BOWMAN FAMILY FOUNDATION

October 17, 2023

The Honorable Lisa M. Gomez
Assistant Secretary
Employee Benefits Security Administration
Room N–5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20002

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Douglas W. O'Donnell
Deputy Commissioner for Services and Enforcement
Internal Revenue Service
U.S. Department of the Treasury
1111 Constitution Avenue, NW
Washington, DC 20224

Re: **File Code 1210-AC11**
Requirements Related to the Mental Health Parity and Addiction Equity Act: Proposed Rule

The Bowman Family Foundation and its advisors, Henry T. Harbin and Beth Ann Middlebrook, thank the Departments for overall excellent proposed rules, "Requirements Related to the Mental Health Parity and Addiction Equity Act" (Proposed Rules). Below please find BFF's comments, concerns and requests for clarifications of the Proposed Rules. Emphasis is added throughout these comments unless disclaimed.

The Bowman Family Foundation (BFF) is a private foundation qualifying as a 501(c)(3) nonprofit organization. The primary mission of BFF is to improve the lives of people with mental health and substance use ("MHSU") conditions. Towards this goal, BFF seeks to advance equity in access to care, including full and fair enforcement of MHPAEA, and implementation of the Collaborative Care Model (CoCM) and measurement-based care.

BFF is the Managing Member of the Mental Health Treatment and Research Institute LLC ("MHTARI"), a tax-exempt subsidiary of BFF which conducts most BFF activities regarding MHSU conditions. MHTARI provides funding to support projects, reports and tools related to improving behavioral healthcare

equity, including achieving full parity in access to in-network MHSU treatment vs. in-network M/S treatment. For example, MHTARI funded (1) the NORC report regarding a patient experience survey that shows stark barriers to accessing care for mental health vs. physical health, (2) the Milliman disparities report which reveals disparities in reimbursement and out-of-network use for MHSU benefits vs. M/S benefits, and (3) the Model Data Request Form (MDRF), a tool which provides templates for quantitative data reporting of key measures related to access to care and MHPAEA NQTL compliance.

Use of MDRF has been adopted as a best practice by the National Alliance of Health Care Purchaser Coalitions and the HR Policy Association. Metrics set forth in the MDRF are now being used in the access reporting templates used by several state insurance regulators. BFF and MHTARI often collaborate with employer coalitions, provider associations, individual providers, MHSU non-profit advocates, and other philanthropies.

A. Enhanced language

We are supportive and appreciative of the enhanced language in the Proposed Rules, including:

- The added purpose statement that plans must not design or apply financial requirements and treatment limitations that impose greater burden on access to MH/SUD benefits than they impose on access to M/S benefits
- The clarification of M/S, MH and SUD benefits and how the conditions, procedures and disorders covered under the plan for each type of benefit are defined
- Expanded definitions for factors, evidentiary standards, processes and strategies
- Clarification that for any benefits provided for MH or SUD, the plan must provide meaningful benefits in every classification of benefits as determined in comparison to the M/S benefits provided in that classification
- Focus on quantitative data as a strong indicator of compliance
- Required relevant data evaluation and the use of data templates to ensure accurate and consistent data reporting
- Added focus on the impact of NQTLs on network composition, access and adequacy
- Requiring a plan or issuer to take reasonable action to address any material differences in access as necessary to ensure compliance, in operation, with the restrictive and design and application provisions

B. Concerns, Requests and Recommendations

1) Application of the Substantially All Test

The first concern is with respect to the application of the Restrictive provisions under (c)(4)(i). The substantially all requirement under (c)(4)(i)(B) states: "Whether the nonquantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits is determined without regard to whether the nonquantitative treatment limitation was triggered based on a particular factor or evidentiary standard." The example provided in the DOL September 7, 2023 webinar was of a plan or issuer that applies a general exclusion for experimental treatment in a classification based on a definition of whether a treatment has fewer than a certain number of peer reviewed studies that demonstrate efficacy. In this example, the exclusion would be viewed as applying to all the benefits in that classification, rather than the benefits that were in fact excluded, as triggered by the factor and

evidentiary standard described above. This NQTL therefore met the substantially all test regardless of the amount of benefits the exclusion, in fact, applied to based on meeting the threshold for triggering the NQTL.

Our concern and request for clarification over this approach can best be expressed by a real-life example:

Example. Inpatient hospital care for M/S conditions is often reimbursed according to Diagnostic Related Groups (DRGs). DRGs are a way to classify M/S hospital inpatient cases into groups that are expected to have similar costs, which helps determine the payment a hospital will receive for providing care to a patient. Hospitals are paid a fixed amount for each patient based on the DRG assigned to the patient which in effect places some limits on length of stay. As a result, plans often do not require prior authorization or concurrent review for DRG reimbursed care.

DRGs are not used for MH/SUD hospital inpatient care in the same way. MH/SUD inpatient hospital care is typically reimbursed according to per diems. Plans therefore typically apply prior authorization, concurrent review and/or retrospective review medical management protocols to MH/SUD hospital based inpatient care (as well as sub-acute inpatient care).

Under this real-life scenario, it is not clear whether the substantially all test would be measured by the plan stating that UM protocols of prior authorization and/or concurrent review apply to all M/S inpatient benefits, and that the factor or evidentiary standard for triggering the application of the NQTL is non-DRG reimbursed care. If this were the approach, even if non-DRG reimbursed inpatient benefits constitute less than 2/3 of the dollar amount of all plan payments for M/S inpatient benefits, the plan would still comply with the substantially all test.

