National Association of Benefits and Insurance Professionals
NABIP
Shaping the *future* of healthcare

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

RE: 1210–AC11

Sent electronically via www.regulations.gov

Dear Secretaries Bacerra, Su, and Yellen:

I am writing on behalf of the National Association of Benefits and Insurance Professionals (NABIP), formerly NAHU, an association representing over 100,000 licensed health insurance agents, brokers, general agents, consultants, and employee benefits specialists. We are pleased to have the opportunity to comment on the proposed rule titled "Requirements Related to the Mental Health Parity and Addiction Equity Act" and published in the *Federal Register* on August 3, 2023.

The members of NABIP work daily to help millions of people and businesses purchase, administer and utilize health insurance coverage. Ensuring fair and complete access to mental health and substance use disorder is paramount to the members of our association and their clients. Further, NABIP members are actively involved in assisting clients with developing and maintaining their non-quantitative treatment limitation (NQTL) analyses as required by the Consolidation Appropriations Act of 2021's (CAA, 2021) amendments to the Mental Health Parity and Addiction Equity Act (MHPAEA). Our members are working to help employer group health plan sponsors who offer both fully-insured and self-funded coverage develop their analyses, and membership spans professionals that work not only as brokers, but also for third-party administrators, issuers, compliance entities, issuers, and other service providers with expertise in the MHPAEA. As such we are grateful for the opportunity the Departments of Health and Human Services, Labor, and Treasury ("the Departments") offer to provide comments on this measure. We have broken up our response by topic, and NABIP members

who specialize in each type of coverage option provided their direct expertise to inform comments in each section.

Meaning of Terms—26 CFR 54.9812–1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2)

The proposed rule would Departments propose to amend the existing regulatory definitions of the terms "medical/surgical benefits,"" mental health benefits," and "substance use disorder benefits" to clearly specify what is medical/surgical (M/S), mental health (MH), or a substance use disorder (SUD) benefit for purposes of complying with the MHPAEA.

The proposed changes would eliminate references to state requirements in order to eliminate confusion between the federal MHPAEA requirements and state-level benefit mandates that potentially conflict with the MHPAEA. It is a known problem that fully-insured plan designs, which have been filed with and approved by state insurance regulators sometimes contain language that does not meet MHPAEA standards but is included in policy design due to state-level benefit mandate requirements. Many states have adopted well-meaning coverage mandates that either pre-date the MHPAEA and therefore are non-compliant, or simply include language that does not meet MHPAEA standards. Plan sponsors offering fully-insured coverage understandably assume that state-approved product offerings are compliant with the federal law, and any effort the Departments can make to alleviate this problem will be a welcome change.

Additionally, NABIP members who work to assist group health plan sponsors attempting to complete their plan NQTL analyses report that self-funded plans frequently include language that is both out-of-compliance with the MHPAEA and directly pulled from state-level mandated benefit requirements prevalent in the plan's geographic area. Plan sponsors and TPAs creating benefit designs for these plans often look to state-level standards and the benefit designs of fully-insured coverage as a model. NABIP members agree with the Departments that this proposed change to the definitions of M/S, MH, and SUD benefits will help to minimize situations where contradictions with state guidelines create conflicts and improperly limit the protections under MHPAEA.

The amendments to the definitions of M/S, MH, and SUD benefits also include clarifications as to generally recognized independent standards of current medical practice. Specifically, under these proposed rules, to be consistent with generally recognized independent standards of current medical practice, the plan's or coverage's definition of "mental health benefits" must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. Similarly, the plan's or coverage's definition of "substance use disorders" must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral,

and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. All of the definitional changes will also clarify that to the extent generally recognized independent standards of current medical practice do not address whether a condition or disorder is a mental health condition or substance use disorder, respectively, plans and issuers may define the condition or disorder in accordance with applicable Federal and State law.

NABIP members support the new proposed clarifications to the definitions. By specifying directly how MH and SUD disorders must be defined for MHPAEA compliance purposes, the regulation will ensure that all plans appropriately cover all MH and SUD services. Currently, many plans use different and more limited definitions, thereby limiting access to appropriate MH/SUD care. Additionally, by using the DSM and ICD as standards of medical practice, the proposed definitions will provide clarity to plans as to whether specific conditions, such as nicotine addiction, eating disorders, autism, and others are considered to be MH or SUD conditions.

In addition to directly specifying that the most recent versions of the ICD and DSM must be used in defining MH and SUD for MHPAEA compliance purposes, the proposed rule provides clarity about which versions of the ICD and DSM are applicable. The measure includes definitions of both the ICD and the DSM, and it then guidance on when required to begin to rely on a new version of the ICD or DSM after it is released, and sufficient time after the adoption of an updated version of the ICD or DSM to ensure that the terms of their plan or coverage are consistent with any changes made from the previous version. NABIP members appreciate the intention behind this guidance about when plan sponsors and issuers must begin to rely on newly published versions of the ICD and DSM but note that it may be overly complicated. Instead, we propose that the definitions simply refer to the most recent versions of both the ICD and DSM, and then specify that if a new version of either is published mid policy or plan year, then issuers and plan sponsors must update their policies, procedures, and applicable plan documents by the start of the next plan or policy year to rely on the newly published version.

Beyond making clarifications to the definitions of M/S, MH, and SUD benefits, the proposed rules define the terms “processes,” “strategies,” “evidentiary standards,” and “factors,” which are all terms related to NQTLs and the development of sufficient comparative analyses required under the CAA, 2021. Under these proposed rules, evidentiary standards generally would not be considered factors, but instead would be the information considered or relied upon in designing or applying a factor. Factors are all information including processes and strategies (but generally not evidentiary standards), considered or relied upon to design and/or apply a NQTL. The proposed rule also provides examples of factors and defines “processes” and “strategies” as types of factors, with “processes” relating to the application of an NQTL, and “strategies” to the design. NABIP members appreciate the specificity in these definitions and

note that the examples provided will be very helpful for future compliance purposes. Even more specific examples of processes, standards, what the Departments consider to be the differences between factors and evidentiary standards, what the Departments will consider to be a complete definition of a factor, and how to assign and specify weight to factors would all be appreciated.

Finally, the proposed rule defines "treatment limitation" to both provide an official illustrative list of NQTLs, and officially establish that the examples included in the proposed rule are just that — examples, and not an exhaustive list. The rule also changes the language in the definition related to exclusions, to specify "a *complete* exclusion of all benefits for a particular condition or disorder is not a treatment limitation for purposes of this definition," rather than using the old term of permanent exclusion. NABIP members agree with the Departments that by changing the existing reference in the definition from "permanent" to "complete," the proposed definition better specifies that it is permissible for a plan or issuer to exclude a particular a condition or service and it not be an NQTL, but that in doing so, the exclusion must be total. To illustrate this even further, NABIP members suggest the inclusion of several specific examples showing what would be permissible exclusions and what would be exclusionary language that creates a problem and/or an NQTL.

Nonquantitative Treatment Limitations—26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4)

The proposed rules establish a three-prong test that plans and issuers must pass to impose an NQTL. To qualify, a NQTL must be no more restrictive when applied to MH/SUD benefits as it is to M/S benefits, the plan or issuer must meet specified design and applications requirements, and the plan or issuer must collect, evaluate, and consider the impact of relevant data on access to MH/SUD benefits as opposed to M/S and take reasonable action to address any material differences. If a plan or issuer fails to meet any of the three requirements, it may not impose the NQTL on any MH/SUD benefits in the appropriate classification. Alternatively, the plan or issuer must make changes to the terms of the plan or coverage or the way the NQTL is designed or applied to ensure compliance with MHPAEA.

This measure also would prohibit plans and issuers from relying upon any factor or evidentiary standard that discriminates against MH/SUD benefits as opposed to M/S benefits. Additionally, the proposed rules require plans and issuers to collect and evaluate relevant outcomes and operational data and then address any material differences in access between MH/SUD and M/S benefits. NABIP members appreciate this specification, but suggest that any final regulation make it clear if the data being analyzed needs to be group-specific, if aggregate-level data will suffice in any circumstance (such as when group-specific data is too sparse to be in any way statistically significant), and if there is a difference in the level of data needed for fully-insured versus self-funded plans.

The Departments make it clear that plans and issuers may apply the three-pronged test in any order they deem appropriate. NABIP members support this approach, as many entities need to review and analyze NQTLs that have been in place for some time. As such, they will need flexibility in how they determine the status of NQTLs and In some cases, it may not be clear what factors and standards were used to design and apply an existing NQTL, and a plan sponsor or issuer will need to reflect back and determine if they want to continue to apply such an NQTL at all, and if so, if there are appropriate factors and evidentiary standards that may be applied to the design and application of the NQTL to ensure parity, and if any modifications are necessary. However, given the flexibility that the proposal gives to issuers and plan sponsors, NABIP members believe it would be appropriate for the Departments to make it clear how often and when NQTL analyses need to be completed, and how long they should take.

