AMERICAN BENEFITS COUNCIL

October 17, 2023

Submitted electronically via regulations.gov

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

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue, NW
Washington, DC 20210

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

Re: Requirements Related to the Mental Health Parity and Addiction Equity Act; Proposed Regulations

Dear Sir or Madam,

I write on behalf of the American Benefits Council ("the Council") in connection with the Proposed Regulations on Requirements Related to the Mental Health Parity and Addiction Equity Act (the "proposed regulations" or "proposed rules") issued by the U.S. departments of Health and Human Services (HHS), Labor (DOL) and Treasury ("tri-agencies"). We are also providing high-level comments on Technical Release 2023-01P, issued by DOL, related to network composition and enforcement safe harbors.

The Council is a Washington, D.C.-based employee benefits public policy organization. The Council advocates for employers dedicated to the achievement of best-in-class solutions that protect and encourage the health and financial wellbeing of their workers, retirees and families. Council members include over 220 of the world's largest corporations and collectively either directly sponsor or administer health and retirement benefits for virtually all Americans covered by employer-sponsored plans.

We begin by emphasizing that the Council and its member companies agree with the tri-agencies that mental health is essential to personal and societal well-being and that America is experiencing a mental health and substance use disorder crisis. Moreover, it is a long-standing belief of the Council and its member companies that mental health coverage is vital to the health and productivity of the workforce, including because mental health conditions and medical conditions are often comorbidities.[1] This is why, even though neither the Affordable Care Act (ACA) nor the Mental Health Parity and Addiction Equity Act (MHPAEA) mandate that large employers offer coverage for mental health and substance use disorder conditions, large employers voluntarily offer such coverage to improve employee well-being while simultaneously improving productivity and business performance.

Long before the COVID-19 pandemic, Council member companies were embarking on investing in innovative solutions to address the mental health and substance use disorder needs of their workforce. These strategies included supporting adoption of collaborative care models that integrate behavioral health with primary care, reducing the stigma associated with mental illness, enhancing employee assistance programs (EAPs) and telehealth offerings and combating the opioid crisis.[2]

When the pandemic hit, employers recognized the toll that isolation, stress and uncertainty was taking on their workers and built on these efforts to help working families across the country access the behavioral health care they needed to get through the crisis. The efforts of employers to expand access to mental health care are highlighted in the Council's *Silver Linings Pandemic Playbook: Shining a Light on Employee Benefits Innovation and Action*, which includes stories of expansions to EAPs, tele-mental health offerings and other mental health benefits and reductions in cost for many of these benefits.[3] And behind these examples were many more employers committed to addressing the behavioral health care crisis.

In fact, an informal survey of large employers conducted by the Council in late 2021 highlighted the commitment of employers to helping their employees through the mental health crisis, with an overwhelming percentage of respondents (87%) stating that supporting and/or expanding access to mental health care for employees is a top priority for their organization.[4] And just as the mental health crisis has continued

---

[1] *See* McKinsey Report, Mental Health in the Workforce: The Coming Revolution at https://www.mckinsey.com/industries/healthcare/our-insights/mental-health-in-the-workplace-the-coming-revolution.

[2] https://www.americanbenefitscouncil.org/pub/?id=2f21fbaf-9ed0-db9b-4aab-ceed75ea80b0.

[3] The American Benefits Council's *Silver Linings Pandemic Playbook* at https://www.americanbenefitscouncil.org/pub/7DD9EBE9-1866-DAAC-99FB-6434BC09AA06.

[4] In late 2021, the Council fielded a survey open to 858 benefits administrators at large employers with operations in the United States. The survey received 70 total responses (including seven partial responses), representing a cross-section of companies based on size and industry.

beyond the pandemic, so has employers' commitment to providing affordable, high-quality mental health coverage. And we have heard that, even as some companies are having to make efforts to cut costs generally, they continue to spend additional resources on mental health coverage and resources, due to the importance of employee mental health.

It is also the case that health insurance providers and third party administrator (TPA), who employers work with to offer coverage, have been focused on improving behavioral health provider networks. According to a 2022 AHIP survey, the number of in-network behavioral health providers has grown by an average of 48% in three years among commercial health plans.[5] In addition, the overwhelming majority of health plans (89%) are actively recruiting mental health care providers, including practitioners who reflect the diversity of the people they serve (83%), and 78% have increased payments to providers in efforts to recruit more high-quality professionals to their plan networks. In addition, employers oftentimes work with specialty mental health vendors, in addition to their TPA or carrier, to enhance their behavioral health networks and to leverage the expertise of the specialty vendor to increase the quality of care, including reducing visit wait times.

To be clear, we understand that, despite actions employers and their service providers have taken to expand access to mental health care, challenges and barriers remain in accessing care, notably the shortage of mental health providers, in general, and lack of in-network providers, specifically. The increase in behavioral health needs has further strained the country's already overburdened mental health system. The Bureau of Health Workforce, Health Resources and Services Administration at HHS estimates that 164 million people in the United States are living in "Mental Health Care Professional Shortage Areas", estimating that an additional 8,289 providers are needed to fill this gap nationwide.[6] This means that almost half of Americans reside in areas where patients have difficulty accessing mental health care services because of a shortage of mental health providers.

To address this issue, we have encouraged Congress to focus its efforts to combat the mental health crisis on removing this fundamental barrier to care – the shortage of mental health providers and those who are willing to join networks. And we have provided extensive recommendations to Congress, including on strengthening the workforce, increasing integration, coordination, and access to care, and furthering the

[5] See AHIP July 2022 Mental Health Survey at https://www.ahip.org/resources/ahip-mental-health-survey.

[6] See HRSA's Healthcare Shortage Workforce Areas at https://data.hrsa.gov/topics/health-workforce/shortage-areas (last visited September 19, 2023).

use of telehealth. And we are continuing our efforts given the critical importance of these issues.[7]

As to the specific matter at hand, the Council, which was engaged when mental health parity legislation was developed, has been and continues to be strongly supportive of mental health parity. While we understand the tri-agencies' view, as expressed in the preamble, that compliance with MHPAEA has not met expectations, we cannot overstate how important compliance is to employers and how many resources, including time, effort and money, Council members and the employer community as a whole have invested in compliance with MHPAEA.

It is also the case that the lack of clear and meaningful implementing regulations and guidance has been a significant barrier to employer-sponsored plans meeting their compliance obligations, specifically with regard to the "comparative analysis" requirement under the Consolidated Appropriations Act, 2021 ("CAA"). This is why we have requested additional guidance over the last several years, and we appreciate that the tri-agencies have recognized the need for additional regulatory clarification and guidance, notwithstanding our comments below. We are hopeful that the current rulemaking, once stakeholder feedback is incorporated, will support efficient and widespread compliance.