Under this approach, in what manner would a plan state that prior authorization and/or concurrent review applies to all M/S inpatient benefits, if in fact, DRG reimbursed M/S acute inpatient benefits are not subject to prior auth and/or concurrent review? Does a plan which states that M/S acute inpatient admissions are in fact subject to prior authorization need to clarify that the prior authorization process is comparable to MH/SUD prior authorization? We do not believe it is the intent of the Departments in adding the no more restrictive provisions of the Proposed Rules to prevent plans or issuers from applying NQTLs such as medical management protocols. However, further clarification would be important with respect to how the substantially all test is to be measured.

2) Application of the Predominant test

BFF agrees with the view of various behavioral health organization stakeholders that plan and issuer processes for utilization management are complex and nuanced, and finding the predominant variation of an NQTL may not be workable in many real-life situations. For example, prior authorization or concurrent review may take varied forms: An admission that requires advance prior authorization prior to the member leaving their local area; admission that requires notification but no clinical review; a non-clinical review based on predetermined standards (called “Fast Certification” by multiple carriers); a first-level or nurse clinical review; a second-level or physician clinical review; and a peer-to-peer clinical review. Within each of these categories some processes may be automated vs. manual, some may be handled by vendors vs. directly by the plan or issuer, and some may have multiple utilization management systems within all of the aforementioned categories. Determining how to combine all of

these elements to arrive at the predominant variation of an NQTL for prior authorization or concurrent review may be impractical or not possible for plans, issuers and regulators without additional clarification.

C. <u>Strong Concern and Request for Removal of Exception for Independent Professional Medical or Clinical Standards</u>

1) What constitutes "independent professional medical or clinical standards"?

We believe that the Departments *intended* that the scope of what constitutes independent professional medical or clinical standards for purposes of the exception in the Proposed Rules applies to UM medical necessity criteria and standards, with the goal of not obstructing the application of criteria supportive of treatment services that improve care and outcomes. However, the Proposed Rules contain no clear definition of independent professional medical or clinical standards other than the parenthetical "(consistent with generally accepted standards of care)". Although the Departments have stated that this is a "narrow" exception, under the Proposed Rules, independent professional medical or clinical standards could apply to:

1) clinical/medical standards for M/S or MH/SUD level of care criteria, such as InterQual or ASAM;,
2) independent standards for length of stay for both MH and MS, such as MCG;
3) diagnostic specific treatment guidelines for providers, such as clinical standards for delivering ABA therapy (not intended to be coverage or payment requirements);
4) clinical/medical standards for network access or adequacy, such as the CMS QHP standards, state regulatory network adequacy standards, NCQA or URAC accreditation standards which include standards for network access.[1]

With respect to 4) above, the current lack of a clear definition for independent professional medical or clinical standards leaves open the scope of this exception to cover state, federal and private organization network adequacy standards. Network adequacy and access standards inherently rely on medical and clinical information.

Clinical knowledge and expertise are fundamental in the development of access standards for all types of M/S and MH/SUD providers: For example:

- identification of provider types and sub-types that are needed and included, establishment of standards for certification or licensure,
- establishment of access standards required for various types of MH/SUD services, establishment of the level of access needed for each.

If certain key MH/SUD providers types and sub-types are not identified and included, then there are no specific access standards for same, and the result is likely to be limited or no in-network care for such

[1] It is important to note that these network adequacy standards are not designed, developed or applied with an eye toward or purpose of achieving parity in the design and application of network adequacy standards for MH/SUD benefits compared to M/S benefits.

provider types and sub-types. Under INN only benefit plans, this is tantamount to no benefits for members who need this care.

Thus, for example, if a plan impartially uses state regulatory network adequacy standards, or QHP standards, it would be exempt from the relevant data evaluation provisions of the Proposed Rule (as well as the restrictive test and the discrimination provision under the design and application test). We do not believe this is what the Departments intended.

With respect to 3) above, many diagnostic specific clinical guidelines for treatment are developed and issued as a guide and standard that define criteria for providers (e.g., measuring blood pressure when treating hypertension), and/or best practices protocols or guidelines that are dependent of various fact specific clinical variables. These diagnostic specific clinical standards are not intended to be a standard for coverage or reimbursement. A plan has and could use these diagnostic specific criteria to develop coverage limits and/or reimbursement limits, e.g., a plan could have criteria that disallows coverage for a claim for an office visit for hypertension if a blood pressure measure was not implemented and disallow reimbursement, relying on the independent standard that a minimum treatment intervention requires a measure of blood pressure.

With respect to 2) above, if an independent standard, such as MCG, recommends a length of stay for specific MH/SUD diagnoses and a plan relies on that to deny any length of stay beyond the MCG guidelines, this could exempt a plan from the relevant data evaluation requirements used to assess compliance with the in operation portion of the design and application requirements, as well as exempting the plan from the restrictive test, and the MCG source automatically not considered to be discriminatory.

2) Substantial variations in the restrictiveness and stringency of "independent professional medical or clinical standards"

An important fact that significantly impacts the soundness of an exception in the Proposed Rules for independent professional medical or clinical standards is that typically, there is no single set of UM clinical or medical standards that have been generally accepted as the national standard. This is the case even in areas with multiple scientific studies regarding efficacy, as conclusions reached by such studies are often varied, or may even be in conflict. In fact, independent professional medical or clinical standards ***vary greatly*** in terms of their restrictiveness and stringency. In addition, such independent professional medical or clinical standards often contain length of stay guidelines that are more stringent and non-comparable to one another, and often contain minimum service requirements for programs or facilities that are not consistent with the terms of the Plan.