Requirement That NQTLs be No More Restrictive for Mental Health and Substance Use Disorder Benefits—26 CFR 54.9812–1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i)

One of the three tests to determine the appropriateness of NQTLs created by the proposed rule is that any such treatment limitation may be no more restrictive for MH/SUD benefits, as written or in operation, than the predominant NQTL that applies to substantially all M/S benefits in the same classification. To aid plan sponsors and issuers in determining if NQTLs meet this test, the proposed rule specifies how the terms "restrictive," "substantially all," and "predominant" would apply in the context of the no more restrictive requirement. If the proposed rules are finalized as written, plans and issuers would be required to follow similar steps to those that apply when analyzing the parity of quantitative treatment limitations (QTLs). These steps would involve determining the portion of plan payments for M/S benefits subject to an NQTL in a classification, then calculating whether the NQTL applies to substantially all M/S benefits in the classification; the predominant variation of the NQTL that applies to M/S benefits in the classification; and whether the NQTL, as applied to MH/SUD benefits in the classification, is more restrictive than the predominant variation of the NQTL as applied to substantially all M/S benefits in the classification.

NABIP members understand the intention behind the Departments proposed approach to determining what "substantially all" means when it comes to M/S versus MH/SUD benefits. Obviously, the breadth of M/S care and benefits covered by a typical major medical plan is far more extensive than even the most generous policy's coverage of MH/SUD benefits and services, just due to the imbalance in the number of medical conditions and corresponding plan benefits that are considered to be M/S as opposed to MH/SUD. For example, under the current rules, a plan that elects to apply a prior authorization NQTL to inpatient care benefits would need to apply it to all MH/SUD and M/S benefits offered at the inpatient level to be completely certain the NQTL is applied in parity. However, in reality, the scope of all MH/SUD inpatient care benefits covered and provided by the plan, may be a small fraction of all of the M/S

benefits offered and covered by the plan. In a time when providers, consumers, plans, and issuers are all working to reduce the number of benefits that are subject to utilization management NQTLs like prior authorization, lack of clarity and a fair test of what "substantially all" means may result in an NQTL being applied to more benefits than in other respects may be necessary.

However, despite the sound idea behind the Departments proposed approach to testing NQTLs for predominance, restrictiveness, and scope of applicability, NABIP members have significant concerns about the methodologies proposed. This measure would mimic the formula used to test the appropriateness of QTLs imposed by a plan by relying on a plan's actual claims costs for M/S benefits subject to each NQTL being tested for applicability, predominance, and restrictiveness. Unfortunately, NABIP members who are involved in assisting self-funded plan sponsors obtain QTL analyses for their plans know how difficult it is to obtain this level of claims data from third-party administrators, and we have reason to believe it will be exponentially more difficult for plan sponsors to obtain the claims dollar data needed to complete the NQTL testing as described in the proposed rule.

When conducting QTL analyses, self-funded plan sponsors often find that third-party administrators do not track the claims dollars data needed in a way that is compatible for testing purposes, even if this data is available, it is produced and housed by divisions within issuers and third-party administrators that do not typically work at the plan sponsor level. Frequently the account managers and other staff members assigned to work with plan sponsors on a daily basis are unfamiliar with these requirements, and there is a need for data analysts on both ends to become involved to attempt to extract appropriate data. A typical employer plan sponsor does not have the resources needed to collect and analyze claims data at this level, and so the use of a third-party compliance vendor is necessary in most cases. It should also be noted that it is exceedingly rare in today's self-funded marketplace for a third-party administrator (TPA) to routinely perform QTL testing on behalf of all its self-funded group plan clients. Of the few TPAs that profess the capability to perform QTL testing for clients, it is a service that is advertised on a limited basis and only done at the direct request of the client, and often for a substantial additional fee.

All of this difficulty exists today when plan sponsors, NABIP members working on the behalf of plan sponsor clients, and third-party compliance vendors attempt to obtain claims cost data for QTL analyses, which due to their numerical and financial basis, directly correlate with claims dollars spent. So, NABIP members have very direct reasons to believe that attempting to obtain the data necessary to determine the scope and predominance of the application of most NQTLs will be even more challenging. A significant concern is that the data needed to test the applicability and predominance of most of the NQTLs that do not apply to all benefits is typically housed by entirely different vendors than those who maintain a plan's claims data. For example, prior authorization is a very common NQTL that applies to a specific list of benefits,

rather than all benefits. So, as the current proposal is drafted, a plan would need to test the applicability of this NQTL and its predominance in order to ensure it is being applied to MH/SUD care in parity. The vendor that could report on how often and when a prior authorization NQTL is applied is typically an entirely separate entity from the vendor that manages claims payments and dollars spent. Even if a self-funded plan uses only one entity, such as a health insurance issuer, to administer its entire plan, the plan's utilization management and pharmacy services (the categories of NQTLs most likely to only apply to certain M/S and/or MH/SUD benefits) are typically managed by either different divisions of the administrating company or entirely outsourced. Further, approximately 20 percent of self-funded group plans use two different vendors to perform utilization management and administrative services for the M/S and MH/SUD components of the plan. Meaning, multiple entities, who operate on different IT systems and who collect data in entirely different ways must provide pieces of necessary information to plan sponsors for correlation and testing.

In applying the proposed methodology, NABIP members are concerned that any one of the following scenarios will happen, thereby stymieing and/or significantly burdening already overwhelmed plan sponsors:

1. One or more of the involved vendors is unwilling or unable to provide the necessary data to perform the calculations.
2. One or more of the involved vendors will only cooperate and release the plan sponsor's own data for a substantial additional fee.
3. The data provided by one or more vendors is formatted in such a way as to render it unusable to a typical employer who sponsors a self-funded plan.
4. The data provided by the multiple separate entities involved with collecting incidence and applicability and claims expenditure data does not correlate due to the use of different definitions, data elements used, terms, coding schemes, or other factors.
5. The data able to be provided by separate involved data spans different timeframes.
6. The data is provided by the multiple involved vendors at drastically different rates of speed, thereby delaying the necessary testing for long periods of time.
7. A plan sponsor does not have the resources to mesh together the varying quality of data provided by different vendors.

An occurrence of any one of these situations will significantly limit a plan sponsor's ability to perform accurate assessments of the prevalence and predominance of NQTLs to M/S services and benefits and thereby determine if these NQTLs apply to MH/SUD benefits in parity. It is entirely possible based on our membership's experience with QTL testing today that many of the above scenarios will happen.

Beyond our serious data collection concerns, NABIP members do not believe that simply relying on claims data cross referenced with incidence is the best way to determine the stringency of application when it comes to NQTLs that typically are not applied across the board to all M/S

and MH/SUD benefits. The scope of a limitation as it applies to either M/S or MH or SUD benefits may not be accurately reflected based on claims dollars spent. For example, what if a plan's prescription drug benefit includes a step-therapy requirement for certain medications, which is a very common NQTL. Say a plan subjects one uncommon M/S medication to step-therapy, and then subjects virtually all MH/SUD medications to the NQTL. On the face of it, that NQTL is not applied to MH/SUD medications in parity and would affect many more plan participants receiving care for MH/SUD conditions than those receiving the M/S care that involved that single drug. However, if the M/S drug is a very high-cost medication, and it is prescribed to even one person on the plan, the claim costs could demonstrate predominance, thereby allowing the application of the NQTL on a much wider basis for MH/SUD.

Due to all these issues, our membership urges the Department to entirely revisit and revise the approach to NQTL stringency, applicability, and predominance testing.

Requirements Related to Design and Application of the NQTL—26 CFR 54.9812–1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii)

Another test the proposed rules would create for plans and issuers to use in determining the parity of an NQTL is evaluating whether the processes, strategies, evidentiary standards, or other factors involved with creating and applying a NQTL to MH/SUD benefits are applied no more stringently than those used in designing and applying the limitation to M/S services in the same benefit classification. So, the proposed rule would prohibit plans and issuers from relying upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. Establishing that factors and standards are nondiscriminatory will need to be a threshold component of required NQTL analyses.

For purposes of these proposed rules, independent professional medical or clinical standards, as well as standards related to fraud, waste, and abuse would not be considered to discriminate against mental health or substance use disorder benefits. However, information is biased or not objective in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances would be discriminatory. The determination of whether information is objective and unbiased would be based on all the relevant facts and circumstances including, but not limited to, the source of the information, the purpose or context of the information, and the content of the information. When determining which information, evidence, sources, or standards should inform the factors or evidentiary standards used to design or apply an NQTL, plans and issuers would not be permitted under these proposed rules to use information, evidence, sources, or standards if they are biased in favor of imposing greater restrictions on access to covered mental health and substance use disorder benefits or not objective, based on all the relevant facts and circumstances. Plans and issuers are specifically prohibited from relying on historical plan data

or other historical information from a time when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA's requirements where the use of such data results in less favorable treatment of mental health and substance use disorder benefits.

