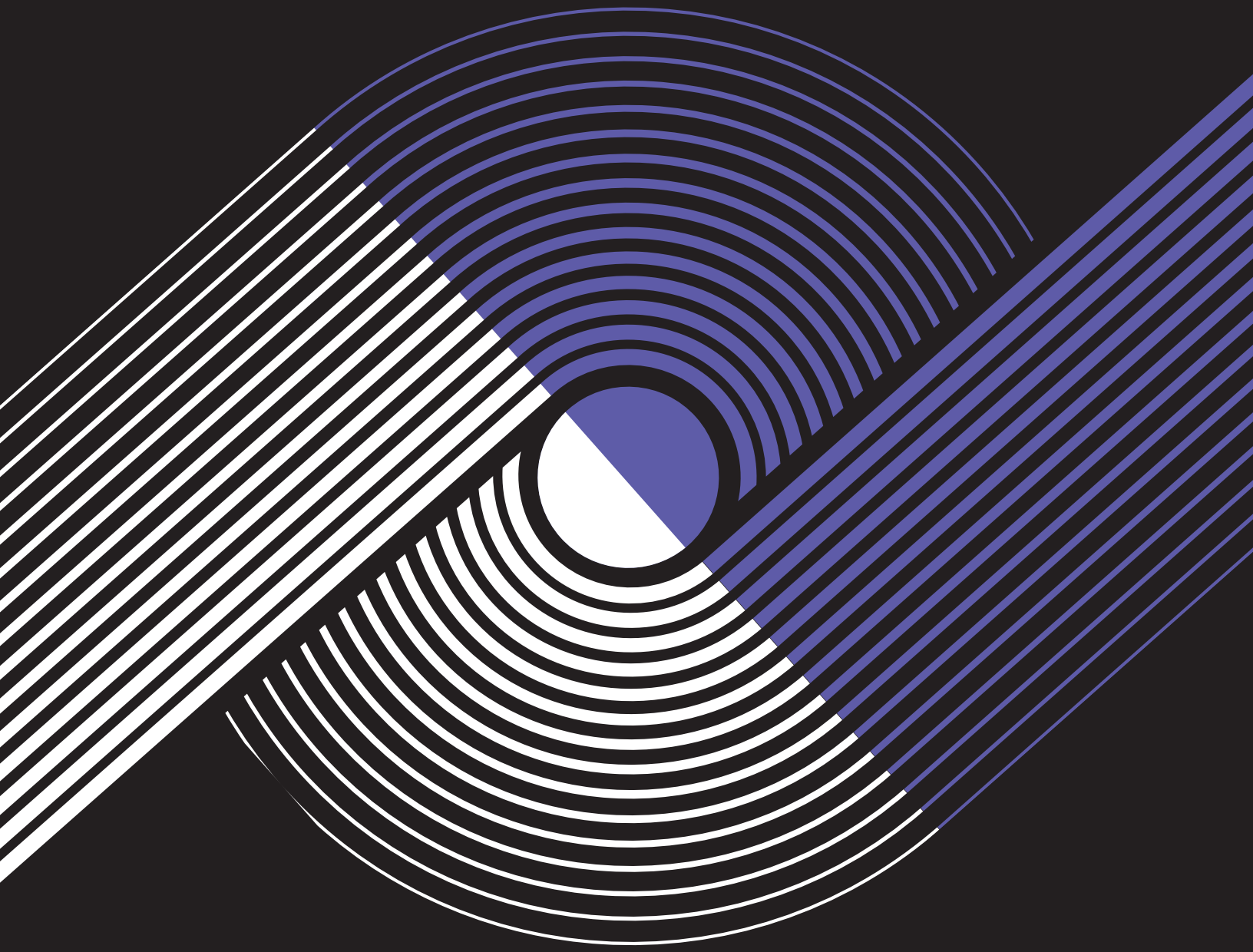

A Path Toward Parity

ENSURING EQUITABLE ACCESS TO PSYCHEDELIC-ASSISTED THERAPY

BRAINFUTURES®

A Path Toward Parity

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Introduction

The nation's escalating behavioral and mental health crisis has been well documented: suicides, overdoses, and substance use disorders (SUDs) are all rising, and rates of disability are steadily climbing as a result of behavioral health disorders. An effective national response demands care that is not only innovative but accessible through adequate reimbursement.

Psychedelic-assisted therapy (PAT) is a new treatment model that is being investigated at leading institutions across the country and around the world, including Johns Hopkins University, Stanford University, and the University of Wisconsin, as well as within the Veterans Health Administration. While no psychedelic medications have yet been approved by the Food and Drug Administration (FDA), industry experts anticipate that the first approval could come as soon as August 2024 with others following shortly after.

The clinical efficacy data on various forms of PAT are promising, and it will be vital for these groundbreaking treatments to be accessible to all patients who need them (Sky, 2022).[1] One cornerstone of equitable access is affordability through insurance coverage because the vast majority of patients will not be able to afford PAT treatment out-of-pocket. The protections offered by the Mental Health Parity and Addiction Equity Act (MHPAEA) will help ensure that health plans are appropriately covering and not placing undue restrictions on patient access to these evidence-based and potentially life-saving treatments.

In the following sections, we discuss the basics of PAT and MHPAEA, as well as the potential barriers to accessing PAT through insurance coverage. In recent years, both federal and state governments have undertaken efforts to step up enforcement of parity laws (see Appendix II for a sample of recent parity enforcement actions) (Departments of Labor, Health and Human Services, et al., 2023; Pestaina, 2022). As this new class of treatments comes to market, health plans, employers, providers, and patients need to understand how MHPAEA can support full coverage for, and access to, PAT for patients in need.

