National Compliance Update
USI EMPLOYEE BENEFITS

September 19, 2024

Departments Issue Final MHPAEA Regulations

On September 9, 2024, the Departments of Health and Human Services ("HHS"), Labor, and the Treasury (collectively, the "Departments") released final rules pertaining to the Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA") with the aim of ensuring that individuals who seek treatment for mental health ("MH") or substance use disorder ("SUD") reasons do not face greater burdens than they would face when seeking coverage for medical or surgical ("M/S") reasons. The Departments' goal is to improve network composition by making MH/SUD provider networks more robust and make it easier for individuals seeking MH and SUD care to actually receive it by reducing roadblocks related to prior authorization requirements and other medical management techniques.

The Departments intend to provide further guidance and compliance assistance materials in the coming months.

The rules do not include the level of clarifying detail we had hoped to see, and compliance will be challenging for plan sponsors. Coordination with carriers and third-party administrators ("TPAs") will be necessary.

Legal challenges to these rules may arise as stakeholders evaluate what's required in these rules against the current landscape given the recent Supreme Court decision in *Loper Bright* that overruled agency deference.[1]

Primarily, these final rules:

- **MH/SUD Determination.** Utilize the most current version of the International Classification of Diseases ("ICD") or Diagnostic and Statistical Manual of Mental Disorders ("DSM") to define MH conditions and/or SUD.
- **Meaningful benefits standard.** Require that, if a plan provides any benefits for a MH condition or SUD in any benefits classification, it must provide meaningful benefits for that condition or disorder in every classification in which meaningful M/S benefits are provided.

[1] See USI's National Compliance Update, Supreme Court Overturns *Chevron* (July 11, 2024).

- **Nonquantitative treatment limitations ("NQTLs").**
  - Design and application requirements. Prohibit plans and carriers from using discriminatory information, evidence, sources, or standards that systematically disfavor or are specifically designed to disfavor access to MH/SUD benefits as compared to M/S benefits when designing NQTLs.
  - Relevant data evaluation requirements. Require plans to collect and evaluate data and, if necessary, take action to address material differences in access to MH/SUD benefits as compared to M/S benefits that result from application of NQTLs.
  - Comparative analyses. Codify the requirement that health plans conduct comparative analyses to measure the impact of NQTLs. This includes evaluating standards related to network composition, out-of-network reimbursement rates, medical management, and prior authorization. For an ERISA covered health plan, the analysis must include a certification that the fiduciary engaged in a prudent process and monitored service providers performing the analysis.
- **Sunset of Opt-out.** Implement the sunset provision for self-funded non-federal governmental plan elections to opt out of compliance with MHPAEA.

BACKGROUND

MHPAEA applies to:

- Employers with at least 51 employees offering a group health plan that provides coverage for any MH/SUD benefits; and
- Fully insured group health plans in the small market that are required to provide all essential health benefits, including MH/SUD benefits.

Briefly, MHPAEA:

- Provides that financial requirements (such as coinsurance and copays) and treatment limitations (such as visit limits) imposed on MH/SUD benefits cannot be more restrictive than the predominant financial requirements and treatment limitations that apply to substantially all M/S benefits in a classification.[2]
- Prohibits separate treatment limitations that apply only to MH/SUD benefits.
- Provides that NQTLs may not be imposed on MH/SUD benefits in any classification unless the processes, strategies, evidentiary standards, and other factors are comparable and applied no more stringently for MH/SUD benefits than for M/S benefits under the terms of the plan (or health insurance coverage) as written and in operation.
  - With respect to NQTLs, the focus is not on whether the final result is the same for MH/SUD benefits as for M/S benefits, but rather on whether the underlying processes, strategies, evidentiary standards, and other factors are in parity.
- Imposes certain disclosure requirements, including a requirement that group health plans conduct a comparative analysis of all NQTLs imposed on MH/SUD benefits and make that analysis available to the Departments and participants and beneficiaries (including their authorized representatives) upon request.[3]

[2] The six permitted classifications of benefits are: (1) inpatient, in-network; (2) inpatient, out-of-network; (3) outpatient, in-network; (4) outpatient, out-of-network; (5) emergency care; and (6) prescription drugs.