We believe it may have been the Departments intent to distinguish a plan's or issuer's internally developed medical or clinical standards or guidelines from those developed through independent third-party organizations. However, we also believe it may have been the Departments perception that there are clearly defined best practice, generally accepted national standards. However, there are not.

As the Proposed Rules read, if a plan impartially uses ANY independent professional medical or clinical standards, the plan is: exempt from meeting the restrictive test; the plan's use of this source or

evidentiary standard is automatically not considered to be discriminatory under the design and application test; and the plan is exempt from the relevant data evaluation requirements.

It is important to note that although outcomes data under the design and application requirements related to "in operation" compliance is still technically required, such requirement is undermined and rendered meaningless by the exemption from the relevant data evaluation requirements. In other words, absent a plan being required to be accountable for the results of the relevant data evaluation requirements, disparities in "in operation" outcomes data is no longer a measure of NQTL compliance. The in-operation component of the design and application requirements, and the CAA requirements for comparative analysis related to in operation compliance become meaningless so long as the plan is impartially using ANY independent professional medical or clinical standards. The disparities in such data are thereby permissible, not relevant and do not constitute any indicator of non-compliance with the in operation (as applied) component of the design and application test, as more fully detailed under the CAA amendment comparative analyses. As outcomes data disparities are an essential part of an "in operation" comparability test, this exemption essentially removes the in operation, or as applied, component of the comparability and no more stringency test. The result is that the only comparative analysis that would be allowed when any independent clinical standards are relied on would be a limited, as written (or design) analysis. Currently, there is no example in the Proposed Rule that demonstrates how an as written analysis would be developed. As we interpret the current language in the Proposed Rule, the plan's use of ANY independent clinical standards would automatically be deemed non-discriminatory and nonrestrictive. How would a plan analyze an independent standard as possibly more stringent or non-comparable if it is assumed to be non-restrictive, considered to not be a "discriminatory factor or evidentiary standard", and exempt from an evaluation of disparities in outcomes?

Example 5 in the Proposed Rule makes clear: "Moreover, the independent professional medical or clinical standards are not considered to be a discriminatory factor or evidentiary standard and, as written and in operation, the plan complies with the design and application requirements with respect to the NQTL, ***regardless of the fact that the application of the NQTL resulted in higher percentages of claim denials for mental health and substance use disorder benefits as compared to medical/surgical benefits."***

This appears to be a significant step backwards in NQTL compliance enforcement.

3) Plans are currently protected from noncompliance determination if data disparities are addressed and are unrelated to non-par application of NQTLs

Under current statutory and regulatory guidance, in designing and applying any NQTL, the full comparative analyses demonstrating comparability and no more stringency, as written and in operation, must be conducted. The Proposed Rule language setting forth the content requirements for NQTL comparative analyses according to the CAA amendment reinforces current guidance. Hence, currently, independent professional medical and clinical standards, medical necessity criteria, and sources or evidentiary standards for such, must be comparable to and no more stringently applied to MH/SUD benefits as compared to M/S benefits. This analysis currently includes a plan or issuer comparing its MH/SUD criteria as consistent with applicable generally accepted national standards.

Currently, disparities in outcomes must be identified and addressed, yet are not solely determinative of NQTL noncompliance. If there are disparities in outcomes, plans and issuers are required to more carefully analyze and scrutinize their processes, factors, evidentiary standards, etc. for comparability and no more stringency, both as written and as applied, in operation. Hence, plans and issuers currently have the flexibility to use different medical necessity criteria or level of care guidelines or standards. If there are disparate outcomes, plans and issuers can demonstrate that those disparate outcomes are not the result of non-par use and application of sources, evidentiary standards, factors, processes, etc.

Plans and issuers do not need to be somehow protected from a finding of non-compliance based on disparate outcomes that may exist, assuming the plan or issuer has demonstrated that these disparities are not due to non-comparable and/or more stringent processes, factors, evidentiary standards, etc. - including the use of independent clinical standards. Therefore, the exception for independent professional medical and clinical standards that exempts plans and issuers from compliance with the "relevant data evaluation" provisions (as well as the restrictive and discriminatory provisions) of the Proposed Rule is not necessary.

4) The essential nature of evaluating outcomes data

The Departments have repeatedly noted how essential measuring and evaluating outcomes data is:

"The 2020 MHPAEA Self-Compliance Tool stresses that **measuring and evaluating results *and* quantitative outcomes** can be helpful to identify potential areas of noncompliance… The 2020 MHPAEA Self-Compliance Tool notes that substantially disparate results are a red flag that a plan or issuer may be imposing an NQTL on mental health and substance use disorder benefits in a way that fails to satisfy the parity requirements."

The following quotes are from the Introduction to the Proposed Rule:

"In evaluating how such processes, strategies, evidentiary standards, and other factors are applied in operation, it is necessary to look at how the plan is administered in operation, which in the Departments' **view necessarily requires review and consideration of quantitative outcomes data to get a sense of how the NQTL functions in the context of the plan's or issuer's administration and provision of benefits.**

Therefore, the Departments propose to add a requirement to provide that, when designing and applying an NQTL, a plan or issuer **must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits, and consider the impact as part of the plan's or issuer's analysis of whether such NQTL, in operation, complies with proposed** 26 CFR 54.9812–1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii)."

