NEW DIRECTIONS

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

Submitted Electronically at: E-OHPSCA-FAQ39@dol.gov

OIRA_submission@omb.eop.gov

RE: Response to the Departments' Request for Comment

This writing provides New Directions Behavioral Health, L.L.C ("New Directions") response comments to the Department of Labor ("DOL"), Department of Health and Human Services ("HHS"), and Department of the Treasury's (collectively the "Departments") request for comment contained in the Departments recently issued "[Proposed] FAQs About Mental Health And Substance Use Disorder Parity Implementation And The 21st Century Cures Act Part [39]" and the "Form To Request Documentation From An Employer-Sponsored Health Plan Or An Insurer Concerning Treatment Limitations."

Contents:

§1 New Directions Behavioral Health Page 2

§2 General Comments Page 2

§3 Comments on FAQ Part 39 Page 4

§4 Comments on Template Disclosure Form Page 7

§1 New Directions Behavioral Health

New Directions is a full-service Managed Behavioral Health Organization ("MBHO") that manages and administers the behavioral health benefits for certain Blue Cross Blue Shield Association health plans in both the public and private sectors, covering nearly 11 million Blue Cross Blue Shield members located in all fifty states. New Directions holds accreditations from both URAC and the National Committee for Quality Assurance (NCQA).

In addition to New Directions' role as a MBHO, since its inception New Directions has been a pioneer, innovator and leader in the areas of Employee Assistance Programs (EAPs), case and care management, and has been an advocate and innovator of fully integrated care models such as Patient Centered Medical Homes (PCMHs).

Our organization is also a founding member of the Association for Behavioral Health and Wellness (ABHW), an association of the nation's leading behavioral health and wellness companies that provide behavioral health and wellness programs to nearly 170 million people. For the last two decades the ABHW has supported mental health and addiction parity, and was closely involved in the writing of the Senate legislation that became MHPAEA, and was later heavily involved in the regulatory process transitioning from the Interim Final Rule (IFR) to the Final Rule.

New Directions strongly believes in the spirit of mental health parity and has always worked closely with its health plan customers to promote the inclusion of expanded mental health and substance use benefit coverage in plan benefit design, and has encouraged equity in the manner in which behavioral health benefits are constructed and applied.

Due to this strong belief in the spirit of mental health parity, since prior to issuance of the IFR New Directions, both independently and through its ABHW membership, has been actively involved in numerous facets of the legislative process affecting MHPAEA and the subsequent subregulatory guidance interpreting MHPAEA.

Because of the regulations' importance to all areas of our business, and our perception that guidance such as that recently issued by the Departments is critical to reduction of uncertainty in the behavioral health industry and health care market as a whole, New Directions respectfully submits the following comments for the Departments consideration:

§2 General Comments

New Directions appreciates the Departments effort to provide additional guidance interpreting the mental health parity provisions of the Public Health Service Act. We believe guidance such as this is critical to impart a better understanding of the Departments' interpretation of MHPAEA.

New Directions Behavioral Health ndbh.com PO Box 6729 | Leawood, KS 66206

New Directions does believe the guidance could be strengthened in a number of ways, which will be detailed below in the sections specific to the respective guidance on which comment is sought.

Additionally of note, the DOL's "Pathway To Full Parity" report to Congress, which was issued contemporaneously by the DOL with the other guidance on which comment is currently being provided, indicates that in 2018 the Employee Benefits Security Administration ("EBSA") intends on issuing "Warning Signs 2.0", a follow up document to the 2016 issued "Warning Signs- Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance."

New Directions strongly encourages that if "Warning Signs 2.0" is created, that it be issued for a public comment period, so that interested stakeholders with direct applicable experience in the market can comment on the illustrative examples and guidance contained in that document. In New Directions experience the manner in which the 2016 Warning Signs document was released, without an opportunity for public comment, nor forewarning of the release, resulted in potentially unnecessary concern with certain of our stakeholders and customers.

Additionally we encourage EBSA to make it a point of emphasis in the proposed "Warning Signs 2.0" to explain from the outset of the document in as conspicuous a manner as reasonably possible, that the guidance contained therein does not implicate a defacto parity violation, and that each parity analysis is unique and dependent upon the underlying processes, strategies, factors, and evidentiary standards used to apply a respective NQTL.