NABIP members understand and appreciate the Departments' hard stance against the use of discriminatory data, information, factors, or standards. However, we note that it will be difficult for the typical plan sponsor, and even third-party compliance vendors to judge if a source is discriminatory. The bar for discriminatory as drafted is fairly arbitrary and applying it may require clinical knowledge and the reliance of assertions from plan vendors that would be next to impossible for plan sponsors to truly verify. Further, the only example of a clear discriminatory source provided is historical plan data from a time when the plan was not in MHPAEA compliance. NABIP members request the inclusion of other direct examples of discriminatory and nondiscriminatory data sources in any final regulation.

Illustrative, Non-Exhaustive List of NQTLs—26 CFR 54.9812–1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii)

The proposed rule both amends and relocates the codified list of potential NQTLs. In doing so, the Departments make it clear that the NQTLs delineated specifically in the proposed rule are non-exhaustive and that the CFR is not to be taken as the only source of potential NQTLs plans should consult when evaluating and maintaining their parity compliance status. Comments are requested on this approach, as many interested parties have asked the Departments to provide a complete listing of NQTLs for compliance purposes. NABIP members do not take issue with the Departments approach and prefer that the list of NQTLs be example-based. Health plan structure and design changes over time, and a clear but specifically non-exhaustive list is an appropriate way for the regulatory language to remain as evergreen as possible. However, we do note that in the preamble to the proposed rule the Departments cite the "2020 MHPAEA Self-Compliance Tool" as another source of potential NQTLs plans should examine. This reference tool created by the Departments is very helpful, but it is long overdue for an update.

Required Use of Outcomes Data and Special Rule for NQTLs Related to Network Composition—26 CFR 54.9812–1(c)(4)(iv), 29 CFR 2590.712(c)(4)(iv), and 45 CFR 146.136(c)(4)(iv)

Both the proposed rule and the MHPAEA NQTL comparative analysis requirements establish that evaluation of how a plan is administered in operation is a crucial part of the NQTL parity review process. The proposed rule specifies that this means the "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." 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. The preamble to the proposed measure specifically ask for comments on whether plans and issuers collect such data as part of their normal business operations, as well as whether there are NQTLs for which the number and percentage of relevant claims denials would not be relevant for evaluating the impact of the NQTL, and any additional guidance plans and issuers would need to comply with the requirements for newly imposed NQTLs or for NQTLs imposed by new plans or issuers, for which relevant data may not be immediately available.

NABIP members can report that group plan sponsors of both fully-insured and self-funded plans do not track any of this data as part of typical business and plan operations. Instead, group health plan sponsors rely on their service providers to maintain and apply their plans and any related NQTLs. As such, in almost all cases, plan sponsors are entirely reliant on their service providers to reliably track such data and then provide it to the plan sponsor in a timely manner. Our members who have assisted group health plan sponsor clients in developing NQTL comparative analyses report that plan service providers are inconsistent when it comes to their willingness and ability to provide plan sponsors with group-specific operational test data based on de-identified claims data and other meaningful quantitative metrics. Service providers range from completely refusing to provide any data, to only proving written analyses of NQTL development and application that address factors and related evidentiary standards used, but do not include any relevant operational data, to only providing aggregate-level data reflective of all of the service provider's group clients or all clients in a given service area or other block of business, to providing partial or complete group-specific metrics. Many service providers refuse to provide data unless the plan sponsor can document that they are under MHPAEA-specific audit by HHS or the DOL. The time it takes service providers to prepare and deliver such data also varies widely. Cooperation with the operational data analysis requirement seems to vary based on the individual service provider involved—there are no reliable trends of providing assistance across types of service providers.

As for NQTLs that do not necessarily require group-specific de-identified claims data for operational evaluation, NABIP members believe that there are some NQTLs that are applied more generally on an overall service provider operational action basis. For example, operational data for many network and provider-based NQTLs, such provider credentialing data, provider reimbursement rates, access to out-of-network providers and/or pharmacies, geographic restrictions, and network adequacy requirements and data will be the same for many different plans, since vendors do not in any way customize these services for specific groups, but utilize the same networks and services and practices for all group plans in a given area that select particular network design options. Similarly, while formularies are occasionally customized, most PBMs only offer one or a few overall formulary designs and utilize the same structures and tiering for all group health plan clients or all clients in a particular area.

Regarding additional guidance that would be helpful for group plan sponsors attempting to evaluate newly imposed NQTLs, NQTLs imposed by new plans or issuers, or NQTLs for which

relevant data may not be immediately available, NABIP members urge the Departments to specifically address what would constitute appropriate compliance in these situations in any final rule. Regarding newly imposed NQTLs, or when a plan changes issuers or service providers, it would be helpful for the final rule to specify a compliance safe harbor for plans that are in the process of collecting relevant operational data related to new NQTLs and/or NQTLs being administered by new issuers or service providers. Additionally, specifying an appropriate window of time for such data collection would be very helpful. NABIP suggests that one year of data is the ideal amount for appropriate evaluation, but no less than six months worth of operational data is necessary to truly test the stringency of a NQTL on a day-to-day basis. As for cases when the plan sponsor cannot obtain the necessary operational data from their service provider, NABIP urges the Departments to directly specify in any final rule that a plan sponsor can meet their compliance obligation and fiduciary duty by simply requesting such information from their service provider, clearly documenting such requests, and advising service providers who do not provide such data needed for the plan to meet their MHPAEA comparative analysis and plan evaluation requirements that they will consider the vendor's refusal to provide data negatively when conducting their routine reviews of plan service providers.

The proposed rule specifies that if a plan's operational data reveals material differences in access to MH/SUD benefits as compared to M/S benefits, then the differences should be considered a strong indicator that the plan or issuer may be in violation of parity requirements. The measure indicates that with the exception of specified network-based NQTLs, a finding of operational concerns would not automatically result in the Departments noncompliance, a plan or issuer would be required to take reasonable action to address any material differences in access as necessary to ensure compliance. In addition, the plan or issuer would need to document any actions taken to mitigate those material differences in their NQTL comparative analyses. According to the Departments, this requirement would allow plans and issuers to explain why material differences in access demonstrated by the outcomes data should not result in a violation of the rules for NQTLs.

NABIP members suggest that in any final rule that the Departments acknowledge that individual group plan sponsors have little to no direct recourse against plan service providers that have operational issues with regard to the direct application of NQTLs to MH/SUD benefits as compared to M/S benefits. Plan sponsors are essentially limited to informing their service providers of any discrepancies identified in NQTL operational testing and requesting an explanation and/or improvement, suspending the application of an NQTL to applicable MH/SUD benefits and classifications, or terminating the plan's relationship with the service provider due to MHPAEA compliance concerns. However, in reality, only the first option is truly a practical one. There may be very good reasons as to why it is impracticable for a plan to suspend the application of an NQTL or terminate a service provider relationship. In fact, it may be contrary to the plan sponsor's fiduciary duty to do so. Accordingly, NABIP requests that any final regulation stipulate that plan sponsors are compliant with the meaningful action requirement if they can demonstrate that they attempted to collect operational data from their vendor(s),

notified all relevant service providers of potential operational issues, and asked them for explanations of all identified concerns and a written plan for improvement actions if necessary.

Network composition NQTLs are a subject of great focus in the proposed rule and states that network composition is the result of the design and application of a myriad of NQTLs and is informed by various processes, strategies, evidentiary standards, and other factors. The measure explains that network composition NQTLs include but are not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage.

According to the Departments, all network composition NQTLs taken together, must be designed, and applied in compliance with MHPAEA's parity requirements to ensure that networks do not materially disfavor access to MH/SUD benefits when compared to M/S benefits. Furthermore, because such NQTLs will inherently impact a participant's or beneficiary's access to mental health and substance use disorder benefits, the Departments explain that material differences in access shown by outcomes data related to such NQTLs should be subject to a higher level of scrutiny than for other NQTLs. Accordingly, the Departments have proposed a special requirement applicable just to NQTLs related to network composition. A plan or issuer will not be considered in parity if in operation the relevant data shows material differences in access to in-network MH/SUD benefits.

However, the preamble to the proposed measure also notes the Department’s awareness that there may be significant challenges for some plans and issuers to ensure operational adequacy when it comes to MH/SUD network composition as opposed to M/S network composition due to provider shortages and the unwillingness of some MH/SUD providers to contract with plans and issuers. So, the proposed rule establishes that if despite taking appropriate action, the relevant data continues to reveal material differences in access due to provider shortages or other factors beyond the plan or issuer’s control, then the Departments would not cite such a plan or issuer for such failures, provided the plan or issuer complies with the other applicable MHPAEA requirements. The proposal does note that plans and issuers should be prepared to document all remediation efforts and demonstrate evidence of provider shortages.