[1] An extensive review of clinical research on seven different psychedelic compounds can be found in BrainFutures' issue brief, *Psychedelic Medicine: A Review of Clinical Research for a Class of Rapidly Emerging Behavioral Health Interventions*.

What is Psychedelic-Assisted Therapy (PAT)?

PAT has been described as the use of a psychedelic substance/medication where **both** the biological and psychological effects of the medication play a significant role in facilitating a psychotherapeutic intervention (Guss et al., 2020). Most PAT clinical trials first involve patient screening and assessment, followed by three types of treatment sessions—preparation psychotherapy, medication administration (with psychological monitoring and support), and integration (Sky et al., 2022).[2]

Although PAT is a newer therapeutic modality, it shares common ground with the traditional combination of psychotherapy and psychotropic medication commonly used in treating patients with mental health and substance use disorders (MH/SUDs). Both approaches aim to address

RECENT RESULTS FROM PAT RESEARCH

- In the second Phase 3 trial of MDMA-AT in patients with moderate to severe PTSD, 86.5% of participants responded to the treatment in the MDMA-AT group compared to 69% in the therapy-only group (Mitchell et al., 2023). At the end of the study period, 71.2% of participants in the MDMA-AT group had made such improvements that they no longer met diagnostic criteria for PTSD versus 47.6% of the therapy-only group.
- In a recent Phase 2 trial of psilocybin treatment for MDD, 42% of patients had a sustained response over 43 days (Raison et al., 2023). This study also found that psilocybin treatment was associated with improvements in exploratory outcomes, including reductions in global disease severity, self-reported depressive and anxiety symptoms, and improved quality of life.
- In a Phase 2b, double-blind clinical trial of single-dose psilocybin for TRD, 30% of patients who received a 25mg dose of psilocybin were in remission at week three. At week 12, double the number of participants who received a 25mg dose of psilocybin had a sustained response (20.3%) compared to participants who only received 1mg (10.1%) (Goodwin et al., 2022).

[2] For an in-depth discussion of the PAT treatment model, see BrainFutures' issue brief, *An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy*.

mental health conditions by combining therapeutic support with pharmacological intervention, which has been shown to be more effective in treating a range of behavioral disorders, including treatment-resistant depression (TRD) and post-traumatic stress disorder (PTSD), than the use of psychotherapy or pharmacotherapy alone (Cuijpers et al., 2020).

At present, there are no FDA-approved psychedelic drugs that are administered using the PAT treatment model except for ketamine, which is sometimes used in this manner off-label. While SPRAVATO® (esketamine) has dissociative effects and has been approved by the FDA for TRD and major depressive disorder (MDD) with acute suicidal ideation or behavior, the treatment is not considered PAT because SPRAVATO® is not necessarily administered with preparatory and integration psychotherapy.

In clinical trials, PAT treatments with various psychedelic substances such as 3,4- methylenedioxymethamphetamine (MDMA) and psilocybin, have shown promise for treating MH/SUDs (see box on next page). As of spring 2024, Lykos has completed Phase 3 trials of MDMA-assisted therapy (MDMA-AT) to treat PTSD and has submitted a New Drug Application (NDA) to the FDA for an approval decision in the coming months (Lykos Therapeutics, 2023). Compass Pathways is progressing through its two-arm Phase 3 trial of its proprietary psilocybin compound for patients with TRD, while Usona Institute has begun a Phase 3 trial of psilocybin for MDD (Haichin, n.d.). Notably, Lykos intends to request FDA approval for MDMA-AT rather than MDMA on its own (Lykos Therapeutics, 2023).

What is the Mental Health Parity and Addiction Equity Act?

Research has repeatedly shown that people living with MH/SUDs have a great deal of difficulty accessing treatment. One reason is that behavioral health care can be unaffordable for many patients, even those who have health insurance (Rapfogel, 2022). Many patients who try to find a mental health provider that is in-network with their plan are unable to do so and therefore must pay higher rates to out-of-network providers, creating both financial burdens and barriers to care (Sky et al., 2023). Congress enacted MHPAEA, effective in 2009, to ensure that health plans provide access to treatment for MH/SUDs, such as depression, opioid use disorder (OUD), or alcohol abuse that is equivalent to access to treatment for physical conditions, such as broken bones, cancer, or diabetes. MHPAEA's fundamental purpose is to ensure that individuals who seek treatment for MH/SUDs do not face greater barriers to accessing health insurance benefits than they would face when seeking treatment of a medical/surgical (med/surg) condition (Departments of Labor, Health and Human Services et al., 2023).

More specifically, MHPAEA requires that any financial requirement and treatment limitation health plans apply to MH/SUD benefits can be **no more restrictive** than such requirements and limitations applied to med/surg benefits in any classification (Departments of Labor, Health and Human Services et al., 2008). Treatment limitations are distinguished between quantitative treatment limitations (QTLs), which are expressed numerically, such as day limits and visit limits, and nonquantitative treatment limitations (NQTLs), which are not expressed numerically, but that otherwise limit the scope or duration of benefits for treatment (Departments of Labor, Health and Human Services, et al., 2010). Examples of NQTLs include medical management standards that limit benefits based on medical necessity or whether a treatment is experimental or investigative, formulary design for prescription drugs, fail-first policies, admission to provider networks, reimbursement rates, etc. (Departments of Labor, Health and Human Services, et al., 2013).

