May 27, 2025

Attorney General Pam Bondi
Anticompetitive Regulations Taskforce
950 Pennsylvania Avenue, NW
Washington, DC 20530

Re: Elimination of Anticompetitive Regulations in Behavioral Health; Docket No. ATR-2025-0001

Dear Attorney General Bondi,

The Association for Behavioral Health and Wellness (ABHW) looks forward to collaborating with the Department of Justice (DOJ) Anticompetitive Regulations Task Force to identify burdensome regulations that stifle market competition. The DOJ has the opportunity to reduce government waste while better meeting patients' behavioral health needs. To support your efforts, we have identified opportunities that discourage high-quality care, add unnecessary red tape, and waste behavioral health care dollars.

ABHW is the national voice for payers managing behavioral health (BH) insurance benefits. Our member companies provide coverage to 200 million people in the public and private sectors to treat mental health (MH), substance use disorder (SUD), and other behaviors that impact health and wellness.

At a time when one in five adults in the U.S. experiences a mental illness each year and we continue to face record-high rates of suicide and overdose, the provisions below compromise the ability of health plans to ensure their members receive the highest quality of appropriate care.

I. The MHPAEA Final Rule is Unworkable

Since its inception, ABHW has been a leader for MH and SUD parity and was instrumental in drafting the legislation for the initial Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008. Our member health plans have worked tirelessly over the past 16 years to implement parity for behavioral health services, innovating new approaches and benefits, addressing provider shortages and lack of access, and driving quality to improve patient outcomes.

ABHW is grateful to the Trump Administration for issuing the non-enforcement policy covering the portions of the MHPAEA Final Rule applicable for plan years beginning or after

January 1, 2025, and January 1, 2026. Additionally, we understand that the Departments are re-examining the current MHPAEA Final Rule and enforcement programs more broadly.

Since January 2025, ABHW has asked the Trump Administration for (1) a one year enforcement delay for the Biden Administration's Final Rule "Requirements Related to the Mental Health Parity and Addiction Equity Act (MHPAEA Final Rule, Final Rule or Rule)," published on September 23, 2024 (89 Fed. Reg. 77586) by the U.S. Department of Labor (DOL), U.S. Department of Health and Human Services (HHS), and U.S. Department of Treasury (collectively, "the Departments"); (2) to withdraw certain provisions; and (3) to reform other provisions to ensure that the application and enforcement are practical, effective, and efficient. The Rule imposes vague guidelines and extensive new requirements, which require substantive guidance that health plans have not yet received, despite the 1/1/2025 and 1/1/2026 implementation dates for key provisions.

The 2024 Final Rule is unworkable. Below, we have shared our concerns with some of the Rules' key provisions because they are inconsistent with the MHPAEA statute and create unsound, unworkable, and burdensome policies that make it challenging for health plans and employers to operate effectively in the health care sector. These provisions divert funding, time, and resources away from helping patients with MH and SUD conditions and create new, onerous administrative requirements. We welcome further conversations with the DOJ to improve mental health parity compliance.

1) **Meaningful Benefits, 26 C.F.R. § 54.9812-1(c)(2)(ii)(A) (Treasury); 29 C.F.R. § 2590.712(c)(2)(ii)(A) (DOL); 45 C.F.R. § 146.136(c)(2)(ii)(A) (HHS)**

We urge the administration to withdraw the regulatory requirements for plans to cover meaningful benefits for every covered MH/SUD condition in every classification, as it conflicts with the MHPAEA statute and creates an unduly burdensome policy.