"Under these proposed rules, the relevant data that a plan or issuer **would be required to collect and evaluate for all NQTLs (in each individual comparative analysis) includes, but is not limited to, the number and percentage of relevant claims denials, as well as any other data relevant to the NQTLs as required by State law or private accreditation standards**."

"Moreover, because of the Departments' specific concerns about standards related to network composition and other related NQTLs, these proposed rules would require that, in addition to the relevant **data required for all NQTLs, plans and issuers must collect and evaluate additional relevant data for NQTLs related to network composition. Such data would include, but would not be limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges).**

For example, plans and issuers may develop or consult several standards to help inform their network composition, such as State licensing standards, quality and performance metrics, patient utilization in particular geographic regions, and overall provider availability. Because plans and issuers generally look to the cumulative effect of such standards, practices, and strategies when designing their networks, it is important that plans and issuers also look to the cumulative effect of such standards, practices, and strategies when evaluating any data and standards related to network composition for compliance with MHPAEA."

In addition, the following quotes from the 2023 Report to Congress illustrate the need for and lack of compliance with quantitative data under the **current regulations and statute**:

"Additionally, plans and issuers that were initially unprepared ultimately submitted comparative analyses ***that often-lacked data showing what happened when the NQTL was applied in operation***. When operational data were included, plans and issuers *often* ***failed to explain numerical inputs, underlying methodologies, or calculations behind summary data that were presented as evidence of a comparable application****. Many plans and issuers also* ***failed to explain apparent differences in access to MH/SUD and medical/surgical benefits, instead focusing only on similarities."***

The exception for independent professional medical or clinical standards, as proposed, completely undermines the significance of outcomes data in performing a design and application NQTL comparative analysis.

5) Examples of independent professional medical or clinical standards

BFF describes the following examples of several commonly used independent professional medical or clinical standards that would meet the exception to the restrictive test, the discriminatory provision, and the relevant data evaluation requirements, the latter of which would obviate the impact of disparate outcomes data, in operation, under the Proposed Rules as currently written.

For example, MCG states that it has unbiased and evidence-based clinical guidelines for both M/S and MH. MCG, to our knowledge, is unaffiliated with any insurer or plan. It appears that a plan impartially relying on MCG as its source or evidentiary standard would meet the exception as currently proposed. However, many of MCG criteria are more restrictive and more stringent than other MH independent professional clinical or medical standards, such as LOCUS.

Moreover, MCG contains Goal Length of Stay (GLOS) criteria that, if were able to be applied by a plan without the plan having to provide any relevant data evaluation, could lead to very disparate, but permissible, discriminatory lengths of stay under MH/SUD benefits vs. M/S. Thus, with the exception as

proposed, disparately high denial rates, or OON use rates or UM administrative burden might be measured but would be ignored.

InterQual Criteria is maintained by Change Healthcare and owned by Optum, the healthcare analytics company owned by UHC's parent, UnitedHealth Group. InterQual may not be deemed "independent" for purposes of a plan whose behavioral health benefit is administered by Optum or UBH, or by UHC as an issuer. However, InterQual would be deemed independent for other plans and issuers, e.g., Cigna, Aetna, BCBS and the self-funded plans they administer. InterQual used by these other plans or issuers would likewise be deemed independent professional medical or clinical standards that would meet the exception as proposed. InterQual has also contained MH/SUD medical necessity requirements consisting of minimum services that must be provided by MH/SUD facilities and providers that may be more stringent than, or potentially inconsistent with the terms of the Plan. Such service requirements, if still part of the criteria, may be used to determine "medical necessity", and programs deemed ineligible based on the services requirements may result in a medical necessity denial, despite the patient's actual medical necessity.

In addition, independent professional medical and clinical standards are updated and change from year to year unilaterally by the organizations that publish them. The exception for independent professional medical and clinical standards, the stringency and restrictiveness of which change from year to year, would truly create an unavoidable and significant loophole in NQTL compliance enforcement.

6) ***Examples of Judicial Opinions related to independent professional medical or clinical standards***

BFF has reviewed several judicial decisions related to a plan's use of MCG and InterQual independent professional MH medical and clinical standards that may be instructive.

In November 2020, a Montana district court held that an ERISA plan administrator improperly denied benefits for mental health residential treatment based solely on **MCG**. (*Jessica U. vs. HCSC*). BCBS Montana relied solely on MCG to conclude that the plaintiff's RTC treatment for an eating disorder was not "medically necessary." Specifically, BCBS found that the plaintiff was not in imminent danger to herself or others, had no issues with self-care, had no severe disability requiring acute residential intervention, had no co-morbid substance abuse disorder, and did not require a structured setting with continued around-the-clock care – standards which are included in MCG. The court found that BCBS erred by relying solely on the MCG guidelines in denying the plaintiff's claim because they involved acute care factors that had limited application to a case involving a non-acute admission. Denial of Mental Health Treatment Benefits Ruled Improper under Milliman Care Guidelines (hinshawlaw.com); Jessica U. v. Health Care Serv. , Cause No. CV 18-05-H-CCL | Casetext Search + Citator