It would also be valuable to note in "Warning Signs 2.0" that a parity compliant application of similar underlying processes, strategies, factors and evidentiary standards used in imposing the same NQTL on both medical surgical benefits as well as behavioral health benefits, may result in different outcomes from the application of the NQTL, and that the regulation is not intended to create "parity" in outcomes, but instead in the manner in which restrictions to benefits are applied.

We believe also that the Departments and the EBSA should strongly consider creating and issuing parallel accompanying guidance that demonstrates potential "green flags" for parity compliance, in which circumstances of NQTL application that are MHPAEA compliant are demonstrated via an example-driven, fact-specific NQTL analysis which is reflective of NQTLs applied by health plans, and the underlying processes, strategies, and evidentiary standards used in that application. We believe this document should be available for public comment after creation as well.

The majority of the guidance thus far issued by the Departments and other agencies have relied on examples and fact patterns in which examples of parity non-compliance are put forth to demonstrate to health plans and MBHOs how benefits should not be constructed or applied. This is the case with the recently issued FAQ Part 39, on which New Directions is currently

providing comment. Of the eight FAQs that address MHPAEA benefit construction compliance (Q2-Q10), six demonstrate a fact pattern of noncompliance, while the other two FAQs (Q5 & Q10) allow for the possibility that the benefit construct described therein is not permissible.

Without definite demonstrations of what constitutes compliant benefit construction, with examples of NQTLs that health plans actually impose, health plans and their MBHOs can never know with certainty that their benefit construction and NQTL application is compliant. This in turn results in heightened administrative and compliance costs, and injects uncertainty into a market where potentially vulnerable consumers would benefit from plan designs that remain consistent and whose benefit construction is parity compliant.

Although New Directions does not endorse, nor is suggesting development of a wholly prescriptive model for what should be considered MHPAEA compliant, or what NQTLs are allowable, some examples demonstrating compliance using industry standard NQTLs, with realistic underlying processes, strategies, factors, and evidentiary standards would be valuable to the industry and to consumers.

§ 3 Comments on FAQ Part 39

FAQ 2

New Directions encourages the Departments to amend FAQ 2 to indicate that the fact pattern demonstrated is illustrative only and the test being applied is an example of one of many potential ways in which a plan would determine if a treatment is considered investigational or experimental.

Although we appreciate the fact that FAQ 2 is attempting to show a circumstance where the underlying processes, strategies, factors, and evidentiary standards for NQTL application are being compared, both the fact pattern presented in the question, as well as the answer, seem to indicate that the test for experimental or investigative treatments (a single professional guideline defining clinically appropriate standards for the condition, and a minimum of two randomized controlled trials) is the standard for determining what is experimental or investigational.

New Directions believes that a consumer who is not accustomed to regulatory interpretation, or the nuances of NQTL application and comparison, will interpret this guidance to mean that health plans must or should use a similar standard for assessing services which are considered investigational or experimental.

In New Directions experience, the test demonstrated in the FAQ fact pattern is not indicative of a method employed by its health plan partners, and therefore we believe the fact pattern demonstrated is unrealistic, and potentially detrimental to a consumer's understanding of how plans determine what is experimental or investigational, and what is accepted as efficacious by the medical and scientific communities.

We encourage the Departments to consider amending this FAQ to demonstrate and reflect statements in MHPAEA at 45 C.F.R. 146.136(c)(4)(iii) Example 4, whereby a plan complies with parity rules in determining medical appropriateness for both medical surgical and behavioral health 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."

FAQ 3

New Directions concerns with FAQ 3 are similar to those discussed for FAQ 2, in that we encourage the Departments to state that the analysis is fact pattern specific, and that the demonstrated methodology may be one of many ways a health plan may determine what experimental or investigational services must be covered.

FAQ 7

This FAQ fails to recognize that health plans may use a multitude of factors when determining reimbursement rates, and that provided the processes, strategies, and evidentiary standards for the application of those factors are applied similarly to both medical surgical and behavioral health providers, application of a NQTL may result in disparate provider reimbursement rates between medical surgical providers and behavioral health providers, while still remaining mental health parity compliant.