The Final Rule creates a "Meaningful Benefits" provision that exceeds the Department's statutory authority because it effectively imposes a benefit mandate that the Departments lack the authority to impose. The Final Rule mandates that if health plans cover an MH/SUD condition in a benefit classification (e.g., inpatient, outpatient, pharmacy), they must provide "meaningful benefits" for that condition in all classifications in which M/S benefits are provided.[1] The Rule defines "meaningful benefits" as generally recognized, independently formulated standards for current medical practice. It also stipulates that such coverage must be "meaningful" and defines "meaningful" to mean that coverage must include at least one "core" or "primary" treatment for the condition in each classification. *Id.*

The Rule is inconsistent with MHPAEA's statutory intent to establish a methodology for comparing M/S benefits to MH benefits and instead mandates access. The statute clearly states, "nothing in this section shall be construed … as requiring a group health plan … to

[1] 26 C.F.R. § 54.9812-1(c)(2)(ii)(A) (Treasury); 29 C.F.R. § 2590.712(c)(2)(ii)(A) (DOL); 45 C.F.R. § 146.136(c)(2)(ii)(A) (HHS).

provide any [MH] or [SUD] benefit. The MHPAEA 2013 regulations clearly state that the Departments "did not intend to impose a benefit mandate through the parity requirements."[2]

What constitutes a "core or primary" treatment is ambiguous. In some cases, a "core treatment" may include a suite of items and services—for example, "core treatment" for major depressive disorder would consist of both prescription drugs and psychotherapy. However, there may also be no "core treatment" for certain conditions in certain classifications.
The Rule also violates the APA's Arbitrary and Capricious standard because it outsources the definition of "core treatment" to third-party authors of clinical literature rather than allowing medical professionals within health plans to determine what qualifies as a core treatment.

2) Material Difference, 26 C.F.R.§ 54.9812-1(c)(4)(iii)(B) (Treasury); 29 C.F.R. § 2590.712(c)(4)(iii)(B) (DOL); 45 C.F.R.§ 146.136(c)(4)(iii)(B) (HHS).

The "Material Difference" provision should be withdrawn because it exceeds statutory authority and is ambiguous.

The final rule mandates that where a health plan's outcomes data suggests a difference in access to MH/SUD benefits as opposed to M/S benefits, the health plan must determine whether the numerical difference is "material" and whether the differences are attributable to an NQTL. NQTLs are non-numerical limits placed on healthcare benefits that aren't expressed numerically, such as prior authorization requirements, step therapy protocols, and limitations based on medical necessity. If the plan uncovers material differences in data outcomes measures, they're required to take "reasonable actions" to address any material differences as necessary to ensure compliance.[3]

Congress did not impose a requirement of parity in access to MH /SUD and M/S benefits in MHPAEA. MHPAEA requires only parity in plan terms and the application of those terms to MH/SUD and M/S benefits.[4]

The material differences in access provision (1) relies on ambiguous, open- ended terms that determine compliance with the material standard including, "material differences," "access," and "relevant data" (2) treats differences in access between MH/SUD and M/S benefits as indicative of a plan's lack of compliance with parity (3) incorrectly assumes that MH/SUD and M/S treatments are comparable and (4) operates as a one-way ratchet in treating material differences in access as presumptive evidence of a violation, without treating a lack of such differences as presumptive evidence of compliance. This failure to provide fair notice to

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[2] See 29 U.S.C. § 1185a(b)(1) ("Nothing in this section shall be construed … as requiring a group health plan … to provide any [MH] or [SUD] benefits."). See also, e.g., Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 75 Fed. Reg. 5,410, 5,420 (Feb. 2, 2010) ("The statute does not mandate coverage for either [MH] or Case 1:25-cv-00136 Document 1 Filed 01/17/25 Page 4 of 554 [SUD] benefits.").

[3] 26 C.F.R.§ 54.9812-1(c)(4)(iii)(B) (Treasury); 29 C.F.R. § 2590.712(c)(4)(iii)(B) (DOL); 45 C.F.R.§ 146.136(c)(4)(iii)(B) (HHS).

[4] The Departments themselves acknowledged in the 2013 regulations that "[d]isparate results alone" do not amount to a parity violation. 78 Fed. Reg. at 68,245.

regulated parties about what conduct is required violates the Fifth Amendment's guarantee of due process.