Just as with all other NQTLs, NABIP members note that self-funded plan sponsors have little to no recourse against Plan network vendors who operationally have meaningful differences between the access they are able to provide to MH/SUD providers as opposed to M/S providers. Network vendors are the ones that enter into and maintain contracts with providers and facilities, credential facilities and providers, establish reimbursement rates, and take all other steps to maintain network adequacy. Plan sponsors merely contract with the overall network provider, and these contracts are ones of adhesion. In order to even determine operational meaningful differences between MH/SUD and M/S providers, plan sponsors are

reliant on their network provider to provide them with accurate, timely, and meaningful operational data, something many network providers have been unwilling to offer to-date. Then, if the plan sponsor is able to detect meaningful discrepancies through the analyses of operational date, they are fully reliant on the network provider to make corrections and/or provide accurate evidence of MH/SUD provider shortages that prevent the composition of a MHPAEA compliant network. Due to these difficulties, our membership requests that any final regulation stipulate that plan sponsors are compliant with the meaningful action requirement relative to network composition NQTLs if they can demonstrate that they attempted to collect operational data from their network vendor(s), provided written notice of potential operational issues, and asked their network provider(s) for explanations of all identified concerns and a written plan for improvement actions if necessary.

Contemporaneously with these proposed rules, the federal Department of Labor issued Technical Release 2023–01P that sets out principles and seeks public comment to inform future guidance with respect to required data submissions for NQTLs related to network composition and a potential enforcement safe harbor. The technical release solicits feedback on the type, form, and manner for the data that plans and issuers would be required to include, along with other relevant data as appropriate, as part of their comparative analyses for NQTLs related to network composition. It also asked for guidance on how to define certain thresholds for required data and a potential enforcement safe harbor to be specified in future guidance that, if satisfied, would demonstrate to the Departments that a plan or coverage provides comparable access to in-network of providers for mental health and substance use disorder benefits as compared to medical/surgical benefits, and the plan or issuer would not be subject to federal enforcement under MHPAEA with respect to NQTLs related to network composition for a specified period of time. NABIP members appreciate the issuance of this technical release and intend to provide detailed comments about the necessity of safe harbor protections for plan sponsors who have little or no control over the outcome of network-based NQTLs under a separate cover.

Independent Professional Medical or Clinical Standards and Standards to Detect or Prevent and Prove Fraud, Waste, and Abuse—26 CFR 54.9812–1(c)(4)(v), 29 CFR 2590.712(c)(4)(v), and 45 CFR 146.136(c)(4)(v)

Under these proposed rules, if a plan or issuer imposes an NQTL that impartially applies independent professional medical or clinical standards to both MH/SUD and M/S benefits, then those standards would not be considered a violation of the no more restrictive requirement or the relevant data evaluation requirements. However, the plan or issuer would still need to comply with the rule's design and application requirements.

However, the preamble to the proposed rule goes on to say that even though independent standards are used, "the plan or issuer would not be permitted to impose an NQTL with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes,

strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than those used in designing and applying the NQTL with respect to medical/surgical benefits in the classification. Similarly, if a plan or issuer imposes standards related to fraud, waste, and abuse in a manner described in the proposed rules, the plan or issuer would still be required to comply with the design and application requirements and the relevant data evaluation requirements in proposed 26 CFR 54.49812–1(c)(4)(ii) and (iv), 29 CFR 2590.712(c)(4)(ii) and (iv), and 45 CFR 146.136(c)(4)(ii) and (iv)."

Frankly, NABIPmembers find the wording of these exceptions to the rule's NQTL design and application requirements for independent professional medical or clinical standards and standards related to fraud, waste, and abuse to be confusing and somewhat contradictory. Due to the ambiguity of the language in the proposal, we are concerned that plan vendors, who already are often reluctant to provide complete information to sponsors of self-funded plans seeking to complete their analyses will use these exceptions as rationale for continuing to refuse to provide data, or to provide plan sponsors with insufficient data, with seemingly little recourse for the affected group plans. For example, most utilization management-related NQTLs rely, in whole or in part, on the plan's medical necessity standards. Plan vendors routinely cite their reliance on independent clinical care standards, such as MCG guidelines, InterQual, and the American Society of Addiction Medicine's care guidelines, as the complete or partial basis for medical necessity determinations. We assume these materials would qualify for the proposed application and design provision exception proposed in the rule, so their use and application could "not be considered a violation of the no more restrictive requirement or the relevant data evaluation requirements." However, "the plan or issuer would still be required to comply with the design and application requirements and the relevant data evaluation requirements."

Under the scope of these two exceptions, what is reasonable for a plan to do in order to comply with the design, application, and data evaluation requirements? Would the plan merely need to review the factors and standards and test the data related to the portion of such an NQTL that does not involve medical necessity governed by an independent source? If said cost was an identified factor, along with medical necessity, would the plan's data analysis and application and design review be limited to merely cost? What if an independent source is just one of many standards used to design and/or apply a specific factor related to an NQTL? NABIP members request clarification on all of these questions in any final rule. We also urge that any final measure include multiple detailed examples about the appropriate application of these exceptions, including detailed information about how a plan could appropriately document an NQTL that only relies on independent professional medical or clinical standards and standards related to fraud, waste, and abuse in an NQTL analysis, as well as examples of how a plan could appropriately document and test an NQTL that relies on these and other factors and standards.

Effect of Final Determination of Noncompliance—26 CFR 54.9812–1(c)(4)(vii), 29 CFR 2590.712(c)(4)(vii), and 45 CFR 146.136(c)(4)(vii)

The proposed rule specifies that if a plan or issuer receives final notice of NQTL parity noncompliance from the relevant Secretary, then they may be directed to cease application of the NQTL until they can demonstrate compliance with the MHPAEA or takes appropriate action to remedy the violation. This stipulation to remove the NQTL would only come with a final determination of noncompliance by the Departments, including a noncompliance determination based on the failure to submit a sufficient comparative analysis to demonstrate compliance. Further, since immediate removal of an NQTL may not be practical or appropriate for a plan on an overall basis, the Departments will review all facts and circumstances involved in the specific violation and nature of the underlying NQTL before requiring its removal. NABIP members support this approach.

NQTL Examples—26 CFR 54.9812–1(c)(4)(viii), 29 CFR 2590.712(c)(4)(viii), and 45 CFR 146.136(c)(4)(viii)

The proposed rules includes thirteen direct examples of the application of the MHPAEA NQTL requirements. The measure revises some examples included in the 2013 final rule, removes other examples that were included in the 2013 regulation, and adds several new examples. NABIP members sincerely appreciate the inclusion of all of these detailed examples, as they will certainly aid plans in the compliance process.

In reviewing the examples, we note that there are multiple situations discussed where a finding is that the NQTL does not meet parity standards because the requirement is not the result of independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse, and vice versa. However, there are no examples provided as how to handle NQTLs where there are multiple standards used, including independent professional medical or clinical standards or standards to detect or prevent and prove fraud, waste, and abuse, as well as other standards that do not qualify for the non-discriminatory exception and the parity issue is related to the non-exempt factors and/or standards. As noted in our comments on these proposed exceptions and how they would work in concert with other factors and standards, our membership would appreciate detailed examples that address such scenarios.

Additionally, in the proposed examples, the facts presented indicate the predominance or lack thereof of the NQTL to M/S benefits. However, there are no direct examples showing how a plan would go about making those calculations. While NABIP opposes the use of the proposed methodology to determine predominance, as discussed in our comments relative to that specific regulatory change, if the change is to be finalized, then our members request multiple specific examples as to how that methodology is to be applied in practice.

Prohibition on Financial Requirements and Treatment Limitations Applicable Only to Mental Health or Substance Use Disorder Benefits—26 CFR 54.9812–1(c)(2)(i) and (c)(4)(vi), 29 CFR 2590.712(c)(2)(i) and (c)(4)(vi), and 45 CFR 146.136(c)(2)(i) and (c)(4)(vi

The proposed rules adds a sentence to the existing rules to clearly indicate that a plan or issuer may not impose any financial requirement or treatment limitation that is applicable only to MH/SUD benefits and not to any M/S benefits in the same benefit classification and remain in parity. The application of a QTL and/or a NQTL solely to MH/SUD treatments or services are inherent parity violations. Furthermore, the proposed rule specifies that if a plan excludes MH/SUD services or treatments due to the expression of another NQTL, such as medical necessity requirements or experimental or investigational exclusions, and that NQTL is applied to M/S benefits in the same classification, then it would not be considered a separately applicable treatment limitation. However, if a plan's exclusion of a MH/SUD treatment or service is not due to the application of another NQTL, and that exclusion is not generated through a process or strategy or informed by an evidentiary standard of a broader NQTL like medical necessity, then such an exclusion would need to be evaluated for parity compliance on its own merits. NABIP members support both of these explicit clarifications.