With this context in mind, below we provide specific comments urging the tri-agencies to make important changes to, and clarification of, certain aspects of the proposed rules. It is our view that the proposed regulations are well-intended, with the goals of supporting access to mental health and substance use disorder benefits and bolstering MHPAEA compliance – goals we share. It is also the case, however, that the proposed rules are extensive and will impose significant new and costly requirements on group health plans. We have identified several aspects of the proposed rules that raise significant concerns, including because they could have unintended negative impacts on participants and beneficiaries, are unworkable, or require substantial additional clarification. While employers are more than willing to do their part to support the mental health of employees and their families, it is essential that any final regulations avoid undermining safe, effective, affordable coverage and are clear, fair and workable.

[7] https://www.americanbenefitscouncil.org/pub/CE9ADF59-1866-DAAC-99FB-E648A34C30AE. See also "Addressing the Healthcare Staffing Shortage," by Definitive Healthcare, finding that mental health providers are among the top provider categories most impacted by staffing shortages, at https://www.definitivehc.com/resources/research/healthcare-staffing-shortage.

In the list below, we provide a brief summary of the categories of comments included in this letter, which among other comments, are explained in much more detail below:

- **List of Nonquantitative Treatment Limitations (NQTLs)**. To enable compliance, we ask that the tri-agencies provide a public list of NQTLs, which the tri-agencies could update periodically, for which plans and issuers must have a comparative analysis prepared, and that in the event the tri-agencies identify additional NQTLs, the tri-agencies would be able to request a comparative analysis for those NQTLs but plans and issuers would be given sufficient time to provide the additional information. This is necessary because it is extremely difficult, and in some cases impossible, to have a comparative analysis at the ready, for each NQTL, if the full scope of what constitutes an NQTL is not known or understood.

- **Substantially All/Predominant Test**. In order to allow plans to continue to use medical management techniques which protect patients and ensure high-quality affordable care, we ask that the tri-agencies decline to finalize the application of the "substantially all/predominant test" to mental health and substance use disorder benefits NQTLs.

- **Required Use of Outcomes Data and "Material" Differences in Outcomes**.

    - As to the general rule**,** we acknowledge the tri-agencies' focus on objective data and outcomes and we also note our concerns with the proposal. We also ask for a uniform set of outcomes data that must be collected and analyzed; that "material difference" be defined; for more information on how a plan can take a reasonable action to address a material difference; and that a lack of a material difference in outcomes data be used to deem a plan to be compliant (or to a create a strong presumption of compliance).

    - As to the rules for network composition, we explain that we understand the focus on the quality of networks and how the immense shortage of providers has undermined efforts to build mental health provider networks. With that context in mind, we ask that instead of applying a heightened material difference standard to the network composition NQTL, that the final rules apply the material difference standard that applies to all other NQTLs. We also ask for more information on how a plan or issuer could demonstrate a provider shortage and its impact on network composition and how a plan or issuer could account for the use of telehealth.

- **Exceptions**. We express support for the exceptions provided from some aspects of the NQTL rules, for NQTLs based on independent medical or clinical

standards and NQTLs designed to detect or prevent and prove fraud, waste and abuse and ask that additional clarity, and definitions inclusive of the evidence-based and data-driven standards typically used, be provided for each exception.

- **Provision of Meaningful Benefits**. For the new "meaningful benefits" rule, we ask that the term "meaningful benefits" be defined, for clarity and administrability and because we are concerned that without a definition this term could be over-interpreted, contrary to the fact that MHPAEA is not a coverage mandate. As to the specific definition, we ask that it be defined to mean the plan provides at least one primary treatment for the condition or disorder at issue, in each classification.

- **NQTL Comparative Analysis**. Regarding the comparative analysis:

    - We thank the tri-agencies for responding to our requests for more detailed guidance. However, we ask the tri-agencies to provide examples of compliant comparative analyses and we note the central role of TPAs in preparation of comparative analyses.

    - We ask that the tri-agencies decline to finalize the requirement that a named fiduciary certify the comparative analysis, as it will be extremely difficult for plan fiduciaries to make this certification, because of the complexity of the rules, and the unique and numerous data comprising the analysis. Instead, we note that fiduciaries should be able to hire experts, as they are obligated to do when expertise is required. If this requirement is adopted, we ask that the scope of the requirement be clarified.

    - We ask for additional clarification on the circumstances in which a plan must provide a comparative analysis to participants and beneficiaries (and in some cases providers), in the event of an adverse benefit determination.

    - We ask for procedural guardrails for plans and issuers prior to a final determination of noncompliance, including a form of independent review.

- **Applicability Date and Good Faith Standard**. We express concerns with the proposed 2025 applicability date and explain the extensive work that will be needed to implement final rules, which in their proposed form, include many new, extensive requirements. We ask that the tri-agencies provide at least a year between finalization and application of any final rules, so that the rules apply for plan years beginning on or after one year from the date the final regulations are issued. We also ask that the tri-agencies apply a good faith compliance standard during the initial period of implementation, due to the complexity of the rules.

- **Technical Release**. We express support for the development of an enforcement safe harbor for plans to demonstrate through data that they meet or exceed standards with respect to the NQTL for network composition and request clarity and provide other comments on the data to be analyzed.

We appreciate the tri-agencies' efforts on these important issues and are happy to discuss any of these comments in more detail if that would be useful.[8]

LIST OF NQTLS

Under the current mental health parity regulations, the tri-agencies provide an illustrative list of NQTLs. The proposed regulations retain the list, with some revisions, and confirm that the list is non-exhaustive. The tri-agencies note that they have added examples to address additional NQTLs, mention certain other NQTLs in the preamble, and indicate that others still may be listed in periodic reports to Congress and in the MHPAEA Self-Compliance Tool. The tri-agencies note that some stakeholders have requested an exhaustive list of NQTLs to provide clarity for the sake of compliance, while others have asked the tri-agencies not to provide such a list because doing so could encourage plans and issuers to create new NQTLs outside of the list or rename NQTLs to circumvent the requirements. The tri-agencies explain they have decided to propose that the list is non-exhaustive because of the broad scope of the meaning of the term NQTL and because terminology may vary.