In September 2019 and April 2020, a Utah district court had similarly found that Regence BCBSOR improperly denied coverage for inpatient mental health services based solely on the plan's application of **MCG**'s residential acute behavioral health guidelines (*Charles & Zoe W. vs. Regence BCBS of OR*). Zoe W. v. Regence BlueCross BlueShield of Or., Case No. 2:17-cv-00824-TC | Casetext Search + Citator

Both cases cited to findings made by a Washington District Court in 2016 in another case in which Regence improperly refused to pay for a patient's inpatient mental health treatment, criticizing the plan for relying exclusively on MCG. (*H.N. v. Regence BlueShield)*
H.N. v. Regence Blueshield, Corp., CASE NO. 15-CV-1374 RAJ | Casetext Search + Citator

The *Zoe v. Regence* court noted, citing to *H.N. v. Regence*:

> "The MCG might be a helpful tool but were not intended to operate as a sole basis for denying treatment or payment. The MCG are to be applied to individual patients on a case-by-case basis and always in the context of a qualified healthcare professional's clinical judgment. . . . Though the MCG are recognized by physicians and hospitals, they are "by no means the sole measure of medical necessity."

The *Zoe v. Regence* court also found that the arbitrary nature of the last date selected by Regence that it would cover services logically related to its statement to the residential treatment provider that "the MCG expects most [patients] can meet treatment goals within 30 days." Plaintiff had been in residential treatment for longer than that, and the court found that Regence's decision to deny further treatment appeared to be based on this maximum time notion, rather than on a case-specific assessment of Plaintiff's clinical needs.

In a suit filed in Monroe County NY Supreme Court, plaintiffs, John and Jane Doe sued Excellus BCBS over its use of **InterQual** Adolescent and Child Psychiatry criteria. Doe v Excellus Health Plan, Inc. :: 2023 :: New York Other Courts Decisions :: New York Case Law :: New York Law :: US Law :: Justia. Excellus determined that a program offered by a particular mental health facility did not meet the InterQual requirements for MH residential treatment. The InterQual requirements based on which the MH facility was disqualified were inconsistent with the language in the Plan defining when residential treatment is covered. In April 2023, the court found that the use of InterQual standards which were not described in the Plan, served to disqualify treatment at a facility otherwise eligible under the Plan's language, and was the basis for Excellus' determination of lack of medical necessity. The NY Supreme Court found that InterQual criteria was used by the Plan to essentially determine that services can never be "medically necessary" at a particular facility or program, regardless of the individual needs of the patient. Therefore, the court refused to dismiss on summary judgment plaintiffs' breach of contract action against Excellus.

The Court also found that by using the InterQual standards to discount a program as a residential care facility, Excellus applied a separate treatment limitation to the mental health benefit that was not applied to the medical/surgical benefit and violated MHPAEA:

> "At the very least, use of the Interqual criteria, in this instance, is a violation of the Mental Health Parity Act and defeats Excellus's entitlement to judgment as a matter of law. In other words, excise the Interqual criteria from the reasoning that resulted in denying the cost of treatment, and Excellus would have no reason not to pay."

The above judicial opinions demonstrate that the use of independent professional medical or clinical standards does not provide any level of assurance of the non-discriminatory and parity compliant nature of NQTLs that are applied using such independent standards. BFF strongly believes that the exception

from the essential Proposed Rule provisions related to restrictive test, discriminatory provision, and most especially, the relevant data evaluation requirements, should be removed from the Proposed Rules. To keep this exception in the Proposed Rules would undermine the design and application requirements already in place, provide a loophole for the restrictive and discriminatory provisions, as well as the relevant data evaluation provisions, and would serve to weaken the ability to enforce parity with respect to UM protocols.

D. Concerns over Exception for Fraud, Waste, and Abuse

Fraud, waste, and abuse risk is a common factor for determining which services will be subject to NQTLs. However, BFF agrees with other behavioral health organization stakeholders that this does not mean that plans and issuers can broadly claim exceptions from NQTL requirements merely because this risk is a component or factor of the NQTL. BFF believes that the Departments should remove the term "waste" from this exception. In theory, the entire purpose of utilization management is to prevent "waste." Therefore, it is very easy to imagine plans and issuers claiming this exception for a broad range of NQTLs under the "prevent waste" category. With respect to fraud and abuse, additional guidance from the Departments would potentially deter misuse of what are intended to be narrowly defined exceptions. In particular, the Departments should provide very specific definitions for these terms with greater definitional clarity that is narrow and tailored in scope to deter misuse.

E. Analyses of Proposed Rule Examples and the impact of independent professional medical or clinical standards exception

In examining the new examples set forth in the Proposed Rules, BFF believes it is important to illustrate concerns over the impact that the exception for independent professional medical or clinical standards would have on NQTL compliance enforcement.

"Example 1—More restrictive prior authorization requirement in operation.

However, for mental health and substance use disorder benefits, the plan routinely approves only 1 day of inpatient, in-network benefits before a treatment plan must be submitted by the patient's attending provider and approved by the plan. In this example, the difference in the duration of approvals is not the result of independent professional medical or clinical standards or standards related to fraud, waste, and abuse, but rather reflects the application of a heightened standard to the provision of the mental health and substance use disorder benefits in the relevant classification."

ANALYSIS: IMPACT OF INDEPENDENT PROFESSIONAL CLINICAL STANDARDS

In this Example 1, the plan is found to have a more restrictive prior authorization requirement for MH/SUD (only one day of approval for MHSUD vs MS) **and** there is no "independent professional medical or clinical standards" that support this difference. As described above, it is possible that an independent professional medical or clinical standard for MH/SUD could recommend a one-day approval for prior authorization for MH/SUD inpatient care.