Other Proposed Amendments— 26 CFR 54.9812–1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii)

The proposed rule would change the standard related to when a plan or issuer provides any benefits for MH/SUD in any classification of benefits and is then required to provide MH/SUD benefits in all classifications for which the plan or issuer offers M/S benefits. Under the revised rule, a plan or issuer would not be considered to provide MH/SUD benefits unless they are meaningful benefits, as determined in comparison to the benefits provided for M/S conditions in the applicable benefit classifications. By changing the standard, the Departments believe they will eliminate circumstances where a plan or issuer provides comprehensive MH/SUD benefits in a classification, but only very limited MH/SUD benefits that same classification. NABIP members support this change, but we note that any final regulation will need to include explicit compliance examples to demonstrate what the Departments mean by meaningful coverage on a practical level.

This measure would also amend the regulatory language to make it explicit that is a plan provides any benefits for a MH/SUD condition or disorder, then benefits would be required to be provided for *that condition or disorder* in each classification for which any M/S benefits are provided. This clarification codifies the Departments longstanding interpretation that this provision applies on a condition or disorder basis. In addition, the proposed rules include two examples to illustrative this change, one on how a plan may not provide coverage autism spectrum disorders generally in a benefit classification and then exclude a specific treatment for that disorder, such as ABA therapy. The second addresses how nutritional counseling

coverage must not only apply to efforts to address obesity or other M/S needs for such counseling but must also cover MH/SUD disorders requiring such treatment, such as bulimia or anorexia nervosa. NABIP members appreciate both the explicit clarification in regulatory language of the Departments widely acknowledge viewpoint, and also the inclusion of practical examples to help ensure compliance.

Another amendment to existing regulatory language in the proposed rule is a specification that plans and issuers may use the permissible sub-classifications under the 2013 final regulations when applying all of the rules for financial requirements and treatment limitations, including NQTLs. While this change is not terribly significant on a standalone basis, it is relevant when applied to the proposed changes to the NQTL scope, applicability, and predominance tests proposed in 26 CFR 54.9812–1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i). As stated in our comments related to this proposal above, NABIP members do not believe the application of tests similar to those used to evaluate the applicable stringency of QTLs to NQTLs is a good idea. As such, we do not support this related amendment to the regulations either.

A regulatory amendment in the proposed rule that NABIP members do support is the specification that MHPAEA comparative analyses and any other applicable information required under the CAA, 2021 are considered to be instruments under which a plan is established or operated. Therefore, ERISA plans generally must furnish those documents to plan participants and beneficiaries upon request within 30 days, as required under section 104 of ERISA and 29 CFR 2520.104b–1. Additionally, amendment language in this proposal establishes that comparative analyses and any other applicable information required under the CAA, 2021 and these proposed rules qualify as documents, records, and other information relevant to the claimant's claim for benefits to which plans and issuers must provide reasonable access, upon request and free of charge. These amendments codify what many interested parties have already believed the Departments view of these documents to be, and so formalization of this approach will aid plans in their compliance efforts.

Finally, the Departments propose to amend 26 CFR 54.9812–1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4)to include a reference to 26 CFR 54.9812–2(g), 29 CFR 2590.712–1(g), and 45 CFR 146.137(g) and to reflect current HHS regulations at 45 CFR 156.115(a)(3). Existing regulations at 26 CFR 54.9812–1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4) state that nothing in paragraphs (f) and (g) of the 2013 final regulations related to MHPAEA's small employer exemption and increased cost exemption, respectively, changes the requirement under HHS regulations at 45 CFR 147.150 and 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, must comply with the provisions of 45 CFR 146.136 to satisfy the

requirement to provide essential health benefits (EHBs). NABIP members support this clarification.

New Rules Related to the CAA, 21 NQTL Comparative Analysis Requirement—26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137

The CAA, 2021 amended MHPAEA, in part, to expressly require plans and issuers that offer both M/S and MH/SUD through coverage plans that impose NQTLs to perform and document comparative analyses of the design and application of all plan NQTLs to MH/SUD and assess their parity status. This measure would add new rules to existing MHPAEA regulatory requirements regarding the CAA, 2021's NQTL comparative analyses requirements, including specific rules relative to the content of such analyses and distribution requirements.

In the preamble to this measure, the Departments requested comments on both the proposed regulatory codification of the capitative analysis requirement, as well as feedback related to the challenges plans and issuers face obtaining the necessary information to perform and document a sufficient comparative analysis. As already stated, NABIP members regularly assist self-funded group plan sponsor clients with the processes of completing and maintaining their NQTL comparative analyses. Our association also fully understands that even if a group plan sponsor or health issuer contracts with one or more entities to provide or administer their benefits and related NQTLs, it does not relieve the employer, issuer, or both of any MHPAEA obligations.

However, as you acknowledge in the preamble to the proposed rule, "The Departments are aware of reports that some plans (or their TPAs or other service providers) and issuers have not documented their comparative analyses and instead wait until the Departments, or an applicable State authority, request comparative analyses, or indicate that the plan or issuer is otherwise under investigation. The Departments are also aware of reports that self-insured plans have been unsuccessful in receiving comparative analyses (or the information required to perform and document comparative analyses) from their TPAs or other service providers in response to a request."

Our association cannot overstate the reliance virtually all employer group plan sponsors have on their service providers to give them the information necessary to complete their NQTL analyses. Additionally, our members cannot stress strongly enough about the lack of cooperation exhibited by many common health plan service providers (including some of the country's largest entities that provide assistance to millions of Americans and group health plan sponsors) regarding providing their group plan clients with access to the information they need to complete and maintain their comparative analyses. Some vendors are not even equipped to provide plan sponsors with information about the factors and evidentiary standards they use in designing and administering NQTLs on behalf of plan sponsors.

For the Departments reference, based on our considerable experience, the access to required data, compliance liability, and assistance available from plan members amongst group health plan sponsors breaks down as follows:

Fully-Insured Group Plans—Group health plan sponsors that opt for fully-insured coverage are entirely reliant on both their plan issuers and state-level regulators for ensuring the coverage options they offer to plan participants meet federal parity requirements. These employers have absolutely no access to any information they might need to prepare and maintain their comparative analyses, other than any information that may be included in the certificate of coverage provided by their issuer and included in the plan's wrap document or other plan documents. To obtain a comparative analysis, group plans need to request one from their issuer. It is extraordinarily rare for issuers to offer to provide one to a group plan sponsor without an express request. When issuers provide a comparative analysis to a fully insured group client, it is often only a written analysis delineating the factors, standards, processes, and strategies used when creating and applying the plan's NQTLs. Some issuers may include operational data in their analyses, but it is typically compiled at a book-of-business level.

Level-Funded Group Plans—Similar to fully-insured groups, plan sponsors who offer level-funded coverage are very dependent on the issuers that provide them with their policy frameworks and administer their plans, including all NQTLs. These entities must rely on these issuers for the information they might need to prepare and maintain their comparative analyses, other than any information that may be included in their policy booklets. Issuers are not completing comparative analyses on behalf of their level-funded groups. These groups must request information from their issuer and any other service providers and are completely reliant on them to provide accurate, timely, and complete information. While issuers vary in their levels of cooperation, in general it is much easier to obtain some level of written details about the factors, processes, strategies, and evidentiary standards used to develop and apply NQTLs than it is to obtain any or complete operational data. Quite a few issuers; however, refuse to provide any information to level-funded groups at all unless they can document a request from the DOL or HHS. Accordingly, these plans can only evaluate the information they have access to too, which often precludes them from being able to make a conclusion about parity either in writing, operationally, or both.

Traditional Self-Funded Group Plans—Group plan sponsors who offer traditional self-funded coverage almost always fully rely on service providers to provide utilization management, network, administrative and claims payment, and pharmacy services to their plan. Some plans rely on one entity to provide all or most of these functions for them, in which case it is almost always a large health insurance issuer or a subsidiary providing these functions. Other self-funded plans "carve-out" all or some of these

functions and use multiple service providers. It is common for plans to utilize multiple network providers to reach different parts of the country, and/or to use two different service providers for conducting MH/SUD and M/S utilization management. It is less common, but still possible, for self-funded plans to utilize different network vendors to provide access to M/S and MH/SUD providers and facilities.

