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U.S. Department of Labor-OASAM
Office of the Chief Information Officer
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Washington, D.C. 20210

Office of Information and Regulatory Affairs
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Room 10235
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Washington, DC 20503

Submitted via email to E-OHPSCA-FAQ39@dol.gov, DOL_PRA_PUBLIC@dol.gov, and OIRA_submission@omb.eop.gov

RE: Proposed MHPAEA and 21st Century Cures Act FAQs Part 39 and Model NQTL Disclosure Request Form (OMB Control Number 1210-0138)

To the Department of Labor and Office of Information and Regulatory Affairs:

The Blue Cross Blue Shield Association ("BCBSA") appreciates the opportunity to provide comments on the proposed FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39, as well as the revised draft model form that participants, enrollees, or their authorized representatives may voluntarily use to request information from their health plan or issuer regarding non-quantitative treatment limitations ("NQTLs") that may affect their mental health and substance use disorder ("MH/SUD") benefits, or to obtain documentation after an adverse benefit determination involving MH/SUD benefits to support an appeal ("model disclosure request form").

BCBSA is a national federation of 36 independent, community-based, and locally operated Blue Cross and Blue Shield Plans that collectively provide health care coverage for one in three Americans. For more than 80 years, Blue Cross and Blue Shield companies have offered quality health care coverage in all markets across America – serving those who purchase coverage on their own as well as those who obtain coverage through an employer, Medicare, and Medicaid.

We commend the Departments of Labor, Health and Human Services and the Treasury ("the Departments") on their commitment to ensuring clarity around plan compliance with the Mental

Health Parity and Addiction Equity Act of 2008 ("MHPAEA") and NQTLs, and share their goal of ensuring that consumers fully understand the rights offered to them under MHPAEA and other related laws. BCBS companies have been steadfast in their commitment to ensure compliance with MHPAEA, and we appreciate the opportunity to provide comments on the recently issued guidance addressing NQTLs and disclosure under MHPAEA and the 21st Century Cures Act.

Upon review of the guidance, we feel that the following issues warrant your heightened attention:

MHPAEA and 21st Century Cures Act FAQs

- **First,** we are concerned that the examples and explanations provided do not account for the nuances and factors that impact coverage and reimbursement in real-world scenarios, and fail to reflect the flexibility that plans and issuers have under the NQTL parity standard.

- **Second,** we recommend that the Departments revise the FAQs to include more examples of instances where:
    - A plan was in compliance (juxtaposed alongside the examples provided where a plan was not in compliance), allowing for a clearer understanding both of what is permissible, and of where there may still be "gray areas" of interpretation.
    - It is *not* in the best interest of the patient for a plan to impose NQTLs in the same manner for mental health/substance use disorder benefits as it is for medical/surgical benefits.

- **Third,** the Departments should provide more clarity and examples of permissible differences in NQTLs across medical/surgical benefits and mental health/substance use disorder benefits. While past FAQs did provide some examples, additional clarity in future FAQs would be beneficial.

- **Fourth,** the FAQs tend to focus on one factor in each example for whether or not a plan is in compliance with the law. In reality, many factors go into each coverage decision and the FAQs should acknowledge that more clearly in the introduction as well as in the explanations. At a minimum, the FAQs should make clear that the Departments understand that many strategies, factors, evidentiary standards, and other factors are frequently applied simultaneously, and that the FAQs generally address how a single of these considerations is applied.

Revised Model NQTL Disclosure Request Form

Regarding the model disclosure form for NQTLs, while we appreciate the clarifications made in the revised form regarding appeals processes and authorized representatives, we believe there are aspects of both the initial and revised form that would benefit from further revisions to simplify the process of requesting relevant disclosures for consumers, patients, and their authorized representatives, while also minimizing burden on health plans and issuers. In addition to simplifying the disclosure process for consumers and their authorized representatives, the Departments should also take steps to simply the disclosure process for plans and issuers that are responsible for responding to information requests. To this end, we suggest the Departments work to develop a

model response form that plans and issuers could voluntarily use to respond to a request for information.

We recommend the Departments revise the model disclosure request form to:

- Adequately account for the administrative cost and burden on plans and issuers that will be generated by the model form and take steps to reduce burden as outlined below.
- Clearly identify when the model form is appropriate for use by individuals enrolled in individual plans and non-federal governmental plans, given the different disclosure requirements between ERISA and non-ERISA plans.
- Eliminate the general information request, or in the alternative, clarify what specific disclosures (e.g., evidence of coverage) plans are expected to provide.
- Eliminate the examples of evidentiary standards, which are overly-complicated and unnecessary for a consumer-oriented form.
- Consistently reference the date the form is *received* by the plan in the 30-day timeframe for response.
- Include the claim number associated with a request for information about a claim that was denied or restricted.