Our interpretation of the current proposed exception is that the use of **any** MH/SUD independent professional medical or clinical standard would allow a plan to implement a more restrictive prior authorization for MH/SUD benefits. As the Proposed Rule states, an independent professional medical or clinical standard is exempt from any **relevant data evaluation requirements,** even if this is a more

stringent prior authorization requirement that leads to higher denial rates for MH/SUD, higher review frequencies and/or higher OON use rates.

As noted above, one current set of independent professional medical and clinical standards, MCG, contains recommended lengths of stay guidelines for MH/SUD. If this standard or others recommend very brief lengths of stay for MH/SUD vs. M/S, our interpretation is that these disparate requirements would be exempt from the in-operation portion of the design and application comparability analyses. While the plan may still presumably be subject to the design, as written, comparability requirements, it is unclear what as written testing would consist of - especially given that this would be considered non-discriminatory, be exempt from the restrictive tests, and exempt from the relevant outcomes data requirements essential to in operation analysis. The Proposed Rules make it clear that quantitative data is essential in determining comparability, in operation. Moreover, if this is exempt from the restrictive tests, and is deemed non-discriminatory, what type of "as written" design testing would there be left to perform? As noted above, there is no single "gold standard" independent professional medical or clinical standards for either M/S or MH/SUD. In fact, there are many and some of these standards are more stringent than others.

"***Example 3—More restrictive peer-to-peer review medical necessity standard in operation; deviation from independent professional medical and clinical standards***.

In operation, the plan covers out-of-network benefits for medical/surgical or mental health inpatient treatment outside of a hospital if the physician documents medical appropriateness, but for out-of-network substance use disorder inpatient treatment outside of a hospital, the plan requires a physician to also complete peer-to-peer review.

. . .

However, in operation, the medical necessity NQTL imposed on out-of-network substance use disorder benefits for treatment outside of a hospital is more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits in the classification because it limits access to the full range of treatment options available for a condition or disorder under the plan or coverage as compared to medical/surgical benefits. The NQTL is not the result of independent professional medical or clinical standards or standards related to fraud, waste, and abuse that qualify for the exceptions to the no more restrictive requirement under these proposed rules. Because the plan violates the no more restrictive requirement, the example does not analyze compliance with the design and application requirements or the relevant data evaluation requirements under these proposed rules."

ANALYSIS: IMPACT OF INDEPENDENT PROFESSIONAL CLINICAL STANDARDS

This Example 3, similar to Example 1, identifies a more restrictive medical necessity requirement for SUD inpatient out of network as compared to MS – specifically, a requirement for a peer-to-peer review that is not required for MS. The example illustrates that because this more restrictive requirement is not the "result" of an "*independent professional medical and clinical standard" it* is deemed to fail the no more restrictive test for this NQTL.

As illustrated in Example 1, a plan could use a MH/SUD independent professional medical or clinical standard that recommends a peer-to-peer review as a best practice or for any reason. Based on the current language in the Proposed Rule, it is our interpretation that the plan could apply this more

restrictive criteria and be deemed exempt from the no more restrictive requirements (substantially all, predominant), and be considered non-discriminatory under the design and application provisions, as well as be exempt from the "**relevant data evaluation requirement,"** which would also result in disparate data outcomes in the in operation application of the NQTL being permissible.

Example 5—Exception for impartially applied generally recognized independent professional medical or clinical standards.

"In new proposed Example 5, a group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The medical management requirement impartially applies independent professional medical or clinical standards in a manner that qualifies for the exception in proposed 26 CFR 54.9812–1(c)(4)(i)(E), 29 CFR 2590.712(c)(4)(i)(E), and 45 CFR 146.136(c)(4)(i)(E). The plan does not rely on any other factors or evidentiary standards, and the processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims based on the impartial application of the independent professional medical or clinical standards by the NQTL.

The proposed new example would conclude that the plan does not violate 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) of these proposed rules. The medical management NQTL imposed on mental health and substance use disorder benefits does not violate the no more restrictive requirement or the relevant data evaluation requirements because the plan impartially applies independent professional medical or clinical standards for both medical/surgical benefits and mental health and substance use disorder benefits in a manner that qualifies for the exception under proposed 26 CFR 54.9812–1(c)(4)(i)(E) and (c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(i)(E) and (c)(4)(iv)(D), and 45 CFR 146.136(c)(4)(i)(E) and (c)(4)(iv)(D), respectively. Moreover, the independent professional medical or clinical standards are not considered to be a discriminatory factor or evidentiary standard and, as written and in operation, the plan complies with the design and application requirements with respect to the NQTL, regardless of the fact that the application of the NQTL resulted in higher percentages of claim denials for mental health and substance use disorder benefits as compared to medical/surgical benefits."

ANALYSIS: IMPACT OF INDEPENDENT PROFESSIONAL CLINICAL STANDARDS

This Example 5 also illustrates a significant loophole that would allow plans to bypass multiple MHPAEA NQTL protections, many of which are strengthened in these Proposed Rules. This statement is unclear "The medical management requirement impartially applies independent professional medical or clinical standards in a manner that qualifies for the exception." What does impartial application mean? The example further states that the plan does not rely on "any other factors or evidentiary standards" and concludes that "the processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits

are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits."