Third-party administrators are not generally completing full NQTL analyses for their employer group clients. A small number of TPAs have contracted with independent NQTL analysis vendors and may provide clients with access to their services, or even coordinate such access, but it is for a pass-through fee in almost all cases. The vast majority of self-funded plan sponsors must work on their own or through their broker to complete their NQTL analysis, and almost all employer group plan sponsors who have done so utilize the services of a compliance vendor or attorney to actually complete and draft their reports. To obtain the data needed by these vendors to complete their NQTL analyses, plan sponsors must request it from their service providers. They must totally rely on their vendors to provide accurate, timely, and complete information beyond what information may be included in their plan documents. While vendors vary in their levels of cooperativeness, in general it is much easier to obtain some level of written details about the factors, processes, strategies, and evidentiary standards used to develop and apply NQTLs than it is to obtain any or complete operational data. It is particularly difficult to obtain complete group-specific data. Quite a few vendors (particularly large issuers who provide administrative service functions to self-funded groups) refuse to provide any information to level-funded groups at all unless they can document a request from the DOL or HHS. Accordingly, these plans can only evaluate the information they have access to too, which often precludes them from being able to make a conclusion about parity either in writing, operationally, or both.

Self-Administered Self-Funded Group Plans (which represent perhaps one percent or less of all self-funded group plans)—Very few self-funded group health plans administer any aspect of their own services. Of those that would be considered self-administered, almost all are Taft-Hartley plans and the level of "self-administration" is limited to the actual payment and processing of claims. These plans still outsource all utilization management functions, rent access to health plan networks (including access to network-negotiated provider contracts and reimbursement schedules), and utilize pharmacy benefit managers for the administration of their prescription drug benefits. Furthermore, many plans that would be considered "self-administered" for other federal regulatory purposes still work with their brokers, attorneys, and others on the payment and processing of plan claims. So, other than any NQTLs directly related to claims processing, these plans are just as reliant on their service providers for the information necessary to complete and maintain NQTL analyses as a traditional self-funded plan sponsor.

Due to the limits on the amount of data available to all group health plan sponsors, and the absolute need for cooperation by all plan service providers in providing written procedural information, documentation of the factors and evidentiary standards used to develop and apply NQTLs on behalf of the plan sponsor, and relevant, accurate, and timely operational data, NABIP members believe that any final regulation needs to include both enforcement relief and clear compliance standards for plan sponsors who are generally making a good faith effort to comply with their comparative analyses obligations. We request that the Departments explicitly specify what group plan sponsors need to do to meet their compliance obligations when they are unable to obtain all or part of the information they need from service providers, including what documentation is required. NABIP also requests confirmation that concluding that the plan sponsor simply does not have enough information to make a complete determination of NQTL parity either in writing, operationally, or both is an acceptable determination for a plan sponsor to make in a comparative analysis when they are unable to obtain necessary data from a service provider, despite making a good faith effort to collect it.

Further, we note that the preamble to the proposed rule specifies that "under ERISA, such service providers may be fiduciaries with respect to private employment-based group health plans, and also notes the Departments are committed to using all available authority to ensure compliance by plans and issuers with MHPAEA for all entities that play a role in administering and designing benefits. If this is truly the case, then NABIP members urge the Departments to clearly delineate in any final rule how plan service providers may be deemed plan fiduciaries of their group health plan clients with regard to MHPAEA compliance. It is also imperative to explicitly specify what assistance the Departments are prepared to provide to group health plan sponsors in establishing the fiduciary status of plan service providers in this manner, and how the Departments plan to enforce the associated responsibilities and liabilities for MHPAEA compliance with these service providers, both on an individual group and overall level.

Finally, the Departments note in the preamble to this measure that they have received questions about when plans and issuers are required to perform and document comparative analyses, and how often they must be updated. The response to this statement in the preamble is a statement that “the requirement to perform and document comparative analyses of the design and application of NQTLs has been effective under the CAA, 2021 for more than two years (since February 10, 2021) and is an independent statutory obligation that is not dependent upon a request by the Secretary or an applicable State authority. It is an affirmative statutory obligation that applies irrespective of any such request.”

NABIP members appreciate the above affirmation from the Departments, as it may make it easier to obtain at least some of the information plan sponsors need from their vendors to develop complete comparative analyses, as many third-party administrators, especially some large health insurance issuers who serve as administrative service organizations for self-funded plans will only provide complete and/or operational data needed for these comparative analyses if the plan sponsor can document a specific request for an analyses from a state or

federal regulator. However, this statement does not answer the initial inquiry completely—how often and when are plan sponsors required to both complete and update their comparative analyses? NABIP members request that the Departments specifically address this issue in any final rule. Specifically, we would like the Departments to specify if analyses should be updated annually. Biannually? Whenever a plan changes a services provider, updates their plan documents, adds, or subtracts NQTLS, and/or modifies benefit options and/or designs? Along with this information, as noted previously in this comment letter, we request that the Departments clearly indicate how long a plan should collect data from new service providers for operational evaluations and how plans should handle transitionary periods when NQTLs are updated, changed, added, or removed?

Content of Comparative Analyses—26 CFR 54.9812–2(c), 29 CFR 2590.712–1(c), and 45 CFR 146.137(c)

The proposed rule outlines the specific content requirements for comparative analyses. Each analysis must include, at a minimum, with respect to each NQTL imposed under a plan or coverage option on mental health or substance use disorder benefits, six specific elements:

1. A description of the NQTL;
2. The identification and definition of the factors used to design or apply the NQTL;
3. A description of how factors are used in the design or application of the NQTL;
4. A demonstration of comparability and stringency, as written;
5. A demonstration of comparability and stringency in operation; and
6. Findings and conclusions.

The proposed rule and its preamble both provide very detailed specifications about what content and documentation the Departments expect each of these six aspects of comparative analysis must contain.

Beyond the six content elements listed above, the proposed rules would require each plan or issuer to prepare and make available to the Departments or applicable state authority, upon request, a written list of all NQTLs imposed under the plan or coverage and a general description of any information considered or relied upon by the plan or issuer in preparing the comparative analysis for each NQTL. Each plan or issuer also would be required to identify all mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL applies, including a list of which benefits are considered to be mental health and substance use disorder benefits and which benefits are considered to be medical/surgical benefits (consistent with the proposed definitions of those terms). Additionally, each plan or issuer would be required to include in its comparative analysis a description of which benefits

are included in each classification. Finally, the plan or issuer would be required to identify the predominant NQTL applicable to substantially all medical/surgical benefits in each classification, including an explanation of how the plan or issuer determined which variation is the predominant NQTL as compared to other variations, as well as how the plan identified the variations of the NQTL.

For plans subject to ERISA, these proposed rules would also require that the plan or issuer provide this list and general description to the named fiduciaries required to review the findings or conclusions of each comparative analysis. Further, each comparative analysis would be required to include a certification by one or more named fiduciaries who have reviewed the analysis, stating whether they found the comparative analysis to be in compliance with the content requirements of these proposed rules.

NABIP members appreciate the specificity the Departments have provided regarding their content expectations for NQTL comparative analyses. In the preamble, the Departments indicate that their content expectations are based in part on the "2020 MHPAEA Self-Compliance Tool" issued by the DOL. As previously noted, this tool is already out-of-date, as it was developed prior to the passage of the CAA, 2021. It certainly does not reflect all of the substantial content requirements outlined in this proposal, and NABIP members request it be updated as soon as possible following the publication of any final rule.

The Departments specifically solicited comments on whether any of these proposed requirements related to the content of comparative analyses are superfluous, unhelpful, or unreasonably burdensome. NABIP members believe that the Departments need to specifically consider the burden they are placing on group plan sponsors with all of these additional NQTL analysis content requirements. While the new content specifications in the proposed rule do reflect sub-regulatory guidance already published regarding compliance with the CAA, 2021 requirements, they are far more extensive than anything that has been required in NQTL analyses previously.

As we have already indicated, self-funded plan sponsors have virtually no independent access to the information that is currently required to create and maintain a compliant NQTL analysis and ascertain parity status of any existing NQTLs. This problem will only be compounded by the extensive new content requirements, which include things like:

"In instances in which the application of the factor depends on specific decisions made in the administration of benefits, the comparative analysis would be required to provide information on the nature and timing of the decisions, and the professional designations and qualifications of each decision maker. For example, for a prior authorization NQTL that uses quality measures as a factor, the plan or issuer would be required to describe the nature of the decisions reviewers make to apply the factor (and the timing of those decisions) and describe the reviewers' professional designations and qualifications (including, for example, whether they are

psychiatrists or psychologists) when using the factor to apply the NQTL to mental health benefits."

"The analysis would also be required to address any deviation(s) or variation(s) from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the NQTL to mental health and substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations."

"Relevant, quantitative data, calculations, or other analyses showing whether, in each classification in which the NQTL applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard. In addition, such documentation would include records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application. Such records could include meeting minutes, or calculations related to quantitative factors, such as costs."

"A comprehensive explanation of how the plan or issuer ensures that, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to medical/surgical benefits. This comprehensive explanation would be required to include an explanation of any methodology and underlying data used to demonstrate the application of the NQTL in operation, and the sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL is applicable."