[3] As previously reported, the Consolidated Appropriations Act, 2021 ("CAA") amended MHPAEA to add this new comparative analysis for NQTLs and require the Departments to annually report on the results of their reviews of health plans comparative analysis.

HIGHLIGHTS FROM THE FINAL RULES

The final rules are lengthy. The following summarizes some of the highlights applicable to employers sponsoring group health plans subject to MHPAEA.

Terms

A plan's or carrier's definition of whether a condition or disorder is a MH condition or SUD must follow the most current version of the ICD or the DSM. If generally recognized independent standards of current medical practice do not address how to treat a condition, disorder, or procedure, plans and carriers may define it in accordance with applicable federal and state law.

Further, the regulations reinforce that the following conditions are MH conditions:

- eating disorders, such as anorexia nervosa, bulimia nervosa, and binge-eating disorder;
- autism spectrum disorder ("ASD"); and
- gender dysphoria.

Additionally, the final rules add new definitions for the following terms and include several examples:

- *Evidentiary standards:* any evidence, sources, or standards that a group health plan considered or relied upon in designing or applying a factor with respect to an NQTL, including specific benchmarks or thresholds.
- *Factors:* all information, including processes and strategies (but not evidentiary standards), that a group health plan (or health insurance carrier offering coverage in connection with such a plan) considered or relied upon to design an NQTL, or to determine whether or how the NQTL applies to benefits under the plan or coverage.
- *Processes:* actions, steps, or procedures that a group health plan (or health insurance carrier offering coverage in connection with such a plan) uses to apply an NQTL, including actions, steps, or procedures established by the plan or carrier as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility.
- *Strategies:* practices, methods, or internal metrics that a plan (or health insurance carrier offering coverage in connection with such a plan) considers, reviews, or uses to design an NQTL.

Meaningful Benefits Standard

If a plan provides any benefits for a MH condition or SUD in any benefits classification, it must provide meaningful benefits for that condition or disorder in every classification in which meaningful M/S benefits are provided. Whether the benefits provided are meaningful is determined in comparison to the benefits provided for M/S conditions in the same classification.

Meaningful benefits require coverage of a core treatment for that condition or disorder in each classification in which the plan or coverage provides benefits for a core treatment for one or more medical conditions or surgical procedures. A core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. If there is no core treatment for a covered MH condition or SUD with respect to a classification, the plan (or coverage) is not required to provide

benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder in every classification in which M/S benefits are provided).

See Exhibit A for examples.

NQTLs

Under the final rules, a plan or carrier may not impose any NQTL with respect to MH/SUD benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all M/S benefits in the same classification. For this purpose, a plan or carrier must satisfy two sets of requirements:

1. the design and application requirements; and
2. the relevant data evaluation requirements.

Design and Application Requirements

The general rule of the design and application requirements requires an examination of the processes, strategies, evidentiary standards, and other factors used in designing and applying an NQTL to MH/SUD benefits in the classification to ensure they are comparable to, and are applied no more stringently than, those used in designing and applying the limitation with respect to M/S benefits in the same classification.

The final rules also prohibit the use of discriminatory factors and evidentiary standards to design an NQTL to be imposed on MH/SUD benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which it is based are biased in a manner that discriminates against MH/SUD benefits as compared to M/S benefits.

Whether information, evidence, sources, or standards are considered to be biased is based on all the relevant facts and circumstances and whether they systematically disfavor or are specifically designed to disfavor access to MH/SUD benefits as compared to M/S benefits. Relevant facts and circumstances, may include, but are not limited to:

- the terms of the NQTL at issue,
- the quality or limitations of the data,
- causal explanations and analyses,
- evidence as to the recurring or non-recurring nature of the results, and
- the magnitude of any disparities.

Historical plan data or other historical information from a time when the plan or coverage was not subject to or was not in compliance with MHPAEA is generally biased, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to MH or SUD benefits as compared to M/S benefits, and the plan has not taken the steps necessary to correct, cure, or supplement the data or information.

Generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate MH/SUD benefits are not biased.

Relevant Data Evaluation Requirements

Plans and carriers must ensure, in operation, that an NQTL applicable to MH/SUD benefits in a classification is no more restrictive than the predominant NQTL applied to substantially all M/S benefits in the same classification. To do so, plans and carriers must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to MH/SUD benefits and M/S benefits. Then, they must carefully consider the impact. For NQTLs related to network composition standards, a plan or carrier must collect and evaluate relevant data in a manner reasonably designed to assess the NQTLs' aggregate impact on relevant outcomes related to access to MH/SUD benefits and M/S benefits.

As the relevant data for any given NQTL will depend on the facts and circumstances, the final rules provide flexibility for plans and carriers to determine what should be collected and evaluated, as appropriate.

See Exhibit B for examples.

The Departments or applicable state authorities may also request other data in addition to what a plan or carrier determines to be relevant data for any particular NQTL included in their comparative analyses.

If the evaluated relevant data suggest that the NQTL contributes to material differences in access to MH/SUD benefits as compared to M/S benefits, that will be considered a strong indicator of a MHPAEA violation. Differences in access are material if, based on all relevant facts and circumstances, the difference in the data suggests that the NQTL is likely to have a negative impact on access to MH/SUD benefits as compared to M/S benefits.

However, differences in access to MH/SUD benefits are not treated as material if they are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect, prevent, or prove fraud and abuse. If material differences in access exist, the plan or carrier must take reasonable action, as necessary, to address them to ensure compliance with MHPAEA in operation.

Examples of possible actions that a plan or carrier could take to comply with the requirement to take reasonable action, as necessary, to address any material differences in access with respect to NQTLs related to network composition include, but are not limited to:

1. Strengthening efforts to recruit and encourage a broad range of available MH and SUD providers and facilities to join the plan's or carrier's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;
2. Expanding the availability of telehealth arrangements to mitigate any overall MH and SUD provider shortages in a geographic area;
3. Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network MH and SUD providers and facilities; and
4. Ensuring that provider directories are accurate and reliable.

COMPARATIVE ANALYSIS

What's Required

Plans and carriers that cover both M/S benefits and MH/SUD benefits and impose NQTLs on MH/SUD benefits must perform and document a comparative analysis of the design and application of each applicable NQTL. The final rules require the comparative analysis to contain, at a minimum, six content elements:

1. a description of the NQTL, including identification of benefits subject to the NQTL;
2. identification and definition of the factors and evidentiary standards used to design or apply the NQTL;
3. a description of how factors are used in the design or application of the NQTL;
4. a demonstration of comparability and stringency, as written;
5. a demonstration of comparability and stringency, in operation, including the required data, evaluation of that data, explanation of any material differences in access, and description of reasonable actions taken to address such differences; and
6. findings and conclusions.

In addition, the final rules require each plan (or carrier) to prepare and make available to the Secretary, upon request, a written list of all NQTLs imposed under the plan. For ERISA covered plans, this list must be provided to the named fiduciaries of the plan.

Finally, for plans subject to ERISA, the final rules require the comparative analysis to include a certification by one or more named fiduciaries confirming the fiduciary's engagement in a prudent process to select one or more qualified service providers to perform and document a comparative analysis in connection with the imposition of any NQTLs that apply to MH/SUD benefits, as well as satisfaction of the duty to monitor those service providers.[4]

Request and Review Process

The final rules set forth the steps the Departments will follow to request and review a plan's or carrier's comparative analysis of an NQTL.

1. After an initial request for a comparative analysis, the plan or carrier must submit it to the relevant Secretary within 10 business days (or an additional period of time specified by the relevant Secretary).
2. If the Secretary determines the comparative analysis is insufficient, the Secretary will specify the additional information necessary, which must be provided by the plan or carrier within 10 business days (or an additional period of time specified by the relevant Secretary).