The FAQ's hypothetical fact pattern puts forth the statement that provider reimbursement rates "are determined based on providers' required training, licensure, and expertise." There is no nuance to the example used and it is not described how those factors are weighted or examined to determine their respective impacts to the provider's reimbursement. Nor does it take into account any conditions for the application of those factors, how the factors interact or potentially supersede one another, and what the ambiguously-termed factors represent to the hypothetical health plan.

In New Directions' experience the scenario described in this FAQ is not representative of, or even similar to, the methodology that health plans employ to set rates. The simplicity of the example fact pattern and the manner in which the FAQ addresses the underlying factors for rate setting, is not particularly helpful for health plans or MBHOs, and sets an unrealistic expectation with consumers that health plans approach provider reimbursement rate setting in this manner.

FAQ 8

Notwithstanding our opinion that network adequacy may not be an NQTL as defined in the Final Rule, New Directions encourages the Departments to amend their analysis in FAQ 8 to allow for the situation demonstrated by the FAQ to be considered MHPAEA compliant.

New Directions believes the approach described in FAQ 8 does not appreciate the fact that a health plan may use geo access and other standards dictated by state and federal law as the

evidentiary standards for access, while also attempting to use innovative, quality-oriented programs and procedures that promote better outcomes for individuals, some of which may rely on access to care within a given timeframe. The FAQ does not expound on the underlying reasons the health plan wants to implement the 15 day standard when the member has “symptoms of a condition,” nor does it state that the visit within 15 day standard is the evidentiary standard by which the plan determines medical surgical access parity compliance.

The intent and spirit of MHPAEA is to ensure that individuals seeking behavioral health care do not encounter impediments to receiving care (thus the emphasis on both quantitative and non-quantitative treatment limitations) that otherwise do not exist with similarly categorized medical and surgical benefits. In FAQ 8, no such impediments exist. It appears the health plan is adhering to an objective access standard which is endorsed by a legislative body that is representative of the member population.

Through other efforts, the underlying rationale of which is not fully described in the FAQ, the health plan happens to exceed the standards used as the plan’s base line evidentiary standard utilized for compliance.

An NQTL analysis should focus on limitations applied to behavioral health services. We do not believe it was the MHPAEA drafter’s intent to endorse a stance where a person seeking medical or surgical care may receive less efficacious care simply because a similar quality or medically/scientifically driven program or metric does not also exist with behavioral health insurance products. Nor do we think MHPAEA suggests that members should not benefit from their insurer attempting to provide them more convenient care at the insurer’s own expense and effort, merely because no analogous medically/scientifically driven program exists with behavioral health insurance products.

FAQ 10

This FAQ implies that health plans make benefit classification determinations based upon members presenting co-morbidities, such as the presence of a behavioral health issue, when determining “why the member came to the emergency room” for benefit classification and payment purposes. This condition determined ad hoc analysis is not representative of the assignment and classification mechanisms New Directions has encountered with its health plan partners.

In New Directions experience, health plans apply an objective framework with consistent strategies and standards to emergency services requests, and based upon that objective and consistent framework, the member’s condition is either designated as medical/surgical or behavioral health in nature.

Although we believe that FAQ 10 allows for this type of application, we encourage the Departments to further emphasize that a members’ ancillary behavioral health condition is not determinative for the classification and assignment of their emergency services.

FAQ 11 & 12

New Directions appreciates and understands that FAQ 11 & FAQ 12 are generally addressing ERISA related disclosure requirements. We encourage the Departments to exclude these examples from this FAQ Part 39 though, as it may insinuate to consumers that a plan's provider directory has mental health parity effects outside of ERISA's disclosure requirements.

Should the Departments elect to not exclude FAQ 11 & FAQ 12 from this FAQ Part 39, New Directions encourages the Department to use a more conspicuous distinction between the parity interpretation FAQs and ERISA related FAQs to indicate to consumers that FAQ 11 & FAQ 12 are intended to demonstrate ERISA related guidance.

§ 4 Comments on Template Disclosure Form

The 21st Century Cures Act requires the Departments to create a document containing "examples illustrating requirements for information disclosures"[1] pursuant to MHPAEA and ERISA, but does not impose any additional disclosure requirements beyond those currently existing in law. In its current proposed form, the "Form To Request Documentation From An Employer-Sponsored Health Plan Or An Issuer Concerning Treatment Limitations" ("Disclosure Form"), creates additional disclosure obligations to which a plan must adhere.