Our interpretation of the language in this Example 5 is that the plan's use of "independent professional medical or clinical standards" is essentially sufficient to meet all NQTL requirements. As the term "impartially applies" is not defined, it would appear that no analysis is required, such as identification and definition of factors, evidentiary standards and comparability and stringency analyses of such. As the use of an "independent professional medical or clinical standards" exempts the plan from the relevant data evaluation requirement, the in-operation portion of a NQTL design and application comparative analysis is bypassed, as this example illustrates.

Moreover, if the denial rate for inpatient OON benefits is 30% for MH/SUD and 5% for M/S, this disparate outcomes data would be considered permissible and compliant because a plan chose an independent professional clinical standard. As discussed above, there is a wide range of MH/SUD independent clinical standards, many of which could be more stringent than M/S.

Example 13—Standards for provider admission to a network.

"Finally, proposed new Example 13 would illustrate how plans and issuers may comply with these proposed rules with regard to parity, including the requirement to collect and evaluate data, with respect to standards related to network composition, including standards for provider and facility admission to participate in a network or for continued network participation, methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of providers and facilities to provide covered services under the plan or coverage. As highlighted above, the proper design, administration, and composition of networks are essential to participants and beneficiaries having access to treatment for mental health conditions and substance use disorders in parity with access to treatment for medical conditions and surgical procedures, and this proposed example illustrates the steps that plans and issuers may take to improve such access.

In this proposed new example, a plan applies NQTLs related to network composition in the outpatient, in-network and inpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The facts of the example stipulate that the plan's NQTLs related to network composition for mental health and substance use disorder benefits satisfy the no more restrictive requirement and the design and application requirements in the outpatient, in-network and inpatient, in-network classifications. It further stipulates that the plan collects and evaluates all relevant data in a manner reasonably designed to assess the impact of the NQTLs related to network composition on access to mental health and substance use disorder benefits as compared with medical and surgical benefits and considers the impact as part of the plan's analysis of whether the NQTLs, in operation, comply with the no more restrictive requirement and the design and application requirements of these proposed rules.

The plan determined that the data did not reveal any material differences in access. That data included metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide

services in rural and urban regions who are in the plan's network; provider reimbursement rates; in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions); and survey data from participants on the extent to which they forgo or pay out-of-pocket for treatment because of challenges finding in-network providers. The efforts the plan made when designing and applying its NQTLs related to network composition, which ultimately led to its outcomes data not revealing any material differences in access to benefits for mental health or substance use disorders as compared with medical/surgical benefits, included making sure that the plan's service providers are making special efforts to enroll available providers, including by authorizing greater compensation or other inducements to the extent necessary, and expanding telehealth arrangements as appropriate to manage regional shortages. The plan also notifies participants in clear and prominent language on its website, employee brochures, and the summary plan description of a toll-free number available to help participants find in-network providers. In addition, when plan participants submit bills for out-of-network items and services, the plan directs their service providers to reach out to the treating providers and facilities to see if they will enroll in the network."

"The proposed new example would conclude that the plan does not violate 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), or 45 CFR 146.136(c)(4). The plan's NQTLs related to network composition comply with the no more restrictive requirement, the design and application requirements, and the relevant data evaluation requirements and the data does not reveal any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as a result of the actions the plan took (as set forth in the facts) when initially designing its NQTLs related to network composition.

Because the plan takes comparable actions to ensure that its mental health and substance use disorder provider network is as accessible as its medical/surgical provider network and exercises careful oversight over its service providers and the comparative robustness of the networks with an eye to ensuring that network composition results in access to in-network benefits for mental health and substance use disorder services, plan participants and beneficiaries can access covered mental health and substance use disorder services and benefits as readily as medical/surgical benefits. This is reflected in the plan's carefully designed metrics and assessment of network composition. The Departments recognize, however, that there are significant challenges to building networks of mental health and substance use disorder providers that result in parity. If, despite taking such comprehensive action in accordance with the requirements of proposed 26 CFR 54.9812–1(c)(4)(iv)(C), 29 CFR 2590.712(c)(4)(iv)(C), and 45 CFR 146.136(c)(4)(iv)(C), a plan's or issuer's participants, or beneficiaries still experience materially greater reliance on out-of-network, rather than in-network, mental health or substance use disorder benefits because of provider shortages that the plan or issuer cannot effectively address through no fault of its own, the Departments would not treat the plan or issuer as in violation of 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4), provided that the plan or issuer is otherwise in compliance with the requirements of these sections."

ANALYSIS: IMPACT OF INDEPENDENT PROFESSIONAL CLINICAL STANDARDS

This new Example 13 illustrates a compliant NQTL analysis for standards for provider admission to a network and lists multiple measures including quantitative outcomes metrics that a plan would need to provide to be compliant. BFF is concerned that the current definition of independent professional clinical and medical standards in the Proposed Rule would include multiple independent network

adequacy and access standards issued by state and federal governments, and/or national accreditation organizations such as NCQA or URAC. These network adequacy standards are clearly clinical or medical as they propose what types M/S and MH/SUD providers should be in a network, what access standards are required for adequate access, identification of what facility sub-types are required, and what level of access is needed for each. Many, if not all, of these independent standards do not have comparable standards for MH/SUD vs M/S. For example, the draft CMS QHP standards have one set of access standards for all MH/SUD facility programs (both inpatient and outpatient) while identifying multiple M/S sub-types of providers/facilities with specific standards for each. This creates a lower standard for MH/SUD. This is true for many state standards as well. Some plans today use these independent network adequacy standards as a source and an evidentiary standard and assert that compliance with these independent professional standards is evidence of a compliant NQTL of network adequacy and access.

