From:	Curtis Garry
To:	EBSA MHPAEA Request for Comments
Cc:	Allison.Ivie@centerroadsolutions.com
Subject:	Walden Behavioral Care Technical Release Comments
Date:	Tuesday, October 17, 2023 6:38:13 PM
Attachments:	image001.png MHPAEA Proposed Rule REDC Comments.pdf MHPAEA Technical Release REDC Comments.pdf

Please see the attached comments provided by Walden Behavioral Care. Thank you for the opportunity comment.

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Monte Nido & Affiliates
Treating Eating Disorders

October 16, 2023

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

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

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

Re: Comments on Technical Release 2023-01P

Dear Secretary Becerra, Assistant Secretary Gomez, and Deputy Commissioner O'Donnell:

Walden Behavioral Care appreciates the opportunity to comment on the Department of Health and Human Services, Employee Benefits Security Administration, and the Internal Revenue Service's (the "Departments") Technical Release 2023-01P, Request for Comment on Proposed Relevant Data Requirements for Nonquantitative Treatment Limitations (NQTLs) Related to Network Composition and Enforcement Safe Harbor for Group Health Plans and Health Insurance Issuers Subject to the Mental Health Parity and Addiction Equity Act (hereinafter "Technical Release").

Monte Nido and Affiliates is a multistate eating disorder treatment organization with 50+ facilities in fifteen states. Our centers provide inpatient, residential, partial hospitalization and intensive outpatient levels of care for individuals with eating disorders and co-occurring mental health disorders including Posttraumatic Stress Disorder and Substance Use Disorders. Our organization's mission is: "Guided by empathy and unwavering support, we challenge harmful norms and work to eradicate eating disorders." We agree to treatment and operational standards including accreditation by the independent accrediting bodies of the Joint Commission and/or Commission on Accreditation of Rehabilitation Facilities (CARF), conduct collaborative research, and work together to address treatment access issues facing individuals with eating disorders and their families.

We strongly support the Departments' proposed NQTL data collection requirements relating to network composition as part of the Departments' efforts to increase access to mental health and substance use disorder (MH/SUD) treatment. Such data collection is critical to ensure that plans and issuers do not impose

treatment limitations that place a greater burden on plan members' access to MH/SUD treatment than to medical/surgical (M/S) treatment. Combined with the accompanying proposed requirements related to the Mental Health Parity and Addiction Equity Act (MHPAEA), the data collection requirements that are envisioned in the Technical Release would be powerful steps in the right direction to increasing access to MH/SUD treatment. We urge the Departments to require that the data points for MH services and SUD services be separately collected, analyzed, and reported, consistent with MHPAEA statutory and regulatory requirements. Data should also be collected for M/S services to facilitate MHPAEA comparisons. We also urge the Departments to require that all data be collected, analyzed, and reported by age group, including children and adolescents, and by race/ethnicity (where possible). The Departments should also develop uniform definitions and methodologies for the collection of all data points so that valid data are collected and can be compared across plans/issuers.

We appreciate the Departments' commitment to ensuring that the data plans/issuers will be required to collect are an accurate reflection of individuals' access to treatment. Given that the Departments' guidance to plans will likely need to evolve over time to ensure such accuracy, we urge the Departments not to proceed with a "safe harbor" for plans/issuers based on data collection that has yet to be validated as meaningful. As we describe below, we believe that a "safe harbor" should not be explored until data collection has been extensively validated. Otherwise, the Departments may give "safe harbor" to plans/issuers that impose discriminatory barriers that inhibit access to MH/SUD treatment.

Our full comments are as follows.

Out-of-Network Utilization

Studies indicate that the percentage of services received out-of-network (OON) is a key indicator of the availability of in-network services. Due to the higher cost-sharing of OON services, individuals rarely choose to obtain care OON if adequate in-network services are available on a timely basis. The landmark Milliman report demonstrates the importance of such data and how frequently MH/SUD care is obtained OON compared to M/S care. The data should be disaggregated by age groups, so that utilization by children and adolescents can be distinguished from adults. This is particularly important given that half of lifetime mental health conditions begin by age 14 and our country's ongoing youth mental health emergency.

We support the Departments' reference to quantitative templates in the Appendix that have already been validated and are in use by employer groups and state regulators. The Bowman Family Foundation Report, which is based on a patient and provider survey conducted by NORC, shows multiple analyses of OON use and access problems, as do other consumer and employer and provider surveys and studies. Recently published research also shows that MH/SUD patients go out of network because of MH/SUD network inadequacies – the same reasons that M/S patients go out of network.

- Insurance rarely covers nutrition counseling for individuals with an eating disorder diagnosis at the outpatient level of care. Coverage is better at higher levels of care as it is a bundled service. Although the ACA requires insurers to cover nutritional counseling for those with chronic conditions—diabetes, hyperlipidemia, obesity, etc., eating disorders is not deemed chronic and patients consistently either forgo treatment or pay out of pocket to see an OON provider.

Percentage of In-Network Providers Actively Submitting Claims

Research studies indicate that collecting this data is critically important to determining the adequacy of a network. Plans/issuers frequently pad their networks by having providers listed as in-network even if they aren't actively submitting claims. This metric can also be important in suggesting the existence of other reasons why providers listed as in-network might not be available, including low reimbursement that incentivizes providers to fill appointments with patients with insurance that pays more and/or cash-pay patients. Again, this data should be disaggregated by children and adolescents. While we welcome the Departments' reference to child psychiatrists and psychologists, all types of pediatric providers should be included. Additionally, it is important to include data on M/S pediatric subspecialists to the lists (e.g., pediatric cardiologists, pediatric neurologists, etc.) for purposes of assessing parity. Examples of providers listed as in-network but not available for plan members are detailed below.

- "I am part of a multidisciplinary outpatient eating disorders team for adolescents and young adults in Virginia. We have a large patient base of patients with state funded insurance. Based on our experience, currently there do not appear to be few if any IOP, PHP or residential programs for eating disorders covered in-network for children with Medicaid in Virginia. Although Medicaid MCOs Optima and Virginia Premier list programs as providing care for eating disorders, those programs tend to provide only one week of inpatient psychiatric care, and that care is usually not specific to eating disorders. In one case, we have recommended an adolescent for a higher level of care for 10 months. The patient has been accepted into residential care, but then insurance has continued to deny coverage despite many appeals. This scenario happens repeatedly in our clinic for patients with Virginia Medicaid."

- "I am a Pediatric Nurse Practitioner at a major Children's Hospital where I work in Adolescent Medicine, specifically with eating disorder patients in both the inpatient and outpatient settings. Eating disorder resources are scarce and insurance continues to be a significant and troubling barrier and source of inequity for our patients, and the examples are endless.

  Recently, we had an adolescent admitted with a new diagnosis of Anorexia Nervosa - Restricting Subtype who required medical stabilization due to her malnutrition and bradycardia. She was medically stabilized, but due to her severity of illness, she remained dependent on an [nasogastric] (NG) tube for all her nutrition. She was ineligible for any residential program in the country based on the combination of her NG reliance and her insurance. The only residential program in the country that accepts Medicaid is The Emily Program, which is in Minnesota, and not possible for many of our families in Washington. To note, the Emily Program in Minnesota does not accept NG tubes, and often refer to their collaborative program, Veritas, who does not take Medicaid. These youth had zero options in the entire country for care.

  We started the application process for scholarships, but we were told that the awards (which may take several months) wouldn't cover the full cost of the programs (for example, 6 weeks at Eating Recovery Center in Denver was quoted at $58,000). Safe disposition planning and no accessible eating disorder treatment was the barrier to discharge. Through the incredible efforts and meal support coaching done by our team, this adolescent began to take her nutrition by mouth, and became eligible for one additional residential program in Oregon, that still required a single case agreement for her to be able to access it. Insurance barriers were the primary factor contributing to

inequitable care in this case, and those of us who work in the field of eating disorder care experience this distressing fact daily."

Time and Distance Standards

We strongly support the Departments' suggestion that the Departments collect detailed data on the percentage of participants/beneficiaries/enrollees who can access specified provider types in-network within a certain time and distance. We strongly agree with the Departments' view that this data would help with the assessment of a plan/issuer's operational compliance with respect to any NQTLs related to network composition. We also recommend that the Departments collect data on appointment wait times, which are an essential metric to measure network adequacy and the most critical for participants/beneficiaries seeking timely access to care. The Department of Health and Human Services has already put forward strong proposed standards for Medicaid managed care and the Children's Health Insurance Program (CMS-2439-P), which establish maximum appointment wait time standards for routine outpatient mental health and substance use disorder services of 10 business days and require such independent secret shopper surveys. These standards align with appointment wait time metrics that have been adopted for Qualified Health Plans.

In collecting data, the Departments should collect data on routine and crisis appointments, including for follow-up and ongoing care. When only initial appointment wait times are measured, plans/issuers can manipulate their practices to have initial "intake" appointments while having long delays in the delivery of ongoing services. Data should be disaggregated by age group to assess wait times and travel distance for children and adolescents.

