD benefits to which the limitation at issue applies in the relevant benefit classification. This could require an extensive list of benefits that we do not believe would be useful to the enrollee in assessing parity compliance. Rather, we recommend limiting the request to identifying categories of services as those are used in the plan or issuer's classification approach, as this is the information an enrollee would need to assess parity. We also note that the form

is about medical necessity information, but the form does not ask for this information.

Enrollees may also believe completion of the form constitutes filing an appeal with the plan. Although ERISA requires disclosure of relevant documents subject to an appeal, a pre-appeal disclosure process does not exist under MHPAEA. The form indicates the enrollee has access to the SPD, the denial notice, medical necessity criteria, and documents on the plan establishment or operation, thus effectively creating a pre-appeal grievance process when that is not required under law. ERISA allows the enrollee to request relevant documents in the context of an appeal, but we do not believe that is the legal authority the form relies on with respect to the disclosure requirements

For all of these reasons, we strongly recommend that the Departments redraft the disclosure form. We recommend striking the "check box" format as to the basis for any denial to avoid enrollee confusion. We believe the form should provide two checkbox options for each of the two specific disclosures required under MHPAEA, and remove all other information, including the general information requests. We believe this would greatly simplify the form, help promote an understanding of MHPAEAs express disclosure requirements, improve the disclosure process, and help improve compliance overall. The Departments can continue to assess the usefulness of the form and whether it should be revised in the future. We do recommend that the Departments add a statement to clarify that the completion and submission of the form does not represent a request to appeal a denial and the disclosure process does not substitute for filing an appeal.

Finally, we want to point out, as a matter of internal consistency that the language regarding the 30-day timeline for plans or issuers to respond differs as stated in the background section and page two of the form. We recommend making the language consistent, preferably using the language in the background section which allows plans to return the form within 30 calendar days of receipt of a request.

Thank you for the opportunity to comment on the issues related to parity implementation and enforcement. ABHW's member companies and I look forward to continuing to work with you.

Sincerely,

Pamela Greenberg, MPP
President and CEO
Association for Behavioral Health and Wellness