The MHPAEA general rule for NQTLs provides that:

> *"A group health plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect*

to medical/surgical benefits in the classification" (Departments of Labor, Health and Human Services, et al., 2013).

MHPAEA was amended by The Consolidated Appropriations Act, 2021 (CAA) to codify requirements that health plans and insurance issuers perform and document comparative analyses of the design and application of NQTLs. In other words, plans must demonstrate that the design and application of NQTLs for MH/SUD benefits are comparable to and no more stringent than the design and application of NQTLs for med/surg benefits, both as written and in operation (U.S. Congress, 2020).

Any plan that covers behavioral health services in any classification of benefits must do so at equity with med/surg benefits in all classifications of benefits to comply with MHPAEA. It is also important to note that by virtue of federal preemption, MHPAEA sets the floor for protection of parity rights when both the federal law and state parity laws apply to an insurance plan. Only when a state law provides greater protections to the consumer will it supersede the federal law (Departments of Labor, Health and Human Services et al., 2013).

The Departments of Labor and Health and Human Services, which share enforcement duties for MHPAEA (depending on the type of health plan), have released extensive guidance to help health plans comply with the law and to support patients and providers in identifying potential violations, including the 2020 MHPAEA Self-Compliance Tool (Department of Labor, Health and Human Services, et al., 2020). As part of the extensive guidance issued, the Departments provided a list of "Warning Signs" that indicate a health plan may be out of compliance with MHPAEA and that the presence of any of these Warning Signs merits further investigation (Departments of Labor and Health and Human Services, 2016). For a complete list of the Warning Signs, see Appendix I.

Coverage Determination and Medical Necessity

Assuming MDMA-AT is approved by the FDA in 2024, health plans will need to determine if and how to cover this treatment. This will be determined by evaluating whether MDMA-AT (and other psychedelic drugs or drug-therapy combinations that follow) meets the plan's criteria for coverage including meeting their "medical necessity" standards for treatment of a disease or condition. As noted above, medical necessity determinations are a type of NQTL.

Criteria for determining medical necessity often rely on published, peer-reviewed evidence, expert opinion, and guidelines from professional organizations. Since PAT requires both a pharmacy element (the medication) and a professional services element (psychotherapy and monitoring/psychological support), insurers may need to make medical necessity determinations for each aspect separately or in combination. Plans are permitted to rely on nationally recognized criteria or set their own criteria for evaluating medical necessity. However, as with all NQTLs, to comply with the requirements of MHPAEA, both the criteria and the plan's application of these criteria must be comparable to and no more stringent for MH/SUD benefits compared to med/surg benefits.

Plans will also need to define under which benefit classification PAT services are placed. PAT could be classified as an outpatient office benefit or as an outpatient other (facility) program benefit. If the psychedelic compound is evaluated separately, this may be placed in the pharmacy benefit classification. Most professional services delivered in a non-facility setting would typically be defined as outpatient office. Interventions that are multi-disciplinary and delivered in a facility are typically defined as outpatient other (facility) e.g., intensive outpatient.

Psychotherapy, whether paired with psychotropic medication or offered alone, has widespread acceptance as an evidence-based and medically necessary approach and is supported by coverage for most payers (Waddill, 2022). The same principles apply to psychotropic medications. Almost all insurers reimburse routinely for psychotropic medication, whether prescribed separately or in combination with various psychotherapies. PAT services are consistent with these established interventions, which are almost universally covered.

Specific NQTLs That Can Be Applied to PAT

There are many types of NQTLs, in addition to the application of medical necessity determinations, that could be applied to PAT benefits. A list of some of these NQTLs that health plans may apply are shown in Table 1 below (See Table 1, "Potential NQTLs Applied to PAT Through Health Plan Coverage"). Even if a health plan offers PAT as a benefit, which NQTLs are applied and how they are applied could limit or permit access to PAT.

These NQTLs do not necessarily violate MHPAEA so long as they are designed and applied comparably and no more stringently for MH/SUD benefits than for med/surg benefits, both as written and in operation. However, if health plans apply coverage limitations for any NQTL in a non-comparable and/or more stringent manner for MH/SUD benefits than for med/surg benefits, either as written and/or in operation, this can create a parity violation.

TABLE 1. POTENTIAL NQTLS APPLIED TO PAT THROUGH HEALTH PLAN COVERAGE

Potential NQTLs Applied to Psychedelic Medication

- Unfavorable formulary tiering (higher cost-sharing tier/higher out-of-pocket cost)
- Quantity and/or dosage limits
- Limits on duration or frequency (how long medication can be used or how many times)

Potential NQTLs Applied to PAT Professional Services only or Combined Professional Services and Medication

- Exclusions of PAT as a treatment
- Classifying PAT as experimental
- Provider reimbursement
- Network admission standards for providers
- Exclusion based on failure to complete course of treatment
- Limit on number of allowed sessions

<u>Restrictions based on:</u>

- Geographic location (e.g., member's state of residence and adjoining states)
- Facility type (e.g., freestanding facilities, not in physician's office)
- Limitations on provider specialty (i.e. psychiatrists, psychologists, psychiatric nurses, social workers, counselors)
- Benefit classification (e.g., only outpatient in-network)

Additional utilization management strategies may be applied to both the drug and professional services components:

- Prior authorization (a requirement to check that service/medication is covered under a member's benefits before initiation of service/medication)
- Concurrent review (requirement for approval of continuing a previously approved service/medication)
- Retrospective review (process to determine coverage after service/medication has been provided)
- Step therapy/fail-first therapy (requirement to use less expensive options/medications with demonstration of failure of response to the required less expensive options)

Examples of Potential MHPAEA Violations for PAT Benefits

While an exhaustive list of potential PAT-related parity violations is beyond the scope of this issue brief, included below are three hypothetical cases that illustrate how health plans could create MHPAEA compliance risks in their approach to PAT.

