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**VIA ELECTRONIC SUBMISSION TO:** [E-OHPSCA-FAQ39@dol.gov](mailto:E-OHPSCA-FAQ39@dol.gov)

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**Re:** Proposed FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21<sup>st</sup> Century Cures Act Part 39; Model Parity Disclosure Request Form; and Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA).

To Whom It May Concern:

Cigna is a global health service company dedicated to helping the people we serve improve their health, well-being and sense of security. We welcome the opportunity to provide comments to the Departments of Labor (DOL), Health and Human Services (HHS) and the Treasury (collectively, the Departments) regarding proposed interpretive guidance of the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) regulations governing nonquantitative treatment limitations (NQTLs), including the disclosure requirement, issued in the form of the "Proposed FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21<sup>st</sup> Century Cures Act Part 39"; revised "Model Disclosure Request" form; and revised "Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act\*" (\*We recognize the revised "Self-Compliance Tool" is not officially open for public comment.)

Cigna genuinely supports efforts to expand access to affordable, quality, evidence-based treatment for those suffering from mental illness and substance use disorders. For the past eight years, we have implemented numerous measures across our medical, behavioral health and pharmacy organizations to ensure compliance with MHPAEA.

Additional guidance on the interpretation of the MHPAEA requirements governing NQTLs is needed given the complexity, vagueness and ambiguity of the regulatory language. However, we believe the

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recently issued proposed guidance goes above and beyond the intent and/or language of the MHPAEA statute and regulations.

**New NQTL Requirements:**

The MHPAEA regulation governing NQTLs requires comparability and the transparency of “any processes, strategies, evidentiary standards, or other factors” used in applying an NQTL to medical/surgical benefits and mental health/substance use disorder (MH/SUD) benefits with a classification. The use of the terms “any” and “or” in the regulation acknowledges that not all factors used in applying an NQTL to medical/surgical benefits and MH/SUD benefits within a classification may be based upon an evidentiary standard.

However, Step Three in the revised Self-Compliance Tool Kit requires plans to identify:

- The source information used to define a factor; and
- An evidentiary threshold at which each factor will implicate an NQTL.

Similarly, the revised Model Disclosure Request Form requires a plan to “identify the evidentiary standards (or thresholds) used to evaluate each factors” upon which an NQTL is based.

A list of highly technical and complex examples of evidentiary standards or thresholds is included in both the revised Self-Compliance Tool Kit and Model Disclosure Form such as:

- Excessive utilization as defined by two standard deviations above average utilization per episode of care; and
- High variability in cost per episode as defined by episodes of care being two standard deviations higher in total costs than the average cost per episode 20 percent or more of the time in a 12-month period.

The new focus on rigid, concrete evidentiary standards is also reflected in Q2 and Q3 of the proposed “FAQs About Mental Health Parity and Substance Use Disorder Parity Implementation and the 21<sup>st</sup> Century Cures Act Part 39” (FAQs) relating to hypothetical plans’ methodologies for determining which services or treatments are considered experimental or investigative.

Requiring issuers and plans to identify the source information and an evidentiary threshold for each and every factor upon which an NQTL is based and/or implicated are new requirements not addressed in the MHPAEA statute and regulations. Requiring NQTLs to be based upon rigid, concrete metrics may result in unintended consequences exposing consumers to MH/SUD care that does not meet the same safety and efficacy standards as medical/surgical care.

**Vital Role of Clinical Discretion:**

The quantity and quality of the clinical evidence and standards used to evaluate the safety and efficacy of MH/SUD treatments pales in comparison to the quantity and quality of the clinical evidence and standards used to evaluate the safety and efficacy of medical/surgical treatments. As such, more clinical studies may be required on the MH/SUD side compared to the medical/surgical side. Clinical discretion plays a vital role in evaluating the available clinical evidence. Clinical discretion is also vital to the management of benefits, as there are no genetic tests, laboratory tests, or imaging tests that can be

used today for determination of diagnosis or treatment responses for MH/SUD diagnoses. This is in stark contrast to medical/surgical services for many conditions that are based on objective test results.

As referenced above, Q2 and Q3 of the proposed FAQs implies NQTLs ought to be based upon rigid, concrete metrics rather than upon clinical discretion which is in direct contrast to the below language taken from the preamble to the Final Rules:

Plans and issuers will continue to have the flexibility contained in the NQTL requirements to take into account clinically appropriate standards of care when determining whether and to what extent medical management techniques and other NQTLs apply to medical/surgical benefits and mental health and substance use disorder benefits, as long as the processes, strategies, evidentiary standards, and other factors used in applying an NQTL to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those with respect to medical/surgical benefits. In particular, the regulations do not require plans and issuers to use the same NQTLs for both mental health and substance use disorder benefits and medical/surgical benefits, but rather that the processes, strategies, evidentiary standards, and other factors used by the plan or issuer to determine whether and to what extent a benefit is subject to an NQTL are comparable to and applied no more stringently for mental health or substance use disorder benefits than for medical/surgical benefits. (78 Fed. Reg. 68245)

The FAQs should be revised to reflect that clinical discretion is allowed in evaluating the available clinical evidence regarding the safety and efficacy of medical/surgical treatments and MH/SUD treatments.

**Proposed Guidance will be Costly and Time and Labor Intensive to Implement:**

Since NQTL methodologies and processes are not described within traditional plan instruments, e.g. summary plan descriptions or insurance certificates, issuers and plans have had to develop documents that describe each and every NQTL applied across medical/surgical benefits and MH/SUD benefits for each and every health plan product offering. This, in and of itself, has been a timely, costly and labor intensive initiative. Implementing measures to amend those processes and documents to comply with the new Step Three requirements referenced in the revised Self-Compliance Tool and Model Disclosure Form will significantly increase the associated costs, time and labor. Moreover, disclosure of this highly technical detailed data will likely be difficult for the average layperson to understand and is likely to add little to no value to the consumer.

**Recommendations:**

FAQs:

- Amend the FAQs to reflect that issuers and plans may use clinical discretion when making NQTL determinations based upon the available clinical evidence as long as the methodologies and processes are comparable and applied no more stringently across MH/SUD benefits as compared to medical/surgical benefits.

Disclosure Request Form:

- Remove "General Information" section.
- Remove the following language that cross references to the new Step Three requirement: "Identify the evidentiary standards used to evaluate the factors" (and examples).

- Remove the following language: "Provide any evidence and documentation to establish that the limitation is applied no more stringently, as written and in operation, to mental health and substance use disorder benefits than to medical/surgical benefits."

Self-Compliance Tool:

- Remove Step Three from the revised Self-Compliance Tool.

In summary, we appreciate the Departments' continuing efforts to provide guidance on the interpretation of the MHPAEA NQTL regulatory requirements, but believe the proposed guidance should be amended to be consistent with the intent and language of the MHPAEA statute and regulations as indicated above.

In the alternative, we respectfully request the Departments delay the effective date of the new NQTL requirements addressed within the recently issued proposed guidance until July 1, 2019.

Thank you for your consideration.

Respectfully,



David Schwartz