MHPAEA requires two types of disclosures: 1) the criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits, and 2) the reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits.[2] New Directions believes the disclosure form requires disclosures beyond what is mandated by MHPAEA to demonstrate mental health parity compliance.

The disclosure form allows for the consumer to submit a "General Information Request," pertaining to the "plan's treatment limitations related to coverage for mental health and substance use disorder benefits, generally." Health plans and MBHOs have been provided no guidance on what "general information" entails. This type of ambiguity is concerning because it does not comport with the types of disclosures contemplated by MHPAEA, and because it creates a paradigm where consumers will expect that most information is "general" in nature and therefore should be eligible for disclosure. We encourage the Departments to offer guidance on what documentation is considered "generally" related to treatment limitations, with the opportunity for public comments on that guidance.

Also problematic is that the form uses a check box approach pertaining to requests related to a denial of, limitation on, or reduction in coverage, and the consumer is encouraged to check "all that apply," and will likely do so as a precautionary measure. In a circumstance where a

[1] Sec. 13001(a) of the 21st Century Cures Act.

[2] 45 CFR 146.136(d)

consumer elects to check all boxes, a health plan is left in a position where an adverse determination may have been issued for one reason, yet the consumer is requesting information on a litany of other unrelated reasons.

This has the effect of forcing a health plan to disclose all information pertaining to its application of NQTLS related to utilization management, in all circumstances, or run the risk of producing a noncompliant disclosure. This check-the-box-approach, with the encouragement to "check all that apply," also does not appreciate the fact that the insurer is in the best position to assess the reason a service request received an adverse determination, since it applied the respective NQTL and issued the adverse determination notice. This form places this expectation on the consumer to interpret a health plan's language, intent, and rationale. This seems counterproductive if the goal is to simplify the process for a consumer and to foster greater understanding of a consumer's benefits.

New Directions encourages the Departments to revise the form to eliminate the check-the-box system currently employed, and in the circumstance of an adverse benefit determination, allow the affected consumer to ask for the "Plan's explanation of the NQTL resulting in my adverse benefit determination." This approach will allow a health plan to determine what NQTL was applied, and will allow the plan some latitude to create a plain language explanation of the NQTL applied and the rationale for it. This approach will sufficiently empower the consumer to pursue an appeal or other action as allowed under state and federal law. This approach also eliminates the circumstance where a health plan cannot adequately fulfill a request due to the consumers potentially errant "check all that apply" approach, and allows a plan to assist their member without the heightened administrative burden and associated regulatory compliance risk with the currently proposed approach.

New Directions encourages the Departments to provide guidance, with a subsequent public comment period, on the Disclosure Form's following language: "Provide the specific plan language regarding the limitation and identify all of the medical/surgical and mental health and substance use disorder benefits to which it applies in the relevant benefit classification." Specifically it would be helpful to understand the Department's vision for what constitutes "the specific plan language" and from what source that information would be pulled.

New Directions encourages the Departments to amend the Disclosure Form's #2 and #3 on page 2, which requires the production of "factors" and also "evidentiary standards". New Directions recommends that #2 and #3 be combined with the addition of processes and strategies. We recommend the following language, "Identify the underlying factors, strategies, evidentiary standards, or processes used to apply the NQTL." We believe this language more accurately reflects the language of Final Rule, and allows health plans an opportunity to explain in plain language, the interaction of the applicable factors, strategies, processes, and evidentiary standards.

****

Thank you for providing the opportunity to comment on the documents related to mental health parity implementation and enforcement. New Directions looks forward to continue working with you to implement MHPAEA in a manner that best serves the needs of consumers, while still appreciating the business implications of that implementation, and its impact on providing high quality, low cost, evidence based care to consumers. If you would like to discuss New Directions comments, please feel free to contact Jarod Patten via telephone at (816) 994-1449, or via email at jpatten@NDBH.com.

Sincerely,

Noreen K. Vergara

General Counsel, SVP & Chief HR Officer

New Directions Behavioral Health, L.L.C.

Coni Fries

Vice President of Government Relations

Blue Cross and Blue Shield of Kansas City