We also urge the Departments to require any plan/issuer that uses a source or evidentiary standard for its network adequacy standards (whether a state/federal government or an independent entity such as NCQA) to identify and explain how the standards were designed, as written, to comply with MHPAEA. The Departments should require that, for any source, a plan/issuer must provide and define all the factors and evidentiary standards relied upon for each MH/SUD network standard (e.g., time and distance) and complete a comparative analysis for each factor to demonstrate that the standard is comparable and no more stringent, as designed, for MH/SUD than for M/S.

For example, MH/SUD outpatient providers often have different characteristics such as smaller size and/or smaller caseloads than M/S providers. It is essential that the Departments require plans/issuers to demonstrate that these different characteristics are considered and addressed in assessing the adequacy of each standard. As an illustration, many MH/SUD professionals can only treat 8 to 10 patients per day, while many Primary Care Physicians (PCPs) can see 30 to 40 patients per day. A network adequacy standard that has equivalent time and distance standards (10 miles / 30 minutes) for one full-time PCP and one full-time Psychologist is not comparable and is more stringent, due to the provider case load.

The Departments should require the same type of analysis for MH/SUD facilities. For example, how are MH/SUD acute and subacute inpatient facilities the same or different as compared to acute and subacute M/S facilities – and how is that considered and addressed by the plan in developing each standard? The plan should be required to describe the factors used to compare types of MH/SUD facilities (e.g., psychiatric versus substance use), as well as capacity (e.g., number of beds, availability of beds) of MH/SUD facilities versus M/S facilities.

We urge the Departments to also ensure that as-written NQTL analysis also address the factors of supply/demand for both MH/SUD and M/S outpatient professional and facility providers, including definitions for these factors, evidentiary standards and sources. Studies, reports or data measuring provider supply (including shortages) and market demand should be required to be provided.

- Hospitals across the nation are reporting the inability to keep up with demand as St. Louis Children's Hospital in Missouri is seeing 8-15 kids per day for behavioral health issues including suicide attempts, eating disorders, anxiety, and psychosis. At C.S. Mott Children's Hospital in Ann Arbor, Michigan, administrators found medical admissions among adolescents with eating disorders during the first 12 months of the pandemic more than doubled the mean for the previous 3 years. At Arkansas Children's, the hospital has seen a 150% increase in mental health disorder emergency room admissions, including a rise in eating disorders. The state does not offer any residential treatment for adolescent eating disorders, which means kids must get sicker to reach an inpatient level of care or find care out of state.

- "My daughter suffers from anorexia. While living in San Francisco she placed herself in a 72 hour hold for suicidal ideation. On exit from the hold, she requested treatment from Kaiser. She was told the first available appointment was 30 days in the future. At that point I panicked, researched programs in the US. A parent will do anything for their child. I flew her to ERC Colorado, and they admitted her. When we asked Kaiser for coverage, they denied as a result of out of network, pre-authorization. I spent close to $200,000 of my retirement funds in treatment costs out of pocket. We used Kantor and Kantor law firm and sued Kaiser. They would not budge and continued to argue that her out of network treatment was unauthorized."

Network Availability and Distribution of Professions

We applaud the Departments for focusing on whether providers are accepting new patients (Section (c)(4)(iv)(A)(2) of the proposed rule), which is a crucial issue in light of the high demand for MH/SUD services. A MH/SUD provider with just a few time slots available does not add significant capacity to plans/issuers' networks. We believe that the Departments should require that any network adequacy standard should consider typical limits on MH/SUD providers, who typically have smaller caseloads, less capacity and limited availability for new patients as compared to most M/S professional providers. (For example, a standard that equates 1 full-time PCP to 1 full-time Psychologist is not comparable in light of the differences in caseloads and capacity).

It is also important to require metrics on the number of available providers who fill high-demand needs in the network, such as those seeing children & adolescents, those who specialize in eating disorders or LGBTQ patients, and those who meet the language needs of the population served by the network. While the Service Utilization metrics below in these same categories would address how much certain services are being utilized, it may be that while there is a reasonable level of, for example, eating disorder services provided by network providers, those providers may be completely full. Thus, it is also important to assess whether new patients with these specialized needs can find available providers.

A robust network has a full range of different professions and training levels to handle the varying needs and more complex problems of the patient population. Thus, we recommend gathering data (on both the MH/SUD and M/S sides) on the percentage of the top 10 different professions that make up the network.

We also support that plans should measure the actual numbers of licensed MH/SUD professionals by geo zip code.

- The recurring theme we hear from patients is the dearth of health care professionals who specialize in eating disorders. This can be registered dietitians who specialize in weight management, which means they see patients who have obesity and seeking weight loss—not an appropriate provider for an individual seeking an RD for eating disorders nutrition counseling. We also have heard of psychologists that do not specialize in eating disorders. This results in patients 1) forgoing care, 2) attempting to access care in-network only to be negatively impacted by the experience or 3) pay out of pocket for an OON provider.

- "I was referred by my therapist to see a nutritionist who specializes in eating disorders. My insurance said they don't cover nutrition for "eating disorders" and after calling multiple in network providers, it was clear that no in network providers were trained or had experience with eating disorders. I tried to get coverage with a single case agreement, but insurance just took us around in circles and denied coverage. I still see this nutritionist for an ongoing eating disorder and have to pay out of pocket which means I can only see her once a month."

- "Our insurance provider didn't have any in-network dietitian providers with eating disorder experience/expertise/certification. They would not agree to cover any of the ED experts in our area. We paid out of pocket for many years. At the height of her illness, we were paying $900 a month. They had many dietitians on their in-network list that specialized in diabetes, obesity, etc.

  Earlier, when we had an HMO, we were given the choice of one dietitian. She had no experience with eating disorders and missed many signs of my daughter's relapse. We weren't willing to risk that again, so we paid out of pocket."

Network Admissions

In assessing network composition and access to MH/SUD services, we urge the Departments to review the criteria and processes by which plans/issuers determine which providers to admit into networks and/or how plans/issuers define when a network is considered "full" or "closed." Reports from MH/SUD providers suggest that they are often denied participation on networks due to the networks being "closed" or "full," even though patients are unable to find appropriate providers in that network. Other providers who are eventually admitted into networks report having to wait as long as nine months to be added.

Plans/issuers should not be allowed to claim a workforce shortage as a reason for access to care issues and simultaneously keep networks locked or slow to accept new providers. Collection of information about processes and criteria will reveal how much responsibility plans/issuers bear for the lack of access to MH/SUD services. For example, plans/issuers should provide metrics on how many providers applied to the network, what percentage were rejected and the reasons for the rejection (e.g., network full, provider not qualified, and the time it takes to bring providers into the network from when they first apply).

- An eating disorder treatment facility is awaiting a final contract with a payer after credentialing approval and agreement on reimbursement rates in October 2022. The contract was sent over and the facility signed the contract and never received a counter signed contract as the payer, "needs to

rethink the reimbursement language and strategy for the type of service you offer. We will revisit your contract after the first of the year in early 2023 when we have more information."

After several email follow-ups, the eating disorder treatment facility received the following in June 2023, "Thank you for continuing to follow up and I apologize for the delay in sending you a contract to add your group to our provider network. We have a hold on adding providers as we continue to finalize internal workflows. Our target is to follow up with you in September 2023 to start the contracting process." There has been no communication since.

The state is in need of eating disorder treatment providers and the local university has reached out to this facility requesting their help as students are presenting with higher acuity than they're able to handle. This delay from the plan is unacceptable while individuals continue to get sicker.

Reimbursement Rates

We applaud the Departments' suggested data collection relating to reimbursement rates, which are critical determinants of network adequacy; many studies show the strong correlation between network access and reimbursement rates. We also commend the Departments for putting forward potential requirements that reimbursement rate data be "compared to billed rates." Reimbursement rates that are not reflective of current market reimbursement can profoundly affect the availability of MH/SUD providers, including current providers' decision to join a network and potential providers' decisions whether to enter the field. We strongly recommend the Departments evaluate the ratio of allowed in-network and OON amounts to OON billed market rates for MH/SUD and M/S. The billed rates of OON providers are the most accurate representation of the market rate. We also support developing additional reimbursement rate measures, such as percent of out-of-pocket (OOP) expenses for enrollees using out-of-network providers for MH/SUD versus M/S care.

With respect to the use of Medicare Fee Schedule and other external benchmarks such as Fair Health, we urge the Departments to utilize significant care to avoid perpetuating historic (and ongoing) disparities between MH/SUD and M/S reimbursement rates that are embedded in these benchmarks. We urge the Departments to recognize that Medicare and other claims databases and benchmarks rely on historical data that embeds legacy disparities in reimbursements between MH/SUD and M/S. Additionally, we strongly believe that caution is warranted with respect to Medicare because it:

- Is not subject to MHPAEA;
- Does not have allowed amounts for certain sub-types of MH/SUD providers (e.g., sub-acute inpatient care and the full range of MH/SUD professional providers);
- Does not cover some MH/SUD services for children and adolescents given that this population does not participate in the program;
- Only recognizes IOP and PHP levels of care in limited settings; and
- Has a structure that undervalues the work of MH/SUD professionals, which CMS recently acknowledged in its recent Physician Fee Schedule proposed rules.