HYPOTHETICAL 1: CLASSIFICATION OF TREATMENTS AS EXPERIMENTAL

Payers often avoid reimbursing medical services by classifying them as "experimental." Each plan sets its own criteria for treatments that it considers experimental, but these criteria must be applied comparably and no more stringently to MH/SUD benefits than to med/surg benefits. A typical plan might classify a treatment as experimental if there are fewer than two randomized-controlled trials supporting its use for a specific indication and no professional organization recommends it as part of its treatment guidelines (Centers for Medicare & Medicaid Services, 2019). If the plan were to deny coverage for a MH/SUD treatment that meets this standard for experimental treatments but applied less stringent criteria to med/surg benefits, that could be a MHPAEA violation.

While every plan typically has its own specific standards for determining which treatments are experimental, there is a substantial body of research supporting various forms of PAT in the treatment of MH/SUDs (including numerous randomized controlled trials). BrainFutures has published an extensive review of the clinical research on psychedelics and psychedelic-assisted therapy containing more than 200 studies, including 67 randomized controlled trials (Sky, 2022).

Additionally, BrainFutures and the American Psychedelic Practitioners Association—a professional organization representing PAT providers—recently published Professional Practice Guidelines for Psychedelic-Assisted Therapy (American Psychedelic Practitioners Association, BrainFutures, & Guidelines Working Group, 2023). The American Society for Ketamine Physicians, Psychotherapists, and Practitioners has also published standards of practice for sub-anesthetic use of ketamine (Sullivan et al., 2020).

FDA approval for MDMA-AT and/or other PATs or psychedelic drugs will also demonstrate that these treatments should not be considered experimental.

HYPOTHETICAL 2: MORE STRINGENT AND NON-COMPARABLE APPLICATION OF MEDICAL NECESSITY CRITERIA AND EXPERT SOURCES

FDA Risk Evaluation and Mitigation Strategies (REMS) are important to protect patients from the risks of certain medications. Health plans may use the FDA REMS for psychedelic medications/PAT as a source for determining whether to cover the treatment by requiring that the PAT service meet all of the REMS criteria. For example, the FDA indication may state that PAT is only for a treatment-resistant disorder. The FDA may define TRD, for example, as failure of two prior antidepressant medication trials.

A plan may, however, apply more stringent criteria than the FDA, such as requiring a failure of three antidepressant medications for PAT services. This would be considered a more stringent and non-compliant application of the NQTL unless the plan can demonstrate that it applies the same or a more stringent set of criteria than required by the FDA for med/surg treatments as well.

Some FDA-approved clinical trial protocols for PAT require multiple medication administration sessions to achieve clinical improvement. If a health plan that is relying on the FDA as a source and evidentiary standard denies coverage for a patient who may need multiple treatment sessions, this could also be a parity violation unless equivalent restrictions are applied to med/surg benefits.

HYPOTHETICAL 3: PRIOR AUTHORIZATIONS AND FAIL-FIRST POLICIES

Plans frequently adopt prior authorization policies, mandating that patients and providers receive approval from the insurer before proceeding with treatment. This aims to reduce utilization of medical services that may be deemed unnecessary. However, health plans are not permitted to apply more stringent prior authorization policies or criteria for MH/SUD benefits than are applied for med/surg benefits. For example, a plan might require prior authorization for all intensive outpatient mental health care or services like PAT. If there is no similar requirement for med/surg benefits in the same benefit classification, or if the requirement is implemented more stringently in operation (for example, through more frequent concurrent reviews), this could be a parity violation.

Similarly, payers often implement fail-first policies that require patients to attempt and fail at other, less-expensive treatments first before approving reimbursement for a treatment like PAT. In this instance, a payer could require that patients first try psychotherapy and/or other approved medications for the same condition before authorizing PAT. Again, this would be a violation of MHPAEA unless similar requirements and restrictions are in place for med/surg benefits.

Summary

PATs are a highly promising set of innovative treatments poised to become available in the coming years for patients living with some of the most prevalent and debilitating mental health conditions such as PTSD, depression, and SUDs. These scientific and clinical advancements offer hope for those who have found little relief from existing treatment options. For the potential of these treatments to be fully realized, it is crucial that patients across income spectrums have access to PAT as a covered insurance benefit without undue restrictions, in line with currently existing access standards for all other healthcare services.

BrainFutures has engaged with several health insurers, finding a broad awareness of the ongoing research trials and an interest in the potential of these new treatments—especially for patients who have not responded to treatment as usual. As enforcement of parity laws intensifies at both the federal and state levels, health plans and insurers are called to design their coverage policies with due diligence to prevent parity violations. Any restrictions placed on PAT must not be more stringent than those applied to comparable med/surg benefits. Imposing harsher restrictions would not only expose these organizations to legal ramifications, but also, more critically, disadvantage patients in urgent need of care amidst a worsening mental health crisis.