As we have previously explained to the tri-agencies, it is extremely difficult, and in some cases, impossible, to have an NQTL comparative analysis at the ready, for each NQTL, if the full scope of what constitutes an NQTL is not known or understood, due to the broad and vague definition of what is an NQTL. And contrary to the concern expressed that plans and issuers would use a list of NQTLs to circumvent the rules, a list of NQTLs is needed precisely because plans and issuers want to be sure they are fully compliant with the requirements for all NQTLs. This is particularly important due to the serious penalties for failing to comply with the comparative analysis requirement and because of the extensive resources (and time) that will be required to complete each comparative analysis, for each NQTL, under the proposed regulations, if finalized. That said, we understand that the tri-agencies are hesitant to provide a fully exhaustive list, due to concerns that the tri-agencies may later identify a new type of NQTL and want flexibility in enforcement and the ability to respond to new plan designs.

In order to address both the tri-agencies' concerns and the need for clarity and certainty for plans and issuers, we ask that the tri-agencies provide a list of NQTLs for which plans and issuers must have a comparative analysis prepared. In the event the

[8] We note that we are separately submitting a comment letter with several other employer and issuer groups that amplify the comments made in this letter.

tri-agencies identify an additional NQTL, the tri-agencies would be able to request a comparative analysis for that NQTL but plans and issuers would be given sufficient time (*e.g.*, 90 days) to provide the additional information, due to the work that would be needed to prepare the analysis, in particular because the analysis will address a novel area. Additionally, for any NQTLs not listed in the MHPAEA regulations as an NQTL, the final regulations could state that, as a threshold matter, the tri-agencies will work with a plan or issuer to determine whether certain plan activity is considered an NQTL (*e.g.*, case management that is an additive program, rather than treatment limitation), and if the tri-agencies determine it is an NQTL, the timeframe to supply an analysis would be extended to permit plans and issuers sufficient time to conduct an analysis when requested to do so. The tri-agencies would also be able to update the public list of NQTLs over time, as new NQTLs are classified as such by the tri-agencies.

SUBSTANTIALLY ALL/PREDOMINANT TEST

Under the proposed rules, in order for an NQTL to apply to a mental health or substance use disorder (MH/SUD) condition, it must first apply to "substantially all" (at least two thirds) of M/S conditions in the same classification, and then, only the most common (or "predominant") variation of the NQTL that applies to M/S conditions may apply to MH/SUD conditions (the "substantially all/predominant test").

We appreciate that the apparent goal of this rule is generally to support access to mental health care and make the NQTL test less subjective. However, we are concerned that, despite its intent, this rule could actually have negative, although unintended, impacts on participants. This is because applying the substantially all/predominant test to NQTLs could eliminate common medical management practices designed to improve patient safety, health outcomes, quality and affordability.

We understand that some may be of the view that less medical management is always beneficial for participants – but based on our members' experience providing benefits for many millions of Americans, we want to emphasize that is not the case. Medical management is not applied to undermine access to care. We have heard directly from our plan sponsor members that medical management is driven by quality concerns, not cost concerns. Moreover, medical management policies are resource intensive and not implemented lightly; they are used strategically to address important quality and safety issues. More specifically, medical management is essential to manage quality and cost; confirm the level of care is appropriate; ensure treatments are safe, medically necessary, accord with generally accepted standards of care and are clinically proven; and help prevent unexpected out-of-pocket costs for participants and beneficiaries seeking non-covered or not medically necessary services. As noted above, providing access to mental health care is of the utmost importance to employers -- but not just access to *any* care, rather, access to high-value, effective, safe, affordable care. To

do this, plans need tools to root out care that is not safe, high-quality, evidence-based, or necessary.

We have heard several specific concerns that certain medical management practices could be undermined in the MH/SUD context (because they are not applied to substantially all M/S benefits or are not the predominant variation of the NQTL that applies to M/S benefits), including, for example, that the new standard could require the removal of concurrent review for inpatient MH/SUD services. This removal of concurrent review is concerning because concurrent review as applied to MH/SUD services protects patients from unnecessary risk and supports improved outcomes for patients by ensuring individuals are not receiving inpatient care for longer than is medically necessary or advisable, which is an important control for this kind of high-level care. In contrast, many medical/surgical inpatient services are not subject to concurrent review because the related providers are reimbursed a fixed dollar amount regardless of the patient's *length* of stay (based on Diagnosis Related Groups (DRG)). [9] As a result, the concurrent review of such medical/surgical services would not impact the inpatient stay given the provider is reimbursed the same amount regardless of the length of the inpatient stay. There are only a small number of DRGs utilized for MH/SUD services, in part because the length of stay for inpatient care for MH/SUD services is much less standard.

Another concern is that under the proposed standard, plans likely would not be permitted to impose prior authorization on any benefits in the outpatient MH/SUD classification. This is because there are so many more medical/surgical services in the outpatient benefit classification than MH/SUD services, and plans and issuers likely will not impose prior authorization on at least two-thirds of the outpatient medical/surgical benefits and, therefore, will not meet the "substantially all" test. However, in the context of the MH/SUD specialty, prior authorization is a crucial tool for certain services to ensure patients are receiving high-value, safe care and to protect against care that is ineffective, unsafe or not evidence-based.[10] This is of particular

[9] Medicare and commercial insurers reimburse for medical/surgical hospital services based on DRGs. The DRGs are a patient classification scheme which provides a means of relating the type of patients a hospital treats (*i.e.*, its case mix) to the costs incurred by the hospital.

[10] *See* "Improving the Quality of Health Care for Mental and Substance-Use Conditions" by the Institute of Medicine of the National Academies, citing numerous studies showing problems in the quality of care for mental and/or substance-use problems and illnesses including failure to provide evidence-based care, variations in care that occur when evidence-based care is lacking and unsafe care, at https://nap.nationalacademies.org/catalog/11470/improving-the-quality-of-health-care-for-mental-and-substance-use-conditions. *See also* GAO Report "HHS Should Facilitate Information Sharing Between States to Help Prevent and Address Maltreatment in Residential Facilities", January 2022, finding issues with reporting and monitoring maltreatment at youth treatment facilities and recommending improved state oversight and stronger enforcement to hold facilities accountable, at https://www.gao.gov/assets/gao-22-104670.pdf; "Some Addiction Treatment Centers Turn Big Profits by Scaling Back Care," KFF, January 31, 2023, addressing private equity investment in treatment centers and finding that only a handful of states require that licensed addiction treatment centers offer

concern in the MH/SUD space because of the existence of providers who promote treatment to families in need, notwithstanding the fact that the care provided is often low-quality, ineffective, or unsafe for participants and possibly extremely costly, which could leave patients with a significant financial burden and/or adverse outcomes. In addition, for certain treatments that are related to a specific diagnosis and requiring long-term services, prior authorization is important to assure the appropriateness and quality of the treatment as well as the patient's long-term wellbeing.