Nonetheless, we recognize that the Departments, multiple state regulators, and research organizations (such as Milliman) have documented significant disparities between Medicare allowed amounts and plans/issuers' allowed amounts for MH/SUD providers versus M/S providers. As described below, the ultimate determiner of parity for any reimbursement comparison is the access to services (i.e., adequacy)

within MH/SUD networks in comparison with M/S networks. Indeed, reimbursement rate comparisons could actually show that MH/SUD providers are reimbursed at the same level as M/S providers, yet if MH/SUD network inadequacies persist, plans/issuers should be required to increase rates further for MH/SUD providers to address network inadequacies, as plans/issuers do for M/S.

While taking into account that the Medicare fee schedule and other external benchmarks may have legacy disparities embedded for MH/SUD services compared to M/S services, we have seen that they can be used as tools to demonstrate parity non-compliant reimbursement rates. This was the case in the U.S. Department of Labor and New York Attorney General's 2021 lawsuit against United Healthcare and United Behavioral Health (UBH) and resulting settlement agreement, which were based, in part, on UBH's disparate reductions from baseline rates derived from Medicare.

The Departments have made it clear that when faced with M/S provider shortages, if plans increase reimbursement rates for M/S providers to ensure adequate M/S networks, they must increase rates to address MH/SUD providers shortages as well to ensure adequate behavioral networks. The Bowman Family Foundation publication, "Federal Parity Law (MHPAEA): NQTL of In-Network Reimbursement Rates: Non-Comparable Use of Factors of Provider Leverage a/k/a Bargaining Power and Workforce Shortages" references federal data that shows there are more zip codes in the U.S. with Primary Care Physician (PCP) shortages than Psychiatrist shortages. Yet, there is relatively low out-of-network use for PCPs, and PCPs are routinely paid more than Psychiatrists for the same evaluation and management billing codes. Key quotes include:

- "Nationally, the average in-network reimbursement for MH/SUD professional office visits from commercial insurers was approximately 2.5% below Medicare reimbursement, and OON use of such visits was approximately 17%, i.e., 5.4 times higher than for primary care providers."

- "Nationally, the average in-network reimbursement for primary care professional office visits from commercial insurers was approximately 20% above Medicare reimbursement, and OON use of such visits was approximately 3%."

- "HRSA identifies "Health Provider Shortage Area" (HPSA) designations, which indicate that demand far exceeds supply. As reported by Kaiser Family Foundation, this national data as of Sept. 30, 2021 shows more shortages for PCPs than for mental health providers (7447 vs. 5930 shortage areas)."

The Departments guidance in the 2020 Self Compliance Tool is also clear:

"NOTE – Plans and issuers may attempt to address shortages in medical/surgical specialist providers and ensure reasonable patient wait times for appointments by adjusting provider admission standards, **through increasing reimbursement rates, and by developing a process for accelerating enrollment in their networks to improve network adequacy.** To comply with MHPAEA, plans and issuers must take **measures that are comparable to and no more stringent than those applied to medical/surgical providers to help ensure an adequate network of MH/SUD providers,** even if ultimately there are disparate numbers of MH/SUD and medical/surgical providers in the plan's network…" (Emphasis added).

As with all quantitative data metrics, multiple measures are important to accurately assess the compliance of any NQTL. Consistent with the current regulations and enforcement, as well as the Proposed Rules, reimbursement rates for MH/SUD providers are a key aspect of in-network access to care. We have seen that plans/issuers use reimbursement rate increases to establish and maintain adequate M/S networks, especially in addressing shortages of M/S providers. MHPAEA requires plans to take the same measures for MH/SUD providers to ensure adequate networks. Below are a few examples of how reimbursement rates impact providers and patients alike:

- A plan issued a 20% reimbursement rate reduction for nutrition counseling services for conditions the plan deemed "not chronic." Eating disorder diagnoses were part of the "not chronic" carveout along with conditions commonly seen with eating disorders, including irritable bowel syndrome (IBS) and polycystic ovary syndrome (PCOS). This same plan had also provided dietitians in their network the same rate for over 12 years forcing many dietitians to leave the network entirely.

Aggregate Data Collection

We strongly support the Departments, when reviewing self-funded employer group plans, to require relevant data to be collected and evaluated for both employer group enrollees as well as enrollees of the employer's third-party administrator (TPA) or other service provider in the aggregate. We agree with the Department that individual employer group plans may lack sufficient data.

Service Utilization Data

In assessing network composition and access to MH/SUD services, we urge the Departments to require plans to report on utilization rates for specific MH/SUD services and level of care. These utilization rates should be compared to estimates of participants/beneficiaries with these conditions, as well as utilization rates for M/S services. Examples of services providers, settings, and levels of care on which we urge the Departments to collect utilization data include:

- Child and adult psychiatrists, child and adult psychologists, master's level social workers and mental health counselors, psychiatric ARNPs, psychiatric PAs, all acute and sub-acute inpatient sub-types, and sub-types of outpatient facility programs, such as IOP, PHP, ABA, MAT, eating disorders, etc.;
- Each of the levels (and sub-levels) of care described in The American Society of Addiction Medicine (ASAM) Criteria and the age-specific Level of Care Utilization System (LOCUS) family of criteria developed by the American Association of Community Psychiatrists and the Academy of Child and Adolescent Psychiatry, as well as the average length of stay / treatment units and denial rates by each of these levels of care;
- Service utilization by MH/SUD diagnoses;
- High-demand needs such as services for children and adolescents, eating disorders, and services by providers who meet the language needs of the population served by the network;
- Cognitive behavioral therapy;
- Dialectical behavioral therapy;
- Coordinated Specialty Care;
- Medications for opioid use disorder (MOUD);
- Medications for alcohol use disorder (MAUD); and

- Medications for bipolar disorder, schizophrenia, major depressive disorder, and other MH/SUDs.

- As stated above, nutrition counseling/medical nutrition therapy services for individuals with eating disorders are underutilized because there is no coverage, limited to non-existent networks of dietitian specializing in eating disorders, or individuals having to navigate a plan ping ponging between M/S and MH/SUD seeking coverage for this service.

Safe Harbor

The Technical Release also requested feedback on the potential of a "safe harbor" for NQTLs related to network composition. We urge the Department not to proceed with a safe harbor at this time. We understand the desire to effectively target the Departments' enforcement resources. However, network adequacy has always been difficult to define and easy to mismeasure. Thus, a safe harbor has the potential to be harmful if the data collection requirements do not capture a complete picture of participants/beneficiaries' access to MH/SUD services. Given the significant work that the Departments need to do – and likely refinements that are necessary over time – to ensure collected data is complete, accurate, and meaningful, a safe harbor should not be considered in the near future. Such a safe harbor should only be considered when the Departments and key consumer stakeholders are confident that the data collected accurately captures actual access to MH/SUD services. If a safe harbor is put in place prior to this occurring, it could cause enormous damage by giving noncompliant plans/issuers a "safe harbor" against accountability. Furthermore, an issuer residing within such a "safe harbor" would almost certainly escape meaningful oversight from any applicable State authority.

Meaningful Data & Preventing Data Manipulation

To ensure that the proposed requirements relating to outcomes data and actions to address material differences in access are meaningful, we urge the Departments to issue standardized definitions on all data points and on methods for gathering and reporting data. For example, the Departments propose collecting data on the number and percentage of claims denials. Yet, there are many ways that plans can collect, and potentially manipulate, such "claims denials" data. For example, the Departments should make clear that failure to pay a claim in part or in full constitutes a denial and must find ways to capture common practices of undocumented denials that occur verbally through peer-to-peer reviews. Additionally, plans can manipulate denial data by approving each visit or day of treatment (thereby increasing the denominator) while telling the provider verbally that further visits/days will not be approved, which is another common occurrence. Such practices can result in meaningless data that bears little resemblance to what individual patients experience. The Appendix to the Technical Release lists templates already in use, including the Bowman Family Foundation's Model Data Request Form, which includes a section on Denial Rates. We support the continued use of templates that address the issues set forth above.

Disaggregating MH and SUD Data

We also encourage the Departments to make clear that MH and SUD data must be collected and analyzed separately. When MH and SUD data is simply aggregated, it can hide important discriminatory impacts.

Conclusion

Monte Nido & Affiliates
Treating Eating Disorders

We direct the Departments to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. All the stories provided have been sent previously to DOL for review. If the Departments are not planning to consider these materials part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

Thank you for the opportunity to comment on this important issue. If you have further questions, please contact Molly Perlman, MD, MPH, CEDS, Chief Medical Officer of Monte Nido and Affiliates at mperlman@montenidoaffiliates.com.

Sincerely,

Curtis Garry

Curtis Garry, MHA
AVP of Hospital Operations
Walden Behavioral Care

Monte Nido & Affiliates
Treating Eating Disorders

October 16, 2023

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

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

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

Re: 0938-AU93; 1210-AC11; 1545-BQ29; Requirements Related to the Mental Health Parity and Addiction Equity Act

Dear Secretary Becerra, Assistant Secretary Gomez, and Deputy Commissioner O'Donnell,

Walden Behavioral Care appreciates the opportunity to comment on the Department of Health and Human Services, Employee Benefits Security Administration, and the Internal Revenue Service's (the "Departments") proposed rule, Requirements Related to the Mental Health Parity and Addiction Equity Act (hereinafter "2023 Proposed Rule").