We encourage patients, providers, and payers to thoughtfully consider MHPAEA's requirements now so that PAT can be readily available and accessible upon FDA approval to patients who may benefit from this emerging treatment modality.

Appendix I

Warning Signs of Potential Parity Violations – Conduct Comparative Analysis

The Departments of Labor and Health and Human Services have released guidance to alert plan sponsors to certain provisions within health plans that could signify a failure to comply with mental health parity requirements. This guidance outlines recent indicators, termed "Warning Signs," and provides a comprehensive overview of MHPAEA requirements (Departments of Labor and Health and Human Services, 2016). The following provisions quoted below can be found on their website.

PREAUTHORIZATION AND PRE-SERVICE NOTIFICATION REQUESTS

- **Blanket Preauthorization Requirement:** Plan/insurer requires preauthorization for all mental health and substance use disorder services.
- **Treatment Facility Admission Preauthorization:**
  - Plan requires preauthorization for all inpatient and outpatient treatment of chemical dependency and all inpatient and outpatient treatment of serious mental illness and mental health conditions.
  - Plan requires preauthorization or concurrent care review every 10 days for MH/SUD services but not for med/surg services.
- **Prescription Drug Preauthorization:** Plan/insurer requires preauthorization every three months for pain medications prescribed in connection with MH/SUD conditions.
- **Extensive Pre-notification Requirements:** Plan/insurer requires pre-notification for all MH/SUD intensive outpatient program treatment, and extended outpatient treatment visits beyond 45-50 minutes.
- **Medical Necessity Review Authority:** Plan's/insurer's medical management program (precertification and concurrent review) delegates its review authority to attending physicians for med/surg services but conducts its own reviews for MH/SUD services.

FAIL-FIRST PROTOCOLS

- **Treatment Attempt Requirements:** For inpatient SUD rehabilitation treatment plan/insurer requires a member to first attempt two forms of outpatient treatment, including the intensive outpatient, partial hospital, outpatient detoxification, ambulatory detoxification or inpatient detoxification levels of care.
- **Progress Requirements:** For coverage of intensive outpatient treatment for MH/SUD, the plan/insurer requires that a patient has not achieved progress with non-intensive outpatient treatment of a lesser frequency.

PROBABILITY OF IMPROVEMENT

- **Likelihood of Improvement:** For residential treatment of MH/SUD, the plan/insurer requires the likelihood that inpatient treatment

will result in improvement. Plan/policy only covers services that result in measurable and substantial improvement in mental health status within 90 days.

WRITTEN TREATMENT PLAN REQUIRED

- **Written Treatment Plan:** For MH/SUD benefits, plan/insurer requires a written treatment plan prescribed and supervised by a behavioral health provider.
- **Treatment Plan Required within a Certain Time Period:** Plan/insurer requires that within seven days, an individualized problem-focused treatment plan be completed, including nutritional, psychological, social, medical and substance abuse needs to be developed based on a complex biopsychosocial evaluation. Plan needs to be reviewed at least once a week for progress.
- **Treatment Plan Submission on a Regular Basis:** Plan/insurer requires that an individual-specific treatment plan will be updated and submitted, in general, every 6 months.

OTHER

- **Patient Non-compliance:** Plan/policy excludes services for chemical dependency in the event the covered person fails to comply with the plan of treatment, including excluding benefits for MH/SUD services if a covered individual ends treatment for chemical dependency against the medical advice of the provider.
- **Licensure Requirements:** Plan/policy requires that MH/SUD facilities be licensed by a State but does not impose the same requirement on med/surg facilities.
- **Geographical Limitations:** Plan/policy imposes a geographical limitation related to treatment for MH/SUD conditions but does not impose any geographical limits on med/surg benefits.

FAQs About Mental Health and SUD Parity Implementation and the 21st Century Cures Act Part 39

The Department of Labor and the Centers for Medicaid and Medicare Services (CMS) have issued the following guidance document to assist payers in implementing both MHPAEA and the 21st Century Cures Act (Center for Medicare & Medicaid Services, 2019). The excerpts below are quoted directly (though not in their entirety), and the original can be found on their website.

GUIDANCE ON EXCLUSION OF TREATMENT THAT PAYER DEEMED EXPERIMENTAL

Q1. My health plan document states that it excludes coverage for treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD benefits. For both medical/surgical benefits and MH/SUD benefits, the plan generally follows current medical evidence and professionally recognized guidelines on the efficacy of treatment. With respect to both medical/surgical benefits and MH/SUD benefits, the plan's documents state that the plan excludes coverage for treatment as experimental for a given condition when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition, and fewer than

two randomized controlled trials are available to support the treatment's use with respect to the condition.

The plan defines autism spectrum disorder as a mental health condition. More than one professionally recognized treatment guideline and more than two controlled randomized trials support the use of Applied Behavior Analysis (ABA) therapy to treat certain children with autism spectrum disorder. The plan, in practice, excludes coverage for ABA therapy to treat children with autism spectrum disorder under the rationale that the treatment is experimental or investigative. With respect to medical/surgical conditions, the plan covers treatment when supported by one or more professionally recognized treatment guidelines and two or more controlled randomized trials. Is this permissible under MHPAEA?