We provide more details on these and related recommendations in the comments below.

We appreciate your consideration of our comments. We look forward to working with the Departments on improving the FAQs and disclosure request process, for consumers, patients, and their authorized representatives, and for other stakeholders.

If you have questions or want additional information, please contact Anshu Choudhri at anshuman.choudhri@bcbsa.com or 202-626-8606.

Sincerely,

Kris Haltmeyer
Vice President, Legislative and Regulatory Policy

COMMENTS ON PROPOSED FAQS ABOUT MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION PART 39 AND THE 21ST CENTURY CURES ACT

Question 2

Issue:

In reference to experimental and investigational treatment, the FAQ implies that there is an accepted standard ("a requisite number of randomized controlled trials") among payers and that a specified number of randomized controlled trials (in this example, one or two) is sufficient when making coverage determinations. This kind of over-simplified methodology is not, in fact, the norm.

Recommendation:

The FAQ should be modified to account for the distinction between new and existing interventions, and how clinical trials may or may not be juxtaposed alongside professional standards or expert opinion depending on the availability of evidence.

Rationale:

Because the availability of evidence often varies when making coverage decisions, plans have to consider a number of factors when evaluating the effectiveness of the evidence that is available. For new interventions (e.g., treatments), effectiveness is determined by scientific evidence. For existing interventions, effectiveness is determined first by scientific evidence, then by professional standards, and then by expert opinion. New interventions for which clinical trials have not been conducted because of epidemiological reasons (i.e., rare or new diseases or orphan populations) are evaluated on the basis of professional standards of care or expert opinion[1].

Question 3

Issue:

The FAQ describes a violation of MHPAEA because the text of the plan sets forth the same evidentiary standard for defining experimental as the Hayes Medical Directory ratings below "B". The plan applies a different evidentiary standard, which is more stringent for MH/SUD benefits than for medical/surgical benefits because the unconditional exclusion of treatments with a "C" rating for MH/SUD benefits is not comparable to the conditional exclusion of those treatments with a "C" rating for medical/surgical benefits.

Recommendation:

The FAQ fails to account for the clinical discretion that is imperative for making appropriate, individualized coverage decisions, and should be modified to illustrate that the plan is "probably not" in compliance with MHPAEA, rather than a definitive "no".

[1] http://216.230.117.100/hmd/~/media/0114C8523BFE47869963FDE71B2D5B14.ashx

Rationale:

Plans evaluate and weigh the available evidence based on its quality and applicability**,** and creating a rigid standard for the way in which plans evaluate the limited evidence available could ultimately make it more difficult to ensure that patients receive quality care. Plans consider the sample size in studies, the treatment population, and other key study design factors to determine if a treatment would be appropriate for a particular patient. Furthermore, without the discretion and flexibility to make decisions based on an individual's circumstances, a plan may, in some cases, not be able to cover an experimental treatment that a provider believes will be beneficial. Alternatively, a patient could also be placed on an experimental treatment that may be unlikely to work or could be harmful.

Question 4

Issue:

The draft response indicates that the use of Pharmacy and Therapeutics ("P&T") committees must comply with MHPAEA's NQTL standard, and in the case of a deviation from nationally-recognized treatment guidelines for a MH/SUD medication but not for a medical/surgical medication, the deviation should be evaluated for compliance with MHPAEA's NQTL requirements, (for instance, by determining (1) whether the expertise of the members of the P&T committee in MH/SUD conditions is comparable to their expertise in medical/surgical conditions, and (2) by determining whether the committees' evaluation of nationally-recognized treatment guidelines in setting dosage limits for medications for both MH/SUD and medical/surgical conditions is comparable).

Recommendation:

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

Rationale:

The important factor for whether a plan is in compliance with MHPAEA should be based on the process used to achieve the end determination, not the composition of the P&T committee. This is so because the composition of the P&T committee does not, in and of itself, limit the scope or duration of benefits for treatment, and therefore is not an NQTL.

Question 6

Issue:

The FAQ references an example where step therapy is seemingly applied inconsistently across medical/surgical benefits (one unsuccessful attempt at outpatient treatment in the last 12 months required before a patient is eligible for inpatient, in-network benefits) and mental health/substance

use disorder benefits (two unsuccessful attempts at outpatient treatment in the last 12 months are required before a patient is eligible for inpatient, in-network SUD benefits). The FAQ concludes that the plan is probably not in compliance with MHPAEA.