3) New Comparative Analyses Requirements, 26 C.F.R. § 54.9812-2(c) (Treasury); 29 C.F.R. § 2590.712-1(c) (DOL); 45 C.F.R. § 146.137(c) (HHS).

ABHW urges the administration to withdraw the new regulatory obligations for comparative analyses, as they are unlawful and impose unnecessary and excessive documentation requirements.

The Rule's changes to the comparative analyses of NQTLs add significant new documentation requirements not required by MHPAEA and lack the specificity and clarity necessary for health plans to understand whether their documentation will be determined to be sufficient to demonstrate parity.[5] Health plans are still awaiting clarifying information and illustrative de-identified examples regarding the development and application of NQTLs, which were required by the 21st Century CURES Act of 2016 and the Consolidated Appropriations Act of 2021 (CAA 2021) but have yet to be produced.

The Final Rule significantly reconfigures the 5-part test outlined by MHPAEA to a 6-part test in the regulations. The Departments do not justify this arbitrary departure from the clearly delineated structure of the statute. More troublingly, the Final Rule adds new requirements that are not addressed by the statute. First, the Final Rule substantively transforms the text that identifies what types of "factors" to analyze. The Final Rule requires health plans to analyze the factors and evidentiary standards "used to design or apply the NQTL."

This Final Rule imposes burdensome requirements for health plans to develop written documentation to justify their every decision, rather than aligning with MHPAEA to require an analysis of the comparability of the types of processes, strategies, evidentiary standards, and other factors that the plan applies to its decision-making. The new comparative analysis requirements violate the APA's Arbitrary and Capricious standard as they use undefined terms and fail to specify the information health plans must provide for compliance. This is heightened by the fact that Departments' continue to assert that not a single comparative analysis they have reviewed to date meets their expectations (as stated in the 2023 and 2024 Report to Congress on MHPAEA), coupled with the fact that the Departments have yet to create a model comparative analysis that would satisfy their expectations.

4) Non-Quantitative Treatment Limitations (NQTL) Cease and Desist Provision, 26 CFR 54.9812-1(c)(4)(v)(A), 29 CFR 2590.712(c)(4)(v)(A), and 45 CFR 146.136(c)(4)(v)(A).

ABHW requests that the administration withdraw the regulatory provisions authorizing regulators to prohibit the application of an NQTL that the regulators find to violate MHPAEA because this provision is unconstitutional and ambiguous.

[5] 26 C.F.R. § 54.9812-2(c) (Treasury); 29 C.F.R. § 2590.712-1(c) (DOL); 45 C.F.R. § 146.137(c) (HHS).

The Final Rule includes a new enforcement provision that authorizes federal and state regulators to prohibit health plans from applying an NQTL if the plan's comparative analysis does not adequately demonstrate compliance.[6] The Departments indicate that inadequate documentation is now a strong indication of substantive non-compliance. Prior to the Final Rule, regulators found that all initial documentation submitted to date was insufficient. The fact that, to date, regulators have not found any comparative analysis submitted by a health plan to be fully adequate will raise the arbitrary and capricious nature of this new enforcement authority.

Our members' concerns are further exacerbated by the highly subjective nature of interpreting the exceedingly ambiguous new regulations and the near certainty that different federal and state regulators will arrive at differing conclusions about the sufficiency of plans' analyses. Indeed, federal and state investigations to date have already arrived at different conclusions, with plans that operate in multiple markets submitting virtually identical documentation to different regulators and receiving findings of non-compliance from some and no findings from others. This is especially problematic given that the Departments have not adopted an appeals process to provide a formal review of these decisions. Health plans and insurers should have the opportunity to be heard at a meaningful time and in a meaningful manner. Substantial procedural protections are required here, as the consequences of following a final determination of noncompliance are severe.

5) Mental Health Benefits Definition, 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2).

ABHW urges the DOJ to withdraw and revise the definition of "Mental Health Benefits" because it is unduly burdensome and unsound.