BFF is concerned that such independent network adequacy standards would automatically be deemed non-discriminatory and compliant with the no more restrictive tests and would be exempt a plan from the relevant data requirements for all the in-operation metrics outlined in this example. It is unclear from the Proposed Rule whether the exception for independent professional clinical standards would apply to only the part of the NQTL to which the standards are applied, or to the entire breadth of the NQTL. As stated, we do not support the exception for independent professional clinical standards at all. We also foresee a tremendous loophole in NQTL compliance if the exception were to apply to an entire NQTL when the independent clinical standards are used for a part of an NQTL.

It is important to note that network adequacy standards are not designed, developed or applied with an eye toward or with the purpose of achieving parity in the design and application of network adequacy standards for MH/SUD benefits compared to M/S benefits. The use of such standards to permit an exception to key NQTL enforcement provisions of the Proposed Rule would undermine the Rule and MHPAEA's goal of access to behavioral health care.

F. Instructive Prior Guidance issued by the Departments

BFF takes note of the very instructive references to prior guidance that the Departments included in the introduction to the Proposed Rules. We cite to excerpts below of some of the very helpful and impactful prior guidance that has been issued:

"Specifically, the Departments have jointly issued 15 sets of FAQs with 96 questions, eight enforcement fact sheets, six compliance assistance tools and templates, seven reports to Congress, six press releases, and seven consumer publications. In general, the Departments' FAQs are designed to provide additional guidance and clarification on how MHPAEA applies in specific contexts and are informed by questions raised by interested parties and scenarios encountered in the context of the Departments' enforcement efforts. "

"FAQs Part 39 also provides guidance on how the law and regulations apply to treatments for eating disorders, opioid use disorder, and ASD, as well as exclusions for experimental or investigative treatments, and standards for provider admission to a plan's or issuer's network, including the methodology for determining reimbursement rates for mental health and substance use disorder providers.[66]"

"In addition to FAQs issued after the promulgation of the 2013 final regulations, the Departments have issued, generally every 2 years, an updated compliance program guidance document (the MHPAEA Self-Compliance Tool), which is intended to help plans and issuers, State regulators, and other interested parties comply with and understand MHPAEA and the additional related requirements under ERISA that apply to group health plans. The Departments most recently issued the MHPAEA Self-Compliance Tool in 2020 (2020 MHPAEA Self-Compliance Tool).[67] The 2020 MHPAEA Self-Compliance Tool includes an illustrative, non-exhaustive list of NQTLs, a process for conducting NQTL comparative analyses, a list of the types of documents and information that a plan or issuer should have available to support its analyses, and illustrations of specific fact patterns to aid in compliance.[68]"

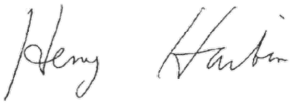
"The 2020 MHPAEA Self-Compliance Tool stresses that measuring and evaluating results and quantitative outcomes can be helpful to identify potential areas of noncompliance. For example, comparing a plan's or issuer's average reimbursement rates for both mental health and substance use disorder providers and medical/surgical providers against an external benchmark of reimbursement rates, such as Medicare, may help identify whether the underlying methodology used to determine the plan's or issuer's reimbursement rates warrants additional review. The 2020 MHPAEA Self-Compliance Tool notes that substantially disparate results are a red flag that a plan or issuer may be imposing an NQTL on mental health and substance use disorder benefits in a way that fails to satisfy the parity requirements. Other warning signs of potential noncompliance identified in the 2020 MHPAEA Self-Compliance Tool include generally paying at or near Medicare reimbursement rates for mental health or substance use disorder benefits, while paying much more than Medicare reimbursement rates for medical/surgical benefits, and reimbursing psychiatrists, on average, less than medical/surgical physicians for the same evaluation and management codes.[70]"

BFF found it very helpful for the agencies to summarize the extensive prior guidance issued in the Final Rule and since then. BFF recognizes that much of the new guidance in the Proposed Rules does not necessarily consist of new requirements but provides greater details and examples for much of the guidance provided over the years. Many issuers, plans and advocates have been requesting such additional examples of comparative analyses.

Even the new language on network composition and the data evaluation requirements, while providing greater detail and instruction, does not in many instances create new requirements. For example, prior guidance requests plans and issuers to identify all sources and evidentiary standards used for network admission standards and access. Many plans state that they use NCQA or other sources. NCQA, while not providing accreditation for MHPAEA, has numerous measures of network adequacy for MH/SUD and separately for M/S. Plans have consequently been providing outcomes data on compliance with many of the data elements identified in the Proposed Rules such as: out-of-network requests and claims analyses for both M/S and MH/SUD, data showing compliance with MH/SUD timeliness standards, development of and compliance with geo access measures, new patient availability, provider network shortages and market trends that impact utilization. Plans who use these sources are already monitoring and collecting these outcomes measures.

The Bowman Family Foundation appreciates the opportunity to submit comments on the Proposed Rules. If you have any questions or would like to discuss these comments in more detail, please contact Henry Harbin htharbin@aol.com or Beth Ann Middlebrook bethannmiddlebrook@gmail.com.

Sincerely,



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