We also note that we have heard concerns that based on the way the rule is designed (*i.e.*, the ability to impose medical management on MH/SUD services is predicated on application of medical management to M/S), in some instances, plans or issuers could be forced to subject more M/S services to medical management to allow the plan to continue to apply medical management to MH/SUD benefits to ensure those benefits are appropriate and medically necessary. We do not have a sense of the extent to which this will occur but raise the possibility for the tri-agencies to consider given that such a result would seem contrary to sound health policy in that it would not increase access to mental health benefits for participants and beneficiaries but rather result in the application of potentially unnecessary and undesired medical management practices to M/S benefits.

We have also heard concerns that disallowing front-end reviews of MH/SUD benefits will create uncertainty for consumers, who may end up with a retrospective review of medical necessity which could mean that after services are rendered, consumers will learn the services were deemed not medically necessary and so are not covered by the plan. Consumers and providers generally benefit from certainty on payment and clarity on coverage prior to undergoing treatment – not after the fact. In addition, we note that removal of medical management from MH/SUD benefits, which is an essential tool to ensure only care that is needed is covered, and the increased cost of compliance in implementing this complex piece of the rule, should be expected to increase costs to the plan, and as a result, to participants and beneficiaries.

In order to protect patients and ensure high-quality, affordable care, and given the essential need for plans to be able to apply appropriate medical management in the MH/SUD contexts, we ask that the tri-agencies decline to finalize this aspect of the proposed rules. We appreciate the sensitivity to the fact that, as noted above, in some cases these medical management techniques are applied more often to MH/SUD care

---

medication for opioid use disorder and follow other best practices, at https://kffhealthnews.org/news/article/some-addiction-treatment-centers-turn-big-profits-by-scaling-back-care; and "Lack of Buprenorphine Access for Adolescents in Residential Facilities," NIH, June 27, 2023, finding that only 1 in 4 residential facilities that treat adolescents in the U.S. for opioid use disorder offer buprenorphine, the sole FDA-approved medication for 16- to 18-year-olds, revealing a lack of access to an effective treatment for opioid use disorder in adolescents, at https://www.nih.gov/news-events/nih-research-matters/lack-buprenorphine-access-adolescents-residential-facilities

than M/S care and how, at first blush, it could seem desirable to substantially undermine the application of medical management to MH/SUD benefits. But it is essential for the tri-agencies to understand that based on our members' experience, such a change could actually harm patients by reducing the quality of care, putting participants at risk of receiving ineffective or unsafe treatments and of being subject to greater financial liability.

It is also important to note that while we are recommending that the tri-agencies not finalize the application of the substantially all/predominant test to NQTLs, medical management techniques, to the extent they constitute NQTLs, will still be subject to the host of other substantial requirements that would apply to NQTLs if the rule is finalized, including the proposed use of outcomes data and design and application requirement, to ensure that these important aspects of benefit design are provided in parity.

We also note that, while we appreciate the exceptions the tri-agencies propose for NQTLs applying independent professional medical or clinical standards or standards designed to detect or prevent and prove fraud, waste and abuse, which we discuss later in this letter, those exceptions do not fully address our members' concerns with the application of the substantially all/predominant test to NQTLs because of the varied ways medical management techniques are applied in plans, to improve health outcomes and reduce waste and ensure patients only receive medically necessary care.[11]

REQUIRED USE OF OUTCOMES DATA AND "MATERIAL" DIFFERENCES IN OUTCOMES

In General

Under the proposed regulations, when designing and applying an NQTL, a plan must collect and evaluate "relevant data" in a manner reasonably designed to assess the impact of the NQTL on access to MH/SUD benefits and M/S benefits. In general, relevant data includes the number and percentage of claims denials and any other data relevant to the NQTL required by state law or private accreditation standards. The proposed regulations provide that the tri-agencies may specify in guidance the types, form and manner of collection and evaluation for the required data.

Except for NQTLs related to network composition, discussed below, under the proposed regulations, to the extent the relevant data shows "material differences" in access to MH/SUD benefits as compared to M/S benefits, the differences will be considered a "strong indicator" of noncompliance. In that case, the plan must take

[11] If the application of the substantially all/predominant test to NQTLs is retained, additional clarification is needed on the key terms and how they apply. For example, for "predominant variation", "variation" has not yet been defined and there is confusion about how that concept applies to the provider reimbursement NQTL in particular.

reasonable action to address the material differences in access as necessary to ensure compliance and must document the actions taken.

We begin by noting that we understand the tri-agencies' focus on objective data and outcomes. We also note that the proposal is a major change and will require the collection and analysis of substantial data and that the rule has caused concern because it appears to impose a nearly un-rebuttable presumption of noncompliance if a material difference is identified, even if the NQTL satisfies all the other prongs of the NQTL test and even if the differences in outcomes have nothing to do with noncompliance. In order for these rules to be workable, we provide the following recommendations:

- For plans and issuers to implement this rule, we ask that the tri-agencies provide a uniform set of outcomes data that must be collected and analyzed. Requiring plans and issuers to collect and analyze "any other relevant data" is too broad and unclear to be operationalized. This list of required outcomes data could operate similar to the NQTL list we suggested earlier – that is, the tri-agencies could provide a clear list of outcomes data that plans and issuers must analyze and have at the ready, but the tri-agencies may also request additional outcomes data, allowing reasonable time for plans and issuers to produce that data.

- To make this rule administrable, fair and clear, we ask that the tri-agencies define "material differences." Without a definition, there will be a high degree of concern and confusion, including because of the significant consequences associated with non-compliance and because of the importance to employers of complying with mental health parity. There is also some concern that, without a definition, DOL and HHS and their different regional offices may, inadvertently, apply the term in an inconsistent manner, which would only add to confusion among stakeholders. As to the definition itself, we ask that the tri-agencies use a definition that sets a high-standard for what constitutes a material difference, so that clear outliers and major differences in outcomes are identified rather than moderate variations in outcomes which are often attributable to factors beyond the control of the plan or issuer.

- We also ask that the tri-agencies define what constitutes a "reasonable action" that plans and issuers are required to take to address a material difference. This is especially important for NQTLs that are common plan structures, like network composition, and not benefit limitations.

- We also note that if there are material differences, then the plan or issuer has a burden of proving compliance, but if the differences are immaterial, the agencies will not rely on the data to demonstrate compliance. In this regard the rule is not symmetrical. We ask the tri-agencies to modify the rule so that where there are no material differences in outcomes data, the plan or issuer will be deemed to be in compliance or there will be a strong presumption of compliance.