Monte Nido and Affiliates is a multistate eating disorder treatment organization with 50+ facilities in fifteen states. Our centers provide inpatient, residential, partial hospitalization and intensive outpatient levels of care for individuals with eating disorders and co-occurring mental health disorders including Posttraumatic Stress Disorder and Substance Use Disorders. Our organization's mission is: "Guided by empathy and unwavering support, we challenge harmful norms and work to eradicate eating disorders." We agree to treatment and operational standards including accreditation by the independent accrediting bodies of the Joint Commission and/or Commission on Accreditation of Rehabilitation Facilities (CARF), conduct collaborative research, and work together to address treatment access issues facing individuals with eating disorders and their families.

We strongly support the 2023 Proposed Rule's overarching goal to increase access to mental health and substance use disorder (MH/SUD) treatment by addressing treatment limitations that place a greater burden on participants/beneficiaries' access to MH/SUD treatment than to medical/surgical (M/S) treatment.

We strongly support the provisions highlighted below. We are especially supportive of the statement of the purpose of the regulations and law and the corresponding requirement that plans analyze the impact of a

nonquantitative treatment limitation (NQTL) on access to MH/SUD services as part of the comparative analysis. We further support the data collection and reporting requirements of the rule, especially with respect to the comparative analyses of NQTLs and network composition, as such requirements are essential to ensure compliance with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) given the longstanding history of practices to disparately limit access to MH/SUD services.

To fully realize the promise of the 2023 Proposed Rule's many extraordinarily strong provisions, the Departments must eliminate the proposed exceptions relating to "independent professional medical or clinical standards" and "fraud, waste, and abuse." To be clear, we strongly support requirements for plans/issuers to follow independent professional medical/clinical standards (generally accepted standards of care) and believe it is critical to combat fraud, waste, and abuse to safeguard the health and well-being of consumers. However, as structured, the proposed exceptions threaten to undermine significant parts of the 2023 Proposed Rule, potentially making its promise of increased access to MH/SUD services by combatting discriminatory treatment limitations illusory. Furthermore, we believe that these exceptions are not firmly based in MHPAEA's statutory text and that the underlying legitimate issues are most appropriately and effectively addressed within the existing (and proposed) NQTL rules.

Our full comments are as follows, with priority areas on the exceptions near the beginning.

29 CFR § 2590.712, 45 CFR § 146.136, AND 26 CFR § 54.9812-1 – PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS

Purpose – (a)(1)

We strongly support the purpose of the 2023 Proposed Rule. If the problematic proposed exceptions to core requirements of the 2023 Proposed Rules are eliminated, the Proposed Rule would significantly strengthen implementation of MHPAEA. When MHPAEA was enacted 15 years ago, the intent was to prohibit discriminatory treatment limitations that limit the "scope or duration of treatment." However, the current regulations have been insufficient to hold plans and issuers accountable for treatment limitations, including NQTLs, that place a greater burden on access (and, therefore, are more restrictive) to MH/SUD treatment as compared to M/S benefits.

We have seen how plans and issuers have engaged in elaborate, post-hoc rationalizations for why treatment limitations that place a greater burden on access to MH/SUD care are nonetheless compliant with the existing rules. While these rationalizations have never been convincing and state and federal regulators are increasingly holding plans and issuers accountable, the current regulations have not adequately placed the emphasis on the disparate burden that treatment limitations frequently place on plan members' access to MH/SUD treatment as compared to M/S treatment. Instead, too often, plans and issuers (as well as many regulators) have lost sight of an obvious, fundamental question under MHPAEA: the degree to which a "treatment limitation," in fact, limits access to MH or SUD treatment. We strongly support the Departments anchoring MHPAEA, including its implementing regulations, to whether plans/issuers' treatment limitations disparately limit access to MH/SUD treatment. Examples of treatment limitations our providers have faced include:

- An employer plan reduce reimbursement rates for PHP delivered via telehealth from 100% to 80% without clinical rationale. Upon this change in plan coverage, the enrollee decided to not access treatment given financial concerns.

- Another plan issued a 20% reimbursement rate reduction for nutrition counseling services for conditions the plan deemed "not chronic." Eating disorder diagnoses were part of the "not chronic" carveout along with conditions commonly seen with eating disorders, including irritable bowel syndrome (IBS) and polycystic ovary syndrome (PCOS). This same plan had also provided dietitians in their network the same rate for over 12 years forcing many dietitians to leave the network entirely.

- A plan offers nutrition counseling coverage provided via telehealth for enrollees with a diagnosis of diabetes or renal disease but would only provide in-person coverage for nutrition counseling for individuals with an eating disorder diagnosis.

Other common themes include engaging in concurrent review with plans and issuers only to receive authorization to deliver care for a very limited number of days. For patients in residential treatment, which is 24/7 care, plans and issuers have authorized 3 days of care and then the provider needs to get back on the phone with the plan. If a patient is enrolled in residential treatment, their eating disorder is severe, and it will not be medically appropriate for that patient to step down to a lower level of care after 72 hours. It is common practice for eating disorder treatment sites to have to negotiate authorization for care in increments of 3 days, 5 days or 7 days. Plans and issuers will also deny a level of care and authorize a lower of care if the patient has gained enough weight and that is the only metric used to determine coverage.

Substantially All / Predominant Test for NQTLs – (c)(4)(i)

We strongly support applying the substantially all / predominant test to NQTLs. The statutory language of MHPAEA is unambiguous in its requirement that treatment limitations applicable to MH/SUD benefits must be "no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits…" This test already applies to financial requirements and quantitative treatment limitations, and it should apply to NQTLs as well, which are also a "treatment limitation" under MHPAEA. Thus, we agree with the 2023 Proposed Rule's requirement that, if an NQTL is not applied to "substantially all" (i.e., two-thirds under the longstanding regulations) M/S benefits within a classification of care, plans/issuers may not apply the NQTL to MH/SUD benefits within that classification. If a plan/issuer does apply an NQTL to "substantially all" M/S benefits within a classification of care, a plan/issuer must then show that the NQTL applied to MH/SUD benefits within that classification is no more restrictive than the predominant variation applied to M/S benefits within the classification.

For example, one plan's documents explicitly stated "eating disorders are a behavioral health diagnosis and not covered under medical nutrition therapy [not a M/S diagnosis]. Only the symptoms of an eating disorder (e.g., obesity) would be covered, but an actual condition, bulimia would not be covered." This forces the provider and patient to be ping ponged back and forth between the MH/SUD and M/S sides of the issuer and is an example of a treatment limitation that is not grounded in legitimate medical necessity criteria.

Another example is the treatment limitation for atypical anorexia, which is covered within the DSM-V and filed under "other specified feeding or eating disorder." It is not uncommon for individuals with this eating disorder subtype to be in a higher weight body. One of our member sites has seen patients with atypical anorexia not receive authorization for treatment even though they present with the same symptoms as someone with a smaller body. If an individual does not present with a low enough body weight, insurance

companies will outright deny treatment. The individual then becomes sicker in order to "qualify" for treatment.

"Independent Professional Medical or Clinical Standards" Exception to NQTL Requirements – (c)(4)(i)(E), (c)(4)(ii)(B), (c)(4)(iv)(D), and (c)(4)(v)(A)

We support the Departments' desire to incentivize plans/issuers to follow "independent professional medical or clinical standards (consistent with generally accepted standards of care)" when imposing NQTLs. All plans/issuers should be following these standards and adherence to clinical standards is often identified as a factor or evidentiary standard in NQTL analyses.

However, we urge the Departments to remove the exception, which we believe is deeply flawed and will be exploited by plans/issuers to limit access to needed MH/SUD services. While we appreciate the Departments' statement in the preamble that this exception (along with the "fraud, waste, and abuse" exception) is meant to be "narrow," the experience of individuals, families, and providers under the existing regulations indicates that plans/issuers will adopt and implement significant benefit exclusions and administrative barriers based on either exception.

We remind the Departments that they included a "clinically appropriate standards of care" exception to MHPAEA's NQTL requirements in their 2010 interim final regulations. Importantly, in the final regulations, the Departments removed this exception. The Departments wrote:

> [C]ommenters raised concerns that this exception could be subject to abuse and recommended the Departments set clear standards for what constitutes a "recognized clinically appropriate standard of care." For example, commenters suggested a recognized clinically appropriate standard of care must reflect input from multiple stakeholders and experts; be accepted by multiple nationally recognized provider, consumer, or accrediting organizations; be based on independent scientific evidence; and not be developed solely by a plan or issuer. Additionally, since publication of the interim final regulations, some plans and issuers may have attempted to invoke the exception to justify applying an NQTL to all mental health or substance use disorder benefits in a classification, while only applying the NQTL to a limited number of medical/surgical benefits in the same classification. These plans and issuers generally argue that fundamental differences in treatment of mental health and substance use disorders and medical/surgical conditions, justify applying stricter NQTLs to mental health or substance use disorder benefits than to medical/surgical benefits under the exception in the interim final regulations.