Self-funded plan sponsors do not have independent access to any of this information. They must obtain data from their plan vendors, rely on such vendors to provide information that is both accurate and timely, and then engage with compliance vendors and attorneys to transform what information they may obtain into compliant analytical reports that meet the Departments' specific criteria. The preamble to the proposed rule assumes that third-party administrators will largely perform NQTL analyses for their self-funded plan clients. That assumption is not based on market reality. Furthermore, since in many cases a single third-party administrator is only one of many plan vendors that share responsibility over the creation, maintenance, and application of plan NQTLs, it is not practical to assume that such administrators would even be capable of performing complete analyses on the part of all self-funded group health plans.

Instead, the current NQTL analysis requirements essentially require plan sponsors to contract with an independent compliance vendor or attorney or both to prepare and maintain their reports. While sometimes a third-party administrator refers the plan sponsor to such a vendor, or even works with the vendor on behalf of the group client and passes through the compliance vendor's fee, it is ultimately the group plan that is bearing the cost and responsibility of compliance. The new specifications will only compound this issue.

As it stands, the market rate for a baseline NQTL analysis is between $8,000-$75,000. This does not include additional costs that are associated with professional assistance in responding to requests from state and/or federal regulators. These rates will only climb exponentially if the Departments require plan sponsors to obtain the level of information required by the proposed rule. As such, our membership urges the Departments to consider the economic and administrative burden they are placing on plan sponsors with this proposal, and to contemplate both simplification and compliance relief in any final regulation.

Requirement To Provide Comparative Analyses and Notices to the Departments and Other Individuals and Entities—26 CFR 54.9812–2(d) and (e), 29 CFR 2590.712–1(d) and (e), and 45 CFR 146.137(d) and (e)

These proposed rules would establish that if the Departments or a relevant state authority requests a comparative analysis, plans and issuers must provide it within ten business days of receipt of the request. After a plan or issuer responds to an initial request for a comparative analysis, if the relevant authority concludes a plan or issuer has not submitted sufficient information for it to review the requested comparative analyses, the proposed rule would require the plan or issuer to furnish this additional information to the relevant Secretary within ten more business days. If the relevant authority makes an initial determination that the plan or issuer is not in compliance, then the plan or issuer must specify the actions they will take to bring the plan or coverage into compliance provide and demonstrate compliance to the Departments no later than 45 calendar days after the initial determination of noncompliance. While these proposed rules would codify the statutory requirement to make comparative analyses available to the applicable state authority upon request, these proposed rules do not otherwise apply the timeframes and processes regarding the secretarial request process to requests made by applicable state authorities.

NABIP members support the determination by the Departments to not impose the federal response timelines on state-level requests. These timelines should be determined by the relevant state regulators. Regarding the federal response timelines in the proposed rule, NABIP members believe the ten-day windows specified are very short. Furthermore, our members who have assisted group plan sponsor clients with NQTL analysis requests from the Departments report that individual investigators often provide extensions to these deadlines based on facts and circumstances. Therefore, we request in any final rule that either the potential for extensions be clearly delineated, or that the response windows be lengthened to at least 30 days, or both.

If the relevant Department makes a final determination that the plan or issuer is not in compliance following the 45-calendar-day corrective action period, these proposed rules would provide that, within seven calendar days of the receipt of the final determination of noncompliance, then plan or issuer must provide a standalone notice that is not combined with any other notices or disclosures, to all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of these proposed rules. The plan or issuer would also be required to provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same time frame.

These proposed rules require that the notice be written in plain language, in a manner calculated to be understood by the average plan participant or beneficiary, and include the following statement prominently displayed on the first page, in no less than 14-point font:

"Attention! The [Department of Labor/Department of Health and Human Services/Department of the Treasury] has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act."

The measure also includes numerous other specific content requirements for a compliant notice. While NABIP generally prefers that the Departments provide complete sample notices for group plan sponsors to use, since this greatly increases the odds of compliance success, we understand that since each notice would need to be entirely group and situationally specific, the requirement does not lend itself to the development of a template. As such, we appreciate the very specific content requirements outlined in the proposed rule, and we suggest that any final rule be accompanied by sub-regulatory guidance and online compliance resources to guide affected plans and issuers in drafting their own compliance notices, should they be required to produce and distribute them.

Under these proposed rules, a plan or issuer would be required to make the notice available in paper form. The plan or issuer may also make the notice available electronically (such as by email or an internet posting) if the format is readily accessible, the notice is provided in paper form free of charge upon request, and, in a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email that the documents are available on the internet, provides the internet address, and notifies the participant or beneficiary that the documents are available in paper form upon request. If the plan in question is subject to ERISA, then the plan or issuer would also be required to ensure that the notice is provided to any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within seven calendar days of receipt of the final determination of noncompliance, so that the service provider or fiduciary can appropriately take the violation into account when making claims determinations.

Regarding notice distribution, NABIP members ask the Departments to reconsider the proposed paper distribution requirement. In our membership's considerable experience dealing with plan participants and providing them with required notices, paper copies of notices are very unlikely to go unread. In addition, there are the environmental and cost impacts of producing and distributing paper notices. Instead, NABIP members support the electronic notice distribution requirements in the proposed rule. Also, we note that the seven day distribution requirement is very short. At minimum, this should be changed from simply days to business days, but preferably it will be extended in any final rule to 30 days.

In cases of an adverse benefit determination, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage would be required to make these comparative analyses available to participants or beneficiaries, and providers or other individuals acting as their authorized representative, upon request. Additionally, under these proposed rules, plans subject to ERISA would be required to make these comparative analyses available to participants and beneficiaries upon request, as these proposed rules are instruments under which a plan is established or operated. If a provider or other person is acting as a participant's or, beneficiary's, authorized representative, plans subject to ERISA would be required to make this analysis available to the provider or other authorized representative. NABIP members support these requirements relative to the distribution of comparative analyses to plan participants, beneficiaries, and authorized representatives.

Applicability of the New Requirements—26 CFR 54.9812–1(i), 29 CFR 2590.712(i), and 45 CFR 146.136(i) and 26 CFR 54.9812–2(g), 29 CFR 2590.712–1(g), and 45 CFR 146.137(g)
The new provisions of the proposed rule, if finalized, would apply on the first day of the first plan year beginning on or after January 1, 2025. Until the applicability date, plans and issuers would be required to continue to comply with existing MHPAEA statutory and regulatory requirements, including new sub-regulatory guidance. In particular, the preamble to this measure notes that "the proposed delayed applicability date for these proposed rules does not alter a plan's or issuer's obligations under the statute. As such, plans and issuers must continue performing and documenting comparative analyses of the design and application of NQTLs in accordance with the statutory requirements and make them available to the Departments or applicable State authorities before the applicability date of these proposed rules, if finalized."

The members of NABIP appreciate the Departments' recognition that implementing policy changes of this magnitude will take plans and issuers time and the inclusion of an implementation delay of new requirements until plan years beginning on or after January 1, 2025. However, we also note that the process of finalizing any new parity rules will take time, and in all likelihood, at least some of the potential new requirements offered in this measure will be altered. Plans, issuers, and other service providers who are not directly affected by the MHPAEA rules, but on whom plan sponsors especially must rely on for compliance purposes need at least one year, if not more to make the substantial changes any new rules will mandate.

As such, we request a transition period of at least one plan year for all plans, including those whose plan years reset on a non-calendar year basis. So, unless any final rule is fully issued before the end of 2023, NABIP request an implementation timeframe for new and revised provisions of plan years beginning on or after January 1, 2026.

Sunset of MHPAEA Opt Out for Self-Funded Non-Federal Governmental Plans

Prior to the passage of the Consolidated Appropriations Act of 2023 (CAA, 2023), sponsors of self-funded, non-Federal governmental plans were permitted to opt out of compliance with the requirements under MHPAEA, among three other requirements categories of title XXVII of the PHS Act. The CAA, 2023, included provisions that sunsets the election option with respect to MHPAEA. The proposed regulation would amend the existing MHPAEA rules to align with the CAA, 2023, including providing transition relief for collectively bargained plans. NABIP members support these amendments.

Applicability of MHPAEA to Individual Health Insurance Coverage

The current MHPAEA rules provides that the group market regulation implementing MHPAEA apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market. Therefore, through cross-reference, the proposed amendments in this rule, if finalized, would apply in the same manner to health insurance issuers offering individual health insurance coverage. Further, HHS proposes another cross-reference to make clear that the comparative analysis requirements apply to health insurance issuers offering individual health insurance coverage in the same manner that those provisions apply to group health plans and health insurance issuers offering coverage in connection with such plans. These provisions would apply to health insurance issuers offering individual health insurance coverage for policy years beginning on or after January 1, 2026. NABIP supports the addition of the regulatory cross references that fully extend all group MHPAEA compliance requirements to individual coverage that is also subject to the MHPAEA.