Recommendation:

The Departments should more consistently acknowledge throughout the FAQs that there are instances where there will be permissible differences in NQTLs, based on the quality of the evidence or treatment options available for a condition. The explanation should be re-worded to clarify this fact.

Rationale:

Rigid comparisons of numbers in evaluating NQTL compliance does not always tell the complete story. Just like in medical treatment, the number of attempts a patient may need before moving to a more resource-intensive treatment depends on how many treatments are available (e.g., there may be four classes of differently acting drugs available as alternatives in one case, but only one alternative class in another). The focus should be on evidentiary standards, including clinical determinations, and not implying that a numerical differential likely leads to non-compliance.

Question 7

Issue:

The FAQ describes a scenario where it is not permissible for a plan to have the same reimbursement rates for physicians and non-physician practitioners for medical/surgical benefits, but to pay reduced reimbursement rates for non-physician practitioners for MH/SUD benefits.

Recommendation #1:

The Departments should recognize that plans consider a wide array of factors in determining provider reimbursement rates (e.g., using Medicare RVU times a conversion factor to set medical base rates while using internal claims payment history to set MH/SUD base rates). The focus should be on using a comparable process, which could lead to differences that are still compliant with parity.

Recommendation #2:

The Departments should specify, by including language similar to that in the final regulation for implementing MHPAEA, released on November 13, 2013, that plans may permissibly consider a "wide array of factors in determining provider reimbursement rates for both medical/surgical services and mental health and substance use disorder services, such as service type; geographic market; demand for services; supply of providers; provider practice size; Medicare reimbursement rates; and training, experience and licensure of providers.**"**

Rationale:

The oversimplification of this example as currently written could potentially be confusing to patients, as it is not the ultimate outcome of the rates themselves that would be indicative of noncompliance, but rather the process that is used to set the reimbursement rates**.**

Furthermore, the FAQ incorrectly implies that plans in both commercial and government programs pay the same rate for physician and non-physician services, which is not the case. The Departments should also acknowledge in the FAQ the inherent differences in overhead costs between medical/surgical services and mental health services (e.g., the use of more expensive equipment that may be used by a primary care physician compared to a behavioral health practitioner) and that reimbursement rates through commercial and government programs take these considerations into account.

Furthermore, one complicating factor that is different on the MH/SUD side (compared to medical/surgical) is that there is a much broader array of independently functioning MH/SUD professionals with wide variations in training. There may be individuals working independently as billable providers that have four years of education, alongside those with 12-15 years of education. When comparing a Psychiatrist and Psychologist – both are doctors – payment parity here would be reasonable. But to suggest that payment parity exist between a MH/SUD doctor and a social worker would be an unreasonable requirement under the NQTL rule. Importantly, there is a heterogeneous population of MH/SUD providers in behavioral health – many individuals work with fewer years of education – that often times provide the same services (*e.g.*, counseling). This dynamic is very unique to this field and does not occur in any other area of medicine. The reality of the MH/SUD delivery model should be accounted for when considering parity comparisons for reimbursement rates.

Question 8

Issue:

The FAQ describes a scenario where a plan is not in compliance with MHPAEA because it does not utilize a standard relating to availability of appointments in creating its provider network for MH/SUD services, but does for medical/surgical providers.

Recommendation:

Given the well-documented shortage of behavioral health providers, the FAQ should recognize that parity in process does not necessarily result in equal medical/surgical and MH/SUD networks. To provide balance and be consistent with illustrations included in the Self-Compliance Tool Kit, the FAQ should be revised to show how factors used in network admission standards, when applied in a manner that is comparable to and no more stringently for MH/SUD than medical/surgical benefits, can result in different outcomes that are permissible under MHPAEA.

Rationale:

Due to shortages of providers in some areas, the resulting provider network is not itself indicative of non-compliance; rather the process for establishing the provider network is the measure of compliance. Only if the plan did not use comparable processes, strategies, and evidentiary standards, and other factors in creating its provider network would this be an example of non-compliance.

Question 9

Issue:

The FAQ provides an example where a plan provides benefits for the treatment of eating disorders but excludes all inpatient, out-of-network treatment outside of a hospital setting for eating disorders, including residential treatment (which it regards as an inpatient benefit). The plan covers inpatient, out-of-network treatment outside of a hospital setting for medical/surgical conditions if the prescribing physician obtains authorization from the plan and the treatment is medically appropriate for the individual, based on clinically appropriate standards of care. The FAQ concludes that the plan is not in compliance with MHPAEA.