No. The plan's application of the NQTL to MH/SUD benefits is not permissible because, in operation, the plan applies the NQTL more stringently to certain MH/SUD benefits than to medical/surgical benefits. **A medical management standard limiting or excluding benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA.** A group health plan or group or individual health insurance issuer may impose an NQTL on MH/SUD benefits if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors used by the plan in applying the NQTL to MH/SUD benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in applying the NQTL to medical/surgical benefits in the same classification. [Emphasis added].

Although the plan as written purports to exclude experimental or investigative treatment for both MH/SUD and medical/surgical benefits using the same standards, in practice, it imposes this exclusion more stringently on certain MH/SUD benefits, as the plan excludes ABA therapy, despite the fact that professionally recognized treatment guidelines and the requisite number of randomized controlled trials support the use of ABA therapy to treat children with autism spectrum disorder. Accordingly, the plan's exclusion of certain MH/SUD benefits—in this case, for ABA therapy—does not comply with MHPAEA because the plan applies the NQTL more stringently to these MH/SUD benefits than to medical/surgical benefits.

Q2: My health plan documents state that the plan excludes coverage for treatment that is experimental or investigative for both medical/surgical benefits and for MH/SUD benefits. The plan defines experimental or investigative treatments as those with a rating below "B" in the Hayes Medical Technology Directory, with exceptions for certain treatments that have a rating of "C" only where an exception is determined to be medically appropriate. However, in operation, the plan reviews and covers certain treatments for medical/surgical conditions that have a rating of "C" only when an exception is determined to be medically appropriate, while denying all benefits for MH/SUD treatment that have a rating of "C" or below, without reviewing the treatments to determine whether exceptions are medically appropriate. Is this permissible under MHPAEA?

No. A medical management standard that limits or excludes benefits based on whether a treatment is experimental or investigative is an NQTL under MHPAEA. A plan or issuer may impose an NQTL on MH/SUD benefits if, under the terms of the plan as written and in operation, the processes, strategies, evidentiary standards, and other factors used by the plan in applying

its NQTL with respect to MH/SUD benefits are comparable to, and applied no more stringently than, those used in applying the NQTL with respect to medical/surgical benefits in the same classification.

Here, although the terms of the plan set forth the same evidentiary standard for MH/SUD benefits and medical/surgical benefits (defining experimental as having a Hayes Medical Technology Directory rating below "B," with exceptions for those with a "C" rating where medically appropriate), the plan applies a different evidentiary standard, and the standard is more stringent for MH/SUD benefits than for medical/surgical benefits because claims for medical/surgical treatments with a "C" rating are reviewed to determine whether an exception is medically appropriate while claims for MH/SUD treatments with a "C" rating are denied without review by the plan to determine whether an exception might be medically appropriate. The fact that the plan ultimately denies some medical/surgical benefits that have a rating of "C" does not justify the total exclusion of treatments with a "C" rating for MH/SUD. Accordingly, the plan's medical management standard does not comply with MHPAEA.

To comply with MHPAEA, the plan must apply the same exception for MH/SUD treatments in the same classification if the plan, in operation, provides an exception based on medical appropriateness for medical/surgical treatments. To ensure that its approach is compliant with MHPAEA and that it will be able to satisfy participants' requests for documents, the plan should document in writing the availability and requirements of its exceptions process, as well as the factors relied upon in determining how the exception process applies to both MH/SUD and medical/surgical benefits.

2020 MHPAEA Self-Compliance Tool

The Department of Labor provides an extensive tool that helps health plans comply with MHPAEA. It is also a resource for state regulators to determine if health plans under their jurisdiction are in compliance. The excerpts below are quoted directly from the Self-Compliance Tool; the original can be found on the Department of Labor's website (Department of Labor, Health and Human Services, et al., 2020).

GUIDANCE ON APPLICATION OF EVIDENTIARY STANDARDS

Illustration 5: A patient with chronic depression has not responded to five different antidepressant medications and therefore was referred for outpatient treatment with repetitive transcranial magnetic stimulation (TMS). This specific treatment has been approved by the FDA and has been the subject of more than six randomized controlled trials published in peer reviewed journals. The plan denies the treatment as experimental. The plan states that it used the same criteria to deny TMS as it does to approve or deny any MH/SUD or medical/surgical benefits under the plan. The plan identifies its standard for both medical/surgical benefits and MH/SUD benefits as requiring that at least two randomized controlled trials showing efficacy of a treatment be published in peer reviewed journals for any new treatment. However, the plan indicates that while more than two randomized controlled trials regarding TMS have been published in peer reviewed journals, a committee of medical experts involved in plan utilization management reviews reviewed the journals and determined that only one of the articles provided sufficient evidence

of efficacy. The plan did not identify what specific standards were used to assess whether a peer review had adequately evidenced efficacy and what the qualifications of the plan's experts are. Lastly, the plan does not impose this additional level of scrutiny with respect to reviewing medical/surgical treatments beyond the initial requirement that the treatment has been the subject of the requisite number and type of trials.

Conclusion: The plan's exclusion fails to comply with MHPAEA's NQTL requirements because, in practice, the plan applies an additional level of scrutiny with respect to MH/SUD benefits and therefore applies the NQTL more stringently to mental health benefits than to medical/surgical benefits without additional justification. To come into compliance, the plan could ensure that that any additional levels of scrutiny are imposed on both medical/surgical and MH/SUD benefits comparably, including by establishing standards for when a peer review has adequately evidenced efficacy, and that the qualifications of the plan's experts are similar for both MH/SUD and medical/surgical benefits.