The Departments also confirmed that a panel of experts convened by the U.S. Department of Health and Human Services (HHS) could not identify situations supporting the clinically appropriate standard of care exception, noting that:

> HHS convened a technical expert panel on March 3, 2011 to provide input on the use of NQTLs for mental health and substance use disorder benefits. The panel was comprised of individuals with clinical expertise in mental health and substance use disorder treatment as well as general medical treatment. These experts were unable to identify situations for which the clinically appropriate standard of care exception was warranted—in part because of the flexibility inherent in the NQTL standard itself.

We urge the Departments not to revisit this flawed standard. In 2013, the Departments correctly determined that, rather than operating as an exception, clinical appropriateness was most properly placed squarely within the framework of the regulations' NQTL requirements. Furthermore, we believe that such an exception lacks a firm basis in MHPAEA's statutory text, which requires that treatment limitations applicable to MH/SUD benefits be no more restrictive than the predominant treatment limitations applied to substantially all M/S benefits and includes no exceptions to this standard. We also note that the Consolidated Appropriations Act, 2021's (CAA, 2021) amendments to MHPAEA adopted the NQTL regulatory framework in statute without any exceptions to the framework.

Additionally, we believe the "independent professional medical or clinical standards" exception is likely unworkable. For example, if a plan/issuer claimed that independent professional medical or clinical standards justified the imposition of prior authorization or retrospective review under the "design and application" test ((c)(4)(ii)), how would the substantially all/predominant test ((c)(4)(i)) be applied to the prior authorization or retrospective review NQTL? Also, how would outcome data collection and analysis requirements ((c)(4)(iv)) assess an NQTL's impact on access if a plan/issuer could just claim that some undetermined part of the decreased access was due to following purported "independent professional medical or clinical standards"?

Even if we believed that an "independent professional medical or clinical standards" exception were theoretically appropriate or workable, which we do not, we have deep concerns that this term's current ambiguity and lack of definition will allow the exception to swallow the proposed strengthened NQTL requirements in paragraphs (c)(4)(i)(E), (c)(4)(ii)(B), and (c)(4)(iv)(D). If the Departments permit this to occur, the Departments' fundamental objective in putting forward the 2023 Proposed Rule will be severely undermined, and individuals will still be subjected to discriminatory treatment limitations that restrict access to care. In fact, we fear that the exception could even result in the 2023 Proposed Rule weakening the existing regulations.

To incentivize plans/issuers to apply clinical standards that adhere to independent professional medical or clinical standards, we urge the Departments to require plans to document in their NQTL analyses how their clinical standards and practices deviate from independent professional medical or clinical standards as described below. To make such analyses meaningful, the Departments should adopt a definition of "independent professional medical or clinical standards" that is tied to criteria/guidelines developed by the relevant nonprofit clinical specialty associations.

An increasing number of states have adopted a strong definition of "generally accepted standards of care" for MH/SUDs. Strong definitions have been enacted in Illinois, California, Georgia, and New Mexico. We support the following version of these states' definitions for "independent professional medical or clinical standards," which we view as synonymous with "generally accepted standards of care":

> "Independent professional medical or clinical standards" mean standards of care and clinical practice that are generally recognized by health care providers practicing in relevant clinical specialties such as psychiatry, psychology, clinical sociology, social work, addiction medicine and counseling, and behavioral health treatment. Valid, evidence-based sources reflecting independent professional medical or clinical standards are peer-reviewed scientific studies and medical literature, recommendations of federal government agencies, drug labeling approved by the United States Food and Drug Administration, and recommendations of nonprofit health care provider professional associations and specialty

societies, including, but not limited to, patient placement criteria and clinical practice guidelines.

We note that the Departments' example framing in the preamble of "independent professional medical or clinical standards" – that these standards "must be independent, peer-reviewed, or unaffiliated with plans and issuers" – is far too weak. Such a framing could allow for nontransparent, proprietary criteria created and licensed by for-profit publishers to establish "the independent professional medical or clinical standards." It would likely be argued that such criteria are developed "independently" (even if they are influenced by financial self-interest of the publishers seeking continued licensing agreements with managed care organizations), "peer-reviewed" (even if the reviewers are unidentified and cannot be publicly vetted for their purported expertise or potential conflicts of interest), and "unaffiliated with plans and issuers" (even if these companies communicate with payors/licensees about desired changes to their criteria). Thus, we believe any such requirements must be much stronger as outlined above.

In using these standards to assess criteria/guidelines and medical necessity determinations in connection with an NQTL analysis, it is essential that the Departments tie a strong definition of "independent professional medical or clinical standards" (as we have suggested above) to criteria/guidelines from the relevant nonprofit clinical specialty associations. Key nonprofit criteria include The American Society of Addiction Medicine (ASAM) Criteria and the age-specific Level of Care Utilization System (LOCUS) family of criteria developed by the American Association of Community Psychiatrists and the American Academy of Child and Adolescent Psychiatry.

Tying this definition to nonprofit clinical specialty association guidelines and criteria is essential because they are:

- **Fully transparent and accessible.** Consumers, providers, and other stakeholders can readily access the criteria being used to determine whether specific MH/SUD services are, in fact, appropriate to meet individual patient needs.
- **Developed through a consensus process that protects against conflicts of interest.** The authors and reviewers of nonprofit criteria are publicly identified. Credentials, expertise, and potential conflicts of interests can be evaluated by the public.
- **Externally validated.** Nonprofit clinical criteria are subject to rigorous peer review, validation studies in real-world clinical settings, and are reviewed in professional and scholarly journals.

As early as 1997, research published in the *American Journal of Psychiatry*, the official, peer-reviewed journal of the American Psychiatric Association, sounded warning bells, concluding that: "Our findings underscore the necessity of determining the validity of all criteria used to assess the appropriateness of medical care. Wide acceptance of an instrument is clearly not sufficient to justify its use. The need for validation studies is particularly great when proprietary criteria are not available for public scrutiny."

Once a strong definition is in place that is tied to nonprofit clinical professional association criteria/guidelines, we urge the Departments to put in place the following requirements:

- **Evaluate divergence from "independent professional medical or clinical standards."** The Departments should require plans/issuers to analyze how any MH or SUD criteria/guidelines they use diverge from "independent professional medical or clinical standards." Such an analysis would also be done for M/S benefits within the classification of care and would be subject to the NQTL comparability and stringency test. Given the Departments have previously found that plans/issuers

have simply issued conclusory or generalized statements of compliance, it would be critically important for the Departments to analyze criteria/guidelines that plans use to ensure the accuracy of plans' conclusions.

Further, the Departments should utilize groundbreaking work done by the New York State Office of Mental Health (NYS OMH), which evaluated mental health plans' medical necessity criteria against "Guiding Principles" that represent generally accepted standards of care. In its reviews of 69 health plans' criteria, NYS OMH found that all plans' clinical criteria were deficient. If plans exclusively utilize and adhere to specified nonprofit clinical specialty association criteria/guidelines, the Department could follow NYS OMH's example by permitting plans/issuers not to conduct such an evaluation for these specified nonprofit criteria/guidelines.

- **Require specific data reporting for the medical necessity/appropriateness.** The special rule should require specific data collection and analysis requirements relating to medical necessity/appropriateness. Such data should include the number of authorizations issued for participants/beneficiaries by each of the levels (and sub-levels) of care described in the ASAM Criteria and the age-specific LOCUS family of criteria.

- **Prohibit plans/issuers from withholding their criteria/guidelines for MHPAEA review.** We have heard disturbing reports that plans/issuers do not make the criteria/guidelines they use available for MHPAEA compliance reviews. Where an NQTL relies on such criteria/guidelines that are not made available to regulators, it would be impossible to determine the NQTL's MHPAEA compliance. The Departments noted in their 2023 MHPAEA Report to Congress that plans/issuers did not provide external guidelines they claimed to use as evidentiary standards. The Departments should explicitly require that plans/issuers make available any criteria/guidelines they use to federal and any applicable State authorities (as well as to participants/beneficiaries), without any exceptions for purported "proprietary" or "confidential" criteria/guidelines.

By removing the "independent professional medical or clinical standards" exception, creating a strong definition for this term that is tied to nonprofit professional association criteria/guidelines, and putting in place the above requirements, we believe that the Departments can advance this important issue without allowing plans/issuers to continue practices that will inhibit access.

One member site provider who has treated eating disorders patients for 15 years has stated that depending on the plan/issuer, she could determine if treatment would be authorized by particular providers based on a patient's lab results. She would consistently request what medical necessity criteria the plan/issuer was utilizing to make their determination and never provided an answer or documentation of the criteria. The plan/issuer "black box" of medical necessity criteria must end as it severely limits access to MH/SUD care.