---

[4] At a minimum, the DOL expects the fiduciary to:

- review the comparative analysis prepared by or on behalf of the plan with respect to an NQTL applicable to MH/SUD benefits and M/S benefits;
- ask questions about the analysis and discuss it with service providers, as necessary, to understand the findings and conclusions documented in the analysis; and
- ensure that a service provider responsible (in whole or in part) for performing and documenting a comparative analysis provides assurance that, to the best of its ability, the NQTL and associated comparative analysis complies with the requirements of MHPAEA and its implementing regulations.

3. If the Secretary makes an initial determination of noncompliance, the plan or carrier has 45 calendar days to specify the actions it will take to comply and provide additional comparative analyses.
4. If the Secretary makes a final determination of noncompliance, the plan or carrier must notify all participants, beneficiaries, and enrollees enrolled in the plan or coverage not later than 7 business days after the Secretary's determination. The final rules set forth specific content for this notice and require that a copy of the notice be provided to the Secretary and relevant service providers and fiduciaries.

Plans and carriers must make a copy of the comparative analysis available when requested by any applicable state authority, a participant or dependent who has received an adverse benefit determination related to MH/SUD benefits. ERISA-covered plans must provide the analysis to participants and dependents within 30 days of a written request.

If a plan receives a final determination that an NQTL is not in compliance with the comparative analysis requirements, including because the plan has not submitted a sufficient comparative analysis to demonstrate compliance, the relevant Department may direct the plan to not impose the NQTL with respect to MH/SUD benefits unless and until the plan or carrier demonstrates compliance or takes appropriate action to remedy the violation.

EFFECTIVE DATES

The final rules generally apply to group health plans and group health insurance coverage on the first day of the first plan year beginning on or after **January 1, 2025**. This includes the new fiduciary certification requirement.

However, the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and the related requirements in the provisions for comparative analyses apply on the first day of the first plan year beginning on or after **January 1, 2026**.

Until the applicability date, plans and carriers are required to continue to comply with the existing requirements, including the CAA amendments to MHPAEA.

SUNSET OF MHPAEA OPT-OUT

HHS discontinued the ability for self-funded non-federal governmental plans to opt out of compliance with MHPAEA effective June 27, 2023.

EMPLOYER NEXT STEPS

The final rules require plan sponsors and carriers to:

- Define whether a condition or disorder is an MH condition or SUD in a manner that is consistent with the most current version of the ICD or DSM.
- Offer meaningful benefits (including a core treatment) for each covered MH condition or SUD in every classification in which M/S benefits (a core treatment) are offered.
- Not use factors and evidentiary standards to design NQTLs that discriminate against MH conditions and SUDs.
- Collect and evaluate relevant outcomes data and take reasonable action, as necessary, to address material differences in access to MH/SUD benefits as compared to M/S benefits.

- Include specific elements in documented comparative analyses and make them available to the Departments, an applicable state authority, or individuals upon request. ERISA plans must include a certification that they have engaged in a prudent process and monitored their service providers.
- Look for further guidance and developments.

In addition, plan sponsors should:

- Note that compliance with MHPAEA rules as they currently exist remains ongoing and is an enforcement priority of the Departments.
- Continue to carefully evaluate their health plans for compliance with MHPAEA, especially in light of new requirements, and be prepared to respond to requests by the Departments for this information. Notably, this will include an analysis of network adequacy. Coordination with carriers, TPAs and other service providers will be essential.
- Review their plan's current limits on MH/SUD and the plan's written comparative analysis to determine whether changes are required in light of recent enforcement efforts.
- Evaluate whether to make plan design changes beginning in 2025.
  - However, the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and the related requirements in the provisions for comparative analyses apply on the first day of the first plan year beginning on or after January 1, 2026.

All plan sponsors have the above responsibilities, although, realistically, in a fully insured arrangement plan sponsors will not have flexibility as to plan design changes and carrier compliance will be crucial. For self-funded plans (including level-funded) it will be important that TPAs are able to support MHPAEA compliance.

> ***USI Note***. In the preamble to the final rule, the Departments noted that TPAs and other service providers are expected to work closely with plans to support their needs by providing data and other information about the design and application of NQTLs applicable to MH/SUD benefits and to M/S benefits so that comparative analyses can be performed and documented (regardless of whether the Departments or an applicable state authority have requested them). Any ERISA-governed group health plans that contract with service providers refusing or otherwise failing to provide the requisite information should notify DOL.