Recommendation:

The Departments should consider addressing a number of additional Residential Treatment Center (RTC)-related NQTL issues:

(1) Plans' ability to reimburse only for covered benefits delivered by a licensed clinician in the RTC setting (and excluding care provided by non-licensed professionals) where the same standard is applied to medical/surgical benefits;

(2) Plans' ability to conduct prior authorization for RTC stays; and

(3) Plans' ability to require either state-based licensing or third-party certification of RTC facilities (and to exclude facilities that fail to meet these licensure/certification requirements) where the same standard is applied to medical/surgical benefits.

The Departments should also consider offering an example of a compliant way to limit RTC therapy, based on the RTC-related issues identified above.

Rationale:

Residential treatment centers are unique in that there is a lot of variation in licensing and certification requirements for these intermediate levels of care. Furthermore, with recent concerns of fraud/abuse nationally in the RTC space (e.g., patient brokering of those suffering from opioid use disorder or substance use disorder), there may be more stringent standards applied on the MH/SUD side to ensure that patients are receiving medically appropriate care. These fraud and safety concerns are not appropriately accounted for in the explanation, as currently written.

Question 10

Issue:

The FAQ describes a scenario where emergency room care is provided for an acute condition affecting a patient's physical health that arises as a complication of a MH/SUD condition. The FAQ seems to state whether the benefits are considered MH/SUD benefits depends on whether the terms of the plan (in accordance with applicable Federal and State law) define the particular acute condition as a medical condition or a MH/SUD condition.

Recommendation:

The Departments should provide more clarity on whether this is applicable only to Emergency Room services. The Departments should also provide guidance on how plans should treat the medical manifestations of a chronic MH/SUD disorder.

Rationale:

The lack of clarity in this example creates confusion about how to review compliance in different, yet related circumstances. For example, the guidance does not address how a plan might analyze MHPAEA compliance if it considered speech deficits to be medical/surgical, even if the underlying condition were autism spectrum disorder (assuming it was defined as a mental health/substance use disorder under the terms of the plan). Furthermore, the FAQ appears to be in conflict with Page 14 of the Self-Compliance Tool Kit, which states that "Plans and issuers should clearly define which benefits are treated as medical/surgical and which benefits are treated as MH/SUD under the plan". The example in the FAQ seems to imply that circumstances may dictate medical/surgical or MH/SUD benefits.

COMMENTS ON THE FORM TO REQUEST DOCUMENTATION FROM AN EMPLOYER-SPONSORED HEALTH PLAN OR INSURER CONCERNING TREATMENT LIMITATIONS

Cost and Burden Estimates

Issue:

The Departments' burden estimate only considers the impact on enrollees and their authorized representatives to complete the model disclosure request form. It fails to consider the increased cost and burden imposed on plans and issuers that will be responsible for responding to requests using the model form.

Recommendation:

The Departments should account for the administrative cost and burden on plans and issuers generated by the model form and take steps to reduce the burden as outlined below. As stated above, BCBSA believes the Departments could simplify the disclosure process and meaningfully reduce burden on plans and issuers by working to develop a model response form that plans could voluntarily use to respond to a request for information.

Rationale:

The increasingly granular direction of the guidance makes the process of demonstrating that NQTLs are being applied comparably and no more stringently to MH/SUD benefits than to medical/surgical benefits extremely burdensome. We believe this increased burden will result in significant administrative costs that have not been adequately accounted for in the Departments' burden estimates associated with the model form. The inclusion of the "other" category of treatment limitation may significantly impact the cost burden because it invites requests relating to plan design features that are neither quantitative treatment limitations nor NQTLs, and so there is no supporting information to provide. Yet, the plan/issuer will be forced to evaluate whether the disclosure is necessary under the Final Rule.

While the Departments may assert the model form does not impose any new obligations on group health plans or issuers than already exist under current law, the reality is that plans and issuers will experience a significant increase in the number of information requests as a result of the model form. Increased resources will be necessary to compile and respond with the requested information. This may involve extensive manual efforts, expensive legal representation, and new systems and configurations in order to be able to timely respond to requests within 30 days.

Instructions

Issue:

The instructions suggest the model form can used by individuals in both private ERISA plans as well as plans not subject to ERISA.

Recommendation:

The instructions should more clearly identify when the model form is to be used by individuals enrolled in coverage that is not through a private-employer plan, including individual plans and non-federal governmental plans.