We have several stories of patients being forced out of treatment or dropped to a lower level of care when not medically appropriate by plans/issuers based solely on weight gain. This has tremendous deleterious effects on the patient's treatment plan. Below are examples of lack of medical necessity criteria to explain denials:

- "The client was referred to a residential treatment facility for anorexia nervosa. The client had been hospitalized for 2 weeks months prior due to low weight and heart rate. The client had a BMI of 17.4 and was only 18 years old. This was her first residential treatment. Insurance denied client

residential treatment stating that it had "been awhile" since she was hospitalized and she "seemed to be doing better". With a BMI lower than the lowest "normal" parameters, at a crucial age, and this being the first treatment, residential denial did not seem to be appropriate.

The client then was stepped down to PHP level of care, due to insurance denial at residential level. Client is attending 7 days/weekly due to need for support. Payer only approves 5 days at a time (less than a week of treatment) and requires ALL group notes to be sent at every review. Payer takes 3-5 days to respond with a determination on continuation of care, and when determination is received, it is already time to submit the next review given the small number of visits approved at each review. Client feels that they are always on the cusp of being denied treatment due to frequency of reviews and length of determinations."

- "At residential treatment once I reached close to my idea body weight, insurance cut me off at extremely short notice (2-3 days) even though I was extremely mentally unstable and not ready to leave. The forced discharge was based off my BMI alone and did not take into consideration any mental aspects."

- "I went to residential eating disorder treatment and found out on day 2 that my insurance was refusing to cover. Even after my treatment team made a case for me, they denied coverage due to not having any past documented [eating disorder] treatment and having a "healthy" BMI at time of admission. After multiple attempts [by] my [treatment] team making a case for me, my insurance did not cover me, and I had to pay out of pocket and received a "scholarship" from the treatment facility to stay there for 28 days due to how crucial my team felt my time there would be."

"Fraud, Waste, and Abuse" Exception to NQTL Requirements – (c)(4)(i)(E), (c)(4)(ii)(B), and (c)(4)(v)(B)

There is no place for fraud, waste, and abuse in MH/SUD services, just as there is no place for fraud, waste, and abuse in M/S services. We strongly support efforts to ensure that individuals needing MH/SUD care receive the most clinically appropriate care, which is why it is so important for both providers and payers to follow independent professional medical or clinical standards/generally accepted standards of care. Unfortunately, we know that many health plans have sought to exploit claims of "fraud, waste, and abuse" to deny or otherwise limit access to medically necessary care. Some stakeholders report that plans/issuers have switched to routinely conducting mundane audits under the auspices of fraud and abuse investigation units, even though there is no evidence of fraud or abuse. Therefore, we do not support the Departments' attempts to create a "fraud, waste, and abuse" exception to the NQTL requirements in paragraphs (c)(4)(i)(E) and (c)(4)(ii)(B). While we support plans/issuers' legitimate efforts to combat, prevent and detect fraud, waste, and abuse, the Departments' proposed exception (like the independent professional medical or clinical standards exception) has the potential to severely undermine the proposed stronger NQTL requirements.

To combat fraud, waste, and abuse, plans/issuers should incorporate "fraud, waste, and abuse" as a factor for relevant NQTLs, which are subject to MHPAEA's comparability and stringency tests for MH/SUD and M/S. This is the most transparent way to ensure the plans are not inappropriately limiting MH/SUD treatment under the guise of efforts to combat "fraud, waste, and abuse." Locating "fraud, waste, and abuse" within the existing and proposed NQTL requirements also has the advantage of being well-grounded in

MHPAEA's statutory text. In contrast, there is no "fraud, waste, and abuse" exception in MHPAEA's statutory text that would allow plans/issuers to avoid MHPAEA's NQTL requirements, which the CAA, 2021 incorporated into the MHPAEA statute.

As we described above for the "independent professional medical or clinical standards" exception, we also believe this exception is broadly unworkable. For instance, it is unclear how plans/issuers that use "fraud, waste, and abuse" as a factor in designing and applying an NQTL would perform the more restrictive (substantially all/predominant) test. We do not believe the Departments have articulated the analysis clearly, even though the preamble explains that the exception must be separately tested under and satisfy each of the applicable analyses for the NQTL to be applied.

Meaningful Benefits of Treatment of a Mental Health Condition or Substance Use Disorder – (c)(2)(ii)(A)

We support the provision requiring that if any MH or SUD benefits are provided in any classification of care, both MH and SUD benefits must be provided in all classifications of care and the scope of covered MH and SUD benefits in each classification must be "meaningful." Though plans/issuers are already required to provide MH/SUD benefits in all classifications if they provide MH or SUD services in any classification, there has been a lack of clarity on the breadth of MH and SUD services that must be covered. The proposed clarification, therefore, is a very important addition. However, the lack of definition of the term "meaningful" will likely result in significant future disagreement about whether covered benefits are, in fact, "meaningful."

To address this issue, we request that the Departments not only define "meaningful" but also identify "scope of covered services" as an NQTL in the non-exhaustive NQTL list. Every plan/issuer limits the scope of covered MH/SUD services, and any limitation on covered services meets MHPAEA's statutory definition of "treatment limitation" and the current regulations definition of NQTL ("nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage"). Given this, every plan/issuer should already be conducting NQTL analyses for "scope of covered services," yet we are unaware of any that do so. If the Departments identified "scope of covered services" as an NQTL, they would remove any ambiguity that a plan/issue must identify, for any excluded service, the "factor" and "evidentiary standard" that the plan/issuer used for M/S exclusions within the classification of care and determine whether the MH/SUD exclusion met the NQTL comparability and stringency test. A "scope of covered services" NQTL should also be subject to the 2023 Proposed Rule's requirements relating to outcomes data and actions to address access disparities.

Prohibition on Discriminatory Factors and Evidentiary Standards – (c)(4)(ii)(B)

We strongly support this provision, which prohibits a plan/issuer from relying on any factor or evidentiary standard if it discriminates against MH/SUD benefits. This self-evident provision is necessary to ensure that plans/issuers, in designing and applying any NQTL, do not simply attempt to launder their discriminatory intent by relying on a factor or evidentiary standard that itself is discriminatory. This can occur when plans/issuers rely on and perpetuate historic data or discriminatory structures as the basis for how they have designed and applied an NQTL or apply metrics that have not been subject to MHPAEA. For example, plans commonly justify discriminatory reimbursement rates by citing the Medicare Fee Schedule. Of course, Medicare is not subject to MHPAEA and has long undervalued MH/SUD services. The Centers for Medicare & Medicaid Services (CMS) has recognized this undervaluation in recently proposed updates to the reimbursement rate for psychotherapy in the Medicare Physician Fee Schedule

(PFS), but they acknowledge that they still need to develop systemic solutions to longstanding process limitations. In the meantime, MH and SUD clinicians account for almost half of the total providers who opt out of Medicare, with low reimbursement rates cited as a key factor affecting provider willingness to accept insurance and join networks. Given how frequently the Medicare Fee Schedule is used to justify discriminatory MH/SUD reimbursement, we urge the Departments to specify that utilizing the Medicare PFS to justify reimbursement rates will fall within the proposed prohibition of (c)(4)(ii)(B).

Required Use of Outcomes Data & Actions to Address Material Differences in Access – (c)(4)(iv)(A-B)

We strongly support the provision to require a plan/issuer to collect and evaluate relevant data to assess the impact of the NQTL on MH/SUD and M/S benefits and to tie the "type, form, and manner of collection and evaluation" of data to guidance that can be periodically updated. The collection of data using standardized definitions and methodologies is critical to assessing an NQTL's impact on access to MH/SUD and M/S care. A core failing of the existing MHPAEA regulations is that an NQTL's impact on access to MH/SUD as compared to M/S treatment is rarely appropriately measured and analyzed. Instead, plans/issuers rely on process-related justifications and arguments to inappropriately justify disparate access to treatment. By requiring plans/issuers to collect and assess outcomes data and to address disparities in access, the Departments are appropriately bringing the focus of NQTL analyses back to the fundamental purpose of MHPAEA – addressing disparities in access to MH/SUD care.

We urge the Departments to clarify that outcome data must be separately reported for MH and SUD services to conform to the statutory standard. Experience has also demonstrated that a plan/issuer's performance for one set of benefits (either MH or SUD) does not necessarily reflect performance for the other set of benefits.

We also strongly support the requirement that plans/issuers must take "reasonable action" to address differences in access shown by this data. However, we are concerned that the proposed action would only be necessary when such differences are "material," a term that is not defined. We note that MHPAEA's statutory "no more restrictive" standard does not require a "material difference" and would, therefore, establish a weaker standard than the statute. Consistent with the statute's "no more restrictive" standard, we urge the Departments to require plans to take action whenever the data shows *any* difference in access. If the Departments do not alter the "material differences" standard, we urge the Departments to narrowly define the meaning of this term, adopting a low threshold and one that would not require consumers to employ expert statisticians to make use of this important test. Without a definition, plans/issuers will be left to determine whether the differences in access shown by the data are "meaningful." Such a situation will make it extraordinarily difficult for the Departments or any applicable State authority to hold plans accountable.

Special Rule for NQTLs Related to Network Composition – (c)(4)(iv)(C)

We believe that inadequate networks are one of the most significant barriers to individuals accessing needed MH/SUD care. Thus, we strongly support the new proposed rules relating to "network composition," which would address many of these access issues. The special rule relating to network composition NQTLs is particularly powerful because a plan/issuer would fail to meet the requirements of (c)(4)(i) and (c)(4)(ii) "if the relevant data show material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification." This strong requirement should be maintained.