The Final Rule interprets the regulatory definitions for "mental health benefits," "substance use disorder benefits," and "medical/surgical benefits" to require plans and issuers to "characterize items and services as medical/surgical benefits, mental health benefits, or substance use disorder benefits based on the condition or disorder being treated.[7]" This provision means that claims and authorizations for "cross-over services" that are delivered to treat both MH/SUD and M/S conditions—including speech and occupational therapy, urgent care, surgeries (e.g., for gender dysphoria), and a wide range of other services—must be treated as MH/SUD benefits or M/S benefits based on the condition being treated. In other words, the same service delivered by the same provider might be characterized as an MH or M/S benefit depending on the condition being treated.

This interpretation, which has never before been included in guidance and, to our knowledge, has never been enforced, will cause several perverse consequences.[8]

This non-sensical approach requires significant and costly changes to general industry practices related to benefit authorizations, claims determinations, and related health plan

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[6] 26 CFR 54.9812-1(c)(4)(v)(A), 29 CFR 2590.712(c)(4)(v)(A), and 45 CFR 146.136(c)(4)(v)(A).
[7] 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2).
[8] See ABHW Proposal on Definitions for Benefits Under MHPAEA submitted to Departments on May 17, 2023.

operations, most of which are not currently designed to process claims and authorizations differently based on the condition being treated. Health plans with more complex cost-sharing must implement new procedures that apply cost-sharing to diagnosis codes for the first time, and many systems were already set up and filed for 2025 when this rule was published. Additionally, there is an impact on Quantitative Treatment Limitations (QTL) testing. Under parity regulations, plans must analyze our QTLs and our NQTLs. QTLs are numerical limits on the scope or duration of benefits, such as visit limits, day limits, or episode limits, and these have never been a problem. However, this definition requires us to reexamine and restructure our QTL analyses. Lastly, pharmacy claims and authorizations, which have never been linked to pharmacy codes, must now somehow be linked for Parity implementation. The Department's regulatory impact assessment does not account for the high cost and significant disruption to health plan operations across the country, which require plans to reconfigure their claims and authorization platforms to accommodate this new interpretation.

Finally, the Departments' definition for "Mental Health Benefits" confirms that health plans must define MH benefits to include all covered conditions that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter of the most current version of the International Classifications of Diseases (ICD) or that are listed in the current Diagnostic and Statistical Manual of Mental Disorders (DSM). The rule thus defines intellectual and neurodevelopmental disorders, including dementia and autism spectrum disorder, as MH conditions, even if applicable state laws define these conditions as M/S conditions. This overrides state law definitions for MH/ SUD benefits, which creates confusion and is difficult to implement. For example, some states, such as Ohio and New Mexico, currently classify autism as an M/S benefit. Historically, intellectual and neurodevelopmental disorders have not been considered MH conditions. This also diverges from the Centers for Medicare and Medicaid Services (CMS) guidance for Medicaid and CHIP, under which many state Medicaid agencies have defined benefits for intellectual and developmental disabilities as M/S benefits.

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State Parity Laws

Another issue that arises with parity broadly and the provisions we outlined above is the intersection with state parity regulations. We also request that the Trump Administration work with states to rescind state-specific rules that have codified unlawful and unsound federal MHPAEA provisions or adopted their own burdensome parity provisions. If the federal provisions above are rescinded, these state laws that contain the same or similar provisions would remain.

For example, in March 2025, Colorado adopted provisions from the federal MHPAEA final rule, such as meaningful benefits, changes to the definitions of mental health benefits, new definitions for evidentiary standards, factors, processes, and strategies, and requirements for the design and application of NQTLs that we listed above in items 1 – 5. **If the federal MHPAEA Rule provisions above are invalidated, these provisions would remain in Colorado's law.**

II. Network Adequacy Regulations

Certain network adequacy regulations limit health plans' ability to design cost-efficient narrow network plans, curb differentiation, and stifle market innovation. Some of the provisions below add complex network adequacy requirements that don't account for the behavioral health workforce shortage and add administrative burden to business operations. Maintaining compliance with complex network adequacy standards increases business administrative overhead, diverting resources from consumer-focused improvements and competitive pricing.