RESOURCES

- Final Rules, available at https://public-inspection.federalregister.gov/2024-20612.pdf
- Fact Sheet, available at https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/fact-sheets/final-rules-under-the-mental-health-parity-and-addiction-equity-act-mhpaea
- New Mental Health and Substance Use Disorder Parity Rules: What They Mean for Participants and Beneficiaries, available at https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/new-mhpaea-rules-what-they-mean-for-participants-and-beneficiaries.pdf
- New Mental Health and Substance Use Disorder Parity Rules: What They Mean for Providers, available at https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/new-mhpaea-rules-what-they-mean-for-providers.pdf
- New Mental Health and Substance Use Disorder Parity Rules: What They Mean for Plans and Carriers, available at https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/new-mhpaea-rules-what-they-mean-for-plans-and-carriers.pdf

- White House Fact Sheet, available at https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/09/fact-sheet-biden-harris-administration-lowers-mental-health-care-costs-by-improving-access-to-mental-health-and-substance-use-care/
- News Release, available at https://www.dol.gov/newsroom/releases/ebsa/ebsa20240909

USI usi.com/locations

Exhibit A: Examples of Meaningful Benefits

Example 1.

A plan covers treatment for ASD, a MH condition, and covers outpatient, out-of-network developmental screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis ("ABA") therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

Conclusion. Violation. Although the plan covers benefits for ASD in the outpatient, out-of- network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of M/S benefits, including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

Example 2.

Same facts as in Example 1, except that the plan is an HMO that does not cover the full range of M/S benefits, including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification, but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

Conclusion. Permissible. Because the plan does not provide meaningful benefits, including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification, the plan is not required to provide meaningful benefits for any MH conditions or SUDs in that classification. Nevertheless, the plan must provide meaningful benefits for each MH condition and SUD for which the plan provides benefits in every classification in which meaningful M/S benefits are provided, as required. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

Example 3.

A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are MH conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification. Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

Conclusion. Permissible. The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in

comparison to the benefits provided for medical conditions or surgical procedures in the classification.

Example 4.

A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a SUD, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering medications to treat opioid use disorder ("MOUD"). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

Conclusion. Permissible. The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

Exhibit B: NQTL Examples

The regulations include 13 NQTL examples. We have highlighted 3 of them below.

Example 1.

A plan's reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for MH, SUD, and M/S benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology ("CPT") code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for MH and SUD non-physician providers from those paid to MH and SUD physicians by the same percentage for every CPT code, but does not apply the same reductions for non-physician M/S providers.

Conclusion. Violation. Because the plan reimburses non-physician providers of MH and SUD services by reducing their reimbursement rate from the rate for physician providers of MH and SUD services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of M/S services from the rate for physician providers of M/S services, in operation, the factors used in designing and applying the NQTL to MH and SUD benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to M/S benefits in the same classification. As a result, the NQTL with respect to MH or SUD benefits in the outpatient, in-network classification is more restrictive than the predominant NQTL that applies to substantially all M/S benefits in the same classification.

Example 2.

A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both M/S benefits and MH and SUD benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a MH condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

Conclusion. Violation. As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, MH conditions, and SUDs when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care

for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the NQTL for benefits for the treatment of ASD, which is a MH condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the NQTL for M/S benefits in the same classification. As a result, the NQTL with respect to MH or SUD benefits in the outpatient, in-network classification is more restrictive than the predominant NQTL that applies to substantially all M/S benefits in the same classification.

Example 3.

A plan's written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant's or beneficiary's attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a MH condition or a SUD, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

Conclusion. Violation. The source upon which the factor used to apply the step therapy protocol is based is biased in a manner that discriminates against MH or SUD benefits as compared to M/S benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a MH condition or SUD could result in both severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to MH or SUD benefits as compared to M/S benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining comparability and stringency under the NQTL rules and may not be relied upon by the plan.