One plan/issuer has terminated coverage for PHP eating disorder treatment provided via telehealth claiming there is no clinical evidence to prove virtual PHP is effective even though it was covered by the plan/issuer for three years during the pandemic. Given this policy change, one-third of the residents in this state attempting to access eating disorder treatment are barred from doing so unless they 1) relocate or 2) drive hours every day for care that lasts 5-7 days for 4-6 weeks. Upon further discussion with the plan/issuer, their documents contain a clause that excludes "facilities" from being reimbursed for telehealth services and the one code that is an exception to this clause are offering, "drug and alcohol intensive outpatient programs," which are similar in structure to eating disorder treatment facilities.

Not only is this a network limitation issue, it is also a discriminatory policy as addressed earlier in our comments to provide a carve out for SUD facilities to offer virtual PHP services and not the same services for eating disorder treatment facilities.

Effect of Final Determination of Noncompliance – (c)(4)(vii)

We strongly support the provision that gives the Secretaries the ability to direct that a plan/issuer not impose an NQTL after a final determination of noncompliance and urge the Departments to change the "may" to a "shall" to indicate that the plan will not be permitted to apply a non-compliant NQTL. This standard is consistent with (c)(4), which makes clear that a plan that fails to meet any of the NQTL standards cannot impose the limitation and the current (h), which bars the sale of any plan that does not comply with the NQTL standards. We strongly urge the Departments to clarify that if a plan/issuer cannot demonstrate that an NQTL is compliant, it should not be allowed to be imposed. Otherwise, the Departments are allowing participants/beneficiaries to be subject to noncompliant treatment limitations. The result will inevitably be individuals who are wrongly denied access to needed MH/SUD services, placing the health, well-being, and potentially lives of these individuals at risk. Furthermore, we urge the Departments to add provisions that, if a plan/issuer does not comply, the Departments will work with the Internal Revenue Service to assess penalties allowed by MHPAEA.

Additionally, this power should clearly be available, not just to Secretaries of the relevant federal regulator, but to any applicable State authority as well, as set out in the HHS proposed section 146.137(e)(1). State insurance departments have primary enforcement authority for state-regulated fully insured plans and have played a leading role enforcing MHPAEA, particularly given the federal Departments' inadequate resources that allow them to review only a small fraction of overall plans/issuers. Applicable State authorities should clearly have authority to make such a determination under the 2023 Proposed Rule.

For too long, there have been no meaningful consequences when plans/issuers have violated MHPAEA. Through widespread inaction and the lack of meaningful consequences for violations of MHPAEA's requirements, state and federal regulators have prioritized plans/issuers' interests and profits over the ability of individuals to receive needed MH/SUD care. It is now finally time to put teeth into the rules and prohibit plans/issuers from imposing treatment limitations that are not in compliance with MHPAEA. After nearly 15 years since enactment of MHPAEA, barring the application of non-compliant NQTLs is the only way to incentivize plans to more carefully evaluate NQTLs as they design and apply plan benefits and during the comparative analysis.

Examples Relating to Prohibited Exclusions of Autism and Eating Disorder Coverage – (c)(2)(ii)(C)

We strongly support the addition of new examples in the 2023 Proposed Rule, which would make clear that exclusions of key services for autism spectrum disorder and eating disorders violate MHPAEA. While the

Departments have already been taking enforcement action against plans/issuers' discriminatory exclusions of autism and eating disorder services, these examples will remove any remaining ambiguity that these exclusions are inconsistent with MHPAEA's requirements.

- "My insurance company covers only four sessions of medical nutrition therapy per year for a mental health diagnosis. If you have diabetes, they cover an unlimited number of sessions per year."

- "I was referred by my therapist to see a nutritionist who specializes in eating disorders. My insurance said they don't cover nutrition for "eating disorders" and after calling multiple in network providers, it was clear that no in network providers were trained or had experience with eating disorders. I tried to get coverage with a single case agreement, but insurance just took us around in circles and denied coverage. I still see this nutritionist for an ongoing eating disorder and have to pay out of pocket which means I can only see her once a month."

- "My daughter had been diagnosed with anorexia and needed nutritional therapy with an RD and our insurance would not cover therapy for an ED but would have covered it for diabetes. I appealed and brought up the mental health parity act and was shuffled around and ignored. Denied coverage. We had to pay out of pocket for basically all her therapy."

Meaning of Terms – (a)(2)

We support the new and revised definitions in (a)(2) of the 2023 Proposed Rule. These changes significantly improve clarity and will increase access to care. The proposed changes to definitions of "mental health benefits" and "substance use disorder benefits" would ensure that the placement of benefits is consistent with "generally recognized independent standards," which are tied to the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the mental, behavioral and neurodevelopmental disorders chapter of the International Classifications of Disease (ICD). The 2023 Proposed Rule would also ensure that any state laws that define MH/SUDs in a manner that conflict with "generally recognized independent standards" do not reduce plan members' protections under MHPAEA. This has particularly been an issue where autism spectrum disorder (ASD) benefits have been defined as M/S benefits, even though this is contrary to generally recognized independent standards as reflected by the DSM and ICD. Where this has occurred, individuals with ASD have been denied MHPAEA protections.

We also strongly support the Departments' proposed definitions for key terms relating to NQTLs – "evidentiary standards," "factors," "processes," and "strategies." The lack of definitions for these terms, which are foundational to MHPAEA's NQTL requirements, has hindered efforts to hold health plans accountable on discriminatory NQTLs due to frequent disagreements about their meaning.

- For example, nutrition counseling/medical nutrition therapy has been defined as a M/S service and not a MH/SUD service for the treatment of eating disorders.

Non-Exhaustive List of NQTLs – (c)(4)(iii)

We support the revisions to the list of NQTLs, including relating to "network composition," and the clarification that this list is "non-exhaustive." As referenced above, we urge the Departments to add "scope of covered services" as an identified NQTL.

Provisions of Other Law – (d)(3)

We urge to add the following sentence, with any adjustment for code-specific terms to make clear that no part of the comparative analyses or other application information required by 29 CFR § 2590.712-1 / 45 CFR § 146.137 / 26 CFR § 54.9812-2 may be withheld: "All requested plan information shall be made available to claimant and may not be withheld as proprietary or commercially protected information."

29 CFR § 2590.712-1, 45 CFR § 146.137, AND 26 CFR § 54.9812-2 – NONQUANTITATIVE TREATMENT LIMITATION COMPARATIVE ANALYSIS REQUIREMENTS

We strongly support the addition of new requirements relating to plans/issuers' NQTL comparative analyses that they are required to conduct under amendments to MHPAEA enacted as part of the CAA, 2021. These detailed requirements are necessary to ensure there is clarity on what plans/issuers' analyses must contain and to hold plans accountable for following these requirements.

We also appreciate language relating to providing participants/beneficiaries with information summarizing changes the plan/issuer "has made as part of its corrective action plan following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed." The framing of the notice as an "opportunity" for a participant/beneficiary to have a claim for benefits reprocessed is misguided and places the burden on participants/beneficiaries in an inappropriate manner. The participant/beneficiary is not well placed to know they may have been impacted by noncompliant NQTL and to navigate a likely complicated path (that the proposal leaves unidentified) to pursue remedies. Instead, we strongly urge the Departments to place an affirmative obligation on plans/issuers, as part of the corrective action plan, to identify affected participants/beneficiaries, reprocess any claims, notify those who they determine have been impacted by the non-compliant NQTL. We commend the Departments for appropriately shifting the burden away from consumers throughout this proposed rule, and we urge a consistent approach here.

Finally, in (b), we urge the Departments to explicitly reference "any applicable State authority" to ensure clarity that plans' comparative analysis must be made available to state regulators upon request. The relevant sentence should read: "Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary (or to any applicable State authority), upon request, in the manner required by paragraphs (d) and (e) of this section." While this statutory requirement is referenced in (e), some insurers have refused to provide required parity compliance analysis to the applicable State authority upon request if the relevant Secretary has not also requested the analysis. This change will help prevent such false claims by preventing selective citation of the proposed regulations.

45 CFR § 146.180 – TREATMENT OF NON-FEDERAL GOVERNMENT PLANS

We support the language implementing the elimination of self-funded non-federal government plans' ability to opt out of MHPAEA. Hundreds of thousands of public employees and their family members have for too long been denied critical MHPAEA protections as their public-sector employer affirmatively opted-in to discriminating against individuals needing MH/SUD services.

We urge the Department of Health and Human Services to prioritize robust MHPAEA compliance reviews of these plans as soon as their opt out is no longer valid. This is particularly important given that many of these public sector plans opted out of MHPAEA specifically because they wished to continue discriminatory treatment limitations on MH/SUD benefits. The Department should immediately request plans' NQTL compliance analyses to ensure they are taking the necessary steps to comply with MHPAEA.