A. CMS Medicaid Managed Care Regulation

Rescind Key Provisions in the 2024 Medicaid Managed Care Rule
42 CFR 438.68(3), 457.1218, 438.69 (f), 457.1207, 457.121

1) Appointment Wait Time Standards

The Center for Medicaid and Medicare Services (CMS) finalized the Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality rule in April 2024 that requires states to establish and enforce wait time standards for Medicaid managed care plans. The rule mandates that routine outpatient MH and SUD appointments (for both adults and children) be available within 10 business days. It also sets a 15-business-day standard for routine primary care and OB/GYN services.

Medicaid managed care plans must achieve 90% compliance with state-established appointment wait time standards within federal maximums, consistent with Marketplace standards (applicable for the first rating period, January 1, 2027). Annual independent secret shopper surveys will be required to assess compliance with these wait-time standards and provider directory accuracy, with a requirement that provider errors be reported to the state within three business days. The first rating period is applicable July 10, 2028.

ABHW has significant concerns with the behavioral health appointment wait time standards, expressing that they should not be more stringent than primary care standards. We request that the DOJ rescind the requirement for Medicaid Managed Care wait-times. These provisions are an overstep into state management of Medicaid, and national standards cannot account for states' market dynamics.

B. CMS Medicare Laws and Regulations

1) Prohibition on Dual-Listing Providers Across Specialties; Rescind Provision: 422.116(b)(2)

In CMS's Contract Year 2025 Medicare Advantage and Part D Final Rule, CMS finalized a provision that restricts a single provider from being counted in multiple network adequacy specialty categories. This increases administrative burden without allowing providers to be valued for their specific expertise. For example, a provider cannot be counted in the psychiatry category and the outpatient behavioral health category. **ABHW requests that this requirement be eliminated.**

2) **Limited Telehealth Credit Towards Network Adequacy, Amend Provision § 422.116(d)(5)**

CMS finalized a provision in the 2025 Medicare Advantage and Part D Final Rule that offers only a 10-percentage-point credit for telehealth providers in meeting network adequacy standards, which does not sufficiently account for the role telehealth plays in expanding access. Telehealth has proven to be an effective way to expand access to high-quality care, particularly in behavioral health. The United States Department of Health and Human Services (HHS) and CMS have acknowledged the benefits of telehealth and should continue to evaluate ways to improve access, particularly in rural areas or areas with significant provider shortages. **Given the acute workforce challenges limiting the supply of behavioral health providers and the efficacy of delivering behavioral health services via telehealth, CMS should increase the telehealth credit above 10%.**

3) **Minimum Patient Volume Requirements for Behavioral Health Providers: Rescind Provision § 422.116(b)(2)(xiv)(B)(1) and (2)**

A new requirement in the Contract Year 2025 Medicare Advantage and Part D Final Rule requires certain providers, including nurse practitioners (NP), physicians assistants (PA), and certified nurse specialists (CNS), to treat a minimum number of patients before they can be included in network adequacy assessments, potentially excluding qualified providers. For an NP, PA, or CNS to satisfy the Outpatient Behavioral Health network adequacy standards, the NP, PA, and/or CNS must have furnished certain psychotherapy or SUD prescribing services to at least 20 patients within the previous 12 months. **We ask CMS to rescind the 20-patient requirement, as a provider should not have to prove they have served a minimum number of patients. By arbitrarily shutting certain providers out of networks, this requirement impedes access to services.**

4) **Appointment Wait Time Standards: Rescind Guidance**

In the April 2025 Final Letter to Issuers in the FFEs and April 2024 Appointment Wait Time Secret Shopper Survey Technique Guidance for Qualified Health Plan Issuers in the Federally-facilitated Exchanges, which include Medicare Advantage plans, CMS established specific 10-day wait time requirements for behavioral health services. Given current provider availability, these requirements are challenging to meet and could lead to compliance issues. **We request that the DOJ rescind this provision for the MA behavioral wait times.**