GUIDANCE ON MEDICATION-ASSISTED THERAPY (MAT)

Plans and issuers that offer MAT benefits to treat opioid use disorder are subject to MHPAEA requirements, including the special rule for multitiered prescription drug benefits that applies to the medication component of MAT. The behavioral health services components of MAT should be treated as outpatient benefits and/or inpatient benefits as appropriate for purposes of MHPAEA. Plans and issuers should ensure there are NO impermissible QTLs, such as visit limits, or impermissible NQTLs, such as limits on treatment dosage and duration. For example, a limitation providing that coverage of medication for the treatment of opioid use disorder is contingent upon the availability of behavioral or psychosocial therapies or services or upon the patient's acceptance of such services would generally not be permissible unless a comparable process was used to determine limitations for the coverage of medications for the treatment of medical/surgical conditions.

GUIDANCE ON MORE STRINGENT APPLICATION OF MEDICAL NECESSITY CRITERIA FOR MH/SUD VS MED/SURG

Illustration: An issuer did not cover methadone for opioid addiction, though it did cover methadone for pain management. The issuer failed to demonstrate that the processes, strategies, evidentiary standards, and other factors used to develop the methadone treatment exclusion for opioid addiction are comparable to and applied no more stringently than those used for medical/surgical conditions. The issuer re-evaluated the medical necessity of methadone maintenance treatment programs and developed medical-necessity criteria that mirrors federal guidelines (including the Substance Abuse and Mental Health Services Administration treatment improvement protocol for medication for opioid use disorder) for opioid treatment programs to replace the methadone-maintenance treatment exclusion.

Illustration: A plan uses nationally recognized clinical standards to determine coverage for prescription drugs to treat medical/surgical benefits based on the recommendations of a Pharmacy and Therapeutics (P&T) committee. However, the plan deviates from such standards for buprenorphine/ naloxone to treat opioid use disorder based on the P&T committee's recommendations. This deviation should be evaluated for compliance with MHPAEA's NQTL standard

in practice, including the determination of (1) whether the P&T committee has comparable expertise in MH/SUD conditions as it has in medical/surgical conditions, and (2) whether the committee's evaluation of the nationally-recognized clinical standards and decision processes to deviate from those standards for MH/SUD conditions is comparable to and no more stringent than the processes it follows for medical/surgical conditions.

GUIDANCE OF NON-COMPARABLE CLASSIFICATION OF BENEFITS FOR MH/SUD VS MED/SURG

Classifying benefits: In determining the classification in which a particular benefit belongs, a group health plan or group or individual market health insurance issuer must apply the same standards to medical/surgical benefits as to MH/SUD benefits. *See 26 CFR 54.9812- 1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), 45 CFR 146.136(c)(2)(ii)(A).*

1. SPECIAL RULE FOR OUTPATIENT SUB-CLASSIFICATIONS:

- For purposes of determining parity for outpatient benefits (in-network and out-of network), a plan or issuer may divide its benefits furnished on an outpatient basis into two sub-classifications: (1) office visits; and (2) all other outpatient items and services, for purposes of applying the financial requirement and treatment limitation rules. 26 CFR 54.9812-1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), 45 CFR 146.136(c)(3)(iii).
- After the sub-classifications are established, the plan or issuer may not impose any financial requirement or QTL on MH/SUD benefits in any sub-classification (i.e., office visits or non-office visits) that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in the MHPAEA regulations. See 26 CFR 54.9812-1(c)(3)(i), 29 CFR 2590.712(c)(3)(i), 45 CFR 146.136(c)(3)(i), 45 CFR 146.136(c)(3)(iii).

Note: If a plan classifies covered intermediate levels of care, such as skilled nursing care and residential treatment, as inpatient benefits, and covers room and board for all inpatient medical/surgical care, including skilled nursing facilities and other intermediate levels of care, but imposes a restriction on room and board for MH/SUD residential care, the plan imposes an impermissible restriction only on MH/SUD benefits and therefore violates MHPAEA.

Appendix II

Recent Enforcement Actions

State and federal governments are placing a higher priority on enforcing parity laws. Below, we provide illustrative examples sourced from ParityTrack that highlight instances of parity violations and subsequent responses from either the U.S. Department of Labor and/or individual states (ParityTrack, n.d.).

NEW YORK

United to Pay Over $18 million to Settle Disputes Regarding Alleged Parity Violations: New York Federal Court Combines Federal and State Investigations with Class Action Lawsuits (August 2021)

New York Attorney General Letitia James and the U.S. Department of Labor reached landmark agreements with UnitedHealthcare (United), the nation's largest health insurer, over allegations of unlawfully denying MH/SUD treatment coverage for thousands of Americans. United will pay around $14.3 million in restitution to affected customers, including $9 million directed to over 20,000 New Yorkers who faced refusals and/or reductions in reimbursement. These agreements ensure compliance with both New York and federal laws that mandate equal coverage for MH/SUD treatment as they cover physical health treatment. They address United's policies that unlawfully limited outpatient psychotherapy coverage, negatively impacting hundreds of thousands of New Yorkers. Additionally, United will remove imposed barriers and pay over $2 million in penalties, with $1.3 million allocated to the state of New York (New York State Attorney General, 2021).

CONNECTICUT

State Executes Stipulation and Consent Order against 4 Health Plan Subsidiaries with over $1 Million in Fines and Education Payments (July 2020 and January 2021)

The Connecticut Insurance Department released a market conduct examination report on July 30, 2020, focusing on Oxford Health Insurance (also known as Oxford HealthPlans) and United. Following this, on January 1, 2021, these insurers, along with United Behavioral Health, agreed to a stipulation and consent order. As part of the agreement, they agreed to pay fines totaling $575,000 and allocate $500,000 toward educational programs.