- In applying the material difference standard, we also ask that the tri-agencies take into account any relevant context. For example, we have heard concerns with the application of this standard to NQTLs for prescription drugs. This is because there are so many more drugs for M/S than MH/SUD and so the percentages of MH/SUD drugs to which NQTLs apply may be higher than M/S drugs but that is only because the denominator is so much lower for MH/SUD drugs. We ask the tri-agencies to take context such as this into account in applying the material difference standard in different circumstances.

Outcomes Data Related to Network Composition

In addition to the above requirements, for NQTLs related to network composition, relevant data includes additional elements – namely, in-network and out-of-network utilization rates, 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). In addition, in contrast to all other NQTLs for which a material difference in outcomes data is a strong indicator of noncompliance, for NQTLs related to network composition, a plan automatically fails to comply if the relevant data shows material differences in access to in-network MH/SUD benefits as compared to in-network M/S benefits.

On this topic, we begin by noting that we understand why the tri-agencies are focused on this issue and we believe that access to high-quality, in-network mental health and substance use disorder providers is a key component of ensuring access to mental health care. This is why employers are greatly troubled by the shortage of in-network providers and have taken great efforts, along with their service providers, to attempt to strengthen their mental health networks. But as noted above, this has been a challenge due to the shortage of mental health providers in general and lack of providers willing to join networks, coupled with the increase in mental health needs. As noted above, over 160 million Americans live in an area where there is a mental health workforce shortage and over 8,000 providers are needed to fill this gap.[12] This is the backdrop for the Council's continued advocacy in Congress for policies that will strengthen and expand the mental health workforce and leverage telehealth to expand access to care.

This context is essential in evaluating the proposal by the tri-agencies that if there are material differences in outcomes data related to network composition, there will be a *per se* violation of the mental health parity rules. Notwithstanding our support and efforts toward strengthening networks, this heightened standard for the network composition NQTL is not appropriate or reasonable, given the fact that substantial key elements impacting the ability of plans to develop strong networks, namely a national

[12] See HRSA's Healthcare Shortage Workforce Areas at https://data.hrsa.gov/topics/health-workforce/shortage-areas (last visited September 19, 2023).

workforce shortage of MH/SUD providers and the unwillingness of providers to join networks, persist.

Because it will not be feasible to meet these standards in some regions due to the lack of available MH/SUD providers, our members are concerned that plans and issuers could be forced to choose between accepting lower quality providers into networks, which could compromise outcomes and patient safety, or retain existing quality standards and be out of compliance. Because of these major issues, we ask that in the final rules, instead of applying a heightened *per se* violation standard when a material difference in outcomes is identified, the tri-agencies apply the same material difference standard to the network composition NQTL that will apply to all other NQTLs (*i.e.*, that a material difference in outcomes is a strong indicator of noncompliance).

We appreciate that the tri-agencies recognized in the preamble that shortages of mental health and substance use disorder providers could pose challenges to issuers, plans and their service providers. And we also appreciate that the tri-agencies noted that if, despite taking appropriate action, the relevant data continues to reveal material differences in access, such as, because of provider shortages that the plan or issuer cannot effectively address through no fault of its own, the tri-agencies would not cite such a plan or issuer for failure to comply with the material difference outcomes data rule. The tri-agencies go on to say that plans and issuers should be prepared to document the actions they have taken and to demonstrate why any disparities are attributable to provider shortages in the geographic area, rather than their NQTLs related to network composition.

While we very much appreciate the tri-agencies' recognition of the challenges confronting plans and issuers regarding network composition, this does not alleviate our concerns with the heighted standard in the proposal, where a material difference results in an immediate, *per se* violation – especially given our understanding of how widespread and complex the issues are related to the shortage in the labor supply of MH/SUD providers. It is also unclear what information a plan or issuer would need to provide to demonstrate in fact a provider shortage and how the tri-agencies would consider that information, including as it relates to allowing a plan or issuer to avoid a final determination of noncompliance. We ask that the acknowledgement of the provider shortage be retained and added to the regulatory text if the tri-agencies finalize the outcomes data requirement in any form.

As to the specific data that will be evaluated regarding network composition, we urge the tri-agencies not to include a relative comparison of provider reimbursements to billed charges for purposes of this test. This is because billed charges are an arbitrary amount determined unilaterally by an individual provider and generally are not tied to any standard. We do support the use of data that compares provider reimbursement to Medicare reimbursement rates because, unlike billed charges, Medicare rates are an

unbiased, third-party measurement beyond the control of plans and can be viewed as reliable.

We also ask the tri-agencies to consider the role of telehealth in developing the rules regarding network composition. As the tri-agencies are aware, the COVID-19 pandemic represented a substantial shift in the way many Americans sought and received MH/SUD treatment. In addition to expanding the method by which a patient can receive treatment, telehealth allows plans and insurers to address regional provider shortages in ways that alleviate immediate demand while they continue working to grow local provider networks for in-person services.[13] We recognize that telehealth-only MH/SUD treatment may not be appropriate for every patient's need, but telehealth can help increase access, fill gaps left by provider shortages and is often preferred by some patients for its convenience. However, the proposed rules offer no substantive consideration of or credit for the ways telehealth has increased access to patient care for MH/SUD treatment and addressed longstanding provider shortages. If network adequacy is to be evaluated, a concrete method to judge the access impacts of telehealth must be an included consideration and should be taken into account, including in the development of any rules around time and distance standards.

Lastly, quite often, employers hire specialty behavioral health companies, including carve out vendors, to provide behavioral health provider networks and other services to increase access to and quality of mental health coverage and support. We ask the tri-agencies to keep this type of plan design in mind in developing final regulations, to ensure that plans that utilize specialized vendors are able to get credit for the network and services offered, in the mental health parity compliance assessment generally and specifically with regard to the evaluation of network composition. Rules that account for specialized vendors will help support employers' efforts to enhance mental health care and coverage, which is wholly consistent with the tri-agencies' broader objectives in this rulemaking.

EXCEPTIONS

Under the proposed rules, the tri-agencies provide limited exceptions for some aspects of the NQTL rules. Specifically, the proposed regulations contain an exception from the substantially all/predominant test, "design and application" requirements and outcomes data requirements if an NQTL impartially applies independent professional medical or clinical standards. In addition, the rules provide an exception from the

[13] See "What's Working to Expand Behavioral Healthcare Access: 5 Best Practices", by Mercer, October 5, 2023, discussing how access to tele-behavioral healthcare is a top factor explaining increased access to mental health care, at https://www.mercer.com/en-us/insights/us-health-news/whats-working-to-expand-behavioral-health-care-access/.

substantially all/predominant test and "design and application" requirements if the NQTL applies standards to detect or prevent and prove fraud, waste and abuse.