Request For Additional Information

The Departments requested comments on the following specific questions. NABIP's responses to the questions our membership has the expertise to answer (all but question two, which we believe should be answered by providers) are reflected below:

1. **Group health plan sponsors depend on administrative service providers, health insurance issuers, and other TPAs to design and manage their plans in a manner that complies with MHPAEA among other Federal consumer protections. However, plan sponsors are generally responsible for ensuring compliance and could, in certain circumstances, be liable for penalties for any violations. Are there ways that TPAs could be further**

incentivized to facilitate compliance with MHPAEA on behalf of the plans that they design and administer?

Self-funded group health insurance plans attempting to comply with both the CAA, 2021's NQTL analyses requirement and also the requirement for plans to regularly analyze the appropriateness of their QTLs have struggled to obtain group-specific data needed for testing from their relevant service providers. In order to ensure better cooperation from all service providers, including but not limited to TPAs, NABIP members suggest the following: (1) clearly specifying in any final regulation that group-specific data is needed to conduct operational stringency testing of NQTLs that are administered on a group specific basis (e.g., prior authorization, step-therapy, concurrent review); (2) establishing that service providers have a fiduciary responsibility to provider their clients with access to their own data as needed for NQTL and QTL testing; (3) establishing that service providers are expected to provide up-to-date information to plan sponsors in a timely fashion; (4) delineating examples of categories of information required to be provided for testing in any proposed rule's NQTL compliance examples (e.g., number of total MH/SUD and M/S claims subject to prior authorization, numbers approved, numbers denied, numbers appealed, results of appeals, processing time, etc.). Further, NABIP suggests any final MHPAEA rule include an enforcement safe harbor for group plan sponsors who attempt to obtain information from their service providers, but are unable to obtain information from these entities, or who are provided with incomplete data or information that is not provided in a usable form.

3. Code section 9820(a) and (b), ERISA section 720(a) and (b), and PHS Act section 2799A–5(a) and (b), as added by section 116 of title I of Division BB of the CAA, 2021, establish standards related to provider directories. The Departments intend to undertake notice and comment rulemaking to implement the provider directory requirements. Are there ways that the Departments can improve the coverage of and enhance access to mental health and substance use disorder benefits through their implementation of these provider directory requirements, particularly in underserved or rural areas where there may be limited access to the internet?

Provider directories are notoriously inaccurate for all types of providers, including MH/SUD. Attempts to ensure that provider directories are up-to-date and do not include duplications (e.g., the same provider listed multiple times at various locations) would be very helpful, In addition, directories should include accurate information about the ability of the provider to accept new patients, the average wait time for an initial appointment, and any special qualifications of the provider (e.g., language proficiency) would be beneficial for plan participants seeking access to both MH/SUD and M/S services. Finally, MH/SUD providers specialize in different types of care and different kinds of treatment methodologies just like M/S providers do. A directory that included information about each MH/SUD providers area of specialty and types of services offered would be extraordinarily useful to those seeking care.

4. Telehealth has become a vital means of providing health care, including mental health and substance use disorder care, especially in rural areas and in light of the COVID–19 PHE. For the duration of any plan year beginning before the end of the COVID–19 PHE, the Departments issued guidance providing relief from the group market reforms under part 7 of ERISA, title XXVII of the PHS Act, and chapter 100 of the Code for a group health plan (and health insurance coverage offered in connection with a group health plan) sponsored by a large employer that solely provides benefits for telehealth or other remote care services offered only to employees (or their dependents) who are not eligible for coverage under any other group health plan offered by that employer. However, these arrangements were required to continue to comply with certain Federal group market reforms, including the requirements under MHPAEA. How and to what extent has this guidance affected mental health and substance use disorder care and access? Would any further safeguards be needed? How can the Departments use telehealth or other remote care services to enhance access to mental health and substance use disorder treatment under the Departments' existing authority for both routine and crisis care for behavioral health conditions, including through parity requirements with respect to financial requirements and treatment limitations?

Behavioral access to telehealth services for MH/SUD may be limited by requirements that a person be located in the state that the provider is licensed in to receive their services and obtain insurance reimbursement for such services. Additionally, while plans often provide access to telehealth services, ensuring that such benefits are no less accessible for MH/SUD as they are for M/S may be a challenge based on their service providers available. Addressing these issues would be helpful.

5. Under the internal claims and appeals and external review rules implementing the Affordable Care Act, which are generally applicable to all non-grandfathered group health plans and non-grandfathered group and individual health insurance coverage, claim denials related to medical judgment (including for mental health and substance use disorder benefits) are eligible for external review. The internal claims and appeals rules also provide that claimants (or their authorized representatives) are entitled to, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information about the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan. How can the Departments leverage ERISA's and the Affordable Care Act's existing claims procedure requirements to help facilitate access to mental health and substance use disorder benefits? For example, if a plan or issuer denies a mental health or substance use disorder benefit based on the plan's or issuer's determination that a lower level of care would be more appropriate, should the plan or issuer be required to identify the relevant lower level of care? Should plans and issuers be required to provide an explanation

of how a particular NQTL was applied to particular benefits, beyond what is currently required by the claims procedure rules or other related provisions?

One way to ensure the claims and appeals and external review rules are being used effectively might be to specify that plans test how many MH/SUD versus M/S claims are the subject of claims appeals and external review, including the results. In addition, the distribution of the NQTL information to claimants could be mandatory, rather than only upon request.

6. Currently, the minimum value rules under HHS and Treasury regulations at 45 CFR 156.145 and 26 CFR 1.36B–6, respectively, specify that an employer-sponsored plan provides minimum value only if the percentage of the total allowed costs of benefits provided under the plan is greater than or equal to 60 percent, and the benefits under the plan include substantial coverage of inpatient hospital services and physician services. Should HHS and Treasury consider amending the minimum value rule so that it would apply separately and independently to medical/surgical benefits, and to mental health and substance use disorder benefits? Should HHS and Treasury consider amending the minimum value rule to require substantial coverage of mental health and substance use disorder benefits? If so, how should "substantial coverage" be defined in that context?

The current minimum value rules are complicated and employer plan sponsors regularly rely on their service providers to determine the compliance of their various coverage offerings. Changing the calculations so that they apply separately to MH/SUD benefits would make the MV rules even more complicated and make it even more difficult for plan sponsors to ensure compliance on the part of their service providers. It could also require plan sponsors to engage in actuarial services, creating an additional administrative complication and cost for plans.

Requiring substantial coverage of MH/SUD services would be a more effective way of achieving this objective. Substantial coverage could mirror the new definitions of MH and SUD coverage as proposed in this rule.

7. As HHS oversaw the transition to 988 as the new easy-to-remember 3-digit code to access life-saving services through the Suicide & Crisis Lifeline, there has been increased attention to current gaps in access to and provision of a full continuum of behavioral health crisis services. Final rules under MHPAEA do not specifically address mobile crisis services. Similarly, in the establishment of EHBs as part of required benefits for non-grandfathered individual and small group coverage under the Affordable Care Act, there is no specific reference to behavioral health crisis services as part of the EHB categories. The Departments are interested in determining if there are questions as to how these services fit within the existing categories for either MHPAEA, or the EHB categories. Are there aspects of community-based behavioral health crisis services that the Departments should address in the context of MHPAEA? Should the Departments ensure that community-based behavioral health crisis services are classified in the same way as particular medical/surgical services, and what are those particular services? Should crisis call/text/chat center services, mobile crisis and stabilization services

be specifically included as EHBs? Are there ways the Departments can increase access to crisis services with current authorities, including in rural or underserved areas in which there are several challenges to accessing care? How can parity be strengthened across the behavioral health crisis services landscape, including in areas with shortages for behavioral health providers? How can the Departments collaborate with State and local agencies to improve access to existing and future behavioral health crisis services?

Crisis care as described is typically provided at the community level, through police departments and other community-based service providers, rather than as a component of typical health insurance coverage. NABIP believes that these community-level resources are vital, and we believe the Departments should devote resources to ensuring the availability of exemplary MH/SUD crisis resources in every community. However, we believe that the appropriate place for these resources is at the community level, rather than as part of private health insurance coverage. Inserting these services into EHB requirements would be very complex. More importantly, if the expectation became that these were benefits that are offered as part of private insurance coverage, NABIP members are concerned that access could then become limited for other members of the public who do not have coverage affected by the MHPAEA and/or EHB requirements. We would be loath to see any population group unintentionally excluded from these critical services.

We truly appreciate the opportunity to comment on this proposed rule, as well as your willingness to consider the viewpoints of all stakeholders. If you have any questions or need additional information, please do not hesitate to contact me at jgreene@nabip.org or (202) 595-3677.

Sincerely,

John Greene

Senior Vice President of Government Affairs

National Association of Benefits and Insurance Professionals