Rationale:

There are different disclosure obligations for ERISA and non-ERISA plans. While participants generally have a right under ERISA to request the instruments under which the plan is established or operated -- which could include a request for general information (including a plan's NQTL analysis) or a request for specific information about a claim that may potentially be but has not yet been denied -- enrollees in the individual market and in non-federal governmental plans are not entitled to ERISA's general disclosure provisions. These individuals have a right to request information in instances of an adverse benefit determination under the internal claims and appeals and external review requirements of section 2719 of the PHSA. The model form is not appropriate for use by these individuals in the broader circumstances envisioned for ERISA plans.

Issue:

The model disclosure request form includes requests for information on MH/SUD benefits, generally. The instructions give the example of a request for the plan's preauthorization policies for medical/surgical and mental health treatments. However, the specific disclosure required under the law is not specified.

Recommendation:

The general information request is too broad and vague to allow for a meaningful response by plans and issuers and it does not identify the specific disclosure required under the law. Therefore, BCBSA recommends the general information request be eliminated, or the Departments clarify what specific disclosures (e.g., evidence of coverage) are expected to be provided in response to a general information request. In addition, the Departments should make clear that, when an enrollee or their authorized representative requests general information, the enrollee is not requesting the type of NQTL information listed at the end of the form (Items 1-5). To the extent the Departments believe specific disclosures required under the law should contain specific information related to NQTLs, the Departments should consider promulgating guidance about the form, content, and extent of disclosure required.

Rationale:

Clarifying what information plans are expected to provide is important for setting reasonable expectations. If one objective of the form is to encourage plans and issuers to improve the quality of informational disclosures for both individuals and groups, the Departments need to set reasonable expectations about what may be provided in response to a request for general information, such as by noting that plans and issuers are not required to create ad hoc disclosures in response to a request for general information, but may voluntarily create and provide generally applicable informational disclosures that provide general information related to compliance with mental health parity.

Claim/Denial Information Request

Issue:

The model form explains that treatment limits cannot be applied to MH/SUD benefits unless those limits are comparable to limits applied to medical/surgical benefits, and requests that within thirty (30) calendar days of the date appearing on the request, the plan:

1. 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;

2. Identify the factors used in the development of the limitation (examples of factors include, but are not limited to, excessive utilization, recent medical cost escalation, high variability in cost for each episode of care, and safety and effectiveness of treatment);

3. Identify the evidentiary standards used to evaluate the factors. Examples include, but are not limited to, the following:

    - Excessive utilization as defined by two standard deviations above average utilization per episode of care;
    - Recent medical cost escalation as defined by medical costs for certain services increasing 10% or more per year for 2 years;
    - High variability in cost per episode of care as defined by episodes of outpatient care being 2 standard deviations higher in total costs than the average cost per episode 20% or more of the time in a 12-month period; and
    - Safety and efficacy of treatment modality as defined by 2 random clinical trials required to establish a treatment is not experimental or investigational;

4. Identify the methods and analysis used in the development of the limitation; and

5. 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 and surgical benefits.

Recommendation #1:

BCBSA recommends deleting the examples of evidentiary standards in Item 3 above.

Rationale #1:

Consumers who have difficulty understanding basic plan design concepts such as deductibles and investigational therapies are unlikely to understand terms like “standard deviation” and “efficacy of treatment modality.” This level of detail is overly complex and unnecessary for a consumer-oriented form, and may confuse consumers when the plan responds with different evidentiary standards than those listed in the form. The aim of the form should be to simplify the process of requesting relevant

disclosures for consumers, patients, and their authorized representatives. Using technical, jargon-filled language in the form will do more to complicate than to simplify this disclosure process.

Recommendation #2:

The 30-day timeframe should consistently reference the date the request is received in the model disclosure request form.

Rationale #2:

The model disclosure request form is inconsistent in its instructions regarding the timeframe to respond to requests. The Background section specifies that for plans subject to ERISA, "Generally, the plan must provide the documents you request within thirty (30) calendar days of the plan's *receipt* of your request" [emphasis added]. However, page 2 of the model disclosure request form specifies that the requested information should be provided "within thirty (30) calendar days of the date *appearing* on this request" [emphasis added]. These can be two significantly different timeframes and the only verifiable and operationally feasible date that a plan can use is the date the request is received.

Enrollee Contact Information

Issue:

The form prompts the requester to enter certain identifying information on page 3 of the model disclosure request form, including the name and signature of the individual enrolled in the plan or the enrollee's authorized representative, the member number assigned to the enrolled individual, address, date, and email address (if email is a preferred method of contact).

Recommendation:

The model form should allow the individual to enter the claim number if information is being requested about a claim that was denied or restricted.

Rationale:

The claim number is an important piece of information that will help the plan identify the relevant claim and respond appropriately.