In explaining these exceptions, the tri-agencies note that they do not intend to interfere with a plan's or issuer's attempts to ensure that coverage for benefits for the treatment of mental health conditions and substance use disorders is consistent with generally accepted independent professional medical or clinical standards. Similarly, the tri-agencies state that they do not intend to prevent plans and issuers from applying reasonably designed and carefully circumscribed measures adopted for the purpose of detecting or preventing and proving fraud, waste and abuse, noting that these types of provisions generally improve and help to ensure appropriate care for participants and beneficiaries, rather than restrict access to needed benefits.

We very much appreciate the inclusion of these exceptions and strongly urge the tri-agencies to retain these provisions in the final regulations. We agree with the tri-agencies that use of these types of measures are not at all intended to restrict access to care, but instead ensure participants receive appropriate care and that employer and employee healthcare spending are not diminished through fraud, waste or abuse.

For plans and issuers to feel confident relying on these exceptions, it is essential that the final regulations provide clear definitions, to avoid a situation in which a plan or issuer uses a good faith interpretation of either term but then finds itself subject to a contrary tri-agency interpretation as part of a routine audit or enforcement action. We recommend that for the independent professional medical or clinical standards exception, the tri-agencies provide a definition that includes specific examples of acceptable independent standards, such as:

- Professional standards of safety and effectiveness recognized in the U.S. for diagnosis, care, or treatment, including third-party criteria such as InterQual Behavioral Health Criteria; Milliman Care Guidelines; American Society of Addiction Medicine ("ASAM") Criteria; Level of Care Utilization System ("LOCUS") guidelines; Child and Adolescent Level of Care/Service Intensity Utilization System ("CALOCUS-CASII") guidelines; and Medicare National and Local Coverage Determination guidelines.

- Peer-reviewed scientific studies and medical literature, from which a higher level of evidence and study quality is more strongly considered in determinations.

- Independent experts in the field.

- Nationally recognized drug compendia resources such as Facts & Comparisons®, DRUGDEX® and The National Comprehensive Cancer Network® ("NCCN"®) Guidelines.

- Medical association publications, such as those from American Society of Addiction Medicine and the American College of Obstetricians and Gynecologists.

- Government-funded or independent entities that assess and report on clinical care decisions and technology such as the Agency for Healthcare Research and Quality (AHRQ), Hayes Technology Assessment, Cochrane Reviews, National Institutes for Health and Care Excellence (NICE).

- Published expert opinions, including in UpToDate.

- Expert panels convened by accrediting organizations.

These clinical standards are widely relied upon by plans and issuers, and the tri-agencies' inclusion of these clinical standards as examples, as well as other standards the tri-agencies determine may be appropriate, would help promote uniform MHPAEA enforcement and compliance nationwide. It is important to note that any list provided by the tri-agencies should be non-exhaustive, including to provide flexibility to plans if needed and because standards change over time and some could become outdated and new standards could be added.

We also recommend that the tri-agencies establish a standard for the fraud, waste and abuse exception. At the very least, the tri-agencies should provide an example of how plans and issuers would be able to utilize this exception, although any list of examples should be non-exhaustive to allow for flexibility and to account for the range of possible standards. The tri-agencies should explain the documentation a plan or issuer should provide to fit within the exception and if the tri-agencies anticipate requesting evidence from plans or issuers, the tri-agencies should specifically list the required information in the final rule to equip plans and issuers with the knowledge and tools to comply with MHPAEA.

PROVISION OF MEANINGFUL BENEFITS

The proposed regulations provide that if a plan or issuer provides any benefits for a mental health condition or substance use disorder in any classification of benefits, as defined under the rules, benefits for that mental health condition or substance use disorder must be provided in every classification in which M/S benefits are provided. For this purpose, if a plan or issuer provides any benefits for a mental health condition or substance use disorder in any classification, the plan or issuer would not be considered to provide benefits for the mental health condition or substance use disorder in every classification unless the plan or issuer provides "meaningful benefits" for treatment for that condition in each classification, as determined in comparison to the benefits provided for M/S conditions in the classification.

The tri-agencies explain that this requirement is intended to ensure that, when plans and issuers cover benefits for a range of services or treatments for M/S conditions in a classification, they cannot provide, for example, only one limited benefit for a mental health condition or substance use disorder in that classification. The tri-agencies also request comments on this proposal, including whether and how to define ''meaningful benefits'' and whether it would be more practical, for example, to require plans and issuers to provide coverage for benefits for the ''primary or most common or frequent types of treatment for a covered condition or disorder'' in each classification in which M/S benefits are provided.

For purposes of clarity and administrability, it is essential that the term "meaningful benefits" be defined. We are concerned that, without a definition, the term could be over-interpreted by some to mean that plans and issuers must cover all or the vast majority of possible doctor-recommended treatment, including services with considerable quality or efficacy concerns, such as some types of substance use disorder treatments and therapies that raise quality and safety concerns, as well as emerging, unproven treatments. Plans make coverage decisions based on a variety of critical factors such as quality, safety and efficacy of treatments and services and this rule should not undermine the ability of plans to make these decisions in the best interests of the consumers they serve.

As to the specific definition, we recommend that the tri-agencies define the term "meaningful benefits" to mean that the plan or issuer provides at least one primary treatment for the condition or disorder in a classification. We also ask that the rules surrounding what constitutes a primary treatment allow plans to utilize objective criteria and that the standard be clear and workable, so that plans have the certainty they need to comply. Our members have also suggested the definition of primary treatment could be further developed through additional notice and comment rulemaking or a request for information. This would be consistent with the fact that MHPAEA is not a coverage mandate, would protect against overly expansive interpretations of the term and would give plan sponsors the ability to design benefits based on quality, efficacy and safety. It would also meet the tri-agency goal reflected in the meaningful benefits rule to support access to primary treatments for mental health conditions and substance use disorders. We also ask that the tri-agencies provide additional examples of the meaningful benefit rule, as applied.

NQTL Comparative Analysis

In General

The proposed regulations add to the mental health parity regulations a new section to address the comparative analysis required by the CAA, including content requirements and information on the process for submission to the tri-agencies.