OTHER ISSUES

Third-Party Administrators (TPAs)

The Departments have asked for feedback on how third-party administrators (TPAs) "could be further incentivized to facilitate compliance with MHPAEA." We agree with the Departments concern about this issue. Though, rather than "incentivize" TPAs to comply with MHPAEA, we urge the Departments to use all possible avenues to hold both self-funded plan sponsors and TPAs accountable for MHPAEA compliance.

Recent reports have highlighted ongoing problems where TPAs, who are the experts in health plan design and administration and who make critical coverage decisions, refuse to provide essential information, including data, to the employer plan sponsor by claiming that such information is "proprietary" or has "commercial value." TPAs' refusal to provide information and data on plan design and access to benefits fundamentally inhibits MHPAEA compliance and cannot be allowed to stand. The Departments have repeatedly made clear that such plans/issuers must provide such information. In the 2015 MHPAEA FAQ XXIX (Q12), the Departments made clear that information relating to medical necessity criteria purported to be of "proprietary" or "commercial" value must be provided to plan members' upon request. The Departments have also reiterated that information related to MHPAEA compliance, including NQTL analyses, must be provided without restrictions upon request in the 2023 Proposed Rule's preamble.

Yet, we frequently see plans/issuers and their TPAs refusing to provide legally required information, without any apparent consequence. To address the ongoing problems with TPAs hindering compliance with MHPAEA, we urge the Departments in the 2023 Proposed Rule to require plan sponsors to insert MHPAEA compliance provisions into their contracts with TPAs. HHS utilized in a similar approach in 2001 when it required health care entities covered by HIPAA (mainly health care providers and health insurers) to include HIPAA-related provisions in their contracts with outside entities that handle patient information on behalf of covered entities. Without such "business associate agreements," HIPAA's privacy and security protections would have been undermined if businesses handling patient information for billing, accounting, legal, IT, or other purposes could simply ignore HIPAA. These agreements contractually obligate the outside entities to carry on the HIPAA obligations of the covered entities and help them with compliance. The Departments should do the same for MHPAEA by requiring a plan sponsor to enter into a contract with any TPA they hire that includes specific obligations whereby the TPAs must assist the plans in fulfilling their MHPAEA obligations to participants/beneficiaries and regulators.

Finally, we urge the U.S. Department of Labor (DOL) to use ERISA's strong protections to hold TPAs accountable as ERISA fiduciaries and co-fiduciaries. Under 29 U.S.C. 1132(a)(5), DOL may bring legal action against any fiduciaries that violate MHPAEA, including TPAs, as incorporated into ERISA through 29 U.S.C. 1185a. Further, under 29 U.S.C. 1134, DOL is granted the power, "in order to determine whether any person has violated or is about to violate any provision of this subchapter," including MHPAEA, and to "make an investigation" and to "inspect such books and records and question such persons as he [the Secretary] may deem necessary to enable him [the Secretary] to determine the facts relative to such

investigation." Thus, DOL may investigate TPAs for acts or practices that violate MHPAEA and can sue to enjoin such practices. Finally, DOL is authorized under 29 U.S.C. 1135 to "prescribe such regulations as he finds necessary or appropriate to carry out the provisions of this subchapter." We urge DOL to use its substantial authority and discretion to ensure that TPAs have adopted policies and procedures that are MHPAEA-compliant.

MH/SUD Emergency ("Crisis") Services

The Departments have requested feedback relating to MH/SUD crisis services under MHPAEA and the Affordable Care Act's (ACA) Essential Health Benefits (EHB) categories for non-grandfathered individual and small group coverage. Federal policymakers have dedicated enormous effort to standing up the 988 Suicide and Crisis Lifeline and expanding MH/SUD crisis services, which help people get the help they need and avoid needless, and often tragic, encounters with law enforcement. While every benchmark plan includes EMS and emergency transport services, very few include mental health crisis (i.e., emergency) response or crisis stabilization services. This failure to include MH/SUD crisis services under EHB means that many individuals do not have appropriate coverage of these services. A number of states, including California, Virginia, and Washington, have recently required health plans to cover MH/SUD crisis services. Washington has made clear that coverage of MH/SUD crisis services is necessary for health plans to comply with MHPAEA. HHS should include MH/SUD crisis services within the MH/SUD EHB category. Additionally, when finalizing this rule, we encourage the Departments to make clear that, if a plan/issuer covers physical health emergency services (including EMS and emergency transport), it must cover comparable MH/SUD emergency/crisis services (including mobile crisis response) under the same standards (e.g., no prior authorization).

Provider Directory Requirements

The Departments have requested feedback on how to improve provider directories through rulemaking. We urge the Departments to require periodic independent third-party testing of provider directories to assess the accuracy of information and that a sufficient percentage of providers are accepting new patients. HHS has already put forward strong proposed standards for Medicaid managed care and the Children's Health Insurance Program (CMS-2439-P), which establish maximum appointment wait time standards for routine outpatient MH/SUD services of 10 business days and require such independent secret shopper surveys. This proposed rule should be a model for the Departments in individual and group plans. Additionally, plans/issuers should be required to identify providers who are available via telehealth. Finally, the Departments should ensure that participants/beneficiaries who cannot access in-network services on a timely basis can access out-of-network services, with their out-of-pocket costs no greater than the amounts that they would have paid for the same services received from an in-network provider.

Frequently provider directories will appear robust in select specialties like registered dietitians. However, we have heard numerous stories of individuals going out-of-network to find a dietitian that specializes in eating disorders. In one example, a woman seeking nutrition counseling for her eating disorder was referred to the one dietitian in her insurance network to find out during the appointment the dietitian specialized in weight loss, which triggered the patient. Robust network directories that also list the provider's specialties are critical.

Claims Procedure Requirements

The Departments have requested feedback on how the ACA and ERISA's existing claims procedure requirements can facilitate access to MH/SUD benefits. Most fundamentally, HHS and DOL must strengthen enforcement with existing claims procedure requirements, which in our experience are frequently not followed with little apparent consequence. To strengthen participants/beneficiaries' ability to challenge inappropriate denials of MH/SUD care, HHS and DOL should, at minimum, make clear that plans/issuers' NQTL compliance analysis must be made available upon request, with no restrictions for purported "proprietary" or "confidential" information. While we believe this is HHS and DOL's interpretation of existing law, making this explicit in the claims procedure requirements is important.

HHS and DOL should also require that, for any adverse benefit determination relating to MH/SUD, the adverse benefit determination and explanation of benefits should contain clear instructions on how to request and receive any NQTL compliance analysis(es) related to the determination. The requirements should include phone number, email, and address where such a request could be submitted, including on an expedited basis to enable the submission of meaningful urgent appeals and requests for expedited external reviews.

We also support the Departments' suggestion that, should a plan/issuer deny authorization for a specific level of care, the plan/issuer must identify a lower level of care that it believes would be more appropriate, along with information related to the coverage of such service in the plan and the availability of network providers to deliver the lower level of service. We also support the Departments' suggestion that the plan/issuer provide an explanation of how a particular NQTL was applied to particular benefits.

Finally, HHS and DOL should put in place meaningful enforcement mechanisms to ensure that plans/issuers fulfill their obligation to provide participants/beneficiaries with legally required information, upon request. We believe meaningful consequences must include automatic reversal of any adverse benefit determination associated with the request. A potential mechanism is directing independent review organizations (IROs) to automatically reverse adverse benefit determinations when plans fail to provide claimants with any information requested during the internal and/or external appeals process. Otherwise, the claims' procedure requirements to provide information are toothless, and the external appeal process is a meaningless alternative to litigation.

HHS Must Propose and Finalize MHPAEA Rules for Medicaid

While we appreciate the 2023 Proposed Rule, which affects individual and group health plans, it is imperative that HHS move quickly to propose and finalize rules for Medicaid managed care, the Children's Health Insurance Program (CHIP), and Alternative Benefit Plans (ABPs) without delay after the finalization of this proposed rule. The Administration must not allow a strong set of MHPAEA rules for individuals in individual and group plans, but a weaker set of rules for individuals in Medicaid managed care, CHIP, and ABPs. This is particularly critical given that these plans serve lower-income individuals and families who are disproportionately Black, Latino, Native American, and from other marginalized and underserved communities. Many of the entities that serve as Medicaid MCOs also operate in the state-regulated insurance markets and serve as TPAs for employer-sponsored plans. HHS must also finally hold state Medicaid agencies accountable for strong oversight, given most states' deeply inadequate MHPAEA enforcement efforts.

CONCLUSION

Monte Nido & Affiliates
Treating Eating Disorders

We have included numerous citations to supporting research, including direct links to the research. We direct the Departments to each of the materials we have cited and made available through active links, and we request that the full text of each of the studies and articles cited, along with the full text of our comment, be considered part of the formal administrative record for purposes of the Administrative Procedure Act. If the Departments are not planning to consider these materials part of the record as we have requested here, we ask that you notify us and provide us an opportunity to submit copies of the studies and articles into the record.

Thank you for the opportunity to comment on this important issue. If you have further questions, please contact Molly Perlman, MD, MPH, CEDS, Chief Medical Officer of Monte Nido and Affiliates mperlman@montenidoaffiliates.com.

Sincerely,

Curtis Garry

Curtis Garry, MHA
AVP of Hospital Operations
Walden Behavioral Care