The administration should align wait times for behavioral health services with existing standards already applied in the industry, such as the National Committee for Quality Assurance (NCQA) standards, which are already standardized across provider types and will eliminate confusion among stakeholders – plans, providers, and patients. Additionally, at a minimum, CMS should implement a different timeframe for non-emergency behavioral health services, which should be fourteen days, versus the proposed one week. Given that emergency or urgent care is generally made available across the industry within 72 hours, there should be a more differentiated standard for non-urgent care. This seems warranted for non-emergency

behavioral health, with the unprecedented demand for services and limitations in the system and workforce today.

III. Eliminate the DEA's Prohibition on the Prescribing of Methadone for OUD; Rescind Provision 21 C.F.R. § 1306.07

Methadone for the treatment of opioid use disorder (OUD) can only be dispensed directly by federally regulated opioid treatment programs (OTPs), with limited exceptions. 21 C.F.R. § 1306.07 prohibits qualified practitioners from prescribing methadone for OUD and qualified pharmacies from dispensing it. Specifically, the language in the underlying statute does not have this prohibition and instead requires practitioners, including pharmacies that dispense narcotic drugs for maintenance or detoxification, to obtain a separate registration for that purpose annually. Federal statute defines "dispense" (21 U.S.C. 802 (10)) as "deliver[ing] a controlled substance to an ultimate user . . . by . . . a practitioner, including the prescribing and administering of a controlled substance."

The Drug Enforcement Administration (DEA) has restricted methadone to OTPs that directly dispense it rather than to qualified practitioners more broadly. This restriction limits the number of access points for methadone, thereby preventing competition. **21 C.F.R. § 1306.07 is an incorrect interpretation of the underlying statute (21 U.S.C. 823(h)) and should be removed since it constitutes a significant regulatory action that materially harms competition in health care delivery.**

By largely restricting access to methadone for OUD through OTPs that directly dispense it, rather than qualified practitioners more broadly, current regulations prevent competition in methadone treatment. The limited number of methadone treatment practitioners harms patients who do not live near OTPs, especially patients in rural areas.

IV. DEA's Buprenorphine Final Rule, Eliminate Mandatory Prescription Drug Monitoring Program (PDMP) Review; Rescind 21 CFR 1306.51(b)(1)

The DEA's Expansion of Buprenorphine Treatment via Telemedicine Encounter final rule is scheduled to be implemented at the end of December 2025. A provision within the Buprenorphine Final Rule requires practitioners to review the Prescription Drug Monitoring Program (PDMP) data and notate the date and time that such a review took place within the patient's electronic health record (EHR) or paper record. If the PDMP data is inaccessible for any reason, the prescribing practitioner will be required to notate the date and time that such review was attempted, indicate why the PDMP was inaccessible, and will be limited to prescribing a seven-day supply.

ABHW believes that the DOJ should rescind this requirement for a PDMP review, as patients should not be penalized if the PDMP is inaccessible or inoperable. States operate PDMPs independently of one another, and not all states capture the same sets of information. While one state may capture all information from prescribing controlled substances, another may exclude the name of the controlled substance and the location of the patient receiving the prescription or fail to note whether the prescription was provided through

telehealth or in person. The lack of uniformity across the states creates a challenge for implementing this provision.

Conclusion

ABHW is ready to support the DOJ and this administration in ensuring that regulations (1) do not impede fair market competition, (2) are consistent with statute, (3) reduce unnecessary complexity, and (4) safeguard fair access to MH and SUD services. We look forward to working with you to pursue the common goal of improving all Americans' behavioral health. Please contact Kathryn Cohen, Senior Director of Regulatory Affairs at cohen@abhw.org, if you have any questions.

Sincerely,

Debbie Witchey, MHA
President and CEO