As we have previously indicated, notwithstanding employers' commitment to compliance with mental health parity and the significant resources committed to compliance, the inexplicit existing regulatory and statutory text and lack of sufficient guidance on the comparative analysis requirement has caused frustration and confusion, and it has been extremely difficult for plan sponsors and their service providers to comply with this requirement in the absence of clear guidance. This is an issue we hear about constantly from plans sponsors and why we have repeatedly requested guidance over the last several years. Although questions remain as to how to develop a fully compliant comparative analysis, we thank the tri-agencies for responding to those requests by providing the detail included in the proposed regulations.

We do note that we continue to hear from our plan sponsor members that it would be very helpful if the tri-agencies were to provide an example (or examples) of a compliant comparative analysis (which could be a de-identified analysis that the tri-agencies have reviewed), to further show what is needed to comply. We urge the tri-agencies to continue to consider what additional guidance is possible that would further support compliance with the comparative analysis requirement, and we look forward to the forthcoming updates to the MHPAEA Self-Compliance Tool.

We also reiterate, and cannot overemphasize, that employers have worked extremely hard to try to comply with the comparative analysis requirement and have spent significant resources, with the help of experts, including service providers. Employers have also, at times, struggled to find service providers who would aid in the preparation of the analysis or have struggled to get the data needed from service providers in order to prepare the analysis, which has caused concern for employers due to their commitment to compliance with mental health parity. Our sense is that the clearer the guidance on these requirements is, the more feasible it will be for plan sponsors of all sizes to find a service provider who will be able and willing to support the plan in preparation of the analysis.

We also note a key point we often hear from our plan sponsor members – which is that they are completely reliant on their service providers in order to prepare a comparative analysis, including TPAs and carriers, and this reliance will only increase with the complexity of the proposed rules, including the focus on outcomes data. It is service providers that uniquely have the requisite data and expertise necessary to prepare these reports. In some cases, plan sponsors hire other service providers to prepare the comparative analysis but even in those cases, information is needed from the TPA or carrier to complete the analysis.

Because of the central role of TPAs and carriers in preparing, or supporting preparation of, the comparative analysis, many of our plan sponsor members have

suggested that it would be helpful for the tri-agencies to engage with service providers, in the event issues are identified in comparative analyses or otherwise, so that a global correction can be made at the service provider level, to improve widespread compliance in the most efficient manner. We understand the tri-agencies have sometimes undertaken this "global correction" approach and we note that we support those efforts, which reduce inefficiency and burden on the tri-agencies, plan sponsors and their service providers.

Fiduciary Certification

For an ERISA plan, the proposed regulations require that the plan provide to the plan's named fiduciaries, a written list of all NQTLs imposed under the plan and a general description of any information considered or relied upon by the plan or issuer in preparing the comparative analysis for each NQTL (which must also be provided to the tri-agencies upon request). The proposed regulations go on to require plans to include in the comparative analysis a certification by one or more named fiduciaries who have reviewed the comparative analysis stating whether they found the comparative analysis to be in compliance with the content requirements under the regulations. The tri-agencies explain this requirement is intended to "help ensure that plan fiduciaries meet their obligations under ERISA to review the comparative analyses and properly monitor their plans for compliance with MHPAEA."

We begin by noting that employers take very seriously MHPAEA compliance as well as their role as ERISA plan fiduciaries. We have also heard strong concerns from our plan sponsor members that the comparative analysis requirement is so complex and dependent upon medical judgement and expertise, including as envisioned in the proposed rule, that it will be difficult for plan fiduciaries to fully understand or know if the comparative analysis is in fact compliant. Under ERISA, fiduciaries are obligated to hire experts in areas where expertise is required. Navigating the existing NQTL requirements is challenging and the proposed rules indicate the tri-agencies' intent to make profound changes in plans' duties. Fiduciaries would be hard-pressed to possess the requisite information to make such certifications on compliance – this includes with respect to the specific rules as well as the unique and numerous data comprising the analysis. As a result, it should be expected that many plan fiduciaries would feel compelled to retain third party experts and advisors to assist them in making the requisite certification, which is likely to increase plan costs and expenses and potentially participant premiums. And for some employers, such as smaller or less profitable employers, they may lack access to, or the financial means to secure, such third-party support and thus may find themselves lacking the requisite knowledge or expertise to satisfy the certification requirement. Moreover, some members have expressed concern that, due to the complexity of the rules, there may not even been a sufficiently large pool of experts available to retain immediately following finalization of the rules.

As such, we ask that the tri-agencies not adopt the fiduciary certification requirement. It is unclear what added protections would even be created for participants and beneficiaries from this requirement above and beyond what is already available through ERISA's duties of prudence and loyalty. If the requirement is adopted, we ask that the tri-agencies clarify the requirement so that a plan fiduciary understands what is expected of them as part of its review, including whether the plan fiduciary must evaluate whether, in a general sense, the required elements are present, or whether the plan fiduciary is required to do a more substantive review.

Adverse Benefit Determination

Under the proposed regulations, plans subject to ERISA would be required to make comparative analyses available to participants and beneficiaries upon request (and to a provider or other person acting on behalf of the participant or beneficiary, as an authorized representative). In addition, as set forth in the proposed regulations, all non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage would be required to make comparative analyses available to participants or beneficiaries (as well as to providers or other individuals when acting as an authorized representative) upon request in connection with an appeal of an adverse benefit determination.

We understand that comparative analyses are subject to disclosure pursuant to ERISA, but as to the requirement that these documents be disclosed upon request in connection with the appeal of an adverse benefit determination, we note that questions have arisen regarding the application of this rule in various circumstances and we ask that any final rule provide much greater clarity on when and under what circumstances this disclosure requirement is triggered.

For example, is this requirement triggered even where it appears to have no reasonable nexus or connection between the comparative analysis and the facts giving rise to the adverse benefit determination? Take for example a situation where the plan issues an adverse benefit determination to an out-of-network mental health provider, but where the plan provides for no such out-of-network benefits for either medical/surgical conditions or mental health and substance abuse disorders. Must the plan provide a copy of the comparative analyses if the out-of-network provider requests it?

As the tri-agencies are aware, a plan's comparative analyses can be dozens, if not hundreds, of pages in length and absent a clear and obvious nexus to the plan's adverse benefit determination, it seems unnecessary and inappropriate to require that these analyses be provided – especially to providers that may instead seek to use the adverse benefit determination issuance and the NQTL comparative analysis to gain access to information that is not otherwise public and which could be used for purposes unrelated to the benefit denial – one that is likely to cause the unnecessary expenditure

of plan assets and increase the administrative complexity for plans, without having a benefit for the participant or beneficiary.