While numerous aspects of the review met expectations, insurance regulators pinpointed various areas of concern, one of which included United Behavioral Health's failure to comply with the American Society of Addiction Medicine's (ASAM) Patient Placement Criteria (ParityTrack, n.d.).

DELAWARE

Health Plans Fined $1.33 Million for Mental Health Parity Violations in 2020/2021

In November 2020 and July 2021, the Delaware Insurance Department released two rounds of mental health parity market conduct exams that uncovered thousands of violations resulting in $1.3 million in fines. Fines were imposed on these companies for various reasons, including but not limited to failure to promptly inform individuals about claim status, high prescription drug costs, and delays in accessing necessary treatments like methadone for opioid addiction.

Five health plans were audited and fined by the state insurance department:

- United ($253,000);
- Cigna Health Life and Insurance Company ($382,000);
- Highmark Blue Cross Blue Shield Delaware (BCBSD) Inc. ($299,000);
- Aetna Health Plan ($298,000);
- Optimum Choice ($100,000) (Barrish, 2021).

Details of each health plan's violations are summarized below.

United

The market conduct exam covered various aspects of United's operations, including complaint handling, policy holder services, and mental health parity compliance. United received a $253,000 fine from the Delaware Department of Insurance for multiple violations, including:

- Stringent prior authorization NQTLs for MH/SUD benefits compared to med/surg benefits;
- Wrongful restrictions on ADHD and smoking cessation medications, opioid dependence treatment medications, and Vyvanse for binge eating disorders;
- Quantity limit and inappropriate dose restrictions;
- Discriminatory removal of Pristiq from the refill and save program;
- Restrictive criteria on Evzio injection;
- Exclusion of higher tier placement for generic mental health medications and methadone maintenance treatment from outpatient facilities;
- Deficiencies in grievance review time frames, claims payment, and operational issues (Delaware Department of Insurance, 2019a; ParityTrack, n.d.).

Cigna Health Life and Insurance Company

Cigna's market conduct exam revealed issues across various operations, resulting in a $382,000 fine from the Delaware Department of Insurance. Among the violations were stricter prior authorization rules for MH/SUD benefits, improper step therapy limitations, and failure to adhere to ASAM criteria for SUD coverage. Additional deficiencies were identified in grievance processing, communications with insured, and coverage for autism spectrum disorders, among other operational challenges (Delaware Department of Insurance, 2019b; ParityTrack, n.d.).

Highmark BCBSD Inc.

The Insurance Commissioner found the following parity-related violations against Highmark, resulting in a fine of $299,000:

- Exclusion of methadone treatment for OUD until January 2018;
- Improper prior authorization rules for buprenorphine tablets which led to denied access in emergencies;
- Failure to correctly adhere to ASAM criteria for SUD claims;
- Stringent medication criteria for MH/SUD drugs compared to med/surg medications, including improper NQTLs for various medication uses for MDD and OUD (ParityTrack, n.d.)

RHODE ISLAND

State Requires BlueCross BlueShield of Rhode Island to Pay $5 Million in Support of Mental Health Care (September 2018)

Rhode Island's BlueCross Blue Shield agreed to contribute $5 million to enhance mental health services in the state after a state audit revealed non-compliance with federal and state laws. The audit found that prior authorization requirements for mental health prescriptions hindered care and showed disparities in inpatient care frequency and mediation choice, favoring cheaper options over most effective ones. Instead of paying a fine, the insurer will contribute $1 million every year for five years to a fund for mental health prevention (Borg, 2018; ParityTrack, n.d.).

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About BrainFutures

BrainFutures is a nonprofit addressing barriers to the equitable access of evidence-based innovations supporting mental health and well-being, from neuromodulation to psychedelic-assisted therapy. We are a trusted collaborator and educator creating resources for insurers, policymakers, and providers to help inform decisions on insurance reimbursement, infrastructure, and workforce training.

OUR WORK IN PSYCHEDELIC-ASSISTED THERAPY & SUPPORTING THE FIELD

In 2021, BrainFutures launched a three-part issue brief series and coalition-building effort focused on psychedelic-assisted therapy. BrainFutures has released three reports and an accompanying mini-brief in hopes of laying an unbiased foundation for the regulatory and reimbursement work needed in the field.

- *Psychedelic Medicine: A Review of Clinical Research for a Class of Rapidly Emerging Behavioral Health Interventions*
- *Expediting Psychedelic-Assisted Therapy Adoption in Clinical Settings*
- *An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy*
- *The Future of the Field (Mini-Brief)*

In 2023, BrainFutures released a medical coding guide describing a reimbursement strategy to enable psychedelic-assisted therapy providers to receive equitable reimbursement from payers for these service as well as a white paper describing current legal access models for psychedelics in the US. We also collaborated with the American Psychedelic Practitioners Association to publish the first set of guidelines for mental health providers on the practice of psychedelic-assisted therapy, informed by existing clinical research and expert consensus.

- *A Guide to CPT and HCPCS Codes for Psychedelic-Assisted Therapy*
- *Psychedelic Access Pathways: Differentiating Medical, Wellness, and Religious Access to Psychedelics*
- *Professional Practice Guidelines for Psychedelic-Assisted Therapy*

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