In light of the foregoing, we urge the tri-agencies to include as part of any final regulations clear rules regarding when the issuance of an adverse benefit determination triggers a requirement by the plan to disclose its comparative analyses, upon request. Moreover, in considering the development of these rules, we urge the tri-agencies to consider that in many instances the comparative analyses may have little relevance to the plan's claim determination, and so little or no value to the participant or beneficiary, and that production by the plan of such comparative analyses is not without significant cost and complexity.

Procedural Review

The proposed regulations explain how much time a plan will have to respond to an initial determination of noncompliance but they do not explain what happens between that step and a final determination of noncompliance. Due to the importance of these rules, the serious consequences attached to a final determination of noncompliance, and concerns about disparities in enforcement between regional offices, we urge the tri-agencies to provide some procedural guardrails and due process protections for plans and issuers prior to the final determination of noncompliance.

What would be most helpful would be a form of independent review, where for example, the plan or issuer has an opportunity for a meet and confer with the DOL or HHS national office, during which the determination from the regional office is reviewed, along with the documents the plan or issuer submitted and the changes the plan or issuer has made. This would have the benefit of ensuring DOL and HHS are applying the rules in a consistent manner, which would support compliance and provide an additional fairness check in the system for plans and issuers.

Other Comparative Analysis Related Questions

There are some additional, more technical questions, that have arisen and on which we would appreciate additional guidance.

- If a plan does not have an NQTL in place for MH/SUD (*e.g.*, prior authorization), can a comparative analysis be omitted for this NQTL? We believe the answer is yes (*i.e.*, no comparative analysis is needed) but confirmation would be appreciated.

- We continue to receive questions from our members about how frequently the comparative analysis must be updated. We appreciate that general guidance has been given providing that the analysis must reflect the current terms of the plan or coverage, which may require updates when there is a change in plan benefit design, administration or utilization that is not reflected in the current version of

the comparative analyses. Some are concerned about the possible need for very frequent updates, for example, several a year. It would be helpful if the tri-agencies could provide additional detail on expectations regarding updates.

- Much of the discussion and examples on the comparative analysis relate to inpatient and outpatient benefits and we have received questions from members about how these requirements will apply to prescription drug benefits, with the expectation that there could be some differences in application. To provide clarity needed for compliance, it would be helpful if the tri-agencies could provide additional guidance to illustrate each step of the comparative analysis to NQTLs applied to prescription drugs.

APPLICABILITY DATE AND GOOD FAITH STANDARD

Noting the need to strike a balance between the importance of the rules and the time it will take plans and issuers to implement the rules, if finalized, the tri-agencies propose that the regulations apply on the first day of the first plan year beginning on or after January 1, 2025.

We appreciate that the tri-agencies acknowledged that plans and issuers will need time to implement the new rules and we understand that the issues addressed in the rules are of critical importance to the tri-agencies. That said, we are deeply concerned about the ability of plans and issuers to be able to implement these rules by 2025. This is because the rules impose new broad, complex and substantial changes, as discussed above. In short, plans will need to first perform the new NQTL tests, including through analysis of data that systems are not currently designed to capture, and then, depending on the results, make various changes to the plan and the plan's existing comparative analysis. Compounding the concern is the fact that we do not expect the tri-agencies to be able to issue final regulations until well into 2024, to allow for review and analysis of the extensive comments we expect to be submitted.

Employers put a great amount of time and effort into plan design, including any benefit or cost changes, for upcoming plan years. They do so well in advance of the year, so that there is sufficient time to thoroughly analyze and establish any changes and to allow time to communicate and contract with plan service providers as well as with plan participants, typically during open enrollment which often occurs in early fall for calendar year plans. In fact, 2025 plan design is already well underway for many employers.

Notwithstanding employers' commitment to mental health parity, it is simply not feasible for employers to digest and implement final regulations in a matter of weeks or a handful of months, which is what a 2025 applicability date would likely require. That said, employers are committed to implementing final regulations as quickly as

practicable. As such, we ask that the tri-agencies provide at least a year between finalization and application, so that the rules apply for plan years beginning on or after one year from the date the final regulations are issued.

We also ask that the tri-agencies focus on compliance assistance, and apply a good faith compliance standard, during initial implementation of any final rules. We make this request due to the complexity of the new rules and the extensive efforts that will be required for implementation. We expect that employers and their service providers will make great efforts to come into compliance as fast as possible, but we also believe it would be beneficial, reasonable and appropriate for the tri-agencies to work with plans and issuers who are making good faith efforts to come into compliance.

TECHNICAL RELEASE

NQTLs related to network composition are an area of particular focus for the tri-agencies. Consistent with that focus, the DOL published a Technical Release requesting comment on proposed relevant data requirements for NQTLs related to network composition and a proposed enforcement safe harbor. The DOL envisions that future guidance would (1) address the type, form and manner of the required data to collect and evaluate as part of the comparative analyses and (2) define standards for the data elements specified by the tri-agencies and provide a potential enforcement safe harbor for plans that demonstrate they meet or exceed the standards with respect to NQTLs for network composition, for a period of time. The DOL notes that any future guidance would specify a prospective effective date for the NQTL comparative analyses to include the specified data elements. Notably, the requirement to perform and document a comparative analysis of the design and application of each NQTL would continue to apply regardless of whether a plan satisfies the terms of the enforcement safe harbor.

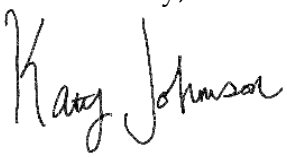
The Council supports the development of an enforcement safe harbor for plans to demonstrate through data that they meet or exceed standards with respect to the NQTL for network composition. The Council agrees with the proposal that the data required for the network composition NQTL would be the same data analyzed for an enforcement safe harbor since this is data that will already be required to be collected. The Council strongly supports aggregate data collection and thinks that if a TPA or carrier satisfies the enforcement safe harbor for the network composition NQTL, that enforcement safe harbor would apply to all plans that contract with the TPA or carrier to administer MH/SUD and M/S services. We also ask the tri-agencies to consider the role of telehealth in developing the rules regarding network composition, including incorporating a concrete method to account for the access impacts of telehealth in the development of any rules around time and distance standards. Telehealth benefits provide access to additional MH/SUD providers and can help fill gaps with respect to network standards adopted by the tri-agencies.

Finally, it is critical that the tri-agencies clearly delineate the standards that must be met in order to satisfy the enforcement safe harbor.

* * * * *

Thank you for the opportunity to comment on the proposed regulations. If you have any questions or would like to discuss further, please contact us at (202) 289- 6700.

Sincerely,



Katy Johnson
Senior Counsel, Health Policy